Master's thesis

NTNU
Norwegian University of Science and Technology
Faculty of Economics and Management
Dept. of Industrial Economics and Technology Management

Viktor Munch Akse
Erlend Frøland, M.D.
Tobias Drage Roti, M.Sc.

How to enter the Public Healthcare Sector?

A qualitative multi-case study using semi-structured interviews to investigate how software-based Health Tech companies tackles the barriers of public healthcare market entry in Norway.

Master's thesis in Entrepreneurship
Supervisor: Professor Elsebeth Holmen
July 2022

NTNU
Norwegian University of Science and Technology

NTNU SCHOOL *of* ENTREPRENEURSHIP

Viktor Munch Akse
Erlend Frøland, M.D.
Tobias Drage Roti, M.Sc.

How to enter the Public Healthcare Sector?

A qualitative multi-case study using semi-structured interviews to investigate how software-based Health Tech companies tackles the barriers of public healthcare market entry in Norway.

Master's thesis in Entrepreneurship
Supervisor: Professor Elsebeth Holmen
July 2022

Norwegian University of Science and Technology
Faculty of Economics and Management
Dept. of Industrial Economics and Technology Management

NTNU
Norwegian University of
Science and Technology

PREFACE

This paper is written by Viktor Munch Akse, Erlend Frøland MD and Tobias Drage Roti M.Sc. All three are master graduate students at the NTNU School of Entrepreneurship.

Akse is the CEO of Fornix AS, a startup that develops software for Virtual Reality (VR) headgear for use by and in the setting of clinical psychology. The vision of Fornix is to treat mental health illnesses such as anxiety disorders and specific phobias with the use of exposure therapy by means of VR-software.

Frøland is working as a resident physician at the Emergency department of St.Olavs Hospital in Trondheim. He attended his first terms of specialization rotating the medical, surgical and psychiatric departments, and worked at a rural GPs office with responsibility for the local nursing home. He has extensive experience as an Emergency Medical Technician and is also currently an editor of a small Norwegian medical journal. He knows the NHCS well.

Roti is the CEO of OmniMod AS. OmniMod is a startup that is developing both hardware and software to supply the logistics industry - both private and public - with automated solutions for handling colli.

It is our common belief that the Healthcare sector in general is in need of developing innovative solutions to meet the requirements of the future and that startups are an important tool to meet these challenges. The aim of this thesis is to identify and describe the barriers to entering the Norwegian public healthcare sector and the ways of which one could hope to overcome these barriers - so that the entrepreneurs of the future will be more motivated to start Health tech startups.

Lastly, we would like to extend our most sincere gratitude towards our supervisor Professor Elsebeth Holmen at The Department of Industrial Economics and Technological Management at NTNU. She has provided us with immensely important insights along the way, and she has had remarkable patience in doing so. Only we know how unbearable it must have been to cooperate with, and guide, such an unruly bunch of young entrepreneurs.

Trondheim, 19th July 2022

ABSTRACT

The world population is aging, and there is an increase in demand on health services, and a relative decrease in available resources. The aim of this study was to investigate how startups might enter the public healthcare sector and provide innovative solutions to meet the challenges of the future. GDP health expenditure is approximated to 8,8% for OECD-countries in 2019. In the US it was nearly double. Most healthcare services in the world are publicly provided or funded. Twelve percent of the GWP is spent on public procurements. Nevertheless - little research has been done in this field. In this study a qualitative method of multiple case study is applied, using semi-structured interviews to investigate the entry barriers to the Norwegian public healthcare market, and how to navigate and overcome these barriers. Both within-case and cross-case analysis were performed. In our data set of seven cases two main findings were prominent. Firstly, there are a lot of laws and regulatory mechanisms that vary from case to case which calls for a resource demanding and individualized approach. Secondly, partnering and cooperation with the industry through either R&D, innovation projects or developing professional relationships with key medical personnel is an important market entry strategy. The study concludes with some suggestions for some important general mechanisms to the procurement process, but the study is limited to a select few Norwegian Software-based companies and is not very generalizable. Thus further investigation is needed to answer the title of our thesis; “How to enter the Public healthcare sector?”

SAMMENDRAG

Verdens befolkning er aldrende, og det er en økende etterspørsel på helsetjenester samtidig med en relativ reduksjon i tilgjengelige ressurser. Målet med studien var å undersøke hvordan startup selskaper kan komme seg inn i markedet til den offentlige helsesektoren og tilby innovative løsninger for å møte morgendagens utfordringer. I 2019 var andelen av BNP som brukes på helsetjenester er 8,8% for OECD-land. I USA var prosentandelen nesten dobbel. De fleste helsetjenestene i verden har enten offentlig tilbyder eller finansiering. Tolv prosent av verdens bruttoprodukt bruk brukt som følge av offentlige anskaffelsesprosesser. Likevel er det lite forskning på området. I denne studien bruker vi en kvalitativ metode med fler-case design og semi-strukturerte intervjuer for å undersøke inngangsbarrierer til markedet for det offentlige norske helsevesenet - og hvordan man kan navigere og overvinne disse barrierene. Det ble gjennomført både case-spesifikke og tverr-case analyser. I våre datasett med syv caser fant vi to fremtredende funn. Først, at det var mange lover, forskrifter og andre mekanismer varierende fra case til case som ga behov for ressurskrevende og individualiserte tilnærminger. Sekundært til disse barrierene fant vi at partnerskap og samarbeid med industrien, gjennom forskning og utvikling (FOU), innovasjonsprosjekt eller å utvikle profesjonelle relasjoner med medisinsk nøkkelpersonell var viktige strategier for å komme seg inn i markedet. Studien konkluderer med at det antydes noen viktige generelle mekanismer for anskaffelsesprosessene. Men studien er begrenset av at det bare er noen få norske software-baserte firma og studien er ikke veldig generaliserbar. Det er derfor nødvendig med videre undersøkelser for å besvare spørsmålet i oppgavens tittel “Hvordan èntre den offentlige helsesektoren?”.

LIST OF FIGURES

LIST OF TABLES

LIST OF APPENDICES

LIST OF ABBREVIATIONS

In alphabetical order

AI - Artificial Intelligence

API - Application Programming Interface

CE - Conformité Européenne (Eng.: European conformity)

CEO - Chief Executive Officer

Difi - Agency for Public Management and e-Government

DFØ - Norwegian Agency for Public and Financial Management

EPJ - Electronic Patient Journal

ESAF - NSE alumni organization

EU - European Union

EØS - European Economic Area (EEA)

FDA - U.S. Food and Drug administration

GDP - Gross domestic Product

GDPR - General Data Protection Regulation

GP - General practitioners ("Fastlege" in Norwegian)

GPA - The plurilateral Agreement on Government Procurement

GWP - Gross world product

HCS - Health care sector

Helfo - Norwegian Health Economics Administration

IT - Information Technology

IKT - Information and Communication Technology

MD - Medical Doctor

NAV - Norwegian Labor and Welfare Administration

NHCS - Norwegian health care sector

HCS - Health care sector

MDR - Medical Device Regulation (EU wide directive)

NOK - Norwegian Krone

NSD - Norwegian Center for Research Data

NSE - NTNU School of Entrepreneurship

NTNU - Norwegian University of Science and Technology

OECD - Organization for Economic cooperation and development

PPI - Public procurement of Innovation

PPP - Public procurement policy

R&D - Research & Development

SaaS - Software as a Service

Sikt - Norwegian Agency for Shared Services in Education and Research

SSB - Statistics Norway

TED - European Public Procurement Database

VR - Virtual Reality

WHO - World Health Organization

WTO - World Trade Organization

LIST OF CONTENT

1 INTRODUCTION

The topic for this paper is the process of startups entering the Norwegian Health care sector. Startups are often characterized by having little resources and experience on one hand, and on the other having a high tolerance for risk and being able to change pace and direction fast. Public health as an industry is quite the opposite. Public agencies and the health care sector separately are both known to be slow moving conservative mastodons and to have lots of resources. Although they are positioned to carry a lot of risk, they generally do not want any risk (Wagrell & Baraldi, 2019; Pickernell, Senyard, Jones, Packham & ramsey; 2013; Melo de Campos & Machado, 2012; Mattsson & Anderson, 2019). Being called a slow moving conservative mastodont often is not considered as a compliment, but when their aim is to protect and serve the general public´s wealth, it is a good quality. These dissimilarities between startups and public health might be a reason for why it is so hard for startups to enter into public health - but this is the question that we are going to investigate in this tesis.

1.1 Background

The Health care expenditure percentage of the Gross Domestic Product (GDP) for OECD countries (Organization for Economic co-operation and development) was on average approximately 8,8% prior to the COVID-19 pandemic. The United States spent 16,8% of its GDP on health care when looking at private and public care combined. (OECD, 2021) For Norway the percentage was 10,5% in 2019.

It is no secret that Healthcare is expensive. The Gross World Product (GWP) for 2019 was 87.752 billions Dollars (International dollar/Geary-Khamis dollars/1990-US dollar). If we apply the OECD-average to the rest of the world it is approximately 7.700 billion dollars in Health care expenses. For Norway the actual number was 42,6 Billion dollars in 2019.

In Norway, as in most other OECD countries, healthcare is publicly funded. As a consequence it is common that all larger investments are products of a procurement process based on tenders. If we look at the GWP again, 12% was spent following public procurement processes, according to 2018 numbers (Bosio & Njankov, 2020). To summarize; the public health care market is enormous, and the way to the big bucks goes through tenders.

In the background section the focus will be to describe some important aspects of general public procurement processes and invitations to tender, and to describe the Norwegian Healthcare sector and the most important devices and definitions that have implications for how a service or a product are categorized with regards to different laws and regulations. Lastly we turn the spotlight on the concept of innovation, entrepreneurship and startups.

1.2 Purpose

As we will present in the background chapter the health care systems of the world are under an increasing amount of stress. The world population is aging on average. This will result in a higher prevalence of morbidity in the population. Simultaneously we have seen an increase in demand in health care services, both in quality and quantity. Health care is already expensive, but at the projected rate there will not be enough resources to tackle the problems of the future, without innovation.

The Purpose of this study is to investigate how startups work and think when trying to enter into public health. We hope to identify the do's and don'ts of securing a deal with a public health enterprise. Our aim is thus that this thesis can serve as a guide for startups into the Norwegian public health system, and inspire to do similar investigations in other countries and regions around the world.

1.3 Literature gap

We were fortunate enough that a former master student from NTNU School of Entrepreneurship (NSE), Besart Olluri 2019, did his thesis on Born-public ventures - startups trying to enter the public market (Olluri, 2020). In an independent literature review he found very little relevant literature describing this phenomena (Olluri, 2019). Olluri actually found that no study had been previously done on born-public ventures. Those findings supported the conclusions of DeGhetto et al (2018) that this field has been overlooked in entrepreneurial academia. We therefore knew that previous literature would be scarce when we narrowed the scope further - looking at only public healthcare. As this sector is faced with future challenges and makes up a significant part of the GDP of countries it is an important field to investigate further not only from the perspective of entrepreneurs, but for the common benefit for future patients that will rely on innovative solutions.

1.4 Methodology

This master thesis is organized and structured according to the IMRAD-framework. IMRAD is an acronym for Introduction, Method, Results and Discussion. The Introduction covers the background information that is provided to the reader to better understand the interpretation and analysis ("Analysis" and "Discussion" chapters in this thesis) of the data - that are presented in the results' chapter. After the discussion we offer a brief conclusion. The Method chapter offers a complete overview in how the study was planned and conducted - also explaining the reasoning behind the methodological choices that were made.

1.5 Research questions and aim

There are mainly two important research questions that we aim to answer.

a) Why do startups experience difficulty with entering the Norwegian public healthcare sector as a market?
b) How do companies overcome these barriers?

These questions are designed to aid the understanding of what the main goal is - namly understanding the answer to our thesis title "How to enter Public healthcare?". We believe this to be a very complex question that starts with understanding which entry barriers that some startups meet, and how they are working to overcome these barriers. Hopefully the study might provide some insight into which strategies are successful.

2 BACKGROUND

In this chapter we will present the relevant literature on the subject of investigation, and aim to equip the reader with the necessary understanding to assess our choice of method and evaluate the results, and our interpretation of them. There was little to no relevant previous literature on the specific field of investigation - public healthcare procurement. We therefore draw on knowledge from more general principles in public procurement and general mechanisms of resistance to change in organizations, etc.

To fulfill the objective of equipping the reader with necessary background information we will explain what innovation and entrepreneurship is, and explain some important aspects to both the public sector and the health care sector - focusing on the themes that are relevant in relation to startups, and especially the Norwegian market. The chapter will be concluded by a summary of the theoretical framework that the study will be based upon.

2.1 The Public Sector

The Public sector is a vast construct compiled by a consortium of different activities, and can also include state owned companies that do not service the public in any way other than creating revenue for the government - which in turn carries the responsibility for its citizens. In this section we will focus on aspects of procurement in general, and pertaining to innovative solutions especially - and the thresholds for when rules for different policies come into play.

2.1.1 Public Procurement Policy (PPP)

Public procurement is by definition the process by which a public administration gets hold off goods and services. In this process there are a set of rules and regulations that govern these acquisitions. There are two main reasons for these policies. First - governmental procurement is often very big and a lot of money is at stake. It therefore makes sense to do a proper quality control before spending these huge sums of money. The second main point is who the money belongs to - when the government is using money they are spending the taxpayers money. So they need to make sure that it is a responsible and safe use of money according to the goals that are set. Without an PPP the public procurement processes are subject to fraud and corruption. Since the 1990s PPP has therefore been standard in most economies. (Bosio &

Djankov, 2020; smallbone, 2016). Because of international trade there are a lot of similarities in the policies across different countries within the same economical zones. Countries that are part of the OECD and/or EU base their national policies on the suggestions that OECD and EU are publishing. though they do still vary from country to country. (Mattson & Anderson, 2019: Melo et al., 2012; Omer 2010; van Winden & Carvalho, 2019; Wagrell & Baraldi, 2019)).

Norwegian Laws and Legislature

For Norway there is one law regulating these policies. Translated to english the name of the law is Law concerning public procurement (2017) - Law of procurement for short. Its first paragraph is defining the purpose of this law:

> *"The Law shall promote the efficient use of the society's resources. It shall also contribute to that the public sector acts with integrity such that the general public can trust that public procurements are made in a way that benefits society."* - ***(Anskaffelsesloven, 2017)***

The law defines all the actors that are subject to it - more or less every public and governmental institution, and the law also regulates some fundamental principles such as requirements concerning acquisition processes and so on. It also states that Norway, by this law, is bound to follow up the international treaties that the country has signed with the European Union (EU) and the World Trade organization (WTO).

Other Legal Regulations

The Procurement Law is a bit general in its formulation, this is according to Norwegian legal law making practice, and differs a bit from other countries outside of Scandinavia. Therefore there are a set of down-hierarchy legal regulations that the law points to for guidance in matters more specific to certain applications. The most important regulation is the Regulations on Public Procurements (Norwegian: Anskaffelsesforskriften). It is a detailed regulation with general remarks, and chapters with appendices for specific sectors. They also make a divide between procurements that exceed the threshold values for EU regulated procurements. The regulations are quite specific and detailed - to such a degree that a summary presentation in this thesis would not be very practical. Instead we will refer to relevant regulations in sections later in this dissertation when or if relevant and practical.

There are two other important regulations for public expenditure, that also regulate the processes and thresholds for regulations on invitations to tender etc, but they are not directly linked to procurements. These are The Norwegian Regulatory Framework for Public Supply (Forsyningsforskriften) and The Norwegian Regulatory framework for License Contracts (Konsesjonskontrakt-forskriften).

Other Relevant Resources

Other mentionable resources for navigation of the jungle of public procurement are the web page “Anskaffelser.no " which offers guidance about e-procurement, social dumping and socially responsible public procurement in Norway. The service is provided by The Norwegian Agency for Public and Financial Management (DFØ). Further there is also a Norwegian Regulatory Framework for the Tribunal of Complaints on Public Procurement, and of course the tribunal itself. Relevant to that there is also a law on the right to document insight into public business. Internationally Norway has signed agreements with the EU and WTO - the last mentioned agreement is known as The Plurilateral Agreement on Government Procurement (GPA) and is an international set of regulations.

2.1.2 Tender

A tender is a bid. When we talk of tenders or the tender process, we often mean that someone has started an invitation to tender, or a coll for bids. This is a popular process for the public sector. A tender process is a formal and structured way of collecting bids that can be compared both with each other and with the specifications of the invitation. The aim is to find the best candidate to sell or deliver a product or service after every thing has been taken into account, and to do so in a fair manner. Common criteria may include price, delivery time, certifications, and so on. There are different criteria and policies applied for different tenders, this is dependent on what the government wants to buy, and the total cost of it. Concerning cost there are different thresholds. To win a tender process for a major government contract can be huge - a make it or break it incident - in the same way the losing the process may cause bankruptcy. In Norway all public tenders are announced online on the Norwegian database for public procurement (doffin.no).

Thresholds for Public Procurement

There are different thresholds for procurement following the laws and regulations in Norway. Often there is a monetary threshold, but they often also only apply for specific situations and it is therefore not easy to provide a simple overview of these thresholds in a general presentation.

The most important threshold is the NOK 100k limit. Everything that does not pass 100k in cost does not need to go through a designated procurement process. Above this threshold the public institution in need of a product or service needs to announce the invitation to tender through doffin.no. If the cost of the project, product or service exceeds NOK 1,1 million then it needs to be submitted to the European public procurement database (TED), also through using doffin.no.

Below we will provide you with a table of procurement thresholds referencing the different letters and paragraphs in the regulations mentioned in the subsections above. The regulations will have to be read in full to understand the non-monetary rules and thresholds that apply for the different situations.

Thresholds for Public tender and procurement processes in Norway

The Norwegian Regulatory Framework for Public Procurement (Anskaffelsesforskriften)		
National Threshold Values		
Threshold Value (NOK)	Type of Procurement	Reference to Regulatory Framework
100.000	All procurements that are covered by the framework	§ 1-1 (And the Public procurement law, § 2)
1,1 Million	Procurements of goods, services and building and facilities work	§ 5-1 (2) letter a
1,1 Million	Special services	§ 5-1 (2) letter b

EU(/EØS) Threshold Values		
Threshold Value (NOK)	Type of Procurement	Reference to Regulatory Framework
1,1 Million	State government goods- and service procurements. and planning- and design contests	§ 5-3 (1) letter a
1,75 Million	Other clients goods- and service procurements. and planning- and design contests	§ 5-3 (1) letter b
44 Million	Building and facilities contracts	§ 5-3 (1) letter c
6,3 Million	Contracts on Health- and social services Contracts on special services	§ 5-3 (2)
650.000	Part-based contracts(goods and services) that are exempt from TED-announcement.	§ 5-4 (8)
8,4 Million	Part-based contracts(building and facilities services) that are exempt from TED-announcement.	§ 5-4 (8)
1,1 Million	State government goods contracts within fields of	§ 5-3 (3)

	Defense and Security. (Goods mentioned in the WTO/GPA-agreement, Norway appendix 4, section 2)	
1,7 Million	State government goods contracts within fields of Defense and Security (other goods)	§ 5-3 (3)
The Norwegian Regulatory Framework for Public Supply (Forsyningsforskriften)		
Threshold Value (NOK)	Type of Procurement	Reference to Regulatory Framework
100.000	All procurements that are covered by the framework	§ 1-1 (And the Public procurement law, § 2)
3,5 Million	Contracts of goods and services and planning- and design competitions	§ 5-2 (1) letter a
44 Million	Contracts on building and facilities	§ 5-2 (1) letter b
8,4 Million	Contracts on Health and social services. Contracts on special services	§ 5-2 (2)
650.000	Part-based contracts (goods and services) that are exempt from TED-announcement.	§ 5-3 (8)

8,4 Million	Part-based contracts (building and facilities) that are exempt from TED-announcement.	§ 5-3 (8)
The Norwegian Regulatory Framework for Licence Contracts (Konsesjonskontrakts-forskriften)		
Threshold Value (NOK)	Type of Procurement	Reference to Regulatory Framework
100.000	All procurements that are covered by the framework	§ 1-1 (And the Public procurement law, § 2)
44 Million	License contracts (building and facilities works and services other than special services AND health and social services)	§ 5-1 (2)
44 Million	License contracts on special services AND health and social services	§ 5-1 (3)

Table 1: *Monetary Thresholds for different tender and procurement processes according to the Norwegian laws and regulations*. (Regjeringen.no, 2022; Konsesjonskontraktforskriften, *2016; Forsyningsforskriften, 2016*)

2.1.3 Public Procurement of Innovation (PPI)

Other rules apply when opting for a test of innovative solutions. Sometimes the public needs new solutions or better ways of meeting challenges. In the cases where readily available solutions do not exist the public institution still needs to find service or product providers. The idea of quality control is still governing, but when no one can be sure of what the best solution is, the rules regulating the process are similarly a bit more diffuse. The former Norwegian Agency for Public Management and eGovernment (Difi) provided a four-step list of how to proceed with PPI in Norway.

a) Describe the task that needs to be done
b) Describe the need that will have to be covered
c) Invite suppliers and developers to a dialog
d) And then lastly either opting for a direct procurement as a innovative project (1), or as a modified innovation friendly invitation to tender (2).

The two alternative outcomes, as mentioned under point d), is either just a normal invitation to tender (2) but with more loosely presented specifications leaving room for interpretations and offering a broader spectrum of alternative solutions. This is an option for when the process a) to c) is not as obscure as first thought. The other option is the fully innovative procurement or project (1). This outcome may take different forms depending on what is to be obtained. It might be an innovation partnership, a pre-commercial procurement, research and development contract, planning- and design competitions, competitive dialogues or best value procurements.

By 2020 Difi was replaced by The Directorate of digitalisation (Digdir), *Digitaliseringsdirektoratet* in Norwegian. Their new web site offers an intricate array of tools and guidelines for digital innovation, especially for the Norwegian public sector. It is too complex to even outline the essence in this subsection.

2.2 The Healthcare Sector

The Health care sector in general is an industry concerned with providing health services - that is services for people in need or wanting any intervention concerning their physical or mental health or well-being. A system for Health care is such a familiar concept to most of us, that the details surrounding how it actually functions does not always stand out. Traditionally one can say that the sector is built up by health care professionals that to a varying degree are products of higher and specialized education performing services with the use of specialized tools or products in specially adapted areas and locations. The cost of everything is either covered by the public or by the patients themselves. Health and medical care have been practiced for ages. Further in this section we will describe some important trends for the sector, and explain some principles that divide the health care system with regards to how a company might work towards entering the market.

2.2.1 Global and Norwegian national trends in the healthcare sector

World wide people's life expectancy is increasing (WHO 2021). This is due to a lot of different factors. Better technology, education and more available resources have led to an improvement in healthcare. Social regulations and advances have also been made to ensure that more people receive health services.

Together with an aging population there is also an increasing demand for better health care and quality of life as well. This demand for better quality in health services is a development that has been experienced in western economies for decades - one could almost argue that there has been a positive development since the start of medicine - but the trend is global. Along with this there is also an increase in worrying that there won't be enough resources, especially human resources, to meet these demands in both quality and quantity. It is therefore essential that the healthcare sector finds more innovative solutions to provide safe and effective services also in the future. (Porter and Lee, 2013).

Covid-19 led to an innovative explosion in the use of tele-medicine. Using video to do consults and follow-ups were previously frowned upon by doctors - but the need for distancing and to protect the in-hospital area from potential contagants forced doctors to use more video consults.

There has also been a rise of focus on patient rights. As people to a larger degree can read and update themselves on illnesses, the interest for looking up their own health data has been increasing. This calls for practical digital solutions that enable such shared access without bending the rules of GDPR and data sharing.

In Norway a big issue the last decades has been the proposed collapse of the primary health care institutions - mainly the services of the General Practitioners (GP), and the physical capacity in all health institutions. It seems that patients should receive a greater deal of their care and follow-up outside of hospital, and as a consequence the hospitals are built far smaller, measured in bed-size than earlier because the patient is more at home now than before, which is thanks to innovation.

2.2.2 In-patient vs. out-patient health services

When patients are admitted to hospital for treatment it is called in-patient activity, or health services. The reasons for admitting a patient to hospital is based on the need of either treatment or investigations that cannot be done outside of the hospital - or because the doctor at the time of referral is yet unsure if the patient can be safely handled outside of the hospital. In short - if you don't need to be at the hospital, you are not getting in.

And out-patient clinics provide health services for those that do not need to be admitted. These clinics can be part of, and located at the same place as hospitals - but the patient will not be there for more than hours before they leave - either back home or to the institution where they normally reside. Out-patients clinics in Norway may also be located far away from the hospital, be privately owned or funded, or they might work as private contractors on behalf of the public health sector. This in-patient versus out-patient divide is an important concept to understand for entrepreneurs because the economical and logistical ramifications are vastly different from running a hospital. It is much cheaper to treat people that do not need admittance, and with the trends described above it is believed that even more patients need to be handled as out-patient cases.

2.2.3 The Norwegian Healthcare sector

Health is quite a broad concept. Health also includes general preventive measures that the government is concerned with - such as limiting the fees on fruit and vegetables which works positively on the public's health, or by negative mechanisms such as taxation of tobacco and alcohol - which is meant to decrease accessibility, thus also having a positive effect on health. Privately driven gyms and other training facilities are also contributing to the overall health of the public, together with loads of other examples.

In this section we will concentrate on the public and private institutions that are concerned with investigating/examining, diagnosing, treating and follow-up of patients in Norway - and not focusing on the general and preventative institutions or regulations.

The Norwegian health care sector is for the most part privately funded. We will focus on the differences in private and public healthcare in the next section. For this section we will

concentrate on the structure of the Norwegian public health sector, as the privat actors also have to adhere to this structure as a whole.

Executive hierarchy

The whole of the Norwegian healthcare sector is governed by the Ministry of health and care services on behalf of the parliament. The parliament makes the laws, and the government, through use of the ministry and its departments, are tasked with managing the healthcare sector in accordance with laws and political regulations. The next hierarchical step are the regional health authorities. They too do not actually provide any concrete health services, but are rather concerned with administrating and executive tasks.

Geographical division

There are four regional health authorities. They are named according to the geographical regions of which they govern. The North-, West-, Mid-Norway- and South-East region. These regional health authorities each govern over a set of health trusts. These health trusts may be large or small, and often also adhere to a specific smaller region. In most cases a practical view would be to see one health trust as being the same as one hospital, although that is not always the case. For example, the St. Olavs hospital Health Trust, is a trust that is composed of the St. Olavs hospital - a 400 bed tertiary regional hospital located in Trondheim. But it also includes Orkdal hospital and Røros hospital - two very small hospitals (tha last mentioned also lacks emergency medical capacity). So the trust is the executive organization that owns and governs these three hospitals - which are all of the hospitals in the former county of South Trøndelag. The two hospitals of the previous North county together form the NorthTrøndelag Health trust. It might be excessive to explain now, but to be sure, the single hospital is the next hierarchical unit beneath the health trusts. They have responsibilities for a population within certain geographical borders.

Demographic division

In lack of a better term, we have called this section “demographic division”. By that we mean that there is a divide that discriminates across different parts of the public regardless of geography, but rather on the basis of age, needs, conditions or other demographic markers. This is a division that is meant to ensure that the people that require medical aid get help according to their needs. The consequences of this is that not anybody can be admitted to hospital - there needs to be an actual medical reason for why one should be granted access to

those resources, so that the resources are not spent all at once, or on things that could have been handled on a lower level.

The system of the Norwegian public health sector is divided in mainly two parts. The primary and the secondary health services. The secondary health services are also commonly referred to as the specialized health services. This is a bit misleading because parts of the primary care are also specialized for their tasks, and GPs also have a specialized degree in family medicine. What this terminology is meant to point out is that the primary sector is more focused with the general public, medical and health problems - while they refer patients to the specialized services if they need further help with specific problems that cannot be solved in primary care.

Example: A GP is expected to control, manage and dose anticoagulant medication for patients with atrial fibrillations. But if the patient is significantly bothered with heart palpitations, or the heart frequency is dangerously high, the patient may need electric conversion of the heart rhythm, which also requires narcosis. So then the GP needs to refer the patient to a hospital for this procedure, before the patient can return to his normal follow-up at his primary physician.

Location of health services

Earlier we explained the difference between in-patient and out-patient work. And as explained in the previous subsection most of the specialized medicine takes place in-hospital, treating so-called in-patients. There are however some out-patients clinics that provide specialized medical services either public or private outside of the hospital, sometimes with agreements with the hospital, and sometimes without any hospital deal.

For the primary services more or less all activity, either it is the GPs office or a physical therapist, is out-patient based. But nursing homes and similar facilities are primary care institutions where patients are admitted for a longer period. Such facilities carry out different tasks. These tasks may vary from end-of-life palliative care for the elderly or mortally ill - or it might be short-termed rehabilitation after operation, fractures or other treatment - with the goal of returning to their own homes. The municipalities are also charged with providing home care services, and administer the assistive technology centers.

2.2.4 Differences in public versus private healthcare in Norway

The health care services in Norway are for the most part publicly funded. That means that it is the government that pays for the services that are being used. During the following subsections we will describe some services and concepts where the division of private and public either merge in cooperation, or is otherwise important to understand for a startup trying to map the market of Norwegian health services.

All-Private Services

All-private services is our term for the health services that are privately owned and driven, as well as privately funded with the cost carried by paying patients or customers. In Norway this is a small part of the health care sector, and in some cases it is more concerned with cosmetics or other improvements that are not actually a healthcare related issue. The patients are therefore to a larger degree customers of a service, than they are patients subjected to care. In Norway such services have been criticized for leeching on crucially needed work labor from the public healthcare services. In the all-private health sector there are higher payments and more money to be made for employees and owners, but it is heavily regulated, and they cannot be concerned with important medical tasks in Norway.

General Practitioners (Fastlege)

In Norway the primary health services revolve around the general practitioner. The Norwegian term is “Fastlege” which is hard to translate properly, but it means that every Norwegian citizen has their own go-to primary care physician. Or at least that is the meaning. A primary care physician is a specialist in family medicine. It should be noted that the Norwegian word for this specialization would be more easily translated to “General medicine” (Allmennmedisin), but for English speakers General medicine refers to what Norwegians understand as Internal medicine.

The GP is tasked by the municipalities to serve a part of their population. The amount by which the GP is responsible is often varying between 1000-2000 patients. The amount of work per patient is dependent on the demography of the patient population. The GP receives a base grant for the number of patients, and that they are reimbursed by Helfo (The Norwegian directorate of Health/Norwegian Health Economics Administration) for each patient contact, following a set of codes that determines the size of the reimbursement. For instance, a simple consult might cost the patient NOK “X” and then the GP is also

reimbursed NOK “Y” from Helfo. If the patient uses more than a specified sum pr. year, they will no longer have to pay deductibles. The GP are themselves responsible for housing rent, buying and servicing equipment, hiring and paying staff and so on. In sum the GPs are a crucial part of the public health care system, but they are in essence privately owned and driven - although mostly publicly funded.

Contract Specialists (Avtalespesialister)

Contract specialists are organ specific specialists, just as the ones in hospital, that work in out-patient clinics with a similar model as the GPs arrangement (Fastlege-ordningen). They are also reimbursed according to a deal with the hospitals, and therefore publicly funded - but are privately owned and driven. Some studies have shown that they can be more effective than the hospital doctors, but there are also a lot of limitations on what can be done outside of the hospital. A lot of these contract specialists also have an all-private part of services as a part of their overall business/clinic. It depends on the referral of the patient, and whether the patient has a condition that gives him or her the right to certain health services, or not. E.g.: A so-called boob-job is not something that one can rightfully claim the public to pay for - BUT - if the patient has severe and chronic back pain because of a large set of breasts, they might be entitled to get a breast reduction procedure.

Choice-optional Hospital Services (Fritt behandlingsvalg)

Since 2015, by law, patients have been able to freely decide where to get hospital treatment in Norway. The arrangement was limited to so-called elective procedures - which means procedures that one can plan in advance, and not emergency procedures. E.g. if a patient needed emergency surgery for appendicitis the patient would not be able to choose to be operated at another hospital, the nearest possible and capable hospital will do it. But if you are going to change your hip joint for a mechanical prosthesis during the next year because of arthritic wear and tear - you could choose to do that in Trondheim, even though you might live in an entirely different region. This law affected how hospitals organized themselves because the patients' choices suddenly had economical consequences for the hospitals. If a hospital had a bad reputation for conducting one specific procedure - all the patients that might normally have been operated at that hospital would now be able to travel to another hospital. Then that hospital would receive the Helfo reimbursement. In this way patients rights mechanisms might have the same consequences as customer/consumer mechanisms.

Dentistry

In Norway, dentist services are not a part of the public health care services for adults. The county provides a public dentist service up to a certain age, but this does not for example include odontological surgery, braces or similar services. As a result, these services, alongside regular adult dentistry, are very expensive in Norway.

2.2.5 Differences in Product Definitions and Their Use

Another important divide is definitions of tools and equipment on the basis of what they are going to be used for. There are different regulations and restrictions for tools and equipment depending on what they are designed for. This applies for both hardware, software and other services.

Drugs, Medicine and Pharmaceuticals

Medicines for use in or on the human body are required to pass a series of approvals. For the most part these processes are linked to R&D. The FDA (U.S. Food and Drug administration) provides a simplified overview of the processes towards getting a drug approved for market use, as seen in table 2.

The Drug Development Process according to FDA

1. Discovery and Development Research for a new drug in the laboratory
2. Preclinical Research Drugs undergo labaratory and animal testing to answer basic questions regarding safety.
3. Clinical Research Drugs are tested on people to make sure they are safe and effective. This research has especially strict ethical and quality regulations.
4. FDA Review FDA review teams thoroughly examine all of the submitted data related to the drug or device and make a decision to approve or not approve it.
5. FDA Post-Market safety Monitoring

FDA monitors all drugs and device safety after products are available for use by the public.

Table 2: *The FDA step-by-step process of drug approval* (fda.gov, 2022)

Similar processes are conducted in European countries and other parts of the world. Some countries have joint committees to approve medication, such as for the European Union. For smaller countries such as Norway - an approval is made by The Norwegian Medicines Agency, but they almost always build their approval on the approvals of other international committees or agencies such as the European one. The process of getting a drug approved is immensely resource-demanding, both in time, money and people.

In Norway there is also a difference between being approved for use by patients, and being approved as a drug that the Helfo will reimburse the cost of. It is the same agency as mentioned above, and its sub-committees that decide which medications will be reimbursed, and for what reasons or conditions. E.g. allergy medicine can be bought without prescription in stores in Norway, but some allergy medication can only be retrieved from pharmacies if the patient has a prescription - and only if the allergy is severe enough will the patient be reimbursed parts of the drug cost. It is the physicians that are the gatekeepers of this arrangement as they are the ones that can assess whether the allergy is severe enough to meet the criteria of an approved diagnosis.

Invasive versus Non-Invasive Use

A lot of medical equipment needs to undergo the same types of approvals as drugs. An important divide is made between whether the equipment is for invasive or non-invasive use. That means; is the product going into the patient (e.g. a surgical scalpel or a protesis) or is it for use outside the body without anything (including drugs) getting into the body or being absorbed (e.g. bandages, prefabricated casts for fractures, braces, etc.). All tools and equipment need to meet some general safety standards such as the European CE-marking, but invasive tools need additional approval from different committees and agencies depending on its suggested use (dsb.no, 2022)

Tools and Equipment for Aiding Decisions

Then there are products that are not even going near the patient, that might still carry consequences for the patient when applied. This might be software or other tools that aim to assist the decision making process of the physician. E.g. If a software uses artificial intelligence (AI) to suggest different forms of treatment for a patient, then it will have to undergo a different quality control process than a software that only lists alternatives for the physician to consider themselves. The logic behind this is that the physician's decision might be affected by the AI giving a certain treatment, and since this has a direct or indirect effect on the patient the public wants to be sure that this is safe - because it affects the physician that has already undergone a major quality control program, namely years of training and education. We cannot therefore uncritically just apply the logic of AI without making sure it is safe or indeed better.

Other Non-Medical Products and Services Used In The Healthcare Sector

The last category for tools we will address is all the other non-medical products used in the health care sector such as e.g. computers, chairs, personal clothing. For most of these products there are no specific health related approval program - in Norway they all ofcourse need to be CE-marked, but other than that they only need to meet the requirements for use set by the user. So if a hospital is buying computers they set their own terms and requirements according to their need. They might specify cost, delivery, service deals, longevity, etc. These specifications are often what is subjected into the process of invitations to tender.

2.3 Innovation

There are many ways of defining or describing innovation. The most liberal will say that almost every process is innovative in some way or another - but that does not really help to understand what innovation is. In this section we will describe innovation in a broad sense, as well as defining the more specific innovative phenomena important for our thesis, namely, entrepreneurial activity, startups and software as a service.

2.3.1 Innovation In A Broad Sense

The Oslo manual is a book of guidelines for collecting reporting and using data on innovation. It has a longer name; The Measurement of Scientific, Technological and Innovation Activities - and was last published in 2018 as a fourth edition. The Oslo Manual provides a definition of innovation, which is used by the OECD. The manual states

innovation goes far beyond Research and development (R&D) as it also involves “users, suppliers and consumers everywhere - in government, business and non-profit organizations, across borders, across sectors and across institutions" (Oslo Manual, 2018). The manual is describing different types of innovation pertaining to marketing, products, processes or organizational innovation - but in general innovation can be described as:

“A new improvement or process (or combination) that differs significantly from the previous products or processes and has been made available to potential users or brought into use by the process.” - **(OECD 2018)**

2.3.2 Entrepreneurship

Entrepreneurship is so linked to innovation that it is difficult to explain entrepreneurship without understanding innovation. Indeed it is so linked that it might be difficult to give an explanation of entrepreneurship that distinguishes it from just being innovation. One definition is that entrepreneurship is the process of how to establish new organizations and also the conversion of technical information into products and services (Shane & Venkataraman, 2000). Entrepreneurship is vital for industrial growth and societal renewal, together with innovation (Braunerhjelm, Acs, Audretsch, & Carlsson, 2010; Praag & Versloot, 2008).

Entrepreneurship as an academic field is fairly new, and would still be considered as a young and immature field compared to other fields of research, although it started back in the eighteenth century with Knight and Schumpeter - focusing on economical effects as well as effects on society that entrepreneurship has. Entering the computer age and with other new and rising technologies the field of entrepreneurial research gained traction as people were questioning the efficacy of the conservative mega-corporations. Entrepreneurs were linked to employment and production growth and providing innovation (Praag & Versloot, 2008) and investigations to how they reach these goals were being made (Landstrøm & Benner, 2010)

2.3.3 Startups

If we view innovation as a process of improving on solutions to problems, and entrepreneurship as the process of implementing such solutions - one might say that a startup is the means by how this process goes about. A startup is a wielder of entrepreneurial activity.

With the words of Schumpeter the entrepreneur is the introducer of innovation (Landstrøm & Benner, 2010). As the terminology suggests, a startup is something new or recently formed. One might say that a startup is started from scratch", although that will not be true - as there is always an idea, a team, some experience or other factors that precedes the startup itself. Startups are often recognized by smaller teams, sometimes just one person, and few resources. The Dotcom-boom of the 90s contributed to a view that a startup also was both rapidly developing, and with a significant risk of failing (Grant, 2020). Although new ventures carry some risk of failure, it is not necessarily true that all startups grow quickly. That depends entirely on the case itself, and the environment of which it is situated in. One of the biggest challenges met by startups is that they have to compete with larger and established corporate bodies (Ries, 2011). Thus, a good idea is not enough, because an idea can be copied and a well-established firm with plentiful resources might develop such an idea faster, and out-compete the startup before it gets tracktion in the market.

2.3.4 Barriers to healthtech innovation

Our experience through discussion with our peers is that there is some skepticism towards embarking on the journey of entering the public health market with a startup. The reasons given are often the perceived high entry barriers to health tech in general, that increase the effects that were mentioned in the end of the last paragraph - namely that one cannot compete with big pharma or healthtech firms. There are also other reasons that introducing change to the healthcare sector might be difficult. Psychological, cultural og political resistance to change - or lock-in mechanisms such as investment, competency, system- or stakeholder lock-ins (De Wit, 2017). To give some examples; there might be a culture or tradition of medical practice on how to perform a certain task that makes it difficult to introduce a new product or manner of performing the same task. Another example, a concrete one, is the ongoing process of the Electronic Patient Journal-system (EPJ) in Mid-Norway called Hell Plattformen. Currently there are amongst the employees a psychological resistance in that it is hard to learn new skills, and they already know the old system well - thus there is also a competence lock-in to the old system (DocuLive). There is a cultural resistance because it introduces a new practice of documenting patient journals that greatly affect the way things have been done for the last decades, and there are political resistance in both questions to general patient safety of using the system, and also in that patients to a larger degree more easily can excess what doctors notes on the patients - this is by the doctors believed to affect

how they formulate these notes, and as a result might self-censor (which would not be to the patient benefit as it limits cross-disciplinary discourse between MDs) or doctors might choose more trivial words so that the patient understand better - but at the cost of medical accuracy that the medical latin and greek provide. On the other hand, Helseplattformen is happening and there is no going back. That is due to investment and stakeholder lock-in mechanisms. It is already too big and expensive to fail. This also has consequences for future innovation as Helseplattformen is such an expensive project that all future innovation EPJ and date services need to be complementary to Helseplattformen. However we have also recently seen that some of these barriers can quickly be overcome if an extreme situation requires it. There was a great resistance to video-consults among doctors prior to the Covid-19 pandemic, but with such a huge and fundamental crisis as a pandemic, the resistance quickly was overcome because of the need of social distancing. In some cases a video consults were the only medical responsible means of conducting a consult. The result is that after Norway lifted all of its restrictions, doctors still use video consults because it is practical and efficient for both doctor and patient, and now there is no longer psychological or cultural resistance, because they have been through a successful process of learning and experience - and invested in video consult solutions.

2.3.5 Drivers and inhibitors of industry development

A bit similar to the barriers as mentioned above De Wit also writes about inhibitors of industry development in general. There might be underlying conditions, industry integration, power structures, risk awareness, industry recipes and institutional pressure, that hinder development (de Wit, 2017). This of course also applies to the healthcare sector. For instance - a hospital is a very traditional and hierarchical environment. There might be a chain of rank with regards to decision-making within a department - where the most senior consulting doctors have last say. If these are affected by the resistance mechanisms of the last subsection - this might hinder the entrance of new solutions or innovation of that department. This is just one example. But there are also drivers of industry development: Economical, technological, political/regulatory and socio-cultural drivers all might stimulate innovation (de Wit, 2017). For the Norwegian public healthcare sector there is always a drive to decrease expenditure. Political drivers might change with change of government, and the socio-cultural drivers might come from both employees of the patients themselves. With reference to the megatrends mentioned in the beginning of this chapter, patients have increasing demands to

the healthcare sector - this in turn also affects the politics. Then there are factors such as new entrants, suppliers, buyers, substitutes or complementary and of course competitors that can also motivate change (de Wit, 2017). These factors might play a lesser role, compared with everything else that has been mentioned in these two last sub-sections. Since a public healthcare system of a country is such a large client it is also often the dictator of how things are done - it is more often that the suppliers have to change, than that the hospitals have to change because the suppliers require it. Also, as far as competition goes - for public health in Norway, and large parts of the world, there is no real competition. Private actors might provide their services according to what the government allows, but if the government does not want competition - then they will regulate the laws in such a way that there will be no more competitors.

2.3.6 Software in healthcare

Lastly in the Innovation sub-chapter we point the limelight towards software. Software has been an increasingly important part of our daily lives for decades. This is true also for the healthcare sector - though there is still a surprising amount of analog paperwork, use of fax machines and other out-dated practices. According to an American survey 83% of US IT healthcare organizations were using cloud services (as of 2014, with a further 9,3% planning to) and 63% of them running on Saas-based applications (HIMSS Analytics Cloud Services, 2014). We chose to focus on software when performing our investigations mainly for two reasons. One - we believe that software will play an increasingly important role in healthcare, and two; A lot of the barriers of introducing newly developed hardware to the healthcare sector are strictly legal or dependent on highly specialized quality approval processes that are not in themselves concerned with the actual phenomena of decision making in procurement processes. We wish to focus on the unwritten mechanisms that govern these processes of procurement and try to understand how to successfully enter into public health - or on the other hand, if all the formalities are in order - how or why might one still not be able to access this market.

2.4 Literature Search and Theoretical Framework

A series of structured literature searches was made to try and identify relevant literature to the specific subject of investigation in this study. The term literature search is used deliberately as there was little to no directly relevant literature to review. Furthermore we are reluctant to

use the “literature review” terminology as this might give associations to an entirely different study and design than our investigations. The Method chapter will provide insight into how the searches were conducted. A structured search was important to substantiate the claim that there is no directly relevant literature to our specific investigations. For that reason the background chapter of this thesis is heavy with descriptions of the environment in which our investigations take place - namely the crosspoint between entrepreneurs and public healthcare.

With assistance some literature describing public organizational buying behavior and decision-making in the public sector in general but it was too narrow of a scope, suited to international affairs, that using that litterature as a framework for our study would be too risky - since there is such little knowledge on the area. An article comparing the purchasing of health services in public and private sector respectively showed that at least in the USA there was a difference in that the public procurement processes where heavily influenced by transactional-based approaches, driven by policy and other regulatory mechanisms - whereas the private procurement processes was relational based using a range of different approaches (Lian et Laing, 2004). This is interesting as it supports the notion that Norwegian public healthcare is presumably heavily dependent on policy for their procurement processes.

To build a framework that would be able to capture the possible phenomenon and themes in such a scarcely described subject it was necessary to be quite general. Applying a too specific or narrow scoped framework for investigation would risk that the investigations were aimed at something that had no relevance to the research question. Therefore we relied on the general mechanisms of organizational resistance to change, both at institution and industry level. De Wit offers insight into the ruling mechanisms and how they might be overcome. Using this as our framework would focus the investigations towards the barriers of entry and how to overcome them, and we also expect the framework to be general enough to pick up on any inductive insight the cases may provide during the interviews on their own accord.

Reference to these mechanisms have already been made in the explanation under the subsection “Drivers and inhibitors of industry development” previously in the background chapter. It would be unnecessary to repeat, especially since the complete insight is readily available in the book “Strategy - An international perspective, 6th edition” by Bob De Wit (2017) on pages 408-409 and 509-510.

This leaves us with a framework that builds around barriers and challenges and how to overcome them, using different strategies. Acknowledging the importance of policy and regulations we concentrate this framework around the procurement and tender processes as well as on the process of approval through the means for research and development.

3 METHOD

This chapter will present the methods for gathering and analyzing data for this thesis. The research design and methodology were chosen on the basis of what was best suited to investigate our research questions. The reasons for our choice will be also discussed in the following sections, as well as limitations and potential biases that we address later in this chapter.

3.1 Research Design

Choosing the correct research design can be difficult because different designs described in business research literature are not necessarily perfectly fitted for the variation within a given subject or field of investigation. The aim of the thesis is broadly to identify and describe interactions and relationships of importance, between two different types of actors.

The research design for this study is a qualitative and descriptive multiple case study, we applied the method of semi-structured interviews as a means of gathering data. Qualitative interview techniques like this focus more on the perspective of the interviewee and allows the interviewer to follow up on the theme that the interviewee brings into the interview without it being part of the predefined questions, focusing also on what the interviewee views as important to their case (Bell et al, 2019). The theoretical framework from previous literature provides the opportunity to draw knowledge through deduction. The open-minded approach of the semi-structured interview format allows for inductive learning, as explained further in Business Research Methods (Bell et al, 2019) featuring a take on multi-case study design, as according to Eisenhardt (1989).

3.1.1 Preparation

The field of this investigation is not very well mapped. Infact, the uncertainties of how one might enter the public healthcare market often disway startups from embarking on that path. When starting the work with formulating the research questions an assumption developed that there is a lack of previous academic literature on the topic. This suspicion was given further support during our work with the preliminary study (Akse, Frøland and Roti 2021). Support for the assumption was also found in the master thesis of a previous co-student (Olluri, 2020). He concluded after his literature review that there was little available literature on the topic

for his thesis, titled “Delineating Born-Public Ventures” and thus had a similar scope for his literature review.

Preliminary study (prosjektoppgave)

As part of our masters program we did a project report. Although that report is an independent piece of work, it served as a preliminary study for our master thesis - providing us with important insight. We did not set out to do a proper literature review as part of that project. This was because we had such a strong suspicion that there was no relevant academic literature on our specific field of interest. We therefore set out to gather data from other sources, and we also conducted a handful of informal interviews to further our understanding within the field of inquiry - so as to better conduct the study for our main thesis. The preliminary study thus gave us important information on how to best formulate our main research questions and hypotheses, and to properly map the market which we wanted to investigate.

Literature search

As stated we did not conduct a proper literature review in our preliminary study, nor did we present the proper reasoning for how we could reach the conclusion that there was no relevant academic literature available on the subject. The correct way of arguing that there is no literature available would be to do a proper literature review, present the findings and then conclude. For our main thesis we will therefore do a structured search to properly demonstrate the amount of literature that is accessible for review, and present the potential findings in the background chapter in a designated subsection.

Course of the literature search

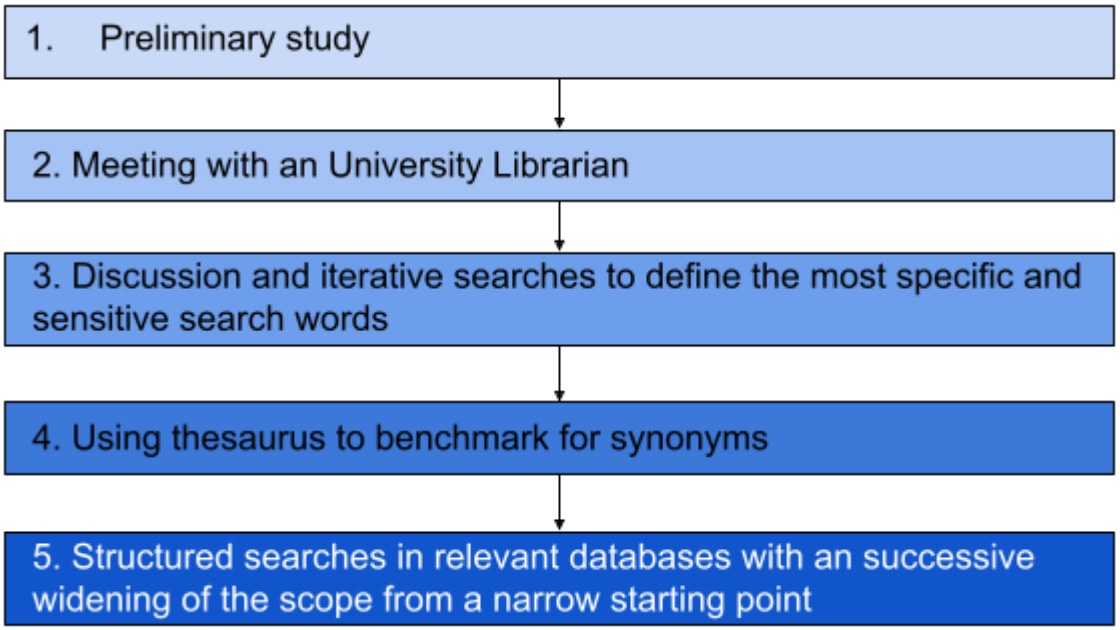

Figure 1*: The figure is showing how we approached the task of a literature search.*

As demonstrated in Figure 1 we followed a predetermined sequence of action to ensure the quality of our search. Appendix 2 offers a Literature search guide that was used to structure the searches. The preliminary study provided insight in the research field (1). We then contacted the NTNU Library services that expertly aided in how to design and conduct good quality searches, and also provided us with insight into which databases we should use to ensure that we were covering all available sources of relevance (2). Thereafter we discussed which search words would be optimal with regards to both specificity and sensitivity of the search. We wanted to identify relevant literature, but we also did not want our search to be so specific that we risked losing out on possibly relevant literature. As a part of this process we did a series of informal and iterative searches to identify key search words (3). After identifying the proper search words we applied a thesaurus tool to identify synonyms to our search words (4). We then conducted searches within two databases - “SCOPUS” and Ebsco’s “Business source complete”-database. We started with a narrow search to identify litterature with very specific relevance, and then removed search words in a predetermined sequence with proportional decreasing relevance and and increasing the scope of the search for literature with uncertain relevance to our field of investigation (5). The details of the searches are presented in the background chapter, together with our findings.

3.1.2 Scope and Selection Criteria for Interviewees

To identify interview objects we needed to take some considerations. When interviewing only a few, opposed to gathering data from hundreds - this selection process is very important. First, we needed to define what constitutes a startup company in this setting- and is the general definition suitable for our application. There are different ways of defining a startup company - and they differ depending on the situation of which the startup is put in. It might be defined by years of existence, number of employees or revenue. The definitions shift depending on the situation and environment. Since there is no clear cut definition of a Health Tech Startup in the Norwegian tax system we have to define this ourselves. Generally we believe that health tech startups remain startups for longer because of the large entry barriers - and so it takes more time and other resources to leave the domain of the startup sphere.

We did not want to limit our scope to businesses that had successfully secured a tender offer through a public procurement, or indeed only tried to apply. This is because we also wanted to identify startups that either had not succeeded or were earlier in the process and had not yet applied. Also there are other ways to enter the Norwegian public health sector than through procurement processes. For reference we also knew through the work of Olluri (2020) that neither the Norwegian national database for public procurement (doffin.no) nor Statistics Norway (SSB) had any statistics on these matters.

The authors of this thesis already have some insight into the domain of Norwegian Health Tech companies, as one of the authors is currently CEO of a Norwegian Health Tech software company, and one author is a medical doctor. All authors are students at the NTNU School of entrepreneurship and part of the study program’s alumni organization ESAF, and therefore have insight into all of the relevant Norwegian Health Tech clusters.

On this basis we set our scope to searching within the startup cluster called Norway Health Tech. Its main focus is to facilitate R&D and industrial cooperation between researchers, the industry and health care professionals. Norway Health Tech has approximately 270 members according to their own webpage. We went through the membership list and read about every

firm, cross-checking them with proff.no that provided the year of establishment, number of current employees and revenue.

Thereafter we discussed a set of agreed upon criteria for what could constitute a startup in this market. But since we had no clear-cut definition we could not act on these criteria with total absolution. We went through this list and further discussed borderline cases using our expert opinion to separate out those that clearly was not a startup based on what is the common perception on what constituted a Health tech startup in a norwegian context. We also excluded from the list those that we believed to have little knowledge to offer on our specific research questions. Lastly we then separated out the startups working with software, as these were the aim of our inquiry.

The reason for focusing on software-startups is that they are more easily comparable to each other, and also that they are not subject to a lot of other requirements that are not directly relevant for the phenomena of procurement or partnership. E.g. a startup developing a medical equipment for surgery such as a implant needs to apply for a lot of approvals and certificates that are important before it can be assessed by the customer - but understanding those processes does not really provide insight into the aim of this thesis - which is investigating the process of actually entering the marked even though all the formalities are in order.

The Process of selecting cases

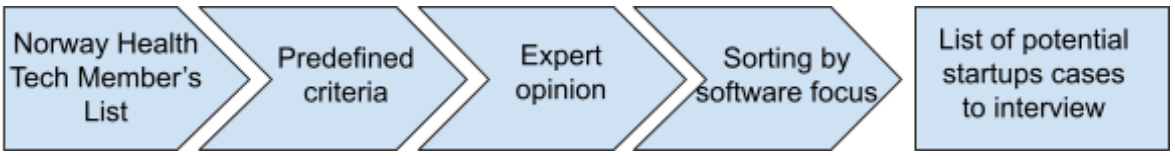

Figure 2*: The process of selecting cases and interview objects for our study.*

Figure 2 shows the workflow for identifying potential startups to be interviewed. The potential startups where thus limited to:

- Located and operating within Norway

- Being a start-up as defined by the authors.
- Working with software-related health tech solutions.
- Working towards or with public procurement, or other innovation partnerships
- Have the time and will to be interviewed.

We did not want to limit the potential subjects to the members list of Norway Health Tech alone because what would exclude those few that have not yet been included so far, or for some reason chosen to stay on the outside. Nevertheless that does not mean they have nothing to contribute

3.1.3 Data Collection And Interviews

As our research design is a qualitative and descriptive multi-case study, we applied the method of semi-structured interviews as a means of gathering data. Qualitative interviews focus more on the perspective of the interviewee and allows the interviewer to follow up on the theme that the interviewee brings into the interview without it being part of the predefined questions, focusing also on what the interviewee views as important to their case (Bell et al, 2019)

Based on the literature we had a framework on which we formulated a series of questions that formed our interview guide. The interview was thus semi-structured in that we did have a guide, but still let us be attentive to what the interviewees wanted to highlight outside of the planned framework. Thus some questions of less importance were skipped, while others were added. The interview guide is available as the appendix 1. This was our primary source of data, and the details concerning the actual gathering is described in the subsection “Recording and Transcribing” below.

We registered the project, including the interview guide, in the Norwegian Agency for Shared Services in Education and Research, “Sikt” for short. This is a newly formed agency as of 1st january 2022 after The Norwegian Center for Research Data (NSD) merged with Uninett AS and The Directorate for IKT and joint services in higher education and research. NTNU is part of the institutions that have a deal with Sikt, and so we are obligated to adhere to their system of approval. This is amongst other things to ensure quality, ethics and that the European Union GDPR regulations are followed. The application regulated how the data is

being stored, for how long, and what it can be used for. The project is registered under the reference number 394285. Interviewees were informed according to the rules of Sikt and consent were recorded as part of the interview.

3.1.4 Secondary data sources

There were two main sources of secondary data sources. One being readily available open and accessible web/internet sources. Most different actors and organizations within the NHCS have their own webpages that provide information about the organization and its structure. So do the governmental agencies too. All Norwegian laws and regulations are also available online at lovdata.no. Finding info is not the problem - it's rather navigating and interpreting it. Secondly we also had some inherent knowledge based in the author's team. Thus insight into the nuances of the NHCS that is not presented online was somewhat effortlessly gathered.

3.1.5 Multiple Case Study

We design the project as a multi-case study. It is a popular design within the fields of social sciences because it is able to construct theory by means of deduction, utilizing qualitative data for different cases (Eisenhardt, 1989). The design is especially adapted for understanding the dynamics governing a well-defined setting or situation (Bell et al, 2019; Eisenhardt, 1989; Eisenhardt & Graebner, 2007). A single case consists of data from our interviews, supplemented by readily available data from open sources like proff.no or the company website etc.

3.1.6 Analysis

Data were analyzed using the analysis technique of Thematic analysis Cases will first be presented in Results, before we conduct a case-by-case (single case) analysis of the data. Following this we conduct a cross-case analysis drawing from the data of several cases to explain the mechanisms in play that are relevant for the themes provided by the literature.

Recording and Transcribing

Interviewees were contacted to schedule video meetings with the interviewer. They had in advance been forwarded the information letter explaining their rights as according to the Sikt approval. They were asked if they had read and understood the content, and if they consented

to joining as a study participant. Interviews were conducted using the Google web application for video consults and meetings (Google Meets) or the Microsoft Teams application. The consent was recorded as part of the interview. The interviews lasted for approximately 45 minutes. The applications allowed for automatic transcribing. Although all interviews were in Norwegian language, this method of transcription was functioning adequately for our use. The material was not returned to the interviewee for quotation quality control. The aim of the transcription is to aid the process of retrieving and analyzing data.

Thematic Analysis

A common and well regarded method for identifying themes in multiple case studies is the techniques of Thematic analysis. Unlike other methods of qualitative analysis it has no direct or identifiable theoretical heritage. The search for themes is indeed also the aim of other validated methods such as e.g. Grounded theory. There are few direct specifications to what constitutes a theme, and the definition may vary a bit across the literature (Ryan and Bernard, 2003; Braun and Clarke, 2006). But the literature offers some insight into what constitutes a theme (Bell et al, 2019):

> *"A category identified by the analyst through his/her data. Related to the analyst research focus (and quite possibly the research questions) Building on codes identified in the transcript and/or field notes. Providing the researcher with the basis for the theoretical understanding of his or her data that can make a theoretical contribution to the literature relating to the research focus"*

The Business Research Method book also offers some recommendations for how to identify themes (as seen in the table below). Repetition is a very important criteria for establishing patterns - but it is still important that the focus is no on counting and quantitative methods - it is all about identifying the themes using the inductive and deductive methods of qualitative research.

Method for Identifying Themes in Thematic Analysis

Repetitions	Topics that recur again and again
Indigenous typologies or	Logical expressions that are either unfamiliar or used in an unfamiliar way

categories	
Metaphors and analogies	The ways in which participants represent their thoughts in terms of metaphors and/or analogies.
Transitions	The ways in which topics shift in transcripts and other materials
Similarities and differences	Exploring how interviewees might discuss a topic in different ways or different from each other in certain ways, or explaining whole texts such as transcripts and asking how they differ.
Linguistic connectors	Examining the use of words like “because” og “since” because such terms point to causal connections in the minds of the participants.
Missing data	Reflecting on what is not in the data by asking questions about what interviewees, e.g. omit in their answers to questions
Theory related material	Using social scientific concepts as a springboard for themes

Table 3: *Method for identifying themes using Thematic analysis* (Bell et al, 2019; Ryan and Bernard, 2003)

3.1.7 Limitations

There are of course limitations to almost every research design - when we choose one method, we simultaneously disregard the benefits of other methods. In general one can say that qualitative research compared with a quantitative method sometimes struggle with the concepts of generalizability. We operate with relatively few cases in quite specific situations. We cannot claim that what we observe will for a fact apply to the next case, as there are too many variables for us to control. Our method is best suited to describe phenomena. Thus will the limitations of our work also be limited by our own capabilities of identifying these phenomena within the data - this also includes our own biases. It is therefore of paramount importance that the reader also use their own deductive skills to draw knowledge from this dissertation. The investigation of this study is also one-sided in that we have not interviewed any of the actors within the NHCS that are working with approvals, tenders of procurement processes.

3.1.8 Author’s reflections and disclaimers

As researchers we are charged with being objective. Nevertheless it is not always easy to correct one's own presumptions or preconceptions. Especially when doing qualitative research which relies on our perception of the data. As a disclaimer it is therefore important to point out that one of the authors is a CEO of a SaaS startup working with actors in the public healthcare sector. Another of the authors is working as a medical doctor within public health. This is of course not just a limitation, but it has also provided some benefit in the analysis - we only ask that the reader keep this in mind when reading the dissertation.

4 RESULTS - CASE PRESENTATIONS

In the Results chapter we will present data from the interviews according to the framework presented in the background chapter that lays the groundwork for our interview guide. In all we present seven different cases. Each case is introduced by a table with some statistics and a designated paragraph, followed by a set of subsections faithful to the framework - focusing on barriers and challenges, how to overcome them, procurement processes and strategies. As these are the result of a semi-structured interview there will be some variation correlating with what the cases brought to light themselves, other than what was related to the framework.

4.1 Case 1

Established	2017
Number of employees	5-10
Revenue (in MNOK)	5.1 - 30
Software-focus	9

Table 4: *Case statistics, case 1* (proff.no)

4.1.1 About the Company

Company 1 has developed a software solution for video consultation, used by the health care sector, especially the primary health care service, like general practitioners (GP). The product development started in the autumn of 2017, and the service was ready for launch by spring 2018. In 2019 the number of sales increased, and GPs made up the majority of these sales. When the Covid-19 pandemic hit, the service's traffic multiplied by a hundred in 2-3 weeks.

4.1.2 Barriers and Challenges

Legality

According to the interviewee, the legal barrier is hard to overcome for any start-up in the NHCS. More concrete for Company 1, there are specific requirements for video solutions in the health sector. There is a rule set called *"Normen" (The Norm directorate)* - *"Norm for informasjonssikkerhet og personvern i helse- og omsorgssektoren"*, that applies to all IT-related services. *The Norm directorate* put out some demands and requirements in 2017 for video-consulting tools: Amongst other things, one must access the tool by logging in with Bank-Id. (An universal digital ID used in Norway).

Furthermore, Company 1 details that before the Covid-19 pandemic, it was not allowed to give sick leave to a patient over video consulting. This obviously changed during the pandemic.

Conservative views and old patterns

The interviewee said that the most typical reason why the service was hard to sell is that the GPs were skeptical about using a video consulting tool to replace or substitute for a visit to the GP's office. Company 1 felt that the doctors were quite conservative in general but had a clear conclusion that the private practitioners were much more open to using the solution if it was suitable for the patients.

"Furthermore, young doctors were much more prone to using the solution than older doctors. The most challenging group was the doctors within ten years of retirement. Those were not going to change anything. That is the problem with cases like this: It demands a change of one traditional working process, which is quite a large ask." - ***Company 1***

The start-up also faced challenges that were more in the category of medical objections: The doctors expressed frustration about being unable to examine patients physically, and so on. Moreover, at the beginning of the venture, the norm was that the customers were not necessarily willing to pay for the service.

Slow and Tender Processes

According to the interviewee, one has to be patient if one plans to start a venture in the Norwegian health care sector and push a comprehensive sales approach. Nevertheless, most go out of business because it is a challenging industry.

"We have sold to the public the whole time and have definitely experienced that to be more tedious to sell to than the private sector, but to sell to the health care sector, in general, is quite hard." **- Company 1**

Large Industry Actors

Some prominent actors in the health care sector possess a lot of the resources required to develop something good. Many of these actors have commercial interests, which do not necessarily want to cooperate with more minor actors. If the smaller actors have developed a valuable service for patients, the existing larger actors might develop that service and integrate it with their current systems.

Specific Markets

Another challenge is that most software solutions are suitable for one market but basically have to start at scratch while trying to enter a new market. This is obviously not true for all software solutions, yet it is more prominent in the healthcare industry than in other industries.

4.1.3 Overcoming Barriers and Challenges

How they sold to the public healthcare sector

As stated previously, Company 1 experienced that selling to the public sector was less trivial than the private sector. However, the start-up discovered that even though the administration of the multiplicities was responsible for procurement, the administration mostly listened to the doctors. Therefore, the main task was to convince the doctors of the value of their service.

"There was, for example, a young, forward-leaning doctor that was very interested in the service. She was hired at the public multiplicities doctor office and was clear to the administration that they should procure the service, and therefore it was." ***- Company 1***

Legality

Company 1 developed the solution in order to meet these laws and regulations, and their solution was the only acceptable tool in the Norwegian market, for use by general practitioners, with respect to the requirements and demands of such tools. This was during the time when the pandemic first hit.
The laws prohibiting doctors from giving sick leave over video consulting were changed in March of 2020, at the beginning of the pandemic.

Changing the Conservative view and old patterns

In addition to going around from municipality to municipality and trying to demonstrate the product, much effort was put into changing the perception of video consultations. They gave lectures to *Helsedirektoratet, E-helsedirektoratet, helse og omsorgsdepartementet* and *legeforeningen* and so on. The company was working closely with *legeforeningen*, the party most interested as this is an IT healthcare service. They wrote other reader's contribution posts about how their service was better than the existing substitutes (the substitutes that were around that time offered video-consultancy services, but with a random doctor, in contrast to your regular general practitioner).

The interviewee details that they got around the skepticism of using video consultancy, as a substitute in contrast to a physical check-up, by bringing up the fact that doctors use a phone to call a patient all the time. Therefore, comparing a video stream to a phone call convinced the doctors that this was a better solution. Moreover, Company 1 discovered that these medical arguments for why one should not use video consultancy really stemmed from the doctors having to change their behavior patterns. The doctors were afraid to fail to use the service, which would not work. Hence, the start-up discovered that one of the most important things to put effort into was showing the doctors how to use the service so that they were comfortable with it.

Slow and Tender processes

The company states that they also most likely would have gone out of business if they had to sell their service through traditional channels, such as procurement divisions (for example, *Sykehusinnkjøp* or *hjemmetjenesten*) and other municipality divisions, in contrast to selling directly to the doctors. In this case the GPs are both users and customers, as most GPs in

Norway own their own practice (including equipment), although the services they provide are mostly publicly funded thru refunds from Helfo.

4.1.4 Procurement Process

According to the interviewee, *Anbudsregelverket* is an obstacle for many companies. Nevertheless, if a company within the NHCS wants to have a commercial deal and sell to municipalities or hospitals, the company has to deal with anbudsregeleverket.
This was also true for the start-up that case 1 revolves around, yet, when the pandemic hit Norway, this changed (at least temporarily):

"At the start of the pandemic, there was no talk about tender processes: The multiplicities said we need this now. Suddenly the process went a lot faster" - ***Company 1***

4.1.5 Strategy

R&D Strategy

The company had a research and development project, an innovation contract with a hospital with financial support from Innovation Norway, where they developed the video solution together with the hospital. However, according to the interviewee, those projects sound good but believes that those projects rarely lead to any sales afterward:

"There is a large appetite for R&D at hospitals, but if one is to sell the products at a later time, you are dealing with other people, with priorities and demands. It takes the point out of the innovation contract because the point is really to create a service/product that the customers are willing to pay for, but that does unfortunately not always hold in the health care sector". - ***Company 1***

According to the interviewee, many barriers were not considered earlier when it comes to procurement. The transition of going from an innovation contract to being able to sell a solution is a relatively large gap, and for most start-ups, it stops there.

Commercial Strategy

The company had a relatively short development time and was therefore early to reach the market with a finished service. The team focused on general practitioners, which are financed

by public funds. According to the interviewee, 80% of the primary health care doctors are private practitioners that have contacted and made a deal with the municipality where they are stationed, while the municipality directly hires the remaining 20%. However, before the pandemic hit, the interviewee said selling the service was pretty hard. Nevertheless, they found a strategy that yielded better results, hence more sales. The early strategy was for the team to travel across the country to promote their services to municipalities, both public and private general practitioners, and present their solutions. This was quite resource-demanding, yet this was the only effective way to sell their services.

"We had to call around to general practitioners' offices and invite ourselves to a lunch meeting. Then we had to travel to that office during lunchtime and present the solution. Sometimes we would have to bring lunch to get the meeting accepted. The norm was that when some health care consultants presented a solution, they often had to bring lunch. So we showed them the solution and helped them get started"

- Company 1

Challenges and Issues with The Strategy

The interviewee said their strategy was not successful before the pandemic. In January of 2020, the start-up successfully made about 6% of the doctors in Norway use video consulting. This was not enough to finance the development of a finished product further, and Company 1 was not optimistic about the future.

Going around the Anbudsregelverket

The company did not have to go to tender processes as they developed a fairly simple solution with a low cost; therefore, it does not trigger a Tender process. If the service is below NOK 100 000, there is no need for a Tender process, while NOK 500 000 is the formal limit for triggering a Tender process. However, they sell licenses for active users of their service. Active users are chosen because it lowers the barrier for the doctors, as they have control of the initial cost. They have found a "loophole" of how to sell their service for such a low cost (initially) that they can sell it for under NOK 100 000. Nevertheless, the total cost can go far over that if the number of users increases, but no one thought of that. Software as a service and using active users to decrease the initial risk is, therefore, a great strategy to not trigger Tender processes.

The Covid-19 Impact

When the pandemic hit, the sales to the municipalities increased radically. Furthermore, other municipalities' services and organizations were fast to buy the solution. The first sales to public hospitals were also made during the pandemic's start. The fact that the start-up's video consultancy tool was the only acceptable tool satisfying the demands and requirements when the pandemic hit, in addition to the fact that the team had already been out a year visiting and promoting the tool to municipalities across the nation, is what the interviewee holds as the reasons why their service was chosen to be used.

Strategies for the Future

The company has tried to reach out to other markets, more specifically, other countries. However, they have discovered that these other markets are saturated: There exist similar services everywhere.

"Companies that offer the same service like us [internationally], and that is the reason why we are in a challenging position today." **- *Company 1***

According to the interviewee, most companies made their final choice when they chose a video consultancy service in march of 2020, and they are not returning now.

"So in conclusion, to penetrate a new (geographical) market now is almost impossible, and we have talked to companies that are developing similar solutions that share that opinion."
- *Company 1*

According to the interviewee, they should have had a far more aggressive strategy to go international. However, it is also noted that during this time, they were fairly preoccupied with serving the Norwegian market, which was the reason why they did not do it back then.

4.2 Case 2

Established	2021
Number of employees	1-5
Revenue (in MNOK)	0-0.5
Software-focus	4

Table 5: *Case statistics, case 2* (proff.no)

4.2.1 About the Company

The second case revolved around a start-up from Trondheim, more specifically, the founding team was enrolled in NTNU School of Entrepreneurship (NSE). The start-up produces mobility equipment for those who struggle with moving their arms. Their goal and vision are to let people with permanent and substantial disabilities have a more independent everyday life. Moreover, over the long term, the start-up hopes its product will be a rehabilitation tool.

4.2.2 Barriers and Challenges

Legality

The start-up states that they must deal with the regulation "Medical Device Regulation" (EU directive) as they are developing medical equipment. They also have to deal with the *Norwegian law of medical equipment* and "*folketrygdeloven"*. The latter is a law that states that if a patient has a substantial and permanent disability, they are entitled to public funds to get some of their function in everyday life. The interviewee states that these are the main regulations specific to their case and that there are more universal regulations for all companies in the Norwegian health care sector to follow.

Constraints of the Norwegian Marked and Healthcare sector

While being asked about knowledge of other start-ups that have been rejected for a project, the interviewee says that in some cases, the Norwegian Health care system has responded that they want the product or service to be validated in other countries first. In other words,

Norway's public health care agency did not want to be the first country to try the service or product and has therefore rejected the project.

Furthermore, the interviewee mentions that some countries are much more developed regarding "software on prescription." Germany is one of the leading countries in this and is, therefore, a potential country where Norwegian software start-ups within health care want first to enter the market.
However, this is also correlated to the market size; the German market is somewhat more extensive than the Norwegian market.

In the Norwegian Health care sector, extremely high requirements exist for a cost-to-benefit analysis. One has to, through clinical trials, show the exact benefit of the service, which is compared to the cost of the service. The interviewee says that one of the projects with *Oslo kommune* involves discovering the cost to the benefit of the product, yet this has to be done by a third party.

Large Organizations Are Fragmented

The interviewee reveals that they have been rejected by certain actors while trying to land an R&D project. *Oslo kommune* is an example of a large organization with multiple agencies and districts. The start-up has faced many rejections from several of these agencies, yet, believes that this was not because they did not believe in their product but because the start-up and that particular agency were not a great match. It is also quite a tedious task to navigate through these organizations as there are no organizational maps of key employees who are the correct person to get in touch with for the start-up.

4.2.3 Overcoming Barriers and Challenges

Legality

The interviewee admits that the laws and regulations of the Norwegian health care sector can be intimidating. It might seem like a significant barrier to starting with health tech. However, there are many examples of start-ups that have been successful. The regulations are not that impossible to overcome and are there to protect the patients. If a start-up is serious about fulfilling the requirements, it can do so, and in return yield credibility and ethos.

Furthermore, if the start-up has been through the barrier of the healthcare system, the start-up can get a better competitive advantage than in any other industry.

How to navigate through fragmented organizations

While the start-up faced rejections from several agencies in large organizations, for example, *Oslo kommune,* it learned to navigate these large organizations. Finding the correct agencies with the right person would yield a better match with the start-up and lead to deals. In other words, it is essential to identify the person responsible for the start-up's targeted customers.

One strategy the interviewee discloses is that they have had a close relationship with user organizations, which leads to getting in touch with some potential future customers. As health care workers follow these potential future customers, the latter sometimes tell the start-up who is their health care worker: For example, their occupational therapist. Then the start-up contacts the health worker, who again alerts their boss.

4.2.4 Procurement process

Company 2 has a fairly complex product that classifies as a medical device. Hence, the laws and regulations are so strict, that the start-up still has a long development time, before satisfying these laws and regulations. As a result, the start-up has not been working on any commercial deals that lead to a procurement process. Nevertheless, the start-up has identified that its primary customer in Norway is *NAV* and the start-up, therefore, knows that it will have to be involved in Tender processes.

The interviewee specifies that he can think of two commercial deals: ordinary public procurement and pre-commercial procurement. The latter is a commercial deal without a fully developed and commercialized product.

Furthermore, the subject implies uncertainty if pre-commercial procurement triggers a Tender process but states that any commercial deals below between NOK 100 000 and 1.3MNOK will not trigger any Tender processes. For example, a service sold for NOK 150 000,- will not trigger a Tender process but still has requirements for "a fair competition." However, the definition of "a fair competition" is fairly subjective and is, in practice, not that high of a demand. There are no strict regulations in contrast to Tender processes.

4.2.5 Strategy

R&D Strategy

The interviewee explains that they have partnerships with *Oslo kommune*, *St. Olavs hospital,* and a company owned by *Helse midt Norge*. Moreover, they are in dialog with both *kommunehelsetjeneste* and *spesialhelsetjenesten*. However, these are not commercial contracts but R&D contracts that entail that these actors either provide financial funds, their employees' time, or both. Some of these agreements where the start-up "hires" the healthcare workers as consultants to further develop their product require a third party like Forskningsrådet, which provides monetary funds.

Commercial Strategy

The Start-up has hired an employee responsible for the commercial aspect and has contact with the health sector. After talking to other start-ups in the health care sector, this was done as the start-up knew that it is imperative to have a close relationship with the market and customer.

The start-up's primary strategy to enter the Norwegian Health care sector is to, first and foremost, build trust with healthcare workers. "We have observed that if we have a great trusting relationship with the health care workers and if they, from a medical perspective, have faith in the service, they will convey this to their supervisors. Moreover, suppose the leader (who is the decision-maker) gets a request from one of their employees. In that case, the leader will have a much more positive perspective on the product than the interviewee sending a “cold-mail” asking them to buy the service. Our primary strategy is to build trust with the health care workers and get them to approve the product from a medical perspective.

The interviewee also elaborates on other strategies, such as being visible at conferences, fairs, and seminars. This is quite beneficial as it gets the start-up's name out there and because many of the correct people who are a good match with the start-up attend these events. However, the interviewee explains the paradigm of a start-up that most likely does not have a fully developed product but still wants to attend the events and show off its product. The problem is that an unfinished product might send the wrong message, and the industry actors get the wrong first impression.

The interviewee is under the impression that the most effective way to enter the market is to focus on the patient and patient organizations. That way, one first and foremost gets much insight into the problem one is trying to solve. Furthermore, the start-up will gain ethos and credibility in the industry as users validate the need for the service.

Alternative Strategies

According to the interviewee, some start-ups have developed the product or service (which requires, for example, testing of the product on users) in less regulated countries, for example, India. This is in contrast to Norway, where there are strict requirements to do patient testing with an unfinished product. This reduces the processing time and is a more "forgiving" process, as the start-up can make their mistakes in the less regulated country and then return to Norway as the product or service is finished. The interviewee is skeptical about this approach and finds that method to be in a somewhat ethical gray zone.

"The ruleset [in Norway] is very strict, but it is really to protect the patients. I think it's an Ethical question if a company wants to reduce the development time by testing their product in a less developed country." - ***Company 2***

Competitors and Other Actors in the Market

The interviewee states that they do not have any direct competition in Norway. Moreover, other actors and start-ups in the market are primarily considered, by Company 2, as something positive because they can "lead the way" and pave the way for other companies. However, this can also go the other way if a start-up fails and the health care organization loses faith in other start-ups. This is especially true in the case of a failed start-up, when a new start-up, with similar technology, wants to establish itself in the market.

Furthermore, the interviewee states that they try to learn from the mistakes of failed start-ups. They have also established contact with other industry start-ups and are members of different health tech clusters and incubators. This is a great way to share and discuss experiences and network.

4.3 Case 3

Established	2010
Number of employees	21-49
Revenue (in MNOK)	30+
Software-focus	9

Table 6: *Case statistics, case 3* (proff.no)

4.3.1 About the Company

The company, referred to as company 3, behind the third case, has founders with experience in health tech, entrepreneurship, and other start-up ventures. Company 3 is closer to a scale-up than a start-up; it delivers products and services to emergency services and has had a significant role in digitizing emergency services in Norway. The result is that the Norwegian emergency responses have better control and flow of data. Furthermore, the accumulated digital data has to lead to previously impossible analyses. A significant percentage of employees at company 3 have experience working in the Norwegian healthcare system. Furthermore, the company has several commercial deals with hospitals, emergency services, and other healthcare companies.

4.3.2 Barriers and Challenges

From an innovation project to commercialization

According to the interviewee, being involved in the innovation community is essential and the starting point for any start-up. However, going from an innovation project to tipping over the considerable barrier of having a commercialized product and selling the product is a huge threshold.

Relationships with the Industry

The interviewee explains that a significant barrier for start-ups is that they lack credibility or a relationship with the HCS.

Different actors within the NHCS want different things

The interviewee details that different actors and agencies within the NHCS exist with different goals and needs. An example of this is the IKT organizations of the NHCS, which according to the interviewee, are practical barriers as they want as few applications to maintain and run as possible. This is in contrast to the clinical and the innovation environment, as they want the most and best solutions. Furthermore, the interviewee expresses the opinion that the IKT organizations are too independent, lack innovation, and are, in general, bottlenecks for the NHCS.

Getting approval and meeting medical demands and requirements

A great barrier in general for start-ups in the NHCS is that the service or products need to get "approved" *[The interviewee refers to getting their service or product to meet all requirements and demands to get accepted as a medical device].* Even though this is necessary in order to protect patients, this is a relatively high barrier. The threshold of the barrier depends on how intrusive the solution is. For example, if one has software that gives decision aid for a doctor, this is classified with the same constraints and requirements and needs to be approved on the same line as (for example) a defibrillator.

The interviewee notes that such software would not be as requirement-comprehensive as clinical testing for medicines, yet one should be absolutely sure that the software works. It is also mentioned that the supplier classifies if the software is a decision aid for the doctor. Company 3, for example, has defined all their software solutions as not a decision aid today but is working towards it. This dramatically reduces the development time and the approved process of the solution.

Third parties are involved in approving the medical equipment, for example, Veritas. This is also mentioned as a barrier and bottleneck as too few parties are involved in the appointment. In 2021, a new directive called MDR [Medical Device Regulation] was introduced to ensure patient safety by setting higher quality and safety requirements for medical equipment meant for the EU market. The directive also aims to promote innovation of medical equipment and ensure equal application of the regulations in the EU. Nevertheless, the interviewee considers the directive as yet another bottleneck and barrier.

4.3.3 Overcoming barriers and challenges

Innovative contracts and Close Relationships with the Hospitals

The interviewee expresses the opinion that the company is a scale-up and not a start-up. Furthermore, the close relationship with the hospitals is one of the most critical aspects of how the company survived the start-up phase and is now considered a scale-up. The interviewee describes how working closely with a hospital during an innovation project was essential to have a successful commercial project with another hospital.

Generally, the interview object considers an innovation project essential to succeed. Most of the projects need to be initiated by the start-up. There are a few cases where the hospitals have approached a company to develop a service, especially after the merging of municipalities, but this is rarely the case. The interviewee also notes that a good strategy is to bring someone who has a relationship to the hospital, which could give the company more credibility while meeting the innovation department of the hospital. The interviewee notes that the NHCS is very relationship-based, so bringing a partner with these relationships is a great advantage.

Furthermore, the interview object explains that several of the innovation projects they have landed (both national and international) is most likely because they have been very conscious of the importance of relationships and have therefore used their network to get credible health care workers to recommend the company to an innovation project.

4.3.4 Procurement process

Company 3 has been successful in entering the Norwegian market yet has been very conscious only of focusing on their local market. Just now, they have started looking at other markets and are aiming to enter the rest of the Scandinavian market. Even though the processes are different, the other Scandinavian countries also have tender processes. How start-ups, scale-ups, or companies in general enter these Scandinavian markets are out of the scope of this paper, yet, company 3 gives an exciting way of approaching the other markets that might be relevant for start-ups trying to enter, either solely in the Norwegian market, or the Scandinavian market.

The company has a dialogue with a health service in another Scandinavian country, where the goal is to land an innovation project. However, the company is merely doing this innovation

project to be in a better position when the national Tender process for that service is available. This way, the company has experience with that country's data systems and its relationship with that actor.

The interviewee shows skepticism toward Tender processes in healthcare. The general consensus in the industry is that the Tender process is not as open as advertised.

"What is important, which is easy to forget, especially if one has not been involved in Tender processes before, is that the influence leading towards a Tender process is at least as important as what goes on after the Tender processes have been announced. That is why the innovation project, the pilot, or the relationship to the actor who announces the Tender process is critical." - ***Company 3***

4.3.5 Strategy

R&D Strategy

When asked if it is possible to enter the market with limited resources, the interviewee says that it is possible, yet one has to be extremely patient. This is compared to start-ups in other industries.

One of the critical R&D strategies of company 3 was not to have too intrusive software. As a result, the requirements and demands for getting approval to use the service were significantly lower. The company has been selling the service for several years and is just now trying to build software that gives decision-aid to doctors. This will obviously increase the service's value and raise the requirements and demands. However, it is vital to take note of the order of how they deployed the service, which is now gradually building up its complexity.

Commercial Strategy

Company 3 has chosen a strategy for growth where they shall ensure growth in the Norwegian market. Their philosophy is that all of their customers should be happy, and the company would not consider going into other geographical markets if they are not happy. However, the company has international ambitions and is planning to do so, yet is focusing on its local market first.

Another important part of the strategy is constantly innovating and improving existing functionalities and developing new ones.

"If we do not improve over time, we will die" - ***Company 3***

The interviewee also notes that minor improvements and innovation over time are much more feasible than more significant innovation gaps, as the latter requires tremendous resources.

The last part of the strategy is to keep expanding the value chain: "Are there any parts of the value chain associated with what we currently do?" Their strategy is to buy other companies that operate in that place in the value chain or develop functionality for it from scratch. In the future, company 3 expects its revenue to be pretty split between itself and the companies they have acquired.

The interviewee underlines that any start-up that wants to enter the market can not in any way underestimate the understanding of the commercial aspects:

"In Norway, we are good at technology and building products, but we often underestimate the need for commercial competence and commercial resources." - ***Company 3***

An example of good commercial understanding is if you have a service prototype to bring a person who has relationships with the targeted actors. Also, to have a person who can do marketing, pricing, and in general, commercialization. There is far too little competence in commercialization in Norwegian start-ups.

Competitors and Other Actors in the Market

The interviewee explains that they have not had any Norwegian competition, only companies that deliver associated functionalities. Those actors are considered opportunities, as they can deliver supplementing services and, for now, at least, are not direct competitors.

4.4 Case 4

Established	2019
Number of employees	1-4
Revenue (in MNOK)	0-0.5
Software-focus	9

Table 7: *Case statistics, case 4* (proff.no)

4.4.1 About the Company

The start-up involved in case 4, referred to as company 4, was started in 2019 due to a spin-off of a university hospital and an established consultancy firm. The company provides 3D holographics for the pre-planning of surgeries using the Microsoft Hololens.

4.4.2 Barriers and Challenges

Legality

As the start-up is trying to reach the market with a medical device, they are not allowed to sell anything before the CE marking legally supports one. However, the CE marking ruleset was changed during the pandemic, so the company has a long backlog of tasks to be completed before trying to achieve a CE marking. The company struggles to do testing, as they are not allowed. A few contracts a start-up may have without the CE marking exist, but all of these are innovation contracts or, at last, not commercial ones.
According to the interviewee, it takes about six to eight years to put the service from "innovation" to the market. This depends on how intrusive the medical device is, but the latter holds true for relatively intrusive medical equipment, where one, for example, exposes a human body to something that is new; then, one has to follow the rules.

Furthermore, the interviewee explains that many companies in the HCS have failed because they have approached the regulatory and CE marking the wrong way.
To further move outside Norway to markets like the US or the middle east, one has to have what is called an FDA approval.

Focus innovation on clinical benefits

Additionally, many start-ups are focused on innovation or the product. They have not paid enough attention to the clinical benefits or considered how it integrates into the clinical pathway. Moreover, the interviewee says that one has to do a thorough Service design innovation, which means ensuring that the end-user wants the service that the company is developing.

Blockers and Stakeholders in the Hospital

According to the interviewee, many natural "blockers" exist who have the power to turn down a project or service. Furthermore, the interview object says it is critical to identify these blockers. One example is that the hospitals have fairly strict GDPR rules. Therefore, many technical aspects must be safe and robust to deploy a software solution. In this example, the IT department is partially hired at a hospital to practically block or prevent some software solutions from being deployed because the safety of the software, or the benchmarking of the security, is not satisfactory.

Lacking Infrastructure of support in the NHCS

The interviewee says that being a part of a community is very important for a start-up. According to the interviewee, many things like legal, accounting, business, and other fields are required to run a business, especially in the health care sector, and there are hugely lacking support. However, the interviewee also states that the pandemic changes things for the better in the innovation environment. Because people were forced to sit at home, more innovation parks exist, like *forskningsparken* and *the cancer cluster.* However, the interviewee expresses that these are a bit "defused parks," "old fashioned" and not thinking too "much out of the box." The interviewee feels there is no good collected platform to encourage technology and entrepreneurship, no education seminar or educational platform. For example, Trondheim and NTNU, have several separate buildings instead of a "main innovation center." In Sweden, they have a lot of larger companies, but also start-ups, in the same industry (but also different industries) that are sitting in large centers or shopping malls.

"We need a mini Silicon Valley in Norway/Oslo" - ***Company 4***

4.4.3 Overcoming Barriers and Challenges

Legality

The innovation contract with the university hospital is the only way to reach the "experimental" center of the hospital, where you are allowed to "play with the research." This is a way of overcoming the “Catch 22” scenario, where one company is not allowed to do testing on patients because the service does not fulfill laws and regulations, yet can not do product development because the company cannot do testing.

The contract with the industrial partner ensures that the intellectual property and patents of the research, with the university innovation contract, go to the company and can be commercially used. In other words, the contract with the industrial partner ensures that technology transfers from research to industry.

Service Design Innovation to Ensure Clinical Benefits

In order to ensure the clinician benefits, the interviewee says that one has to do a thorough "Service design innovation," which means ensuring that the end-user wants the service that the company is developing. This involves researching the environment and how the end-user actually operates.

Identify Blockers and Stakeholders in the Hospital

The interviewee explains that it is essential to identify the stakeholders in a hospital:

"Who are the hospital's stakeholders? Whom does one have to go see to sell it? Who does one have to go to in order to ensure that the service is not going to get blocked?." - ***Company 4***

A stakeholder is anything from nursing personnel, to the IT department, to the clinicians, to the cleaners, in other words, the whole infrastructure.

4.4.4 Procurement Process

Company 4 has no commercial deals, only innovation, and R&D contracts. The company knows that to get into the procurement process, one must have a certified product with CE marking. Therefore, this has not been an area of focus.

4.4.5 Strategy

In general, the interview object expresses that networking is the most typical way to enter the health care system effectively:

"One must know whom to go to, to understand and build a network and know-how to collaborate. I think that is the most important factor." - ***Company 4***

R&D Strategy

The company has an innovation project with a university hospital and an industrial partner. Their general strategy is **to work with clinicians for clinicians** and integrate their service into their everyday tasks. Furthermore, the company takes the clinician to the chief finance officer at the hospital so that the clinicians can explain the benefits directly to the hospital administration. The thought process of the start-up is:

"How do I get my innovation into the top ten innovations, where the hospital finance department would agree that the hospital needs this service: It would benefit and it is efficient. So you have to work with the end-users to get the people who sit at the top [administration and finance] to understand the benefit for the medical and hospital team. So you integrate yourself [or service] into the department to make them sell for you."

- Company 4

Commercial Strategy

The start-up does not have any commercial deals. In order to do so, the company's service needs to be approved as a medical device with a high level of imprudence.

Challenges with the Strategy

The key challenge with this strategy is to get time with the clinicians. According to the interview, the clinicians are extremely busy, so one must have a unique solution or service to attract them. The start-up aims to have a mutually beneficial and dependent relationship with the clinicians so that the start-up needs them and vice versa. However, the clinicians have to take time from seeing patients to consider innovation, which has become even more challenging after the Covid-19 pandemic.

How the startup Deals with Challenges

Nevertheless, to be more efficient with the clinicians' time, to be more credible, and in general, to have higher chances of landing the contract, one should bring the correct team to the meeting. For example, if company 4 is going to meet the IT department of the hospital, the company should bring competence regarding IT development and services.

"Make sure you have the right people with you that can answer questions. If not, it is a waste of time for all of you. So always focus on the team and bring value with you."

- Company 4

Alternative Strategies

The interviewee mentions that different strategies exist to enter the market in other countries. For example, in Germany, where the healthcare system is primarily based on insurance, so that the insurance companies are a targeted group for cooperation.

Another strategy is to go straight to the regional health authorities: The regional health authorities are divided into four geographical sub-groups and can be seen in the figure below, to the left (figure 3). As seen in the right-hand figure (figure 4), the regional health authorities are responsible and in charge of the hospital trusts and, therefore, the hospitals. Therefore, the strategy would be to go directly to these regional health authorities and talk to them about integration, which then again forces hospitals to adopt the technology because it makes them more efficient. Therefore one can go to these authorities to try to start a program.

The structure and divisions of Norway's Healthcare Sector

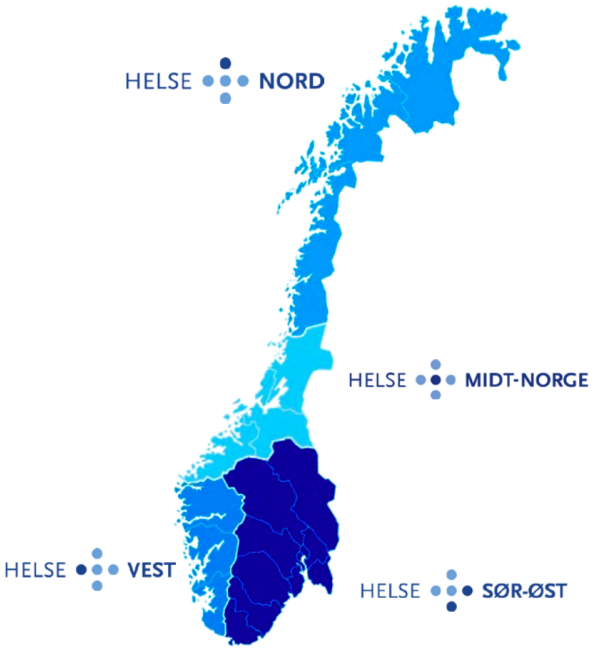

Figure 3: The Four Regional Health Authorities in Norway (Glette, 2018)

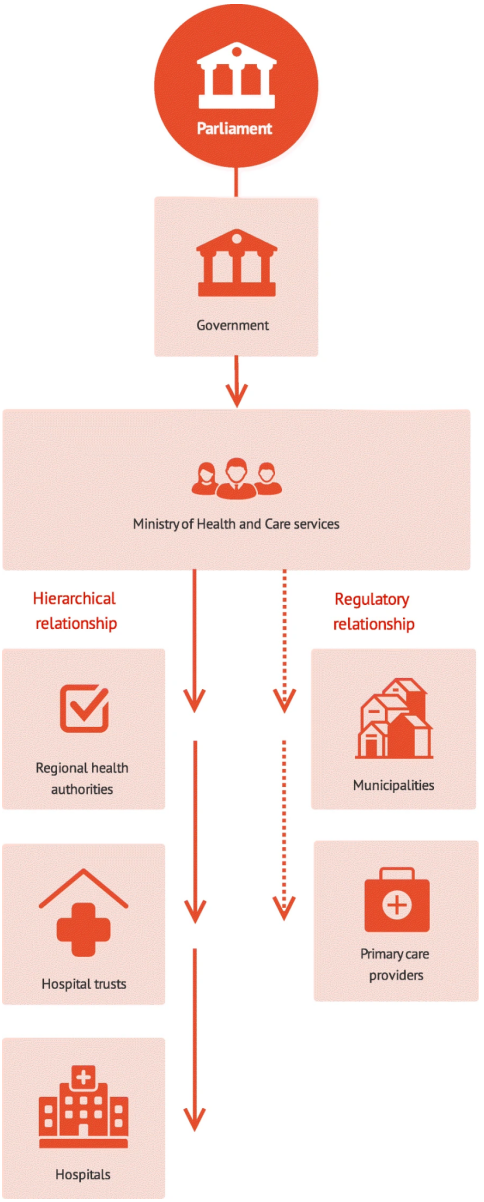

Figure 4: A simplified structure sketch of the NHCS (Glette, 2018)

The last alternative strategy is government lobbying, going to the government and The Minister of Health and Social Services.

Other Actors in the Market

When asked if the company considered other start-ups, scale-ups, and companies in general, to be threats or opportunities, the interviewee explicitly stated that they are viewed as opportunities and possibilities.

"When one has to go through the regulatory route that we [in the NHCS] have to, the more that's doing it at the same time, the more likely we are to get through. As an actor, you can only get a 20% market share initially. So if there are other players out there, they are doing the work for you as well" - ***Company 4***

4.5 Case 5

Established	2018
Number of employees	11-20
Revenue (in MNOK)	1.6-5
Software-focus	9

Table 8: *Case statistics, case 5* (proff.no)

4.5.1 About the Company

Company 5 is a company that stems from medical research conducted in 2014, where two psychologists revealed challenges regarding patient mapping regarding if treatment has any effect. The main challenge that the company tries to solve is: There is a lot of effort, money, and resources put into mental health today, but no one knows the results. What are the quantifiable results of different treatments?

The company sat down with mental health patients and developed a methodology through asking many questions, where each question was tailored and made for the patient. The company has developed software with an AI module that picks these questions for specific patients. The software records the answers of the patients and will alert them if something changes to the patient's mental health, which is again gauged by the accumulated response to all the questions. In the future, the company aims to offer the solution as a medical device.

4.5.2 Barriers and Challenges

Mental Health Treatment is Autonomous

Company 5 explains that in contrast to, for example, a doctor that works in a hospital with a team, treatment for mental health is behind a closed door between two persons. Therefore the therapist is relatively autonomous, can choose their own methods, and usually gauges the progress of the treatment with a gut feeling. Since the solution of company 5 is very clinical, the solution changes the therapist's working method or might challenge the medical field of expertise.

Legality and Validation

The company details that they must consider the *Medical Device Regulations (MDR)* and fulfill that. They also have to consider GDPR, as with most other actors. The interviewee also mentions that they touch upon laws and regulations regarding health workers and journal recording.

The interviewee also states that even though it is not a law or regulation, the industry requires extensive validation of the solution, which is a very high barrier for most start-ups in the NHCS. Hence, this industry is, therefore, more resourceful and capital demanding than other industries. The interview details that if a company answers questions regarding laws and regulations unsatisfactorily, they will always have trouble while trying to enter the market.

"The infrastructure we have sat in place has cost a tremendous amount of money, yet again this results in when we get questions and have a discussion with a potential customer, we can answer all questions and put an end to the discussion there and then, in contrast to using a lot of time and resources to try to find the answers to these questions. No, to be honest, I do not really believe in a careful approach when it comes to start-ups in the NHCS. One has to go full out, full speed ahead. If not, one has to get at least a distributor that can do a lot of the heavy lifting for the start-up" - ***Company 5***

4.5.3 Overcoming Barriers and Challenges

Changing the perspective of the solution

The interviewee claims that today, the consensus around the solution might have changed and that the solution is considered a good supplementation tool and conversation tool to thematize the problems. The company speculates that at the start of their venture, the consensus was

that their solution was the only correct solution and that there was no room for clinical consideration made by the therapist. The interviewee admits that this might have been a misunderstanding at the start and, therefore, a barrier.

Legality and validation

Company 5 explains that they have an employee that works with regulations and laws. Furthermore, they put much effort into 'being everywhere to promote and validate their solution. They have experienced that some of the most important and prominent figures within the NHCS have talked about their solution, yet have been in several meetings with health authorities afterward, where the actor does not know the solution. Then it is critical that the company can answer all questions regarding laws and regulations, end-users, integration, and implementation. If one cannot answer these questions, the company risks appearing unprofessional. It will most likely get a response that this is a prominent solution and exciting technology, but the actor does not have faith that the company will be able to deliver.

4.5.4 Procurement Process

The interviewee admits that the company has suffered because their company and solution has always been a smaller gear that fits into a more extensive system with larger gears. This has made the procurement process fairly tedious. The interview object details that they would have done some things differently if they were to start over:

"If we were to start over again, and to be smart, we would have focused more on integrating into already existing solutions that had larger portions of the market already, like 'Journalsystemet.' We took the door-salesman technique" - ***Company 5***

Nevertheless, company 5 explains that their experience is that the most typical way for companies to enter the NHCS is through Tender processes. Nevertheless, this is usually for more established companies with an established product. If the company and product are still not mature enough, try to get Tender processes that actors have put out that are more R&D focused.

4.5.5 Strategy

R&D Strategy

Company 5 explains that between 2018-2019 the company ran around selling power points. In 2019 they had a development project, not a commercial deal, a regional project that was started to test the solution for company 5. After 2019 a commercialized software solution was ready. By this time, the company and its solution were presented to a vast number of health authorities, and it was decided in 2020 that all municipalities should know what Company 5 is.

The company explains that they have had several innovation contracts. For example, they have delivered part of their solution as a part of a research project, where company 5 is considered a supplier of their service, with funding from the Norwegian research council. They have also had innovation partnerships with health authorities. They are comparing this to a less strict Tender process because in their innovative partnerships, the health authorities have specified what service they require, and then with the company, tried to reach a satisfactory solution.

However, according to the interviewee, the NHCS has not been very familiar with SaaS solutions. Where the NHCS previously has been used for investing in solutions, now the funding goes from an investment cost to operational costs. According to the interviewee, this has caused several challenges and barriers, yet the trend is that there will be more and more SaS solutions. That is why the interviewee explains that an API (Application Programming Interface) solution (API allows for easy integration of services and functionalities) might be a more “smooth” transition, where integration is as seamless as possible.

Commercial Strategy

Company 5 spent a great number of resources and time talking to therapists; they went around and held lectures and conferences, aiming to showcase the solution's clinical benefits. When they had meetings with the municipalities, eight therapists were typically sitting around the table, yet the administrator or the decision-maker was not there. Therefore, if the solution was to be procured, the therapist had to take it to the next level in order to get a purchase decision approved. The interviewee says that there are advantages and disadvantages to this strategy. The disadvantages are mainly that this is a prolonged process,

and the decision-maker might not be informed of the solution or not be interested in hearing about it. The advantages are that since this is a slow process, it results in better anchoring so that, in the future, when the decision-maker understands that a system is required, Company 5's solution is often the first that comes to mind.

"We have seen many examples of actors that have contacted us now, maybe after a year or so, and have now decided they need a solution and that they want ours." - ***Company 5***

By the end of 2020, the first customer was signed, and a new customer (municipality) was signed each second week. They have commercial deals with the municipalities (around 40), the special health service, some of the student health services, and some of the private health services. According to the interviewee, the solution is a "B2B2C" model, meaning that the actors, public or private, buy the solution and again offer the solution to their patients. The latter is the end-user of the solution, yet the patient can never take the initiative to buy or use Company 5's solution; this initiative must come from a health care worker.
Furthermore, as explained, the company often receives requests from actors that they presented one year earlier. However, the interviewee also admits that their solution has been better integrated into a system. Therefore the company can automate a much larger percentage of the data flow because of digitalization.

Weaknesses of the Commercial Strategy

According to the interviewee, the most considerable weakness or drawback with their strategy is that one does not communicate with decision-makers. Integrating with existing solutions, or for example, developing a solution based around an API would have reduced the time to get a larger market share.

When asked about what could have been done differently if the company was to start over, the interviewee explained that they would have put more effort into market research and figuring out the needs of the market instead of having the focus on the technology and the visionary potential of the solution, that the market might not have been ready for.
Furthermore, when asked about general tips for future entrepreneurs that want to enter the NHCS, the interviewee answered:

"I would have taken a close look at existing solutions and technologies. Then I would have asked myself how unique my service or solution is. If the uniqueness is too small, I would have considered if there are other potential customers for such a solution. It is such time and resource-demanding to enter the NHCS, so I would carefully consider the solution and technology compared to other existing solutions. Also, If the solution is to give clinical value, I would have teamed up with some researchers from day one." - ***Company 5.***

Competitors and Other Actors in The Market

The interviewee explains that most NHCS start-ups struggle with the same thing as Company 5: to enter the market. Moreover, the interview objects impression is that start-ups are thinking 'too small':

"To enter this industry, one must draw up a timeline for at least three to five years. If one decides to keep for themselves the first three years, without selling any shares of the company and not involving that many others such that the progress of development is too slow, one basically loses three years. There is only one way to do this: to go all-in, involve others early, grow your company and almost give the impression that this [the business case] is larger than what it actually is. One has to get capital and to cover all of the required fields of the business." - ***Company 5***

Furthermore, the interviewee explains that the problem with the more prominent and established actors is that if a health authority already partially or fully has covered a need, it is tough to get entry as a smaller actor with overlapping functionality. It is a form of segmentation of already existing actors where one does not open to new actors that might have better technology, methods, solutions, and working processes. However, the interviewee also states that the company has observed that the health authorities are starting to rethink this approach as it yields suboptimal results.

The interviewee explains that the company has no direct competitors in Norway and is, therefore, primarily considering other start-ups and larger companies as opportunities. The company takes all meetings with start-ups to evaluate if their solution might be a competitor, measure their impact, and consider if their solution might be added to the company's solution to get a better comprehensive solution "so that one gets that '1+1=3' effect".

Furthermore, with larger established actors, company 5 is always trying to figure out if their solution can be integrated into the established actor's solution.

4.6 Case 6

Established	2021
Number of employees	5-10
Revenue (in MNOK)	0-0.5
Software-focus	9

Table 9: *Case statistics, case 6* (proff.no)

4.6.1 About the Company

Company 6 is a spin-off from a more established Norwegian company and specializes in using VR technology for health care training. The company was officially started in 2021, but the team was working on the case before the official establishment of the company. Whenever a severe trauma injury has occurred, the patient is led to the emergency room, where a team of doctors and nurses awaits the patient. When the patient arrives, time is of the essence. The VR software that company 6 aims to deliver is meant to train for these scenarios. Hence, to shorten the crucial trauma treatment time because doctors and nurses have more experience. One of the founders is from Singapore, and the company, therefore, has connections to hospitals in Singapore. The company has no commercial deals yet.

4.6.2 Barriers and Challenges

Differences in Work Culture and Approaches

The start-up has an innovation contract with two hospitals in Singapore. The Norwegian hospitals were and still are, the priority. Hence, before turning to the Singapore hospitals, the start-up tried to reach an innovation deal with the Norwegian hospitals but was unsuccessful. When asked to speculate why the Norwegian hospitals were slow in their responses and

showed a lack of interest, the interviewee expressed the opinion that there might be a difference in how Norwegian and Singaporean hospitals work. According to the interviewee, the general response time in Europe and Norway is slightly slower.

"For a start-up, time is money, we have a team and everything, so we have to make sure things are moving. We can not sit around waiting for one year, waiting for an opportunity to come, so of course, we are very sensitive in terms of time. So when we speak to the hospitals, maybe because the priority is not on that area at the time, so then the interest is different, or the response is slower. That is the reason why we went to Singapore. Obviously, that is my opinion." - ***Company 6***

Furthermore, the interviewee expresses that Norway is not as open as other Scandinavian countries.

Bureaucracy in Hospitals

The start-up has had some traction from individual therapists. However, the start-up speculates that hospitals lack interest because of bureaucracy, and getting the project approved is harder.

Connections and relationships

A start-up that aims to enter the NHCS with a product requires a lot of product development; therefore, all start-ups need a partner. The interviewee explains that connections play a significant role in the NHCS, and it is therefore challenging for Norwegian start-ups whose core team is not Norwegian.

4.6.3 Overcoming Barriers and Challenges

Connections and Relationships

The start-up uses one of the Norwegian co-founders to reach out to Norwegian health care actors to establish relationships. Furthermore, they have recruited several Norwegian doctors to their medical board. Lastly, they have teamed up with an acknowledged partner that hopefully will increase the chances of success and help the start-up do some of the heavy lifting.

"If you do not have a strong partner, it will be a lot harder" - ***Company 6***

4.6.4 Procurement Process

The start-up is still in the process of development and has had zero to low focus on commercial deals.

4.6.5 Strategy

Why Some Startups Fail

When asked about knowledge of any failed start-ups or failed strategies, the interviewee responds:

"I think that, at the end of the day, when you are innovating a new technology or bringing a new product, it should not be based on what you think, but what the users need. That part is very important. Sometimes we are so absorbed in what we are doing that we fail to see what the user really needs. So I think that is one of the pitfalls. As a tech innovator, it is critical to check back on what the market needs. Engage with the users and talk to them. It is not enough to be a visionary; you have to be very realistic about what people need and what their challenges are. Everything points back to the user" - ***Company 6***

However, the interviewee says that even though one has the perfect product, with the perfect product-market-fit, one is absolutely not guaranteed success. A lot depends on the execution and implementation of the business case. The interviewee gives examples of new users who never had a VR headset experience. They must be comfortable with the VR headset and know how to download required applications. So one might have a fantastic solution, but if the route to using it is challenging, the implementation is not thought through perfectly, and the chances of success are reduced.

R&D Strategy

Company 6 is still in the early stages of development and has just completed its first pilot. The pilot was done in collaboration with two hospitals in Singapore. However, the pilots are co-funded by Innovation Norway. The hospitals in Singapore contributed with knowledge and the content part of the pilot. The interviewee explains that the reason for collaboration with the Singapore hospitals is the lack of interest and traction from Norwegian hospitals. The responses from the hospital were relatively slow. This was before Covid-19 and before

the company was officially established. Then the start-up looked out to Norway, and since there was already a connection with Singapore, the Singapore hospitals were a natural choice. Nevertheless, the interviewee explains that the priority was the Norwegian health care institutions.

Furthermore, the start-up has recently signed a letter of intent with a European institution that certifies trauma doctors to be a part of the trauma team. The goal of the letter of intent is to bring the pilot into a product.

Commercial Strategy

According to the interviewee, the next step for the very young start-up is to do market research to find out the opportunities and pricing. From there, they will be able to develop a strategy. However, the start-up's research found that similar solutions are based on a licensing model.

However, as the start-up is based in Norway, its goal is to reach the Norwegian market first. The interviewee emphasizes that Norway is the priority, but they could not find a partner who wants to work with them or has time to work with them here in Norway.

After the pilots, the start-up has talked to various Norwegian hospitals again and has now recruited some Norwegian doctors for their medical board. The start-up also has talked to simulation centers in order to conduct training.

The European institution that certifies trauma doctors conduct causes in 20 countries in Europe. Therefore, company 6 intends to move into these markets, after the Norwegian market, with a regional office in Norway. Furthermore, they will expand to Singapore for the Asian market.

Competitors and other Actors in the Market

The start-up is a member of Norwegian health tech. However, the interviewee says that since everything is so globalized, the competition is really international and not only national. One has to figure out their edge, the unique value that they bring to the market and clients.

4.7 Case 7

Established	2019
Number of employees	1-4
Revenue (in MNOK)	0-0.5
Software-focus	9

Table 10: *Case statistics, case 7* (proff.no)

4.7.1 About the Company

The start-up in case 7 develops an AI algorithm that recognizes stroke symptoms. In about 50 percent of stroke cases, one gets visible paralysis of the face. The overall goal is to get the patient to the hospital as fast as possible, and in order to do so, one has to recognize the stroke symptoms. What is usually typical today is that one gets a stroke, and several hours might pass before one gets professional medical attention. Company 7 wants to reduce this time as much as possible, and their goal is to recognize stroke symptoms via cameras on PCs, phones, in the car, or even in meeting rooms. There are cameras everywhere, and the start-up wants to develop an algorithm that can utilize these cameras to analyze a person who might have a stroke.

4.7.2 Barriers and Challenges

Legal

The interviewee expressed that there are a lot of regulations and laws the start-up has to consider. However, there is a significant difference between a service that diagnoses a patient independently in contrast to having a service that indicates a diagnosis. In the first case, the service will be viewed as a medical device, and many stricter rules and regulations will follow.

The interviewee explains that the start-up has received legal assistance from Norway Health Tech.

Accumulating Enough Data

The interviewee expresses that one of the biggest challenges the start-ups face right now is accumulating enough data to train their AI. In order to retrieve data, a doctor has to take a picture of the patient's face right after having a stroke. The process of retrieving data is slower than expected as it requires approval and requires satisfactory treatment of data with regard to GDPR. There are several other reasons why this is a challenging task, such that the doctor's priority while treating a patient with a stroke might not be to take a picture.

"Our main challenge now is the retrieval of data. Data comes in but is not fast enough. Eventually, we will get enough data. We just do not want it to take 100 years." - ***Company 7***

4.7.3 Overcoming Barriers and Challenges

How The Startup is Working to Accumulate More Data

As the data accumulation process in Norway has shown to be too slow, the start-up is considering cooperating with a hospital from another European country. The hospital they are cooperating with has started a project that also revolves around stroke, but is not a competing solution. Therefore, the start-up and the hospital might mutually share some data in order to establish a partnership.

Another critical factor in retrieving data is that the model will be more universally applicable for all humans with different ethnicities and not only Scandinavian-looking patients. Therefore, the start-up will eventually have to retrieve data internationally. However, the start-up's strategy right now is to get a working proof of concept in Norway, yet the interviewee expresses that international expansion is essential.

4.7.4 Procurement Process

The start-up still has no customers, yet is in the initial talks with a potential customer.

4.7.5 Strategy

R&D Strategy

The start-up has several R&D deals and projects with public health authorities, whose goal is to develop the product. Currently, the company has no commercial deals or sell to any actors, as they are still in the research phase. However, the company aims to land a pilot in the near future. Furthermore, the R&D deals are from different hospitals around the country and have, therefore, a foot within the network of healthcare actors. This is a pre-sale strategy, as the start-up thinks these relationships will reduce the gap to the next step, which is commercialization. These projects are funded by Norwegian health authorities so that hospitals can spend time and resources in cooperation, with the start-ups, on these projects.

Commercial Strategy

Regarding the commercial strategy, the start-up has not started selling its service. Their current commercial strategy is showcasing and proving the service's willingness to pay. This is done by trying to find customers and map their willingness to pay.

The interviewee says that much time has been spent making cold calls to anyone who might be interested in the solution. A specific doctor was recommended to get in contact with. After calling and pitching the idea and concept, the doctor was so excited that he wanted to help and be the exterior face of the company. Furthermore, the doctor started pulling strings for the start-up and set up meetings with important and prominent people within the NHCS. The interviewee expressed that getting the doctor to partner with them was extremely important, and without the doctor, the start-up most likely would not have the same speed and presence as they have today. After the start-up accumulates enough data, the doctor will publish a study in reputable journals.

Competitors and Other Actors in the Market

The interviewee exclusively considers other actors in the market, even if it is a start-up or an established actor, as possibilities. Company 7 has a unique service and has not yet identified any direct competitors. Hence, the start-up wants to get in contact with any company that might be a potential partner. Moreover, even if there was a direct competitor, the interviewee explains that it still would be considered a possibility as they could retrieve data together.

Company 7 has cooperated with other companies where the aforementioned has accumulated knowledge and valuable experience as a result.

5 ANALYSIS

5.1 Within-case analysis

During this chapter we will do a case-by-case analysis (within-case analysis) looking at each case separately. The presentation is based upon the same framework and follows the same subsections. The aim of the analysis is to go further than just presenting the data - looking at how different factors, together or alone, affected the cases with regards to having positive or negative results. After the case specific analysis, we will do a cross-case analysis - analyzing the themes and phenomena across the cases, looking both at similarities and differences in what is either happening, or not happening - as a result of which factors that are in play.

5.1.1 Case 1 - A blessing in disguise

Company 1 delivers video-call communications solutions explicitly advertised as a secure tool to aid doctors in their assessment of their patients; think “Skype for doctor-patient communication”. We assess their customers to be the doctors themselves as well as the clinics where they worked, with the product users being doctors as well as their patients. Furthermore we believe, based on the interview, that their Norwegian customer will be tilted in favor of public sector hospitals and of mixed private-public actors, that is private sector doctors and clinics working in partnerships with public HCS.

Timing is of the essence

The case of Company 1, as described by the interviewee contains within it several aspects we identify as determinant to the current situation of the company, which includes a successful commercialization run to the Norwegian HCS. Most important of all, was likely the timing of the company in commercializing their solution.

The Covid-19 pandemic arrived at a time when the company was reportedly struggling to convince the industry of the value of their solution. By being in a position, at the outbreak of the pandemic, of being the only credible alternative in Norway for a video-call system for doctors to check up on their patients and with pandemic-related changes to national rules allowing for doctors to grant sick-leave to their patients via a video-link consultation, the company was positioned to take full advantage of the increase in demand for digital healthcare services. It can thus be argued that the timing of the external society-wide shock

that was the pandemic, which caused industry wide pressure on the HCS globally to adapt rapidly to digital healthcare solutions, was a game changer for the company.

What made the game-change possible, was the work the company had done ahead of the pandemic to conform to the necessary rules and regulations that their product would inevitably face. In a heavily regulated industry, being aware and taking action to avoid regulatory pitfalls is necessary for a smooth transition from product development to commercialization. One could easily make the argument, as was implied by the interviewee, that key to the company's ability to capitalize on timing was that it conformed to the regulatory standards demanded of it. Not just during the pandemic event, but also before, when the company still had, albeit fewer, customers

Important to note is that the issue of timing is one that was not known by the company ahead of the pandmeic event, and so was not anticipated. In this case, we therefore believe the factor of timing to be an opportunity of fortune, more than one of design.

Overcoming barriers

Customer understanding and manual in-person product marketing were described as important factors to the company’s recent success, factors which appear to have come about in tandem. The interviewee describes events, such as justifying their product to their customers by using the comparison of a doctor calling their patient by phone for a consultation. Here, it becomes apparent that the company possesses a solid understanding of the customer which they use to amplify the company's marketing message and to lower the barrier to customers. Another good example of this is how the company spotted a customer barrier being the fear of using the product incorrectly, which they promptly addressed by providing hands-on teaching when necessary. Specifically, the barriers that the company overcame by in-person engagement with their customers, would be defined by De Wit as cultural and psychological resistances to change (de Wit, 2017).

Furthermore, one might safely assume that a deep customer understanding is also important to correctly tailor the product to the customer. Though never discussed explicitly during the interview, one might assume this to have also aided the company in optimizing their product to better fit the needs of their customers, instead of just using it to improve their marketing.

Procurement process

Another critical aspect, was and is the way company 1 decided to navigate public procurement processes. As the interviewee implies, the speed with which the company was able to sell their product to the industry once the pandemic appeared can be seen as resulting not just from a significant and sudden demand-shift, but also because of potential customers choosing to *not* conduct a procurement announcement and/or procurement competition. While it is not immediately clear the technical arguments that the customer may have made for this, it might refer to the fact that there were no other alternatives, as stated in § 13-4. of Anskaffelsesforskriften (Anskaffelsesforskriften, 2016), which details viable reasons for skipping tender. In this case, it could be argued that the need existed due to the pandemic, and that there was only one possible supplier. It is also not clear in the interview whether or not this was related to the decision by the company to provide an initial pricing below the 100 kNOK to circumvent the normal requirement for procurement competition in the public sector, which seems unnecessary in the first place if there was no need for a competition. In any event, it was clearly stated in the interview that their pricing strategy was instrumental to not getting bogged down in the tender system. As such, we can assess that an understanding of and an ability to navigate public tender processes has been a key pillar in the success of the company.

Strategy

As we have seen, company 1 appears to have made a strategic choice of becoming familiar with the public procurement process and using this as a key part of their commercialization strategy. This choice appears to have been the correct one. This was not, however, the only strategic decision that was made. The company chose to spend significant resources in traveling and meeting up with their potential customers, in-person. This was a strategic move that appears to have borne fruit, both as a marketing method but also as a method of increasing their customer understanding. Such a labor intensive method to marketing and customer engagement is best understood as rational in the context of a conservative industry, as described by the interviewee, and one where patient welfare and security trumps other concerns. In such a case, as was made clear during the interview, convincing a potential customer may be challenging and requires a focused approach.

It also appears that the company, becoming aware of how to approach a potential customer, i.e by targeting the doctors working at the clinic as opposed to the decision makers on an

organizational level, was critical. This is an example of how customer understanding may enable better targeted messaging, which in this case means talking to the persons who will actually make use of the product and who subsequently may convince the decision makers to actually acquire the product in question.

A final point of interest with regards to strategy, is the company's apparent lack of appreciation for R&D partnerships. Described as being an inefficient way of creating a product that is actually needed, the interviewee implies that the users their products are intended for are very dissimilar in their customer profile to whatever R&D partner they would end up working with. It is clear from the interview precisely why this might be the case, or even if such a belief is actually well founded. Yet, it may be that if the product was mostly intended for general practitioners (GP's), then R&D departments at hospitals may prove to be simply too different of a working place and therefore rightfully unsuitable for customer-targeted R&D development. Due to a lack of more detailed information on this topic, we chose to not speculate further on the validity and possible consequences of a strategic deprioritization of R&D partnerships.

5.1.2 Case 2 - Hardware is hard

Company 2 is developing a conspicuous exo-skeleton for use by individuals with severely restricted personal mobility due to disease or injury. We assess their customers to be certified physical therapists in both the public and private sector, either at an individual or clinic/department-level. The therapists and their patients would then constitute the user group of this product.

A new skeleton is no small thing

This case appears to be heavily defined by the focus on a physically imposing medical device and the longer product development times that are often associated with this type of product. As was made clear by the interviewee, the type of solution they propose will need to satisfy significant regulatory demands. As stated in the interview, this has delayed commercialization activities for the company and increased its time to market. This in turn, may reasonably be expected to increase the risk that investors perceive when it comes to investing in the company, as well as reducing the company's ability to sustain itself in the short and medium term by generating early customer revenue parallel to product development. The flip side of this is the potential for the startup, should it remain an early

mover when it eventually begins market entry, to create a protective moat about its market, in the form of difficult product development, to keep out competitors. This, due to the longer time to market that these competitors could also be expected to have. As of 2022, this appears to still be an attainable future advantage, as there are no competitors in the Norwegian market.

Overcoming barriers

It is unsurprising, given the high level of regulatory approval required and the effects this has on the development time, that R&D partnerships are a key factor in the ever evolving story of this company. This is because research will be necessary to conclusively demonstrate that the final product satisfies the regulatory demands placed on it, and which we assess to be likely significant. Furthermore, quality research could be used to facilitate improving the product in various ways so that it addresses the needs of the customer in an effective manner - the barrier being that the need of the customer, particularly in a heavily regulated industry, may not be obvious to a person without corresponding personal experience. Furthermore, as we expect to be the case generally in the risk averse NHCS, there is the potential barrier with lack of trust. Successful and publicized R&D collaborations with well known and trusted healthcare actors are a method of scaling such a barrier. Though the company seems aware of this, they also seem to struggle somewhat with either convincing potential R&D partners of the merits of the project, or, as was mentioned, “matching” with the right partner. We believe that conducting successful R&D partnerships to be an especially important factor for the viability of this startup in particular, due to the nature of its product and the context of a risk averse industry. As such, the company should consider whether sales skills might be an issue for them, and if it is, find a person with such skills, preferably in the relevant HCS to convey professionalism and trust, to help the company.

Another point of interest is the challenge that the company initially perceived with trying to contact actors in a fragmented market. Having regular contact, and possibly collaboration, with the customer is an excellent way of better understanding the problem to be solved, identifying new ones and how the product might address this. Yet, this contact can be made significantly more difficult to attain if, as in this case, the company struggles to find a relevant hospital department and contact person within it to act as a hypothetical customer and user of the product. Fortunately, this potential stumbling block was overcome by the company, which might otherwise have significantly hampered product development as well

as increased risk during subsequent attempts at commercialization. When considering how a fragmented market poses a challenge to the company's ability to collaborate with their customers, we may also look at the types of persons that eventually become the focus of their attention. These were the therapists themselves, working with the end user for whom the company was making their product, as opposed to the person responsible for procurement, typically the therapists' bosses. We may assess that choosing to focus on the persons who would actually employ the product in their work, would make it easier to be understood when communicating the product's selling points and to make subsequent sales. As mentioned by the interviewee, it is easier to sell to the person who will actually understand the upside, as opposed to someone who will never use it themselves. Not only that, but convincing therapists of the product's potential might also make it easier to gain a potential R&D partnership with the same organization, which in turn could aid product development and later be converted into a paying customer of a "finished" product.

Procurement processes

The fact that the company has chosen to focus primarily on the public sector for its customers and market is in line with the heavy R&D focus and regulatory demands, both of which are often associated with the public health care sector. If one is required to meet high regulatory standards anyway, it makes sense to couple this with public sector entry, as public healthcare represents the larger portion of the NHCS. It is only logical then that the company expects public tender and other procurement processes to be a key part of its future sales activities. This in itself represents a future challenge for the company, as we have seen how said processes may be difficult for startups to contend with. Company 2 does not yet have a plan for this, which we consider to be a strategic mistake, as we have seen how public procurement may be combined with innovation by going for innovation-partnerships or pre-commercial procurement (Anskaffelsesforskriften, 2016)(Anskaffelsesloven, 2016). Even outside of that, knowledge about how procurement is expected to work for the startup *in the future,* i.e when product development and testing is complete, may ultimately shape what the company does *tomorrow,* both in terms of product development and when advertising for potential R&D partnerships.

Strategy

A factor which may have had importance to establishing contact with the right therapists is the strategic choice the company made in connecting with the user organizations that the

patients, intended for the company's product, belong to. Not only does this provide direct access to the relevant patients for discussions and user testing, but it also facilitates contact with their therapists. We assess this relationship to user organizations to be a particularly important factor for the company during their current phase of product development, and for commercialization which will follow later.

5.1.3 Case 3 - Relationships matter

Company 3 works with digitizing various aspects of Norway's emergency services, particularly in terms of enabling better control of data and therefore also the analysis of said data. The company is already commercialized, but has continuous product development to improve various aspects of their offering(s) or add new ones. Their customers are *presumably* the departments and/or clinics responsible for emergency work in the HCS, with the users being the actual emergency workers. It is also, importantly, in a scale-up phase and does not self-identify as a startup. Being a relatively young company, however, and seeming to have enjoyed noticeable commercial success, we still believe their experience with shaping the company to be highly instructive in any context of understanding viable market entry strategies in the public healthspace.

The importance of personal connections

The case of Company 3 is characterized by a founding team with a seemingly significant amount of highly relevant previous work-experience, from both the industry as well as startup ventures in general. Among other advantages brought by this which we will discuss in the subsequent paragraphs, it seems that perhaps more than anything else this has led them to put a significant focus on building connections and networking within the industry. It should come as no surprise to hear that networking would be important for a startup, as the right connections might make a disproportionate difference very early on. An example, provided by the interviewee, is that these relations, by increasing trust, could convince a *potential* customer or R&D partner to go ahead with a collaboration with the company, is solid.

Company 3 would essentially describe it as a "must " for a HCS startup to actively network in the industry and attribute the company's survival to them having done a good job in building connections. This stood out to us, since given the industry background of the founding team, the implication of the interviewee's reflection is "*Those who truly know the industry, know that connections are much more important than anyone realizes*". Given the

credibility of the founders, and the context of a society that is known for a low degree of socio-cultural segregation into different levels of social hierarchy, we feel inclined to take the interviewee's assessment at face value. The immediate implications of this are that startups in the NHCS should pay particular attention to networking and building a positive reputation - perhaps even more than they might expect to be necessary in other countries.

Overcoming barriers

The company's active efforts in building and maintaining personal and professional connections in the industry, can be seen as an ultimately successful effort to overcome a significant barrier. This barrier is the combination of what the interviewee described as a trust based industry and one which is well known to be risk averse and with good reason.

R&D collaborations themselves, also described by the interviewee as critical to the company's success, were recognized as another method of overcoming the trust-barrier. Moreover, it was said to allow the company to familiarize themselves with the collaborating partner, including with systems they used as well as potentially the procurement regime they operate under (relevant for partners in other countries). In a fragmented industry, where different hospitals might do things differently, this is a method of keeping a high level of customer understanding and knowledge but in an elegant manner that will not necessarily require the company to sit down and interview hospital representatives.

With regards to medical device regulations, we have seen how this can potentially be a very significant barrier to market entry, depending on the product being peddled. The company made a clear decision on this topic to postpone the need for EU-wide MDR by specifically presenting their software as something that could *not* be seen as an aid to the user during decision making. This lowered the level of "intrusiveness" of the product, and allowed them to circumvent CE-marking for the time being. Though this barrier can thus only be claimed to have been postponed, the result is the same - it will not and did not prevent them commercializing their product. This would appear to be a clever strategy, though we realize that it might not always be possible to circumvent MDR in this manner if the product is sufficiently intrusive by its very nature.

Procurement processes

The founding team's deep understanding of the market they were entering, and their awareness of the importance of interpersonal relations, also feeds into another critical factor, which is their strategy for dealing with public procurement. At its core, their strategy for this very important aspect of the Norwegian HCS can summed up to a realization that when hospitals announce tender competitions, they may already be a leaning in a certain direction in terms of which actor they prefer to work with, and that this can heavily influence the outcome of the competition that they are required *by law* to host. As such, trust and previous collaboration with said hospital will make the likelihood of successfully winning the competition much greater. Interpersonal relations, as discussed previously, can help with this, but collaborative innovation projects in particular are to be considered an excellent way of creating a clear preference at the hospital, ahead of tender. Which is why the company also sees establishing and maintaining a large number of such projects with different healthcare actors as *essential* for subsequent commercialization.We assess this to be a sound strategy, but one that is dependent on successful previous networking in order to be effective.

Strategy

The company's focus on networking, making connections and collaborating closely and frequently with their customers is a clear strategic choice in and of itself. As we have discussed, this strategy is sound, as it facilitates more efficient product development and market entry from a deeper customer and industry understanding as well as due to increased trust and goodwill from the industry.

It is heavily implied by the interviewee that current diversity in expertise, seen in the company team and in particular in the founding team, was more intentional than accidental. This is reinforced by the statement that this person made, lamenting the lack of commercialization experience and commercial ability to be found in the Norwegian entrepreneurial community, all the while emphasizing that this is something they see as crucial for a startup. It is evident that the founding team prioritized having a mix of different but relevant professional backgrounds, specifically from the industry sectors that the company would be trying to enter, as this was considered particularly important for understanding their market well. One could make the argument that outsiders to the industry might be in a better position for radical innovation, as they are less likely to be affected by industry wide dogma. However, on the flip side, understanding the customer and their

industry well is also clearly an advantage if one is simply trying to make a small initial inroad in a market, which is a valid strategy for startups to aim for (Cfi, 2022) in the very beginning of their lifecycle. Ultimately, we consider having a good mix of professional background and experiences to be a sound strategy for a startup.

Company 3 made another strategic choice in aiming for iterative smaller-scale continuous innovation to their portfolio of products and services, rather than aiming for massive innovation into completely new products or services. Their reasoning was that this, based on experience, would make R&D projects easier to plan, easier to convince partners to join in on and more likely to succeed. This, we assess, makes strategic sense in the context of a stated goal of being seen by the industry as trustworthy - as risky projects might not inspire trust in a famously risk averse industry.

The choice of postponing application for EU-wide MDR, as opposed to giving up on it altogether, is a sign that the company has long term plans of increasing their future competitiveness. With no further details provided on this topic, all we can assess at this point is that this too seems like a sensible strategy. So too do their plans of expanding into other parts of their value chain, as this could make it easier for them to become dominant in their market niche.

After prasing various aspects of their strategic planning, we now look to one area where we question the company's decision. The interviewee clearly states that the company has decided to be very cautious in their internationalization process. In fact, it was stated that the company wants to make sure “all their customers are happy” before they would consider entering another national market. We believe this to be a mistake, as R&D projects, the preferred method of the company to enter a market, tends to take time. If delayed for too long, this could delay their commercialization, possibly leaving an opening for competitors. If nothing else, establishing lots of R&D projects internationally would also give the company the opportunity to familiarize themselves with other markets, information which could then be used to actually make a final decision on whether market entry should be conducted there or not.

5.1.4 Case 4 - To qualify for CE, patience is key

Company 4 delivers 3D holographic imaging to help doctors plan surgeries ahead of time, all the while using 3rd party Microsoft Hololens hardware. From the information provided in the interview, we assess that their customers and users to be the surgical departments at hospitals and the surgeons working there, respectively.

Regulatory constraints should not be underestimated

Looking at case 4 we see a company that is significantly constrained by regulations found in the HCS and with regards to CE marking. As we have seen, the HCS is one where industry rigidity relates to the underlying conditions of regulations of medical equipment as well as a general risk averseness stemming from a primary focus on patient health and safety. This rigidity, however, appears to a degree to be product-dependent. Specifically, dependent on the level of intrusiveness associated with the product. In the case of company 4, presumably due to a very high level of intrusiveness, this has led to severe restrictions on their ability to conduct product development as well as commercialization. The introduction of a stricter system for obtaining CE mark during the pandemic, represents an industry-wide regulatory shock, external to the company and which the company could not control and which made their task harder.

The regulatory aspect, one would expect to greatly contribute to the level of risk associated with this company. Specifically, with an estimated time to market of about 6 to 8 years, and a restriction of *only* being allowed to conduct essential R&D activities in close partnerships with innovation departments at university hospitals, there is very little room for maneuver and hence for making mistakes. This is supported by the interviewee warning specifically against the dangers of underestimating regulatory demands and the need for a well planned approach.

Overcoming barriers

Particularly consequential barrier was the catch 22, that of the company not being allowed to conduct R&D activities themselves, activities which were required for the necessary reporting for a CE mark. Though it appears that the company overcame this barrier without fuss, specifically through innovation partnerships with university clinics, this barrier might have been devastating had they not. This because a lack of R&D would have left the company with a highly intrusive product and no hope of seeing it realized commercially.

Awareness of natural organizational “blockers”, like the IT department being skeptical of possible GDPR risks, and the necessity to find ways around is another example of a challenge to overcome. However, it is not clear in precisely what way such “blockers” actually might have presented a barrier for this particular company, or if this was a particularly challenging barrier to overcome. The inability to actually make sales to their intended customer until MDR is granted obviously represents an enormous barrier for the company and one that they are working to overcome, precisely by conducting the necessary studies and in a sanctioned manner with certain qualified actors. In general, it appears that the advantage of significant industry knowledge is being used effectively by the company to overcome barriers or circumvent them all together. A strong knowledge base thus seems to be a competitive advantage for this company.

Strategy

The company has made a distinct choice during their product development phase of working closely with the clinicians who would eventually be the ones using the product. This has been stated to relate to a desire for the company both to produce a product with the right service design, i.e that it will meet the needs of the customers, and in order to have said clinicians convince the hospital leadership of the merits of the product. This would seem highly sensible, particularly when dealing with a highly intrusive product which the user needs to have complete trust in. As we have seen previously, this strategy is highly useful when dealing with the Norwegian HCS, where the decision makers on procurement typically will have little to no personal relationship to the product the company wishes to sell or the the job it is intended to do. There is also a further goal of making the clinicians dependent on the company’s product over the long term. This can be thought of similarly to what De Wit refers to as system lock-in, wherein the product becomes part of the customer’s new standard of operation, making them more loyal customers (de Wit, 2017). On the surface, this also appears to be a solid strategy. Yet, its success will depend on several factors, including the availability and effectiveness of substitutes for the customer.

Though it is not completely clear from the interview, it seems that networking as a method of gaining access to potential innovation partnerships with relevant clinics may also have been a key part of the company’s strategy. The interview certainly considers networking to be an advisable strategy for companies operating in the Norwegian HCS. Like we have seen in the

previous case being discussed, this perception appears to be linked to a deep understanding of how the Norwegian HCS works. Again, the advantage of networking is clear, when dealing with an industry that is both risk averse as well as occasionally fragmented, meaning it may be difficult to get in touch with the right persons and they are likely to be skeptical unless they have previous knowledge of you and your company.

From a more generalized perspective, it can be said that company 4 has a long term strategy and that they decide their near term plans, as presented in the paragraphs above, according to this. By this we mean that the company clearly communicates and awareness of how and when the company could start generating customer revenue. They explain how although this can only happen in the long term, it is nevertheless necessary to not rush it. We believe this to be a sensible approach for the company going forward, with the caveat that the company leadership has already investigated possible circumvention strategis for MDR and not found any. Because operating in the context of a highly regulated product demands a long term approach with a longer time to market. It may also be that for the company's product, the timing in the industry and society as whole still is not right. This is because the only contextual drivers of change that currently work in their favor are technological innovation and the socio-culutral driver that is increasing digitalization in the HCS. For an intrusive product in a highly risk averse industry, it may be that additional contextual drivers are necessary, such as an economic-political driver that might in the future result from a need to make a declining workforce more efficient in terms of both labor and energy. Or, industry rigidity could be reduced in a hypothetical future restructuring of the industry leading to reduced fragmentation and stronger innovative research centers.

Procurement processes

For company 4, procurement is not an issue they appear to be concerned with at the moment, arguably because it is still several years in the future. We question this relative lack of attention however, as there are ways to combine tender processes with R&D, such as through innovation partnerships and pre-commercial procurements (Anskaffelsesforskriften, 2016). Inadditon, it might reduce the apparent risk on investment in the eyes of investors.

5.1.5 Case 5 - Go big or go home

In the case of company 5, a software is being developed and offered to thelp certified mental health therapists make better judgements when assessing a patient's progression and/or reaction to in response to certain therapy. This is done by having the patient answering questions that the software generates. The answers are then analyzed by the same software. The customers in this would be the mental health clinics in both the private and public sector, with the therapist and patient being the users.

Rapid expansion

A defining feature of company 5 was the conscious decision to aim for very rapid growth early on. They were building connections and having frequent meetups with industry actors very early, which must have been a time- and resource demanding activity. This not only helped with name recognition later on when commercialization began, but also facilitated a deeper understanding of their intended customer groups as well as the problems that the company's product should address. At the same time, resources were put into R&D partnerships with relevant HCS actors to develop the different aspects of the intended product, a process which appears to have occured extremely fast after the company's founding. An advantage of this, apart from the obviously shortened product development period and consequently the time to market, would have been to get the product into the hands of their users (therapists) and end users (patients) more quickly, thereby garnering more user feedback early on. Parallel to all of this, the company appears to have invested into getting a solid understanding of the legal and regulatory frameworks that such a product would operate under and why, enough to communicate this in a clear and confident manner to the industry while networking. Having a person hired exclusively to work with this task, as they now have, is a good example of this. Whilst it is not apparent how long ago this individual was hired for this task, it is apparent that this topic has been a focus for the company and that this has required a share of the company's resources. It does not appear to be coincidental that the company split its focus early on in such a way, or that they have apparently managed to do so in a way that has allowed them to maintain rapid progress without being spread too thin. That this was all planned is very much implied by the interviewee. So too is it implied, that significant capital investment was necessary to have such an accelerated and labor intensive time frame. This is not unexpected, as it is logical that investments would be necessary to maintain such a momentum.

It could be claimed that in a typical rigid industry like the NHCS, a hyper-accelerated approach might be particularly useful. From the interview it is clear that inter-organizational factors like psychological and cultural resistance to change would be at risk of inhibiting the company's early growth. A good example is of how therapists used what was described as a "gut feeling" to assess their patient at certain points. This is combined with the structural inhibiting factor of having to convince the decision makers on procurement indirectly through the clinics' own therapist, and the risk averseness in the industry writ large. De Wit explains in his book how revolutionary change might sometimes be necessary to break through in an industry where the resistance to change is great (de Wit, 2017). Though company five cannot be claimed to have expanded the rules of the industry and as such to have had a revolutionary effect on it, they do appear to have managed a similar effect but on a smaller scale. This "go big early" approach, executed successfully, helps explain the rapid commercialization that the company appears to be experiencing at the moment. In fact, one could argue that this strategy also raised the stakes for the company early on. An unsuccessful approach, either through lack of resources or mismanagement of tasks, could have backfired spectacularly with various results such as a bad reputation in the industry, or by heading down the wrong path in product development and setting the company back.

Overcoming barriers

We discussed in the previous section various challenges that company 5 decided to take on early and at the same time, so as to shorten their time to market and be quickly seen by the industry. Some of these challenges can be thought of as barriers which the company may or may not have successfully overcome. The first barrier that was specifically mentioned during the interview was that the company originally had an idea about their intended product that did not seem to match very well with what their customer base appeared to want or were willing to accept. Originally envisaged a product that would in fact *replace* the part of the therapy where the therapist would go by "gut-feeling", the interviewee seems to indicate that this did not go over well. Instead of tackling the psychological and cultural resistance head on, the company overcomes this barrier by changing the intended use of their product from *replacement* of established norms to that of a *supplement.* This is an example of how understanding not just the customer and their needs but also the culture of their industry is more likely to lead to a product with a better market fit. In fact, this same shift in how they defined their product may also have helped them to completely circumvent the issue posed by medical regulatory regimes, like CE. The difference being that a supplement that the therapist

would use to enrich their own perspective of the clinical situation, is not inherently intrusive and will not be seen to be taking decisions on behalf of a qualified specialist. That the company also claimed a desire to eventually qualify for MDR down the line, shows that they made a decision to delay certain qualification to their product so as to allow for commercialization earlier on. We consider this to be a sound strategic move from an entrepreneurial perspective as well as a necessary one when dealing with an industry that is by nature skeptical of rapid change. Although never mentioned explicitly during the interview, we assess that the decision to focus on supplementation as the focus for their product and the subsequent circumvention of MDR to be critical factors in the rapid commercial growth of the company.

A final barrier that was mentioned relates to organizational rigidity among the customers, and can be subdivided into two subtypes: 1) Integration with existing services, and 2) Lack of communication with decision makers.

The first refers to how the company experienced some difficulty during commercialization from not having a product that would fit well with existing digital infrastructure, like *Journalsystemet,* at the hospitals of their customers. They describe this as a complicating factor during procurement processes and a barrier that they would have overcome sooner rather than later, and so they began to focus on systems integration. They appear to have, or are in the process of overcoming this barrier now. We believe it is possible that the remarkable speed of commercialization that the company has seen might have been greater still if such integration had been among the company's early areas of focus.

The final point is about how the company seems frustrated with the difficulty of getting into contact with the financial decision makers at the potential customer-clinics so that the final part of the sale had to effectively be conducted by in-house clinicians. Though this frustration with not being present for the whole sales process appears perfectly understandable, one could argue that such an approach was in fact necessary. As we have seen, the leadership of a hospital clinic might be unaware and unfamiliar with the possible advantages of the product being advertised, simply because they will not be using it during their work and will thus not be comfortable just trusting in the word of a "salesperson". Bring in someone they trust, however, and who is also qualified to make this assessment, and the picture changes.

Strategy

As we have seen, company 5 pursued a strategy of rapid early growth, which would involve a heavy and *simultaneous* focus on multiple different aspects of their business plan that were identified as critical, such as R&D, marketing, market research and regulatory knowledge. A likely essential part of this strategy was a drive to garner the necessary capital, though the details of this process were not discussed in the interview. Added to this was likely a conscious strategy of circumventing regulatory requirements, at least temporarily, thereby allowing for early sales, also aiding the commercialization process. Integration with native digital systems of their customers appears to also have developed into a strategic choice and a concrete action plan, though somewhat later. Not to be outshined is lastly the focus on developing their product in close collaboration with their customers, and specifically therapist users - allowing for a product with a better market fit. The early indications are that the combination of these strategies has been a huge driver of commercial success for the company. Other than the previously mentioned possibility of starting the systems integration process earlier, we find no fault with company 5's strategic planning and execution.

Procurement processes

Except for mentioning innovation partnerships, which are a part of the set of different procurement processes allowed for by *Anskaffelsesforskiften*, not very much information was provided about the company's approach to procurement. As tender competitions of all sorts are liable to become framed according to a pre-existing preference on the part of the client clinic, it is possible that the company found it easier to attain innovation partnerships or other procurement deals with customers with whom they were previously acquainted.

5.1.6 Case 6 - Network with the industry, not just the user

Company 6 produces VR software that is meant to be used to train healthcare practitioners to better be able to handle emergency situations when they occur, like surgery on an income trauma patient. It is not immediately clear from the interview, but we assess that the intended user group *likely* consists of trauma doctors and maybe nurses in the emergency room at hospitals around the country. That makes the emergency department the de-facto customer.

The Norwegian HCS, from an outside perspective

In the case of company 6, it appears that all or most of the company's founders grew up outside Norway, with at least one (the interviewee) hailing from Singapore, and at some point

relocated either fully or partially to Norway. Throughout the interview there is a theme of frustration and confusion expressed, on the part of the interviewee, with a lack of response and interest from the NHCS about the company's offering. Moreover, the interviewee seems unsure themselves as to why this is and speculates openly about general themes like bureaucracy and differences in hospital culture between Norway and Singapore as being possible reasons. They appear to lean toward a conclusion that the NHCS is simply slow to react, cumbersome and lacking interest for innovation. In our assessment, the interviewee may be implying that the reason for the lack of response has little or nothing to do with the company itself and how it operates, and more to do with problems internal to the NHCS. Our impression was reinforced with the casual nature in which other Scandinavian markets were being described as more open, but without the interviewee providing any information to back this claim. Company 6 is dependent on R&D for their product development and on working closely with their customers and users, and as a result of struggling to connect with the NHCS they decided temporarily to partner with Singaporean hospitals for R&D.

Interestingly, the company indicates that connecting with individual users, i.e presumably the professionals that would employ the product as part of their work, was less of a hassle. In fact, it is implied that several individual doctors have become avid fans of the proposed product. This would seem to support the idea that there is at minimum *some* potential value the company can offer their sers, who in turn are able to recognize that. customer, and that at least some of them are able to realize that. This has led us to conclude that the problems company 6 has with connecting with the NHCS is likely not due to a fundamentally bad product, but likely related to other factors. We propose that a possible reason, as we shall see, may be a lack of actively engaging in networking and other activities designed to gain attention, publicity and trust from the NHCS.

The NHCS contains more than just individual doctors. It includes hospital administrators, innovation and research departments, departments heads, IT departments and much more. The organizational structures and cultural norms within individual hospitals are important to keep in mind when attempting to find the right person to speak to about a possible R&D collaboration. Yet there appears to be little recognition of this on the part of the interviewee, and if it is recognized then it was not brought up during the interview. Case in point, because of the nature of the product and the stated intention to enter the NHCS first, it can be assumed that the larger *public* sector would be the market of focus, yet it is not clear which sectors the

individual doctors who became fans of the company where from and this was never brought up by the interviewee. No coherent strategy was mentioned for which doctors were contacted and why. In this context, we believe that the lack of "apparent interest" from the NHCS is predictable. As we have seen, networking and connections are very likely a determining factor for which actors see traction in the NHCS. Personal and professional connections appear, based on earlier interviews, to be so central to the industry that it might be described as an industry recipe as defined by De Wit (de Wit, 2017), a factor that can act as an inhibitor to industry development. Accordingly, company 6 needs to be frequently seen by the industry and it needs to inspire trust. Actively engaging in industry fairs, attending and speaking at conferences and other industry events as well as engaging with the relevant doctors at relevant departments are all effective ways of networking. Still, the fact that company 6 managed to attain R&D partnerships with Singaporean hospitals may indicate that the HCS of other countries might be less dependent on connections when decisions are made about which partnerships to pursue. The result being a risk that persons experienced with foreing healthcare services might experience significantly more resistance when attempting to enter into the NHCS simply due to a lack of awareness of the importance of connections and the barrier this can pose for a startup.

Overcoming barriers

As we have seen, company 6 reports to struggle significantly with gaining partners for R&D and other development projects in the NHCS. The company claims to now have an increasing number of doctors on their medical board, a potential but unspecified partnership with an apparently "acknowledged actor" as well as some collaboration with another unnamed actor that is simply described as a "European institution for certifying trauma doctors". All of these factors can be seen as activities designed to overcome the barrier of not being taken seriously by hospitals. Whether these activities will yield the intended results and when, is of course an open question. We assess that the company can increase the odds of these actions being successful by also engaging in networking and attention and holding talks at industry events. This will likely amplify the company's message by reaching a larger audience and one that will be more likely to take them seriously.

When company 6 decided to engage with hospital actors in Singapore, this can be seen as another method of overcoming lack of traction. Though we do not have insight into the degree to which these partnerships are working well, the fact that they have actually occurred

is important in and of itself. Yet, the company stated that their goal was to attain R&D partnerships with the *Norwegian* HCS. We therefore consider the Singaporean partnerships to be more of a suboptimal decision made in the face of a barrier, rather than an action to actually overcome said barrier.

Strategy

The company's strategy appears centered around entry into the NHCS and the need to conduct R&D partnership wil local Norwegian actors to facilitate that. Though we agree that focusing on local partnerships to be perhaps the most important strategic choice when trying to enter a famously risk averse industry, we note that the company's strategy appears to be lackluster in other ways. Our impression is that the company needs to take more seriously the consequences of effective countermeasures to a lack of connections and low industry visibility. We assess that their strategy needs to be updated to reflect the importance of actively networking in the NHCS, which may still be underestimated by the company. Moreover, we observe that the company appears to have little knowledge about either the regulatory framework within which said company would operate, or the industry in general. This, however, may just simply be related to the fact that the startup is still very young with the team not having sufficient time to do the necessary market research. On the other hand, knowledge of the industry and market one wishes to enter should be considered important for any startup venture. Therefore we believe it is fortunate that interviewee implies this, market research, to be their next area of focus.

Procurement processes

There was nothing of note mentioned about strategies or assessments regarding future procurement and/or tender competition, with the reasoning being that this is not the time to think of that yet as they are not currently dealing with sales. For a number of reasons, we assess it to be a strategic mistake on the part of the company to not examine the public procurement system that hospitals in Norway operate under. The most immediate reason for this is that, as we have seen, there are concepts such as *innovation-partnerships,* wherein the innovation and later procurement are handled together (Anskaffelsesforskriften § 23-7, 2016)(Anskaffelsesprosedyrer, 2016). There might be possibilities here of "taking two birds with one stone" for company 6, opportunities which may be missed for lack of awareness. Another factor is that procurement processes may influence how company 6 establishes its

pricing model, as this could affect which type of procurement is conducted. We would advise the company leadership to carefully read up on *Anskaffelsesforskriften* and *Anskaffelsesloven.*

5.1.7 Case 7 - Beware of warning signs

The case 7 company uses AI software with the aim of more quickly identifying stroke symptoms. The value proposition is that earlier diagnostics of a stroke leads to quicker hospitalization - which in turn provides quicker treatment and a better outlook for the patients with regards to both quality of life and possibilities of returning to work as a tax paying citizen. Stroke is an illness with increased focus as it is so costly for the society, and the incidence is likely to increase as the world population ages. There is a lot of research on the field, and as a result a lot of data is gathered by several different validated scoring systems. In looking at this particular company, the medical background of M.D Frøland has been used extensively to increase the validity of our assessments.

Ignoring the warnings

It seems there are a lot of warning signs to the commerciability of this solution. The company founders may have started with an idea that all they need is an image, back in 2019 - and now they are so occupied with gathering data that we assess that they may be at risk of developing "tunnel vision". We have identified FOUR possible smoke screens that may have obfuscated some barriers to the commercial viability of this product.

First, data and regulation. Other than the sheer amount needed to gather, there is an awareness of some of the other challenges as well. As mentioned in the interview, the company would need to gather more data if they want to enter markets in other countries due to the differences in facial structure across different ethnicities. They are also aware of the GDPR regulation and the differences in regulation regarding whether a software is used for decision making, or merely providing information. Furthermore, there are legal differences across countries in how personal data is allowed to be stored or used. In addition, the data this company would be collecting will not just be seen as of a personal nature, but in fac patient sensitive data, where a whole range of other regulations may apply. This offers a huge, and some would say discouraging, barrier to the scalability of the solution.

Second. Recruiting a medical doctor to be the face of the company and pitch it to others in the industry may have offered a "fast lane" for the company to rely on the connections of this

doctor as well as be seen as more trustworthy by the industry writ large. But with this explicit reliance on single individuals, how can the company be sure that they are not chasing down the wrong path. We have relied on the industry knowledge of Dr. Frøand when making the following assessment: Partnering with Norwegian physicians a startup should keep two things in mind. One - they are primed for care and may out of politeness or consideration refrain from discouraging idealistic ideas. Second -they are not entrepreneurs. Normally Norwegian MDs do not have a business mindset, nor a business skill set, and a company should therefore be critical to what these individuals may offer to the business plan or development perspective. The physician's expertise lies in their medical insight. So it is instructive for any set of founders to be careful to not overly romanticize their ideas on the account of what the doctor is saying. Founders should remember that they alone are responsible for challenging their own ideas and preconceptions.

Thirdly, and related to the second point, one should also be aware that as the medical fields of research and practice have progressed, physicians have had to specialize further. One medical doctor might have completely different knowledge and skills from another doctor. The more they know within their own field, the less they might know about other fields. As an example one could argue that the value proposition of this firm is faulty due to the discarding of other stroke symptoms. The National Institutes of Health Stroke Scale (NIHSS) is one of several of the medical world's validated tools in stroke diagnostics and treatment. It is a 13 category scoring system with a up to 5 point scale within each category. A lot of the categories need interaction through movement or sensory input etc., to be scored. Relevant for comparison with this company's solution is category 4 of the NIHSS, where the physician assesses facial paralysis by telling the patient to grin (show off teeth), shut their eyes and raise their eyebrows. This allows the physician to assess the presence and degree of potential paralysis. A picture alone will not be sufficient to assess this, and there is furthermore a range of other illnesses that can cause facial paralysis, but at the same time are obviously not a stroke. The NIHSS is also criticized for not identifying a lot of strokes as it focuses on symptoms caused by strokes in the frontal parts of brain circulation. A lot more data and investigations therefore have to be assessed to properly raise the suspicion of a stroke. E.g. A feeling of dizziness or vertigo is a symptom of stroke in the posterior cerebral circulation that would not be identified by either a picture or a video but requires a combination of anamnestic information and medical examinations. This third point is one we assess could lead to significant problems in terms of practitioners' ability to trust in the product.

Fourth, and last, in the theme of romanticizing the solution and not seeing the warning signs - while an entrepreneur might be blinded by the love of their product, there might be others that are so in love with the problem that one together constitutes an echo chamber for false hope. Diagnosing and treating strokes have had a dramatic increase in popular attention, thus there are very many different sources of funding for research and development. And for researchers the value lies in publishing and providing new insight - not necessarily developing a commercial solution that will be accepted by both the industry and regulatory authorities. Therefore one should be critical of viewing continuous research funding as a proof-of-concept. Although sufficient research is a prerequisite for commercialisation in healthcare that cannot be stressed enough - founders should also have a well thought out strategy and plan for how to advance from research to commercialization, if such a move is even possible at all.

Overcoming barriers

As we have seen previously, fragmentation in the NHCS coupled with risk averseness can present a barrier to market entry, and to R&D partnerships in particular, for startups. Company 7 seems to have either successfully scaled, or at the very least greatly reduced, this barrier by partnering with a medical professional, and subsequently establishing various R&D partnerships. Though the company's approach to this barrier seems to have been effective, we still question the wisdom of overreliance on a single medical professional.

The company was aware of some important differences in how software is regulated in law depending on their use or purpose. During the interview they mainly focused on the difference in software that is meant to aid or affect medical decision making versus software just intended for indicating or alerting information for the health care workers for use at their own discretion. For this company it seems that they also have to take notice of regulation of filming and recording data on patients. Handling person sensitive data is governed by the GDPR, regulations - but as this can be defined as patient sensitive data the regulations are even more strict. To overcome and maneuver these barriers the company sought legal assistance in Norway Health Tech. Being a part of an entrepreneurial ecosystem or new venture business cluster gives an opportunity to faster and more easily navigate and solve problems using the experience and competence of collaborating actors (Acs, Z. J., Estrin, S., Mickiewicz, T., & Szerb, L., 2017). Though we seriously question whether the company's

solution will ever be able to be commercialized due to the regulatory complications associated with data collection and analysis, we support the decision to associate with Norway Health Tech as a method of approaching this problem. It is far too early to say whether the company will be able to overcome the regulatory barrier.

There is no doubt that a tool that can rapidly and accurately diagnose a stroke would be worth a lot of money to the public HCS, as well as for the patients themselves. Company 7 views the process of gathering enough data as their main challenge. So much so that they are open to all and any potential partners, or rather, they do not appear to have a preference for types of partners. When asked about how they view competitors - they too are seen as potential partners. In this case and context, we view this liberal attitude to have less to do with openness, and more to do with a lack of a coherent partnership strategy going forward. It seems that other than partnering with a doctor, which has provided some legitimacy and clearly opened doors to R&D collaboration - the company does not appear to have overcome any other barriers. It seems that they are currently heavily preoccupied with gathering data to prove the efficiency of the solution while simultaneously trying to sell it - the latter process being fully dependent on the first.

Strategy

The company's current strategy revolves around R&D partnerships. Specifically, to get an introduction to the different healthcare actors, thus building a relationship with possible future customers or users, and as a means of gathering and analyzing data to prove the efficacy of their product. This is a strategy they share with several of the other cases - as we will discuss in the cross-case analysis. R&D is essential for company 7, because without medically proving the effect of its core product, there will not be any customers. Wrongly diagnosing a stroke will lead to extreme personal and economical cost either way. As an example - failing to identify a stroke might discourage a bystander or first-responder to call for help. And falsely identifying strokes will lead to a disruptive amount of emergency calls and put a strain on health care resources. Understanding such mechanisms are important to not chase bad leads. Therefore the company was pleased when they could partner with a medical doctor that provided help and insight that both led to a faster development, and also opened a lot of doors and possibilities - as a doctor does not only offer insight, but an entrance to the somewhat exclusive club of medical jargon and society. In hospital you need to “talk the talk”, before you are permitted to “walk the walk”. Though we agree that R&D

for product development, as well as a method for building connections, to be a correct area of focus for the time being, we do not agree that it should be the exclusive one. It is our assessment that the company needs to seriously investigate the different opportunities they would realistically have in terms of legally being allowed to operate with the level of patient data they would have to collect. What the company discovers about its regulatory environment long term, can shape the decision the company makes "tomorrow" about product development, to make sure they are heading to the right path so to speak. And, if the company subsequently assesses it to essentially be *impossible* to operate according to their current plans, they would then have an opportunity to pivot their product and company early, as opposed to learning "the hard way" how difficult a crash between reality and dreams can be.

Procurement processes

Currently the company does not have any customers, are not eligible for submitting tenders, and the question is when or if the company will be able to enter the market. Normally we would recommend the company to investigate the future procurement environment it will find itself in, but in this case the need to investigate the *regulatory* space is one we consider so important that it trumps all other concerns save R&D.

5.2 Cross-case Analysis

5.2.1 Overcoming barriers

We see that there were a few common barriers that the seven companies reported to having to deal with. The most prominent of these was a difficulty in getting into contact with the right people for R&D partnerships in the public healthspace, as well as having them take you seriously, i.e having them trusting you. We attribute this to several factors, one being a fragmentation of the industry in the form of structural differences from one health organization to another, and with each organization doing things their own way, i.e according to their own organizational culture. This can make it difficult to actually assess whether a health organization contains the right departments or not for R&D collaboration, as well as pose a challenge in actually discovering which person to contact. This is further aggravated by what many of the companies described as a rigidity in the organizational structure within hospitals in particular, in that decision makers in the relevant departments are often unfamiliar with the clinical aspect of the work of their employees and can therefore be

difficult to bring around. To overcome this, there was a general trend among the startups with the best customer traction to work, collaborate and network closely with the actual practitioners as opposed to decision makers, and having them in turn try to convince decision makers at their clinic. As we have mentioned earlier, we assess this to be the correct method when dealing with this particular problem, even if we give credit to the complaints of company 5 where they felt they had no control over the process where practioniairs were de facto selling the idea to their bosses. A middleground here might be, as with company 3, to set up joint meetings with decision makers as well as clinical practitioners. Another factor is, as we heard from the interviews, a general risk averseness, and psychological and even cultural resistance to change. A good example of the latter is how company 1 had to deal with doctors who were skeptical of their idea because it was unorthodox. We suspect that company 5 also had to deal with a similar cultural issue based on what their software was intended to do, although this was not mentioned explicitly.

The result of this is a situation where it could be difficult to convince hospitals or other public health clinics of a collaboration unless someone there knew you or your company from before, and therefore had "sufficient trust" of you to take you seriously. We believe this to be the real reason behind the comments, from some of the companies interviewed, about how important networking was and still is. Having connections essentially creates "bases of trust" around the various actors in the industry, trust which can subsequently be used as a metaphorical ladder to scale a barrier.

Interestingly, although *all* the companies interviewed reported to be aware to at least some degree of the importance of being trusted or seen by potential R&D partners, customers and the public HCS in general, not everybody seemed to take it sufficiently seriously or understand the connections this could have to networking activities. Companies 1, 3 and 5 for instance seemed acutely aware of the dangers of not being seen or trusted by the industry, to the point where they were willing to prioritize networking activities, early on in their development, when one might expect founders to be busy with product development and market research and therefore less willing to travel around and meet people. This was exactly the impression we got from some of these other companies, like companies 2, 6 and to a certain degree company 7. The trends and implications we see here are two fold. First, we agree that networking and building connections with the industry in general is likely extremely important when deciding to operate in the NHCS, to the point where it might be

worth spending precious resources early on in the company's life cycle simply for networking. Obviously, this should be done in a *targeted* way, meaning to the degree possible it should focus on the types of people the company expects to have to convince and/or interact with frequently during R&D and subsequent commercialization. An example of this is how companies 1 and 5 actively networked with those who would eventually become not just their customers but their actual users. Secondly, we see a trend here that those companies who could show early successful commercialization and that appear to be growing the fastest, also are the ones that have focused early on networking.

Then there is the regulatory barrier, which includes things like MDR and CE marking, that ensures that products designed to operate within the HCS keep to certain standards of safety, privacy, efficacy and more. Perhaps unsurprisingly, every single company interviewed was aware of this potential barrier. And to a certain extent, all of them had at least *some* thoughts on how to deal with it. With the exception of company 1, which stands out from its very Norway-centric regulatory focus, those same companies also saw a need to think of regulatory demands in the EU as a whole. What stood out for us, was that there was a clear distinction between the companies with the best commercial traction and those who had little or none such traction. This difference seems to have been two fold. For one, high traction companies (except for company 1) like companies 3 and 5, were not just *aware* that regulatory requirements could be challenging, but they actively took steps (likely, but not *explicitly* said in the case of company 5) to ensure they could navigate around this hurdle and commercialize early, and still deal with the challenge at a later date when the company was in a more stable financial situation. This should be remembered by startups attempting to enter the Norwegian HCS or any HCS for that matter, to investigate whether such a move could be possible for their product. On the other end of the scale, we have company 7, where we as mentioned are concerned that the significance of the regulatory demands are being vastly underestimated and where we did not observe attempts to postpone or circumvent regulatory needs. That is not to say for sure that there were no such attempts, but that it was not mentioned or in *any way* alluded to or implied during the interview. A final point to make on the topic of regulatory barriers, is that it is not just about investigating the regulatory landscape for the possibility of early commercialization, but it is also about convincing potential investors of the viability of scaling the solution later on.

5.2.2 Procurement

When comparing and contrasting how the seven companies approached the topic of procurement processes in the public sector, the most interesting result was the stark divide we found in the various approaches. In our opinion, this divide is what makes this topic particularly interesting. The responses of the companies to being asked about their plans and thoughts around procurement, ranged from literally *nothing,* to detailed plans for not triggering tender competitions or specific strategies for ensuring such competitions would likely be "tailored" to fit their own company. Company 1 found a loophole to essentially avoid tender all together, but this happened by active investigation and tailoring their messaging when marketing to the industry, it did not come about by accident. Company 3 has taken a different but possibly very effective approach of establishing connections and collaborations ahead of any procurement announcement by healthcare actors, and so they are more likely to understand the needs of these actors and subsequently to win a procurement competition. As we have seen with several of the other companies, the response has essentially been *"we are not commercialized yet, so we are not looking at that now"*. Not only could awareness of the procurement ruleset affect how much effort a company puts into networking and where it chooses to focus these efforts, it could also *potentially* affect product development if one sees an opportunity to better tailor the product or payment model to it. It might even enable early income through procedures like innovation partnerships and pre-commercial procurement. Finally, thorough knowledge of how public procurement works could make it easier to convince investors, as this would communicate an ability to more accurately predict future earning potential. As such, we would recommend startups thinking of entering the NHCS to read up on and become familiar with *Anskaffelsesforskriften* and *Anskaffelsesloven* (respectively, regulations and law on public procurement). Here, too, did we spot a trend of companies having more traction who demonstrated a better awareness of public procurement processes.

5.2.3 Strategy

Looking at how the various companies considered their strategies we found a recurring trend of a heavy focus on R&D partnerships, particularly with the types of organizations that might eventually become customers. In some cases, the reasoning for this focus was slightly different. Like with company 3, that wanted them primarily to build connections and industry-trust, and all the others (except for company 1), that wanted them primarily for

better product development, proof of concept and/or to get a better understanding of their future customers. We should note that we bebelive all of these reasons to be valid, and so the value of R&D partnerships should not be underestimated, even if they do not check all boxes of valid reasons. The exception of company 1 is noteworthy for two reasons. For one, it appears that their intended users were so different from the R&D partners that such partnerships had little real value. And two, they were not developing a therapy tool, whose efficacy could be measured quantitatively, but rather they were developing a video communications product.

Perhaps most interesting of all, and which we have discussed on several occasions already, were the strategies of active networking. Which were often either non-existent, or absolutely central to the company's plans. In any event, it appears that in the cases where networking was seen as very important or even essential, this produced very good results. In the cases where networking was hardly ever mentioned, we noticed an increased level of frustration with rejections from potential R&D partners and a lack of traction in general. We therefore believe that the level of effort a startup company puts into actively networking and building connections in the industry to be a good predictor of the degree of success or failure that the company will eventually experience. The caveat here is that networking activities should be done in an efficient manner, as in actually meeting with the right people from the industry. These should be the kinds of people who would be involved at various milestones in any R&D or customer partnerships, the most important of whom would be the intended users.

Two final things we would like to bring attention two, are two strategies that were not in fact recurring but which we nevertheless see as potentially significant. These are the strategic choices of (eventually) focusing on native-sytem-integration and of "going big early". Both of these are related to company 5. Systems integration makes a lot of sense for a product that will have to handle and process data, as it makes the job of actually using the product easier for the customer, which one could reasonably expect to lower the barrier to market entry. Going big early, essentially refers to getting the capital and people needed as fast as possible and doing several critical activities like product development, marketing, raising capital, market research (including for procurement processes and regulatory regimes) all at the same time. This, if done correctly as seems to be the case with company 5, could really help a startup "take off" quickly. But beware of securing the capital and resources needed for such an intense process.

6 DISCUSSION

In this chapter we will discuss some of the themes and phenomena that we think is especially important to focus on when trying to enter into public health with your startup. We will go a bit further than the analysis, and employ some of our own reflections surrounding these themes and discuss how different approaches could result in other outcomes. This is also necessary because while the analysis covers the aspects related to the applied framework, it does not sufficiently cover or go into depth on the inductive aspects of the study.

After conducting the analysis it was very clear how much network and connections meant for success. During this chapter we will focus on this phenomenon, and the two other themes that over-all were lifted up by the cases - understanding and navigating the structures and systems of the NHCS, and the paths and approaches to an approved service or product. This focus will enable the Discussion chapter to deliver the best additional insight to complement the study as a whole.

6.1 Navigating the NHCS

From a citizens point of view one might perceive the Norwegian healthcare sector (NHCS) as one big integrated entity. Indeed, the Norwegian name for the healthcare sector (“Helsevesenet”) directly translates to the Health creature - which is a very special sounding idiom that might contribute to this notion of a unified sector.

As touched upon in the background section the NHCS is actually quite fragmented. Even explaining the structure in a simple mannen is difficult because it is so complex. Facilities, functions, administration and ownership is divided across different levels of government (state, county, municipal) without necessarily correlating with the demographic profile of the healthcare service users (diagnosis or recendendy of patients etc.). It is a total mix regulated by an intricate set of different laws and regulations, as well as in written rules and culture, and different practices across different hospitals etc. This makes the NHCS difficult to navigate for any entrepreneur.

Properly understanding the structure and pathways of decision making within the NHCS seemed to be essential for success. Entering this market for the first time, or without backing

by someone with domain knowledge, will be difficult. It is therefore more challenging for a startup than a large established MedTech firm that already knows the rules of the game for previous ventures. Still - the way towards market penetration for a specific service or product might be vastly different from another solution, so the process could still be quite labersome for established firms as well.

What we found to be interesting is that among the cases in this study was that although everyone felt that this navigation was difficult - there was an obvious difference in attitude towards this challenging barrier that seemed to correlate with their success. The cases that had experienced success, or some for of goal achievement, had a more positive attitude to this challenge - viewing it as a challenge, and not a problem - as something that was there and something to be overcome or understood - rather than complaining about the system being too rigid, or even nonsensical. As a small startup, or even as a big firm, you are better off trying to work with or around the barriers that you face. If the rules - either written or unwritten - seems stupid, it is moste likley somthing that you have just not understood yet, and it will not get better by being frustrated or negative.

So there are take-home lessons in this section. There is a way around the barriers - because others have already found a way - and your attitude towards the structure of the NHCS can be a marker of how well you understand it. The possible correlation between attitude, understanding and success is speculative, but seems to be a trend in our data that should be investigated further.

6.2 Approach to approval

Somewhat related to the previous subsection is the matter of laws, regulations, approval and procurement processes - and the differences in approach. This difference is a little more palpable than just a difference in attitude and understanding, but one might still define the one approach as “positive” and the other as a bit “negative” - also resulting is a difference in attitude as a result.

The Norwegian laws and regulations are responsible for defining a lot of different aspects of the NCHS, including the approval or procurement processes - and how they should be conducted. The Nordic legislative model (and Norway especially since Norway is not part of

the EU) is renowned for its short and generalized laws that values delegation and dialogue more than detail - forcing participation by the public when enforced (Forskningsmagasinet Apollon, 2019). The consequence is that the laws require some interpretation, alongside their respective regulations (that are subordinate), that can be difficult for lay people. The interpretation of previous sentencing in courts as well as guiding legal principles in Norwegian law such as common sense. As bizarre as it might sound for non-nordic readers, “reasonableness” is one of the most important principles in Norwegian law with the word “reasonable” littering the Norwegian laws.

Translated to the NCHS this means that some of these processes can be difficult and time consuming to understand. They might be further complicated by the fact that Norway is part of the EEA although not a part of the EU - and therefore sometimes have to adhere to European law, which is even harder for lay people to navigate. There are of course professionals such as specialized lawyers working with this on behalf of the actors within the NHCS, but only at a certain level. This means that there has to be some sort of reason to involve the professionals. This could be either the worth of the solution, or the probability of being realized, or some other reason.

Who gets what is not perfectly clear because it seems to be up to lower level administrative staff, somewhat serving as gatekeepers to the good. And which one you get in contact with could be up to chance. It is very seldom a startup gets immediate and direct contact with decision makers, people of actual influence or similar. Thus we hypothesize that there are two ways to tackle this challenge. Either you get “them” to help you, or you need to get your own help. Specifically you are either able to get referred (by means of luck or argumentative skills) to someone within the NHCS that can help you with understanding how that certain institution is practicing or interpreting the relevant rules - OR - you recruit or hire someone that does already understand the system and its rules. Then surpassing the gatekeepers should be easy and the path to progress is cleared.

Actual progress though, is not guaranteed. Actual approval, or acceptance of a tender is still quite laboursome and time consuming. As laws regulate these processes too, they might certainly also be under the scrutiny of interpretation. It is therefore important to understand the specific laws that apply to the different specific situations and understand the customer

and that customer's situation and their interpretation. It is a demanding and complex process and iterative in its nature, but the yields can be rewarding.

There was a pronounced trend in how the different cases met this challenge. Since approvals are key to market entry, and is such an absolute truth - some cases approached the challenge with the strategy that the solution had to be validated or already approved before it was even meaningful to contact the potential customers. And that is arguably true, and often what you are told if you ask the customer. So, discouraging as it might be, in some cases companies had invested a lot of time and resources in validating their solution before making various approaches to the customer. When their strategy is to sell a finished product that makes sense, but getting the approval and validation they need to secure a tender, or having it be procured is really difficult due to the reasons described above.

The other main response was to kind of disregard these absolute facts easily in the process. Some companies did not view the process of procurement as a simple yes/no-decision made in a predefinite amount of time starting from the invitation to tender. They rather view that last lag in the process as the culmination of a much longer race. The cases that seemed to be successful at the present point did not try to present a finished product or service. They applied different strategies along the way to adapt the solution, understand the customer and lay up the groundworks for that final goal. They knew that innovative projects and R&D collaborations were transient and that they sooner or later had to get final approvals, but they kept focus on these processes while occupied by them. With an attentive approach they made changes to the product and the presentation of it, suited to what they expected would fit best with the future tender AND according to how they expected that the presentation would be perceived within the customers understanding of the same situation. As such the real gain in R&D for the entrepreneur is not necessarily getting the product validation itself - because that is a given, it is required - it is rather drawing on the knowledge from the process and studying the users, decision makers and their influencers. It does not matter if you have proven that your solution is best, if your interpretation of what is best is not the same as the ones assessing the tender. And this leads us to the last and arguable most important lesson during this study - as it offers value to both navigating the NHCS, and the approach to approval - to be continued in the following subsection.

6.3 Connections to connoisseurs

The title of this subsection makes a reference to connoisseurs. Connoisseurs are expert judges of a certain subject - most commonly the term is used to refer to experts on wine or food. In the context of this study we are referring to the people that are experts on the NHCS, namly the healthcare professionals.

A good network strategy is everything. This might be counterintuitive to many as the customer in public health is the public - which means that it is the government, organizations or other similar institutions that makes the decisions. And in Norway, commonly known as one of the most robust democracies in the world, the mechanism of dispersed power would presumably be even stronger. And that is true, because there is not one or a small group of persons that are charged with the power of decision - BUT - they are still ordinary people subject to impressions and faults. That makes network strategy more important when facing the NHCS, because there are more people involved on the customer side that you need to understand and interact with. This may be due to the phenomenon of Norwegian leadership structure which has a flat and non-hierarchical structure (Sean Percival, 2022).

It was surprising, during the analysis, how important networking seemed to be according to the more successful cases. When answering questions about different types of barriers their professional relationship or partnership with physicians or other industry players was often highlighted as part of the solution. During this subsection we will briefly discuss the healthcare professionals role in the previous two themes before we also discuss their role in decision making.

In navigating the NHCS, who is better to assist a startups understanding than people that work and live within the system. The right connections could be as valuable to a firm as a concierge to a hotel guest in an alien city. One of the case companies chose a more dramatic allegory describing their medical expert as a jungle guide. If your goal is to understand the NHCS it is not given that a medical doctor necessarily provides the best insight. Tapping in the know-how and domain knowledge necessary to aid understanding that offers your solution increased value is highly dependent on the solution itself. A nurse, physical terapeut or IT personnel could easily provide better information because different professional disciplines have a different base of knowledge. And within a certain profession there are

further specializations and individual capabilities to take into account. Immediately matching with the one that can provide you with everything you need to know is not very probable.

A person with domain knowledge might also be the solution to the challenge of approvals. Although “insider knowledge” does not necessarily have positive connotations to what is considered a good business practice, it nevertheless provides a somewhat suitable parallel to the value their insight offers. We have already addressed the value of an iterative and adaptable approach during projects and collaborations that may lead to a procurement process. This process is valuable because it does provide some interaction with the incorruptible people that assess the procurements later. Trying to have a professional relationship outside of this sphere, or trying to partner with people involved in later decision making on behalf of the public would be very stupid and potentially illegal. Luckily there are a bunch of other people that can aid in the approval approach. Lawyers can provide expert knowledge on the legality. But legal services can also be bought - and if you position yourself well these services might be provided by the public anyways. As research is such a huge part of approvals, healthcare professionals are again one of the best sources of help. Especially for solutions that provide some value to clinical settings which *might* affect the patient in some way or another - clinical research is paramount. Medical doctors are normally well familiarized with medical research. Medical research also is a special brand of research that differs greatly from e.g. business research. The difference between medical and business research somewhat ironically mirrors the differences in corporate culture and structure that was the source of frustration that we described in the first subsection in the Discussion chapter. Other healthcare professionals do not necessarily have the same base research background, but there are exceptions also here. E.g. There might be doctors with phds or further and deeper understandings of what is required to approve a solution from a research point of view that other doctors. Research can also be as specialized within medicine as the specialized practice of medicine itself. And of course there might be other healthcare professionals other than medical doctors that have far better insight in their field than a physician would have.

Lastly we focus on a more general and impalpable quality of entering into a professional relationship with healthcare personnel in specific. Partly because they are users, and partly, due to the flat non-hierarchical leadership structure in Norway - healthcare professionals are some way or another involved in direct or indirect decision making. And the more successful

cases in this study described them as door-openers as opposed to the gate-keepers previously described. One of the guiding mantras of Professor Roger Sørheim at NSE is the guiding question; “Who is the customer?” - a prospective many forget and therefore lose track of important aspects of their business plan. In Norwegian public healthcare this focus would translate to “Who is making the decisions?” and/or “Who is influencing the decision-making process?” - because the customer itself is this larger and somewhat fragmented construct of different people and their considerations.

Healthcare professionals might be highly educated, they might have expert insight or a specific skill set, and in the NHCS the ones responsible for procurements or other decisions might not have the same insight - thus it is necessary for them to get feedback and be influenced by the users - and healthcare personnel can be heavily opinionated. It can be very costly if users are insufficiently included in the decision making process. If the hospital buys a product or service that the doctors refuse because it e.g. does not meet the sufficient standards of patient safety (one of the reasons for the importance of research) then the hospital has little choice. They cannot make the doctors do anything that the doctors have medical reasons for not doing. The most recent example, local to Trondheim, was the decision to postpone the implementation of the Epic EPJ-system. The launch was filled with prestige for the Regional Health Authorities of Middle-Norway, and the postponement of 5 months has so far been estimated to cost 500 Million NOK (Digi.no, 2022). The reason for the postponement was unignorable feedback from the clinical departments. This same force of influence was described as a positive by the case companies that had first-hand experienced how connections through doctors had led to not only opportunities but also actual deals.

Even though the leadership culture is flat and non-hierarchical, the hospitals have a quite strict but mystical intangible hierarchical structure. It might be slightly different between hospitals, but it is easy to understand for people on the inside. Without further comparisons to cults. Trying to give a general description of this hierarchy would surely offend someone within the structure but it would be safe to say that according to our data it seems that physicians in general are highly valued with regards to providing the startup with some important insight. Further and specialized insight would be very situational.

7 CONCLUSION

The main research questions of this study was to investigate which barriers and challenges that startups are faced with when trying to enter the Norwegian public healthcare sector - and secondary to that, how they approached these barriers if present. Our aim with these questions were to identify and investigate themes and trends that might give insight into what it takes to be successful with entering that market.

Using a qualitative method of semi-structured interviews in a multiple-case study design we found that the barriers paradoxically seem to be both obscure and decisive. On one hand there is little as decisive as the law, but on the other hand the law can be subject to interpretation. There are a multitude of different sorts of approvals and requirements that need to be met - and research seems to be very important. Everything, in one way or another, leads to the hard end of the tender based procurement process.

The approach to tackle all these barriers is very specific to each case and the possibilities are diverse. E.g. The path to procurement will look very different for an EPJ-system compared with an application for aiding diagnostics. Nevertheless, there was one factor that the successful cases all highlighted - the huge benefits of network strategy and close professional relationships with the industry or partnering with healthcare professionals.

The cases that struggled more with achievements did not have a clearly defined network strategy nor attentive of the benefits, from the mentioned connections, that the successful companies proclaimed to have reaped. As a result, we speculate, can also be the reason why they seemed to struggle with both navigating the NCHS and their approval processes.

The design and sample size of this study has its obvious limitations in generalizability. It is not certain that the same findings apply to different cases within the same segment, and it is even less certain that the importance of the different mechanisms in play carry the same weight in the procurement processes where companies are offering solutions with more direct effect on patient treatment than that of software based solutions. The study is also quite one-sided in that we have not interviewed any actors from within the NHCS.

7.1 Implications

7.1.1 For future research

Further research on the subject is much needed. We would suggest that future studies make inquiries into the NHCS-perspective of the procurement process. An obvious perspective is that of the administrators charged with the tasks of directing these processes. Do they look at these situations with the same frustration as some of our cases did - or are they perfectly happy with a system they feel that they understand. Are they satisfied with the opportunities and solutions provided by startups, would they like more tender offers from startups and how do they suggest to achieve that?

Then there are the innovation partnerships and R&D projects. These are interactions with another category of actor within the HCS. Often doctors or nurses. What is their take on the situation? This also merges with the user-perspective. Do healthcare professionals want more innovative solutions and interaction with startups? Are they conscious of their role in the great scheme of things and how they might contribute to lifting new solutions into the light?

There is also a third perspective that should be investigated - namely that of the top administration and leaders, also including government organization, agency and policy makers and indeed politicians. Innovating the healthcare sector is a huge worldwide societal challenge. Since the industry is so heavily regulated by laws, regulations and policies it is only natural to also investigate their perspective. Is there a reason that these processes are so cumbersome? Is there willingness to also innovate the process of innovation itself?

Lastly - of course - startups within other segments of the NHCS industry needs to be investigated. Comparative analysis with other countries would also be interesting to give insight into the challenges to international scalability. The benefit with there being little research for earlier is that there is so much still to do.

7.1.2 For startups

For startups and entrepreneurs we hope this paper provides promise to the possibilities to succeed within the NHCS. Difficult is not the same as impossible. As students of the NTNU School of Entrepreneurship it is fitting to quote our school motto; “Not because it's easy!”.

It is a fitting mantra for approaching the NHCS because it is not easy, but that is not the reason we do it either. Referencing our main finding we would also highly recommend hiring, partnering with or befriending someone that knows the industry well.

7.1.3 For actors and organizations in the Public NHCS

The biggest implications for the actors and organizations in the Public NHCS might just be making them aware that from an entrepreneurial/startup perspective, the sector is seen as being very difficult to enter to the extent of being discouraging - so if they want innovative solutions they should be aware of that fact.

8 REFERENCES

Acs, Z. J., Estrin, S., Mickiewicz, T., & Szerb, L. (2017). Institutions, entrepreneurship and growth: the role of national entrepreneurial ecosystems. Retrived from: https://ideas.repec.org/a/kap/sbusec/v51y2018i2d10.1007_s11187-018-0013-9.html

Akse, V., Frøland, E. & Roti, T.,D. (2021). What are the challenges of entering public healthcare with your start-up?

Anskaffelsesforskriften. (2016). Forskrift om offentlige anskaffelser (anskaffelsesforskriften). Retrieved from https://lovdata.no/dokument/SF/forskrift/2016-08-12-974

Anskaffelsesloven. (2016). Lov om offentlige anskaffelser (anskaffelsesloven). Retrieved from https://lovdata.no/dokument/NL/lov/2016-06-17-73

Anskaffelsesprosedyrer. (2016). Anskaffelsesprosedyrer - Innovasjonspartnerskap. Retrieved from https://anskaffelser.no/avtaler-og-regelverk/anskaffelsesprosedyrer/innovasjonspartnerskap)

Bell, E., Bryman, A., & Harley, B. (2019). Business research methods (Fifth edition. ed.) [Book]. Oxford: Oxford University Press.

Bosio, E., & Djankov, S. (2020). How large is public procurement? Retrieved from https://blogs.worldbank.org/developmenttalk/how-large-public-procurement

Braunerhjelm, P., Acs, Z. J., Audretsch, D. B., & Carlsson, B. (2010). The missing link: knowledge di usion and entrepreneurship in endogenous growth. Small Business Economics, 34 (2), 105{125. Retrieved from https://dx.doi.org/10.1007/s11187-009-9235-1 doi:10.1007/s11187-009-9235-1

Cfi.no (2022). Retrvied from: https://corporatefinanceinstitute.com/resources/knowledge/strategy/beachhead-strategy/

DeGhetto, K., Sutton, T., & Zorn, M. L. (2018). Institutional drivers of born-public ventures [Journal Article]. Journal of Entrepreneurship and Public Policy, 7 (1), 14-33. Retrieved from <GotoISI>://WOS:000427152000002 doi: 10.1108/jepp-d-17-00012

De Wit, B. (2017) Strategy- An International Perspective - 6th ed. edition

Digi.no. (2022). Retrieved from: https://www.digi.no/artikler/kommentar-helseplattformen-i-midt-norge-blir-fem-maneder-forsinket-hvorfor/519183 (Accessed 17.07.2022)

dsb.no (2022). Retrvied from: https://www.dsb.no/lover/produkter-og-forbrukertjenester/artikler/fakta-om-ce-merking/ om CE-merking, punkt 2.2.5.2)

Eisenhardt, K. M. (1989). Building theories from case study research. Academy of management review.

Eisenhardt & Graebner. (2007). Theory Building From Cases: Opportunities And Challenges

Forskningsmagasinet Apollon (2019) Retrived from: https://www.apollon.uio.no/artikler/2019/2_tema_korte_lover.html

Forsyningsforskriften (2016). Forskrift om innkjøpsregler i forsyningssektorene (forsyningsforskriften). Retrieved from: https://lovdata.no/dokument/SF/forskrift/2016-08-12-975

Glette (2018): Retrieved from: https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-018-3769-3 (Accessed 12.12.2021)

HIMSS Analytics Cloud Services. (2014). Retrieved from: https://www.ehcos.com/wp-content/uploads/2017/02/Final-Report-himss-analytics.pdf

Konsesjonskontraktforskriften (2016). Forskrift om konsesjonskontrakter (konsesjonskontraktforskriften). Retrived from: https://lovdata.no/dokument/LTI/forskrift/2016-08-12-976

Landstrom, H., & Benner, M. (2010). Entrepreneurship research: A history of scholarly migration.

Lian et Laing. (2004). Public sector purchasing of health services: A comparison with private sector purchasing [Journal Article] Journal of Purchasing and supply management

Mattson & Anderson. (2019); Melo et al. (2012); Omer. (2010); van Winden & Carvalho. (2019); Wagrell & Baraldi. (2019).

Melo, P., de Campos, D. D., & Machado, C. (2012). The new public procurement directives and the ppc: Practical implications of eu law on the portuguese public procurement code [Journal Article].

Regjeringen.no. (2022). Retrived from: https://www.regjeringen.no/no/tema/naringsliv/konkurransepolitikk/offentlige-anskaffelser-/andre-kolonne/terskelverdier/id2522847/ (Accessed 01.07.2022)

Fda.gov. (2022). Retrieved from: https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process (Accessed 04.07.2022)

GRANT, M. (2020). Startup. Retrieved from https://www.investopedia.com/terms/s/startup.asp#:~:text=A%20startup%20is%20a%20company,capitalists%2C%20crowdfunding%2C%20and%20credit

OECD. (2021). Retrieved from: https://www.oecd-ilibrary.org/sites/ae3016b9-en/1/3/7/1/index.html?itemId=/content/publication/ae3016b9-en&_csp_=ca413da5d44587bc56446341952c275e&itemIGO=oecd&itemContentType=book (Accessed 02.07.2022)

Olluri, B. (2019). Term paper: Born-public ventures [Literature review].

Olluri, B. (2020) Master Thesis: Delineating Born-public Ventures [Master Thesis].

Omer, D. (2010). Enterprise and innovation and ppps in germany: Recent developments [Journal Article].

Oslo Manual (2018). Retrieved from: https://www.oecd.org/science/oslo-manual-2018-9789264304604-en.htm

Percival, Sean. (2022). Working with Norwegians [Book]

Porter and Lee (2013): Retrieved from: https://hbr.org/2013/10/the-strategy-that-will-fix-health-care

Praag, C. M., & Versloot, P. H. (2008). The economic bene ts and costs of entrepreneurship: A review of the research. Foundations and Trends in Entrepreneurship, 4 (2), 1. Retrieved from https://search.proquest.com/docview/205809954?accountid=12870 (Copyright - Copyright Now Publishers 42 Inc 2008; Last updated - 2010-06-07)

Ries, E. (2011). The lean startup : how constant innovation creates radically successful businesses. London; New York: Portfolio Penguin. Retrieved from http://www.amazon.de/The-Lean-Startup-Innovation-Successful/dp/0670921602/ref=sr12?ie=UTF8&qid=1396199893&sr=8-2&keywords=eric+ries

Shane, S., & Venkataraman, S. (2000). The promise of entrepreneurship as a eld of research. The Academy of Management Review, 25 (1), 217{226. Retrieved from https://dx.doi.org/10.5465/amr.2000.2791611 doi: 10.5465/amr.2000.2791611

Smallbone, D. (2016). Entrepreneurship policy: issues and challenges [Journal Article]. Small Enterprise Research, 23 (3), 201-218. Retrieved from https://search.proquest.com/docview/1869847602?accountid=12870

doi: http://dx.doi.org/10.1080/13215906.2016.1270227

van Winden, W., & Carvalho, L. (2019). Intermediation in public procurement of innovation: How amsterdam's startup-in-residence programme connects startups to urban challenges [Journal Article].

Wagrell & Baraldi. (2019); Pickernell, Senyard, Jones, Packham & ramsey. (2013). New and young rms [Journal Article]; Melo de Campos & Machado. (2012); Mattsson & Anderson. (2019)
WHO (2021). Retrieved from: https://www.who.int/news-room/fact-sheets/detail/ageing-and-health

9 APPENDIX

9.1 Appendix 1: Interview Guide

Intervju-veiledning

Generelt

I løpet av intervjuet bør tema knyttet til nedenforstående spørsmål dekkes. Rekkefølgen er ikke viktig. Det er langt viktigere at intervjuobjektet får tid til å formidle fritt i henhold til hva hen selv tenker er relevant. Du skal ikke avbryte intervjuobjektets flyt og tankerekke. Hvis man mot slutten av intervjuet finner at man ikke har dekket vesentlige tema som nevnes nedenfor kan kan stille avklarende spørsmål til slutt.

Disclaimers

- Når vi snakker om avtaler snakker vi om avtaler med offentlige aktører fra det Norske Helsevesenet.

Strategi og forslag til eksklusjon av oppstarter til intervju

- **MÅ Inkluderes**:
  -Må være norsk start-up eller selskap
  -SW-aspekt (feks må Bio-tech også ha noe SW relatert).
  -Må ha, eller planlagt, kommersialisering til det offentlige helsevesenet.
  -Må ha tid, anledning og lyst til å intervjues.
- **Prioritering**:
  -De som har kun SW > kombinert HW/SW eller biotech/SW,
  -Prioritere de som allerede har startet prosessen (inkludert pilotprosjekter) > de som planlegger og enda ikke har begynt.

-Muntlig bekreftelse på info-letter: Sendt inn søknad til “Norsk senter for forskningsdata og Direktorat for IKT og fellestjenester i høyere utdanning og forskning. og fått godkjenning. Godkjent GDPR hensyn: Opptak, lagring av data, sletting av data etter bruk osv. Trenger consent.

NB: Husk å spørre om tillatelse om opptak, transkribering og nevn søknad til GDPR-NTNU organ.

Spørsmål

1. *Kan du fortelle litt om hva ditt firma driver med? Konkretiser produkt/tjeneste.*

2. *Kan du fortelle oss om din rolle i firmaet?*

3. *Har dere en avtale med en offentlig helseaktør i dag som dere selger produkt eller tjenester til?*

4. *Har dere tidligere forsøkt å selge eller tilby tjenester/produkter til en offentlig helseaktør? Har dere, eller vet dere om andre, som har forsøkt å lande en avtale som har falt gjennom.*

5. *Hvordan arbeidet firmaet deres strategisk med å forsøke/eller lykkes med å lande en avtale? Mer bredt: (I forhold til kun EN avtale): Hva er en den generelle strategien for å få innpass i det offentlige helsevesenet? I store trekk.*

6. *Hva ser dere på som de sentrale utfordringene for strategien dere har valgt.*

7. *Hvilke andre strategier kan man bruke for å oppnå samme mål?*

8. *Hva oppfatter du er den vanligste måten å "entre" markedet på?*

9. *Hvilke andre, mindre tradisjonelle måter, kan man vurdere for å "entre" markedet? (F.eks. Innovasjonspartnerskap)*

10. *Har du en opplevelse av ulikheten i strategi, tidsaspekt og suksessfaktor for disse metodene?*

11. *Hva vet du om gjeldende lovverk relevant for tilbud av tjenester til en offentlig helse-leverandør?*

12. *Hvordan ser dere på andre aktører i markedet - oppstartsselskaper, samt store etablerte aktører - representerer de trusler, eller muligheter?*

13. *Hvordan forholder dere dere til disse, imed utgangspunkt til strategien dere har valgt å komme dere inn i det offentlige helsevesenet.*

14. *Åpent spørsmål:* Kan du tenke deg noen andre gode tips å komme med for selskaper som ønsker å komme seg inn i det norske helsevesenet? Hva ville du gjort annerledes om du skulle startet på nytt i dag?

Temaer (gitt metodedel og intervjuguide)

Strategies (precommercial/R&D & commercial), procurement process, barrier and challenges, overcoming barriers

NB: Strategies may end up being one topic as a whole, or if necessary divided into pre-commercial (R&D) strategies if one chapter is too long/too complex.

9.2 Appendix 2: Literature search guide

Søk og søkeresultater

Dokumentet er ment for å gi resultater på søk, med ulike søkeparametere, samtidig som det skal forsikre om at vi ikke kaster bort tid på å søke opp de samme søkene.

Økonomi -> Business source complete

https://bibsys-almaprimo.hosted.exlibrisgroup.com/primo-explore/dbsearch?vid=NTNU_UB&lang=en_US

SCOPUS:

https://www.scopus.com/search/form.uri?display=basic#basic

Huskeliste og lignende

- Husk å markere "Peer reviewed", som er kravet for litteratur brukt under masteroppgaver.
- Husk å eksportere søkeresultatet, etter man har gjort et søk. I det minste ta screenshot e.l.
- Bruk de samme eksakte søkeordene på de ulike databasene; EBSCO (Oria) & SCOPUS.
- Husk å bruke "thesaurus" under SCOPUS søkemotoren til å finne synonymer til søkeord.
- Husk å bruke * for å "få alle mulige alternative formuleringer fra stammen av ordet"**: Health* startup* norw***
- ***Viktig å vise hvordan vi har gjort det til senere, slik at andre kan gjøre det samme***

Fremgangsmåte

1. *Gjør et "perfekt" søk. Dette er funn. Vi bruker* thesaurus for å finne synonymer. *Husk å huke av "contains" og ikke "start- wtih"

2. På thesarus finn andre relevante søkord. Feks: “startup*” blir feks: “business enterprises” eller “NEW business enterprises”, “NEW business enterprises”, etc.

Søkeord (stammen av ordet - ikke inkludert thesaurus):

- **Norw* (skal inkludere Norway, Norwegian, og alt annet…)**
- **Start***
- **Health***
- **Soft***
- **Public***

Master's thesis, 2022

Viktor Munch Akse, Erlend Frøland M.D., Tobias Drage Roti M.Sc.

NTNU
Norwegian University of
Science and Technology

NTNU SCHOOL *of*
ENTREPRENEURSHIP