INTERNATIONALISATION OF AI-DRIVEN HEALTHCARE STARTUPS

An assessment of the potential impact of institutional characteristics on the internationalisation of AI-driven healthcare startups in a complex business environment

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MSc. Economics and Business Administration (International Business)

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Abstract

This paper seeks to investigate the internationalisation of AI-Driven healthcare startups, and how or if institutional characteristics are leading to shifts in strategy when entering foreign markets.

This paper will integrate the Business System Theory as the main framework for exploring the logical and causal relationships between the institutional characteristics and the business system characteristics. Entering foreign complex business environments in a highly regulated industry can be challenging, and there are multiple institutional characteristics that are having impact on the business systems characteristics of the firms. Current research argues that firms are being shaped by their home-country institutional characteristics, as well as it is necessary to know why firms choose a particular entry-mode to gain an understanding of their strategic choices. Therefor we will also examine, how home-country institutions are underpinning internationalistation, as well as entry modes of AI-healthcare startups in foreign markets.This will be examined through the context of Danish AI-healthcare startups entering the U.S. market, where we will conduct a comparative case study of two Danish AI-healthcare startups, to assess how these companies were influenced differently by institutional characteristics.

To get a thorough understanding of the companies and markets in question, this paper relies on both secondary and primary data. The secondary data has provided a fundamental understanding of the relevant challenges and topics, whilst the primary data has been used to get a thorough understanding of the startups internationalisation approach and their approach towards the U.S. market in particular. This data is collected through interviews with C-level executives of the examined companies. Additionally, we conduct an interview with a healthcare industry expert to gain a deeper knowledge of the challenges that Danish startups are facing when approaching the U.S. healthcare market

Our research led us to identifying four institutional characteristics as being of major influence when entering these foreign markets, and this paper is therefor focusing primarily on these four institutional characteristics – namely regulations, the construction of the healthcare market, institutions supporting AI-development, and the attitude towards the products in the foreign markets – and how they shape the penetration of the market.

Our findings indicate a strong relationship between the host-country institutional characteristics and adaptions in the business system characteristics of the examined companies. The institutional characteristics shaped the entry-modes, timing of market entry, access to market knowledge, as well as attitude towards partnerships. We also identified that there was a linkage in home-country institutional characteristics underpinning internationalisation the Danish AI-healthcare startups.
Although our findings found that the examined companies behaved similar in some ways, we also found a fundamental difference in their responses to some institutional characteristics.

This study contributes to the International Business literature by integrating AI-healthcare startups specifically into the context of internationalisation. There has previously been conducted research on the respective elements, such as on AI-healthcare, Startups, and Internationalisation, but we identified a Literature Gap in explaining the causal relations between these topics. We believe it is relevant to extend the literature on startups navigating in complex business environments in a highly regulated industry in a matter of internationalisation, since we see a strong increase in AI-healthcare startups, as well as our research examined the strong impact it can have on the future of healthcare.

We expect that our findings can help shed a light on the challenges that AI-healthcare startups are facing when internationalising, as well as facilitate a starting point for future research.

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1 Introduction

In recent years, there has been a rapid increase in research within the field of artificial intelligence (AI). Although the concepts of AI have been discussed since the mid-1950s, there has been a resurgence in AI-driven products and technologies in recent years because of advances in processing and storage technology, big data, and more extensive data quantities. Some scholars have identified the current leaps in technological advancement as the four industrial revolution – and identified AI as a critical force in this revolution (French et al., 2021). This rapid technological development is currently reshaping industries and disrupting existing business models. At the same time, the implementation of AI technologies is also leading to social change and some sort of anxiety in our societies (Canals & Heukamp, 2020).

The applicability of AI spans wide. Today, we see AI being implemented in various industries such as manufacturing, logistics, design, and others (Gero & Sudweeks, 2012; Chien et al., 2020; Klumpp, 2018). However, one industry in which AI is expected to have enormous potential is healthcare. The capturing of patient- and industry data through electronic health records over the past many years has enabled the application of AI to process and analyse big data repositories within the healthcare industry (Young, 2022), leading to the development of algorithms and products both within administrative tasks within the healthcare industry – such as bill payments, scheduling, and other duties, as well as within the practice of medicine. Deloitte (2020) identified the following eight application categories to become impacted by AI technologies in the future: Imaging, Labs, Monitoring, Real World Data, Virtual health assistance, Personalised Apps, and Robotics.

Although the apparent potential of implementing AI technologies into the healthcare industry, which AI possess, the industry has been relatively slow and reluctant to embrace the opportunities. This has primarily been due to uncertainties and perhaps a lack of understanding of the technology and how to use it most effectively. Other factors, such as liability, algorithm, and data protection, impact the adoption of the technology as well, and the industry itself is still emerging in the healthcare sector (Davenport & Kalakota, 2019).

When assessing the landscape of AI-driven healthcare products, as well as the general emergence of the industry, it appears that *startups* are a significant source of change that develops and uses emerging technologies to reinvent existing products with a higher degree of efficiency or create entirely new products (Chakraborty et al., 2021). Despite the substantial

importance of startups to the emergence of AI within the health industry, this research area has been relatively under-researched. The research article by Chakraborty et al. (2021) examines 110 journals in health informatics and information management. However, only five articles analysed the state of health-tech startups in healthcare service delivery. The themes of these five articles contained Technology Adoption, Electronic Health services, Business planning and framework, Psychographics and Regulations. Current research of AI-driven healthcare startups has thus typically been based on which problems the products are solving, such as whether the product focuses on virtual assistance, image recognition, telemedicine services, and business models (Garbuio & Lin, 2019).

This paper aims to contribute to another dimension that we believe needs attention. This dimension concerns the internationalisation of AI-driven healthcare startups. The Internationalisation of startups is a well-researched area, and in recent years there has been a general increase in the pace of internationalisation of startups, which also has been of academic interest. This is primarily due to technological development (Hennart, 2014). Today, it is possible to operate in a market without physically being present. This leads to an increasing wish of companies to explore new markets and their potential. Even startups recognise this potential and start to explore foreign markets in the early stages of their business but are facing several challenges, similar to those that larger companies are facing, but also challenges that are caused by their size and newness (Neubert, 2018). As the countries in the world are becoming more and more digitised, the digitised startups will have even easier access to internationalise rapidly across borders (Benalieva & Dhanaraj, 2019).
However, the internationalisation and thus strategic challenges it brings upon startups that are specifically developing AI-driven products have not been examined extensively, which is why we believe this needs to be investigated.

The reason we believe that it is necessary to research AI-driven healthcare startups specifically is twofold. Firstly, these companies face the same challenges as larger AI-driven healthcare companies. Hee Lee & Yoon (2021) identified some of these challenges as challenges regarding cybersecurity, privacy, accountability, and loss of managerial control. Also, these companies are navigating in a highly regulated industry, giving rise to massive challenges.
Secondly, the very nature of being a startup gives rise to substantial challenges. These challenges can be identified as lacking financial resources, the acquisition of the first paying customer, and thriving in technological uncertainty (Nobel, 2011; Giardino et al., 2015).

Amongst these challenges, Young (2022) also argues that AI-driven healthcare startups specifically can face scrutiny from clinical stakeholders who question whether the startups' solution has sufficient clinical credibility.

To examine these challenges, this paper will integrate the business system theory (BST). The framework allows us to explain logical and causal relationships between firm-level constructs and institutional-level constructs and will help us to provide an answer to our research question. Our findings aim to advise startups in order to internationalise successfully and what kind of role the institutional environment of the foreign market, as well as of the home market, plays when entering a foreign market and developing a strategy to establish in this market.

To put these challenges into perspective, this paper will be based on the context of Danish AI-HC startups that have worked towards internationalising their operations to the U.S. market. We will conduct a comparative national business system analysis, laying out the national business systems in these two respective countries, and then by conducting a case analysis of two Danish AI-HC companies, we will assess how these companies have adapted their business operations when entering the U.S. market due to the institutional environment.

The application of the framework of Business System Theory to the context of the paper will help us to understand to what extent institutional characteristics of the home-country, Denmark, and the host-country, the U.S., impact the companies' internationalisation approach and the adaptation to the institutional context of the host-country. We will do so by conducting a comparative analysis of the institutional characteristics in the two countries to assess which institutional characteristics are shaping the business characteristics of the firms. To fulfil the picture, we will also examine the entry mode the two Danish AI-HC companies chose. Understanding the motives of the choice of entry mode will help to understand strategic choices regarding internationalisation (Rana, 2014). Therefore, we will implement the conduction of entry modes into our analysis in order to develop a detailed understanding of the internationalisation process and a valuable answer to the research question.

1.1 Research Question

All the above have led us to the following research question and sub-questions:

How are institutional characteristics influencing Danish healthcare AI-enabled startups' adaption to the U.S. market?

- Are home-country institutional characteristics underpinning internationalisation?
- Are host-country institutions impacting the choice of entry mode?
- Are host-country institutions leading to adaptations of the strategical approach?

2 Methodology

In this chapter, we will present and explain the methodological approach we have applied to validate our Thesis. This chapter is important as it provides the reader with an overview of the philosophical positioning and the choices we have made as researchers, which impact the direction of the study. According to Arbnor and Bjerke (2009), the methodological section explains and outlines the ideas about how researchers perceive reality and how we find and create knowledge (Arbnor & Bjerke, 2009). Therefore, it is important to have a firmly grounded and explained methodological section.

We will divide this section into three broader parts; Philosophy of science, Method, and Research Design. Each sector will justify our choices made within the fields. The philosophy of science section will explain how we perceive reality and how we believe truth can be achieved or knowledge can be generated. The method section will justify what choice we made to the overall structure and approach of the study. Lastly, the research design section will justify the considerations made in relation, e.g. data collection, data type, choice of market etc.

2.1 Philosophy of science

For any research paper to be validated, we as the researchers have to present our view of the world for the reader to understand in what context the research paper has been conducted and how the reality is perceived through the eyes of the researchers (Kuada, 2012). The philosophy of science has been very well described by Andreas Beck Holm, who defines it as "the systematic study of how scientific knowledge is produced, substantiated and used in society" (Holm, 2018).

The philosophy of science helps us to explain how knowledge is generated, presented and adopted in society according to our view as researchers, and a research paper will inevitably, with the researchers being aware of it or not, have a structure or impact based upon the researchers preconceived knowledge and fundamentals relating to epistemology, ontology and our world view in general (Kuada, 2012).

Philosophy of science is made up of different paradigms, which explain how the researchers approach a phenomenon and how it is being examined. Paradigms were first introduced into the philosophy of science by Kuhn in 1970 when he presented a theory explaining how every field of research possesses commonalities towards a phenomenon, such as how the researchers approach the research question, useful questions to ask about a phenomenon, and how the results or findings should be interpreted. These commonalities or characteristics are what he narrated as paradigms (Kuada, 2012).

2.1.1 Ontological

Ontology is a term which describes the nature of what the researcher wants to accumulate knowledge about- this is what concerns the understanding of the "reality" the researchers are a part of. Typically, this term is seen from two different broad perspectives by researchers in the social science world; one group of researchers perceive reality as something constructed externally outside of the individual's control, and the individual is then affected by this reality. The other group of researchers perceives reality as a unique one created by each and every individual. This means that reality is a social construct created by the cognitive levels of the individual (Kuada, 2012).

For this research project, we believe society and reality are created and shaped on an individual level, latter mentioned perspective of researchers within our field, as some of the institutional levels a made on cognitive levels and by the broad, general acceptance in society and by society.

2.1.2 Epistemological

Epistemology is a term which describes what we perceive as the "truth" or, in other words, "how we know what we know", whether it be as observers of the external world and reality or as individuals within. It is perceived by some scholars within our field that the truth can be explained or obtained by acting as external observers, and simply observing the broader social world is enough to find the real truth. Once again, other scholars believe you need to go to a

deeper intersubjectively level and understand the frame of reference in which the individual resides within (Kuada, 2012).

In this section, we will explain two of the dominant research philosophies, which are considered to be how we generate knowledge as researchers. The two philosophies are; Realism and Critical realism. We will then explain which philosophy is applied to this research paper.

2.1.3 Realism

Realism is a philosophical approach where the researcher perceives the social world as an external reality to the individual cognition (Kuada, 2012). Realists believe the world can be understood, and every observation we make brings us closer to this truth, which is in the world external to individual cognition. They furthermore believe the world can only be changed if we understand the causes which generate the truth in the world as the social world and the phenomena within occurs whether or not we are aware of them (Bell et al., 2019).

2.1.4 Critical Realism

Critical realism takes a different approach than realism when it comes to the domain of research. In the scope of critical realism, researchers believe that there is a world and it is real; however, it is impossible to reach an absolute truth as the truth or theories can be proven and later falsified, which will change the first assumed truth (Easton, 2010). Furthermore, in critical realism, Andrew Sayer noted, “Social phenomena such as actions, texts and institutions are concept dependent. We not only have to explain their production and material effects but to understand, read or interpret what they mean. Although they have to be interpreted by starting from the researcher's own frames of meaning, by and large, they exist regardless of researchers' interpretation of them.” (Sayer, 2001). This philosophy or paradigm, critical realism, will be applied to provide us with an understanding of the institutions the Danish AI-HC startups operate within, both in their domestic market and the foreign market they try to enter. Furthermore, critical realism will help us provide an understanding of how the institutions impact and shape the startups in the social world.

2.2 Method

For this research, the method is going to be a comparative case study. The comparative case study allows us to undertake multiple company cases to illuminate our research question from multiple angles. This choice of study form also fits well with our philosophical approach, where

we seek the truth and believe the current truth can later be falsified- by applying multiple cases to the study, we will come closer to a valid truth in the social world of where the Danish AI-HC startups operate.

It is a common research method within the IB field, and it brings a great understanding and basis for the analysis of institutional factors in society and their impact on companies.

2.2.1 Comparative Case Study

A case study is a study where the researchers go in-depth with the specific case and are often conducted over time. It can be conducted as a single-case study or a multi-case study (Zainal, 2007). A case can be that of a single company, a challenge, a policy, a program etc. (Goodrick, 2020). There has been critique concerning the case study, as it can appear vague and generalising when it does not specify what kind of case it is concerning, and it is argued that "scholars use the word case with relatively little consideration of the theories and metatheories embedded in these terms or in the methods that use cases" (Ragin & Becker, 1992).

Even within the terminology and research method of case studies, there are multiple categories. Yin (2014) has described different categories of these case studies; he specifically has noted down three categories; descriptive, exploratory, and explanatory.

The descriptive case study entails conducting the research and study as the case is going on. This can be in narrative form as an observer noting what is currently happening in the data set the observer is analysing. It seeks to describe the natural phenomenon which is happening in the data (Zainal, 2007).

The exploratory case study seeks to explain and explore any phenomenon happening in the data that the research finds of interest. It entails looking at the data and asking general questions about what can be explored and illustrated from it. An example of an exploratory case study could be a pilot project where you have a data set and explore all the phenomena happening within (Zainal, 2007)

The explanatory case study aims to explain the phenomenon happening in the data closely. It illustrates both at a surface level and a deep level to arrive at the best explanation. Using

explanatory case studies, it is possible for the researcher to propose a theory explaining a phenomenon as well as test the theory with the dataset (Zainal, 2007).

The comparative case study adds extra dimensions to a research paper as it allows the researchers to compare multiple cases in the same setting and the criteria revolving around the cases. The extra layer is important to the validation of the study and to help us reach as close to the truth as possible. For our research, the comparative case method will be in the exploratory category as we set out to understand what various barriers and obstacles there are for the companies examined and interviewed and how they individually have made actions upon them. Furthermore, the comparative case study is going to consist of qualitative data gathered through qualitative interviews with two companies. The justification of the data will be explained in a later section.

2.2.2 Justification of comparative case study

We chose the comparative case study to be able to illuminate our research question from multiple aspects, and the comparative case study will assist us in providing AI-HC startups with an understanding of institutional characteristics and their impact on the startup and their approach to foreign markets. To come up with such a generalisation, we need to investigate complex and multiple levels of society and their impact on the startups- these phenomena include; institutions, domestic market and foreign market conditions, society, and business system theory. Hence, the comparative case study brings the validation which will help us get closer to truth and a broader generalisation of the impact these phenomena have on the Danish AI-HC companies, as it allows us to analyse and compare their decision-making process, their experiences, and their actions taken before and after entering the American market.

2.3 Research Design

According to John Kuada (2012), the research design is the blueprint and action plan of your comprehensive research or study. The section will provide the reader with a clear and logical understanding of how the researchers have intended to answer the research question presented in the introduction. The section should also provide the reader with an understanding of how the researchers work towards analysing the data, validates the choice of their data, and arrives at a conclusion (Kuada, 2012).

In this section, we seek to explain and illustrate the action plan of the research paper, where we will provide the reasoning behind our methodological approach to conduct a study which can explain our research question.

2.3.1 Why the US market?

The US market as the market of interest for our research paper can be justified from various standpoints and logical characteristics. We will explain and justify the choice of the market selection here, as well as the dominant institutional characteristics that may impact the internationalisation of the start-ups;

Firstly, the US market has for a long time been Denmark's largest non-European export market, and recently it became Denmark's overall largest export market in the world, surpassing Germany. In 2021, the total trade between Denmark and the US was worth approx. $15.7 bn, and the exported good from Denmark to the US is mostly; industrial machinery, pharmaceuticals, and green tech. The US recognise and acknowledges the Danish advancements in health and life science, and in 2020, Denmark exported life science-related goods for $7.45 bn to the US (U.S. Department of State, 2022; Ministry of Foreign Affairs of Denmark, n.d.).

On a similar note, a second factor playing its part in the selection of the US as our choice of foreign market for the Danish startups within AI-HC is the sheer market size and potential of the healthcare sector in the U.S., even on a local scale. A city such as Houston, Texas, where they have what is called the Texas Medical Center (TMC), they have more than 19,300 hospital beds, whereas, in comparison, Denmark has approximately 15,000 in total for the entire country. This means that if a Danish AI-HC startup can enter the US market in a single city such as Houston or the like, there is already a greater potential than the entire domestic market of Denmark (City of Houston Texas, n.d.; Statista, 2022).

Thirdly, conducting a study about business system theory and institutions become more valid and thorough if the researchers possess vast and practical experience from the country. Here it became an opportunistic choice as one of the researchers has been living and working in the country for a longer period of time, gaining local and cultural experience with the market. Furthermore, the researcher gained knowledge and experience about the institutional conditions and markets through the position with the Danish Trade Council in Houston, Texas. This unique

opportunity also made it possible to achieve and conduct interviews with high-level decision makers of Danish AI-HC startups who are trying to enter the US market.

Lastly, the digital landscape of the U.S. is providing strong institutional foundation for digital or technological companies to try and enter the market. One of the institutional factors in the U.S. which provides a strong market for technological and digital companies is the amount of money spent domestically in the U.S. on R&D. The U.S. is the number one country in the world in terms of domestical expenditure on R&D in total $657 bn in 2019 (Hourihan, 2021). Another strong institutional characteristic is the digital mindset of the U.S. - specifically referring to Silicon Valley, California, and the numerous gigantic digital companies with headquarters there e.g. Amazon, Google, Tesla, etc. The cluster of digital companies, as the cluster of healthcare companies in Denmark, brings along a great foundation for knowledge sharing, innovation, and talent recruiting (Henry-Nickie et al, 2019).
Very similar to the U.S., Denmark is a highly digitalised and innovative country and in fact one of the most digital countries in the world. In 2021, Denmark ranked no. 1 on the DESI (Digital Economy & Society Index) which is an annual report of the EU countries' digitisation within; Human Capital, Connectivity, Integration, and Digital Public Services (European Commission, 2021). Here we are dealing with two countries the most digital competitive country in the world (USA) and the fourth most in the world (Denmark) – this provides the Danish AI-HC startups with an already well-established understanding of similar institutions in the two markets (Statista, 2021).
The U.S. also has established accelerator programs for startups very similar to Denmark. These accelerator programs will provide funding and support for the startups in the country or the startups entering the country. This is a way for the startups to enter the foreign market as well as coping with the institutional factors in the market and gain legitimacy (Mansoori et al., 2019)

These multiple factors justify our choice of the U.S. market as our main market of focus and to examine the institutional obstacles encountered as well as choices made by the Danish AI-HC startups trying to enter the market.

2.3.2 Selection of cases

When selecting cases, the researchers have to keep their research area or problem in mind. The case or cases has to be selected from criteria that can help explain and illustrate what the researchers are trying to explain. Yin (2014) mentions, that if your theory is straight forward

and you do not require the highest degree of certainty, the case study can consist of just two-three cases to obtain the level of certainty and interpretation of the research question needed. On the other hand, if your case study and research question require high levels of certainty Yin proposes five, six, or more cases to obtain a satisfactory level of certainty (Yin, 2014).

For our case study, we want to broadly illustrate some of the factors Danish AI-HC startups have to take into consideration and how they affect their decision making in terms of strategic approach to the U.S. market. For this purpose, we have decided to apply two cases to our case study; Radiobotics and Teton.ai. Both startups have their domestic market in Denmark and want to push for the U.S. market. Furthermore, both cases are also within different branches of AI in healthcare, thus providing the research paper with different perspectives on the obstacles and barriers we are focusing on. By comparing the two startup cases, we will be able to answer and conclude on our research question.

An opportunistic moment also played a part in the selection of companies as one of the researchers possesses contacts who can reach out to the companies and set up contact, which otherwise could have proven to be more difficult and time-consuming. Hence, the selection of the companies has been limited to current or previous partners of the Danish Trade Council of Houston for a more effective selection and planning process.

2.3.3 Data collection

This section will focus on our empirical data, what kind of data it is, how it is gathered, and why it is relevant.

2.3.3.1 Data Type

For this research paper, we collected three types of data to support our validation for a conclusion on the research question proposed; literature, secondary data, and primary data. These three types of data will provide us with a great foundation and understanding of the gap we are researching, as well as provide us with the option of arriving at a valid conclusion when examining the case studies incorporated in the research paper.

Literature data

At first, we gathered an interest in AI and its possibilities within healthcare, and we started reviewing journals, articles, reports, and books on the topic. It helped narrow us down to a research gap within the research field of International Business and AI in healthcare. In our

literature review, we have presented the data which has been reviewed to find the topic, which essentially helped us produce the final research question and problem formulation. In the literature review, we present the gap and the research already conducted on the topic. It explains and justifies our choice of the topic. Furthermore, the literature data has helped us come to an understanding of a theoretical approach to the research question which could help us explain the gap in the research. The theory inspired by reviewing the literature is the Business System Theory, which we will apply to the analysis of the empirical data.

Secondary data

The secondary data has been collected from websites and articles about the case companies in focus, the business system theory approach, for a general understanding of the AI-HC field in our society today, to gain a scope of the American healthcare system where relevant for the paper, and to understand the institutional aspects trying to be illuminated by this paper. Secondary literature concerning the market and market conditions has been gathered as well and is providing us with a deeper insight into the conditions of the market and how they impact the Danish AI-HC startups when entering the US market. The secondary data is used to provide us with an even greater understanding of the research topic and to assist the analysis to become more thorough and ultimate achieve a higher level of validation with the conclusion.

Primary data

Our primary data is qualitative data we have gathered first-hand, and it has been gathered through interviews with decision-makers of the case companies in this paper, as well as a sector expert from the Danish Trade Council in Houston. The companies provided us with important and relevant actors within the companies which could answer our questions and provide us with knowledge which will help us arrive at a valid conclusion to our research question.

In total, we gathered data from two companies and one sector expert. The first interview was with the sector expert through the consulate, who provided us with a deeper understanding of our research topic, which helped us understand what questions were relevant to examine and ask the companies. Through the insight and expertise provided by the sector expert, we managed to come up with a standardised semi-structured interview manuscript which would be the foundation of our interviews with the case companies and still leave space and time for follow-up questions with the companies.

The data collected from the case companies has been crucial for our paper, as it has provided us with the necessary empirical data sets to analyse and help provide an understanding and enlightenment of the topic in the end. The interviews were set up with help from the Danish consulate, and out of four potential case companies we reached out to, three companies were able to find time for interviews via online meeting platforms such as Microsoft Teams, one encountered illness and had to cancel, and the last company simply could not find the time for an interview. The interviews were, on average, 30 minutes, with the exception of the first interview with the sector expert, which took 60 minutes (see table 1).

Subject	Name	Company	Position	Duration	Area of Expertise
American Health & Life Sciences + Danish AI-HC startups					
	Christina Brinch Clark	The Trade Council in North America	Sr. Commercial Advisor	1h	American and Danish Health & Life Sciences industry
Case Companies					
	Mikkel Wad Thorsen	Teton.ai	CEO and Founder	30m	Danish AI startup trying to enter the US market
	Stine Mølgaard Sørensen	Radiobotics	COO and Co-Founder	30m	Danish AI startup trying to enter the US market

Table 1: Case Companies Overview

2.3.4 Interviews

As mentioned, the primary data collection happened through interviews with employees in decision making roles at their respective companies. The goal of the qualitative interviews is to see our research topic from the perspective of the interviewee and to gain insight into their real-life and world experiences, which we can later analyse and interpret to answer our research question in the most effective way (King, 2004; Kuada, 2012). This section will explain three different main interview methods and the considerations we made to justify the choice of interview method for this paper.

2.3.4.1 Structured interviews

A structured interview is an interview method or structure where the interviewer has prepared the questions for the interviewee beforehand. It is a list of predetermined questions and leaves room for little to no follow-up questions along the process. This interview method is very efficient if the purpose of the interview is to get clarification on specific questions, and the data can be easier to group and potentially quantify if needed (Gill et al., 2008). However, this way of conducting interviews does not invite for a lot of depth with the interviewee and their perspectives of the world and society in which they operate, and the goal of the interview data

for this paper is to gain insight into these perspectives of our interviewees, the structured interview method will not meet our requirements.

2.3.4.2 Unstructured interviews

As opposed to structured interviews, the unstructured interview method contains little to no predetermined questions, and the interviewer would typically ask the questions based on the responses from the interviewee. An unstructured interview would start off with a very open-ended question and then go from there. This way of conducting interviews is great if there is a lack of knowledge within the area which will make predetermined ideas and theories difficult to know about. However, as it is a very open dialogue with little power over the direction of the interview, it is a method most often used where there is a need for significant depth within the topic (Gill et al., 2008)

2.3.4.3 Semi-structured interviews

The semi-structured interview method combines the two previous methods. With the semi-structured method, the interviewer and the interviewee have the possibility to both guide the questions within certain areas of interest and, at the same time, explore the mind and opinion of the interviewee and their perspective of the topic. It provides the interviewer with a beginning structure and allows for follow-up questions to gain a deeper understanding of the answers provided. For the interviewee, the method helps guide and provide boundaries to the topic at hand (Gill et al., 2008).

2.3.4.4 Our choice of interview method

To increase the validity of this paper, we decided to collect primary data in the form of interviews with relevant interview partners that have a certain knowledge within the conducted research context and can provide fundamental knowledge and insights. These interviewees work within the industry of healthcare and specifically focus on Artificial Intelligence in healthcare. Our interview partners were consultants of the Danish foreign ministry in Houston, as well as founders and employees of Danish AI-HC startups that have already entered or plan to enter the healthcare market in the USA. These interviewees provided specific market information and insights regarding the applied countries and industries.

After carefully looking into the advantages and disadvantages of the three interview methods mentioned in this section, we chose to follow a semi-structured approach. This type of interview

is conducted with one interviewee at a time and includes open-ended questions, which turns the interview into a more fluent conversation compared to the structured interview approach. Often used questions in this type of interview are why and how questions. This can uncover some unpredicted issues within the conducted topic that the researcher was maybe not even aware of (Adams, 2015).
In addition to that, using the semi-structured approach for interviews reduces the risk of influencing the interviewee with the choice of questions and possible answers. It also encourages fluent communication and creates a better atmosphere since it allows a more fluent conversation compared to a structured interview. Additionally, it is possible to understand the reasons behind the given answers and provide more in-depth knowledge. The collection of qualitative primary data makes it possible to compare it to previous and future data.

By using semi-structured interviews, the researcher, or interviewer, faces some challenges. A semi-structured interview is more time-consuming compared to a structured interview or a survey and therefore requires more resources. Furthermore, there is a need to interview enough people to be able to draw conclusions from the findings of the interviews and make them representable. The danger of influencing the interviewee by the used questions is not fully eliminated in the semi-structured interview but is highly decreased compared to the structured interview questions (Adams, 2015).

3 Literature Review

The aim of the literature review is to introduce and review relevant literature to establish an understanding of the current research that is relevant for being able to answer the research question of this paper. To establish this understanding, we have identified five themes of research we will review. The five themes will be identified below, whilst there will follow a short justification of why we assess this specific theme and how it will help us to establish a theoretical understanding of the overall aim of this paper:

Themes	Aim of Review
1. Integration of AI into the healthcare sector	To establish a fundamental understanding of AI within the healthcare sector. This will be done by giving a historical overview, a general introduction to the technical fundamentals of AI, and finally, putting this into the context within healthcare.
2. Startups and their role in the emergence of the AI-HC industry	Since the aim of this paper is to assess startups, we will give a review of the literature regarding startups. Our aim is to describe how startups are having an impact on industries and put this directly into the context of AI-HC.
3. Internationalisation of AI-HC startups	The aim is to establish the theoretical context of the internationalisation of firms. Why do firms internationalise, and why do they choose a specific market to penetrate?
4. The National Business System Theory	The aim is to establish an understanding of the Business System Theory and the constructs of the theory that will help establish an understanding of *if* or *how* Danish institutional characteristics are underpinning the internationalisation of startups, as well as *if* or *how* U.S. institutional characteristics are shaping the company's strategy when entering the market.
5. Entry modes to foreign markets	According to Rana (2014), the understanding of Strategic Choices of companies in Business Systems will not be complete without knowing why firms choose a particular entry mode. Therefore we will review relevant entry-mode literature to establish the foundation of a discussion regarding the entry-mode of the case firms to the U.S. Market.

Table 2: Overview of Literature Themes

3.1 Integration of AI into the healthcare sector

In this section, we will review the historical and theoretical integration of AI into the healthcare sector. Firstly, we will review the historical advancement of AI technology. Secondly, we will give a more technical introduction to the field, laying out the technological background. Thirdly, we will demonstrate how and why AI today is being implemented in the healthcare sector.

3.1.1 Historical advancement of AI technology

In its very nature, the field of AI dates back to the 1950s. It is widely considered that a workshop at Dartmouth College in 1956 was the birthplace of AI as a field of research. This happened at a conference held in Hanover, New Hampshire, where 20 of the brightest minds within computer and cognitive science were gathered. It was at this conference that it is believed the term Artificial Intelligence was being used for the first time (Haenlein & Kaplan, 2019).
After a period of almost two decades with significant success in the field of AI technology, including substantial funding for AI research, the number of projects and the excitement towards this topic increased. But the progress was not as fast as expected during the following years, and no substantial advances were made (Haenlein & Kaplan, 2019)

Because of the digitalisation and the massive amount of data that has been created in recent years, AI has become an important topic again and is today already part of daily life. Facebook, for instance, is using AI technology for their image recognition algorithms (Haenlein & Kaplan, 2019).

Overall, it is expected that AI will have a transformative impact across all industry sectors. Furthermore, it is expected that AI will have a fundamental impact on social structures and the global economy in the coming years – in the same way as previous general-purpose technologies (GPTs) had in the 19th and 20th centuries through steam engines, railroads, electricity, electronics, and the internet (Howard, 2019).

3.1.2 Technical foundation of AI technologies

AI is not only one technology - it is a collection of different technologies that are based on data (Davenport & Kalakota, 2019). According to Shinners et al. (2020), AI and its potential within healthcare rest in analysing unstructured data, detecting abnormalities, providing correlations,

and automating and assisting human tasks. These functions will be realised by using Natural Language Processing algorithms, Deep Learning, and Machine Learning programmes.
The aim of this section is to introduce these three technologies.

Machine Learning (ML):

Machine learning can be used to analyse structured data and is a statistical technique for fitting models to data and learning by feeding models with data. Machine learning is the most common form of AI and can be applied in precision medicine to predict treatments that will be most likely to succeed based on various patient attributes and treatment contexts (Davenport & Kalakota, 2019).

A more complex form of machine learning is the neural network. It has been well established in healthcare research for many years and is applied in healthcare too. The neural network technology can be used for the categorisation of patient data. It can determine whether a patient will suffer from a particular disease based on the patient data and can therefore be used to prevent these diseases and start an early treatment. A neural network can make these predictions by viewing the problem in terms of inputs and outputs and weights of several variables that link inputs with outputs (Davenport & Kalakota, 2019).

Figure 1 shows the function of a neural network and how the different variables in it are connected. This is presented in order to provide an easier understanding of the neural network since the technology is quite complicated.

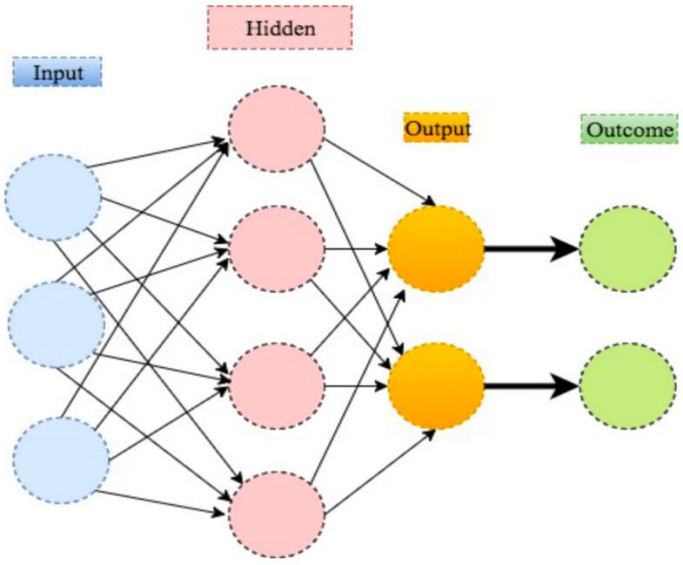


Figure 1: A neural network, how it works and the connections between the different variables (Jiang et al., 2017)

Natural Language Processing (NLP):

Natural language processing refers to applications like text analysis, translation, speed recognition and other functions related to language. It is applied in several tasks that relate to healthcare like the creation, understanding, and classification of clinical documentation and research; the analysis of unstructured patient/clinical notes; transcription of patient interactions; preparation of medical reports etc. (Davenport & Kalakota, 2019).

Another AI technology that can be used to automate tasks in healthcare is robotic process automation. This technology can be used to perform structured digital tasks for administrative purposes. It is often applied within a computer program that is used for repetitive tasks like updating patient records or billing. One advantage of robotic process automation, compared to other AI technologies, is the low price, the transparency of the functions, and the ease of programming (Davenport & Kalakota, 2019).

Even though there are some AI technologies that are more used than others, in today's world of healthcare, the described technologies are often combined with each other to optimise processes in order to get the most valuable outcomes (Jiang et al., 2017).
Figure 2 shows a possible workflow in which machine learning and natural language processing are being combined and how they generate data for each other.

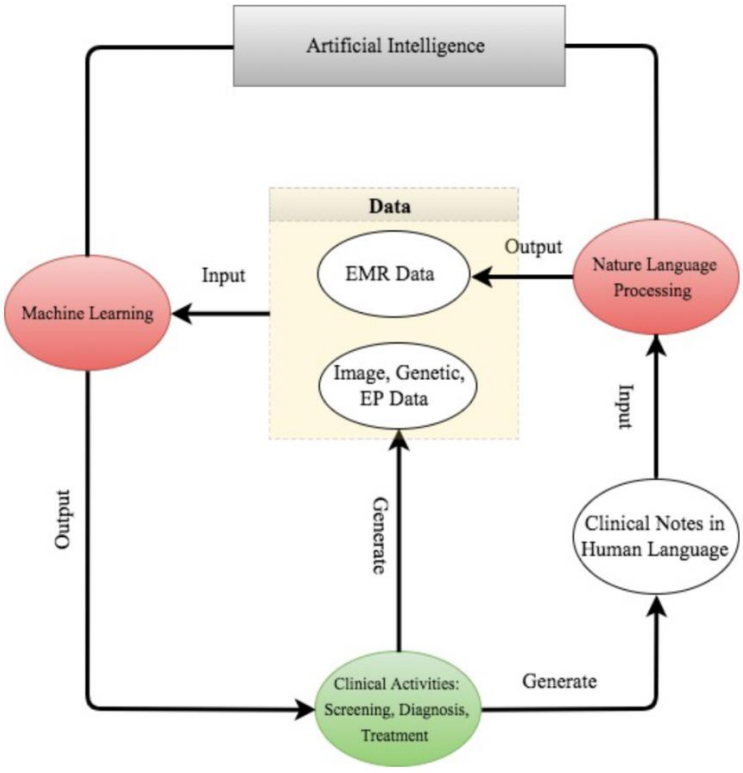


Figure 2: The connection of machine learning and nature language processing in a workflow (Jiang et al., 2017)

Deep learning (DL):

Based on the classical neural network, deep learning is perceived as ”a modern extension of the classical neural network technique” (Jiang et al., 2017) with many layers. Deep learning makes it possible to analyse neural networks with a larger number of layers and can therefore be used in order to identify more complex non-linear patterns in large data sets. The amount of data and the complexity of data rapidly increased during the last years. Thus deep learning is perceived as a suitable method for finding complex patterns in the data sets. Especially in healthcare, deep learning technology is being implemented in imaging analysis to recognise potential cancer for example. Another application of deep learning in healthcare is speech recognition (Jiang et al., 2017; Davenport & Kalakota, 2019).

3.1.3 Why and how is AI being implemented into the healthcare sector

The aim of this section is to put AI into a theoretical context within the healthcare sector. This will be done by firstly reviewing why AI is necessary to address the challenges of the long-term sustainability of healthcare sectors, whilst secondly, we will address specifically how these challenges are being met with the assistance of emerging AI technologies.

Which demands are AI technologies tapping into within the healthcare sector

When it comes to the aspect of human health, society and thus healthcare sectors around the world, there are multiple challenges that will need to be addressed. These challenges vary from country to country, but research shows that multiple of these challenges are common in many countries. First and foremost, these challenges are of a demographic nature. Many countries face an increasingly elderly population. Furthermore, citizens today are experiencing multiple chronic conditions (Kingston et al., 2018; Shaw et al., 2019). These challenges can become a massive burden for the long-term sustainability of the healthcare sector, which also has increasingly become a concern in many countries. These challenges are giving rise to increasing demand for healthcare personnel, which will put increased pressure on the economic operations of these healthcare sectors. Therefore, it is necessary to implement and integrate smart innovation and technology that will help take the pressure off the personnel and, at the same time, free up resources at the hospitals, which ultimately can lead to an increased level of service in the healthcare sector, and at the same time reduce the long-term costs (Bergman et al., 2015). Besides contributing to the level of service and reducing long-term costs, AI is also being regarded as having the potential to improve access to the healthcare sector (Nsoesie, 2018).

How are these challenges being met with AI technology?

As previously discussed, it is being assessed that one of the industries in which AI can have a transformative impact on the healthcare industry. This transformative impact will be made by using AI technology to develop products and services that will support and assist doctors and healthcare personnel in diagnosing and treating patients, as well as assisting in monitoring citizens and helping them make healthier choices (Deloitte, 2020). According to Shinners et al. (2020), AI and its potential within healthcare lie in analysing unstructured data, detecting abnormalities, providing correlations, and automating and assisting human tasks. These functions will be realised using the previously introduced Natural Language Processing algorithms, Deep Learning, and Machine Learning programs.

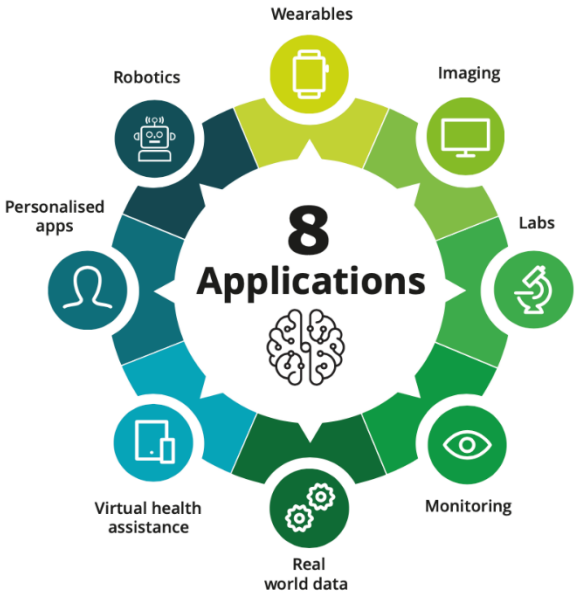


Figure 3: 8 categories of AI-HC technologies (Deloitte, 2020)

In a report from Deloitte (2020), it is assumed that AI within healthcare can potentially save 380.000 to 403.000 lives annually in Europe. This can be done by integrating AI into the European healthcare sectors. Deloitte (2020) argues that, since the field of AI-HC innovation development is happening so rapidly, they believe it is important to clarify what AI can do and where. Therefore, they categorised eight specific technical areas which they believe will contribute to saving lives in the future. Below, we will briefly introduce these eight categories identified by Deloitte (2020) and their function:

Wearables: Wearables monitor patients or citizens in real-time. This technology is being integrated into wearables such as accelerometer bracelets, smart watches, and activity trackers, with the aim of responding to health events if one should occur.

Imaging: Mainly being used within radiology and pathology, imaging refers to capturing and processing image scanning data to support the diagnosis of respiratory diseases, cancers, or cardiovascular conditions.

Laboratory applications: This contains support laboratory applications for data analysis, as well as for research and development. As of today, there are AI applications in pathology, laboratory database management and infection testing.

Physiological monitoring: Covers the monitoring and detection of health conditions, abnormalities, and normal physiology. Also, this can cover eye-tracking technologies in neurology.

Real-world data: AI can be used to analyse large-scale datasets of entire populations. This can be relevant for patient recruitment and retention in clinical trials.

Virtual Health Assistance: Covers technologies that somehow provide virtual care or help to patients or support healthcare professionals. These could, for example, be smart-speaker devices that are being used to transcribe clinical data and extract information or virtual scribe.

Robotics: Robotics can be used to support patients and healthcare professionals with daily tasks. Robotics is being used as a supportive assistant tool for surgery, as well as auxiliary robot assisting nurses also have been developed.

Besides the obvious potential AI has within the healthcare sector, AI technologies are also posing challenges to the healthcare sector. Amongst these challenges, it is yet unknown what impact AI technologies will pose on health professionals, organisations, and governments (Hamet & Tremblay, 2017). It appears that AI technology in this industry has been slow to be implemented due to uncertainties and perhaps a lack of understanding of the technology and how to use it most effectively. Other factors, such as liability, algorithms, and data protection, have an impact on the adoption of the technology as well, and the industry itself is still emerging in the healthcare sector (Davenport & Kalakota, 2019).

When it comes to the full utilisation of AI-HC technologies, Deloitte (2020) argues that there are several policy recommendations that need to be fully implemented in order to fully unlock the potential of AI within healthcare. These initiatives are targeted toward the European Union Member States to ensure harmonisation across all member states. The seven policy recommendations are the following:

1. To develop a policy framework which aim is to build trust and foster the adoption of AI in healthcare.
2. To build and maintain an environment of regulations that is based on the already existing regulations to further enable and stimulate technological innovation and evolution.
3. To build infrastructure and data policy that is in line with the European Health Data Space project. The aim shall be to foster seamless access, connectivity and sharing of high-quality, harmonised data.

4. To develop partnerships and clear governance across healthcare academia, professionals, decision-makers, and industry across all member states.
5. To ensure commercial reimbursement and incentive mechanisms to support patient access, as well as foster innovation in Europe.
6. To define data format standards to advance data interoperability. The aim is that data can be generated and transferred in a more consistent way across member states.
7. Increase the level of AI skills amongst healthcare personnel and also increase the digital health literacy amongst citizens and patients. (Deloitte, 2020)

3.2 Startups and their role in the emergence of the AI-HC industry

The aim of this section is, therefore, to establish the necessary constructs for establishing a discussion on the role of startups in the emergence and development of the AI-HC industry. The constructs needed for this discussion are the following: Firstly, we will define what a startup is. Secondly, we will demonstrate the general effect startups have on industries. Thirdly, we will put these constructs into the context of the healthcare industry to be able to discuss the impact of AI-HC startups on the healthcare industry specifically.

3.2.1 Definition of a startup

The aim of this section is to demonstrate why we have chosen to use the term startups. The term *startups* are still evolving, and many scholars have made efforts to define the term. Graham (2012) defines it as "a company designed to grow fast" (Graham, 2012). Only being lately founded does not make a company a startup. He states that growth is the most important thing a startup should aim for - everything else is followed by growth (Graham, 2012).

However, in this paper, we stick with the definition of Unterkalmsteiner et al. (2016), who defines a startup as being small in size, creating a new product or service under extremely uncertain conditions, having no prior operating history, and aims to create a scalable technology and business model. Langley (2018) adds that the funding of these firms varies – and goes all from their own capital to different venture capital modes.

As previously mentioned, we have chosen to define the firms that are being examined in this paper as startups. However, there are other terminologies that probably could have been used since these have similar characteristics to those of startups. In Hennart's (2014) definition of Born Globals/International New Ventures, he describes those as having foreign sales from the very start or shortly thereafter, whilst Oviatt and McDougall (1994) define Born Globals as "A business organisation that, from inception, seeks to derive significant competitive advantage

from the use of resources and the sale of outputs in multiple countries." (Oviatt & McDougall, 1994). Wennekers & Thurik (1999) use the more generic term of small firms to describe the importance they have on entrepreneurship and economic growth.
The companies that are being examined in this Thesis could possibly have fallen under the scope of these definitions since they all have started the internationalisation process very early on in the process. However, we believe defining them as startups gives a more justified picture of the situation of the firms since it hasn't been the strategy from day one to internationalise, but has instead been a process that has happened whilst the company has matured in their home country market. As a result of these reflections, we believe that the term AI-HC startups provide us with a terminology that is theoretically justified and is also within the scope of this project.

However, navigating the business environment as a startup can be very challenging. Studies show that 60% of startups are not surviving the first five years of operation, while 75% of venture capital-funded startups are failing (Nobel, 2011). In their efforts to understand the high degree of startups that are failing and the challenges that startups face, Giardino et al. (2015) found that the major challenges for startups developing software were within acquiring the first paying customers and thriving in technological uncertainty. Besides the challenges of acquiring the first paying customers and the technological uncertainty, there can be a structural lack of tangible and intangible resources within startups due to their smallness – these resources could, for example, be a lack of financial or human resources (Wymer & Regan, 2005), which can have an impact on the growth of a startup.

3.2.2 The role of startups in the development of industries

The aim of this section is to demonstrate the role startups play in industries and how they might lead to the development of the industry. In the previous section, we discussed how there are other typologies of firms that have similar characteristics to startups. However, when discussing the role startups have in the development of industries, we will widen the scope to include some of these types of firms that have similar characteristics. The aim is to gain an understanding of how startups are shaping industries – we will include the perspective of Wennekers & Thurik (1999), where they examine the role small firms and entrepreneurship have on economic growth.

Schumpeter (1934) argued that new firms were the driving force of change, as well as an engine for economic development. Although Schumpeter argued this almost 90 years ago, this

argument is still valid. In today's modern open economies, the driving force of entrepreneurship is more important for continuous economic growth than ever. This is primarily a result of the rise of Information and Communications Technology (ICT), as well as globalisation. These two factors are pushing for structural change since they require a reallocation of resources, which leads to an increased demand for entrepreneurship (Wennekers & Thurik, 1999). At the same time, as it is evident that small and entrepreneurial firms play a major role in economic development, we have seen an increase in the number of small companies since the 1970s. When examining the 500 largest American firms, the so-called Fortune 500, we see a large drop in employment, which indicates that economic activity has moved away from large firms to small firms. From 1970 to 1996, the employment share dropped from 20% to 8,5% (Carlsson, 1992; 1999). According to EIM (1997), the same tendency has been seen in Europe since small business employment growth in Europe exceeded that of large companies in the period from 1988 to 1998. Digging deeper into why this tendency occurs, Brock and Evans (1989) identify four reasons for why they see this shift has occurred: (1) an increase in labour supply that is leading to lower real wages and coinciding with an increased level of education, (2) a relaxation of entry regulations, (3) a change in consumer taste, and (4) a result of creative destruction.
When discussing this shift from larger firms to smaller firms, Acs (1992) argued that the importance of small firms had increased. He identified four consequences of the increased importance of the small firms: (1) entrepreneurship, (2) routes of innovation, (2) industry dynamics, and (4) job generation. He further argues that the role small firms play in the economy is important since they serve as agents of change through their entrepreneurial activity, thus being a constant source of innovative activity, stimulating and leading industry evolution and creating new jobs. When it comes to the development of new innovative solutions within industries, startups are seen as an important source of development of industries. They are a source of innovation that is developing and using emerging technologies to invent new products or to reinvent existing products with new technologies (Chakraborty et al., 2021).

Within the healthcare industry, we see the same pattern. Startups are currently dramatically changing the healthcare industry by offering solutions that change the way that diagnoses and treatments are being prevented and treated. This is being done by innovative technologies, such as AI (Garbuio & Lin, 2019).
Garbuio & Lin (2019) further argue that although a large amount of work is being conducted by traditional technology providers, they believe that the real power of AI is in opening up opportunities for startups to work on solving specific problems with verticals and applications.

Also, startups that are well-positioned in the market will be in an optimal position to innovate new opportunities in the healthcare market, as well as be well-positioned to work with traditional companies that are lagging behind in the digital transformation. However, operating as a healthcare startup appears to be a business environment that is quite complex and comes with great risk since the percentage of failure is very high - 98% of digital healthcare startups are failing (Chase, 2016)

3.3 Internationalisation of AI-HC startups

The aim of this section is to introduce the dimension of the internationalisation of firms. Today, there are numerous factors a company needs to consider when entering a new market, such as knowledge, strategy, risk, market, and industry conditions. Numerous articles written by International Business (IB) scholars have aimed to research and investigate the various conditions and how they impact the companies when entering new markets as well as what they need to consider when internationalising, e.g. Johanson & Vahlne (1977); Porter (1979); Peng et al. (2008).

Firstly, we will address the institutional impact on the internationalisation of firms. Secondly, we will address the internationalisation of startups, whilst thirdly, we will directly address the specific context of this paper, namely the internationalisation of highly digitised startups within the healthcare sector.

3.3.1 Institutional impact on internationalisation

A market condition which is increasingly seen as critical for economic growth and development is the institutional context of the markets the companies are operating within, i.e. domestic country context and foreign country context (Glückler, 2020).

The institutional context and institutional factors located in the different markets inevitably have an impact on the companies' strategy and how they should "behave" in the markets to gain legitimacy and, ultimately, a successful foothold or position in the market. However, institutional factors are not all homogeneous throughout the landscape and industries, which means no universal approach can be made for all companies and industries. Yet, some scholars argue that the institutions have a homogeneity effect on the entering companies as they must play by certain regulative norms and rules, which can be interpreted as similar and have a homogeneous effect on the companies who wants to gain legitimacy. An example of such institutions could be the European Union which, as a regulative institution, determines and

regulates certain outlines which a company must comply with to enter and gain a position in the market (Feng & Genna, 2003).

There is already conducted an extensive amount of research on institutional context and factors from IB scholars on existing markets, the established institutions within the markets, and how these different elements play a role in the companies' strategic choices and the innovation of the company, e.g. Lee et al. (2014), King et al. (1994).

3.3.2 Internationalisation of startups

The aim of this section is to review literature that is relevant to describe the internationalisation process of startups. Firstly, we will introduce traditional internationalisation literature, whilst secondly, we will adapt to describing internationalisation within the dimension of startups.

As we have previously described, the traditional way of looking toward the pace of internationalisation has to a large extent, been described by Johanson & Vahlne. In 1977 they argued that the internationalisation process of a firm is based on a firm's ability to learn, and they developed a model – the Uppsala model - explaining the steps towards foreign expansion in sequential steps. However, in recent years, there has been an increased pattern of companies entering foreign markets very early in their company life cycles. This is quite a contradiction to the original work of Johanson & Vahlne (1977).

Hennart (2014) argues that the increased pace of internationalisation has affected the global market drastically and will also continue to do so. He attributed this increase in pace primarily to technological development which has made the world more interconnected.

On the opposite side of the incremental or gradual internationalisation process, such as the Uppsala Model by Johanson and Vahlne, Michael Rennie (1993) first coined the term "Born Globals". Born Globals are defined by Knight & Cavusgil (2004) as "entrepreneurial start-ups that, from or near their founding, seek to derive a substantial proportion of their revenue from the sale of products in international markets." and is a term used interchangeably in IB literature with International New Ventures by Oviatt & McDougall (1994) – however, 'international' in IB literature and field of research is more commonly associated with accessing one or more foreign markets, whereas 'global' is considered involvement in many markets (Coviello et al., 2011).

3.3.3 Internationalisation of digitisation startups within the healthcare sector

Now we have outlined the internationalisation process of startups and the institutional impact on these. This section will dig deeper into the internationalisation of digitised startups and connect it to the AI-HC aspect of our paper.

The AI-HC startups in this paper are highly digitised which can also impact how and when the companies decide to internationalise. As we have mentioned, there have been great technological advances in the world which have made it easier, especially for digital companies, to internationalise earlier and faster. In 2015, the healthcare industry in the USA ranked in the lowest thirds of industries and their digital maturity, which could indicate an open scene for outside companies such as AI-HC startups from, e.g. Denmark in this case, to come and fill the gap and by that giving the incentive to internationalise fast (Edelmann, 2019). Another factor within healthcare internationalising startups is the continuously mentioned lack of AI advancements in the healthcare sector of the U.S. and the many positive aspects it could bring to the industry if the industry is ready to start integrating the new technology (Goldfarb & Teodoridis, 2022; Davenport & Kalakota, 2019).

With the economy of the world becoming more and more digital, the speed and cost of internationalising a digital startup have greatly improved. Banalieva & Dhanaraj (2019) propose an internationalisation theory based on the digital economy in the world today. They mention the advantages of a digital company in a digital world of internationalisation vs the companies that might need human capital in a foreign country to be operative. The digitised company will have a less restrictive approach to internationalising as their product and knowledge will be easily transferred to the foreign market, whereas a less digitised company would need human assets in the foreign market and train/transfer their knowledge to them. Banalieva & Dhanaraj (2019) further defined the advantage as firm-specific assets for a digital and a traditional physical company – they predict with their research and theory that the digital companies and networks will become the dominant organisational mode in IB.

This section has argued that digitised startups have easier access to knowledge and internationalisation earlier on as well as the healthcare industry in the U.S. has good incentives to internationalise rapidly and gain as large a market share as possible.

3.4 The National Business System Theory

The main theoretical framework that is being used for this paper is the Business System Theory (BST). The aim of this section is to give a review of this theory. Since the BST has its roots in institutional theory and also refers to organisation theory, we will firstly review the importance of understanding the institutional context when entering a foreign market and provide a short explanation of organisation theory to provide a fundamental understanding of these. Secondly, we will give a thorough introduction to the BST perspective.

Organisation theory conducts the relationship between organisations and their environment, how these relationships affect the participants in organisational functioning, and how organisations affect the distribution of privilege in society. A central concept is organisational design or also called organisational form. Organisational design or form is important because "the ability of societies to respond to various problems depends on the availability of organisations with different capabilities." (Greenwood et al., 2021).

Institutional theory refers to firms' adoption of specific business behaviour to better fit in a new market and achieves access to resources as well as support from stakeholders (DiMaggio & Powell, 1983; Oliver, 1991; Scott, 1995). There is no universally agreed definition of the term Institutions; thus, several researchers tried to introduce their own definition. Jepperson (1991) defines Institutions as "socially constructed, routine-reproduced, program or rule systems", while Scott (1995) describes them as "[...] social structures that have attained a high degree of resilience. [They] are composed of cultural-cognitive, normative, and regulative elements that, together with associated activities and resources, provide stability and meaning to social life. [...] Institutions connote stability but are subject to change processes, both incremental and discontinuous." Scott (1995) proposes three pillars that shape human behaviour in society: regulative pillar, normative pillar, and cognitive pillar. On another note, Whitley (1992) introduces another perspective on institutions. He splits institutions into two categories: background institutions and proximate institutions. Background institutions are of a more informal and cultural cognitive dimension. They are shaped by historical, cultural, and behavioural rules. On the other hand, proximate institutions are being driven by more formal initiatives.

Business System Theory

This paper will apply the Business System Theory (BST) to answer the research question.

BST draws on the convergence of sociology, organisation theory and political economy. In the context of IB, it refers to organisation theory and institutionalism to conduct how the interactions of humans, firms, and certain institutional characteristics, usually in a national context, shape firm strategies, competencies, human capabilities, and rationales. Additionally, BST aims to show how these interactions influence a particular business system in society and how firms can act as institutional entrepreneurs by shaping the institutional characteristics of a certain context (Rana & Morgan, 2015). It primarily focuses on the effect that national-level institutions have on firms since "it is at this level that institutions tend to be strongest" (Rana & Allen, 2018).

In most of the literature, BST is applied in the context of MNCs, but we will change the context and adapt it to startups internationalising to foreign markets since we believe the BST can be applied to startups and will give us valuable insights for answering our research question.

Rana & Morgan (2015) describe that BST provides a framework that can be applied across different contexts. It conceptualises ways in which institutions shape firms' strategies and structures and key aspects of institutions. There are several characteristics that can shape the business system and thus, influence firms' strategies and institutional context: ownership and governance, network relationships, and internal management dynamics. Since BST uses a broader definition of the term institutions, it can provide a framework that shows how the societal context shapes business system characteristics and, in turn, how it influences firms and firm behaviour. This is perceived as the key distinguishing characteristic of the BST (Jackson & Deeg, 2008).
Whitley (1992) defines typologies of national business systems to provide a better understanding of the characteristics of business systems and how unique features and differences in the institutional context develop different types of business systems in different countries.

Rana & Morgan (2015) define four core dimensions the BST presents:

- Companies' strategies, structures, entrepreneurial dynamics and venture creation processes are being shaped by the institutional environment (e.g. regulations)
- Companies can shape institutions through their strategies, power, and actions
- Companies are embedded in institutional systems that are connected to different levels, and the most important ones are global, national, regional, provincial, and sectoral level

- Through continuous interaction between companies and institutions, companies develop strategies to respond to the institutional environment and reorganise internal processes to overcome challenges they are facing through the institutional environment

A business system includes three main components:

- Nature of companies (nature of ownership & governance)
- Market Organisation (Networks/relationships with other firms and organisations)
- Authoritative Coordination & Control within a company (Internal management dynamics) (Rana & Morgan, 2015; Rana & Allen, 2018).

These three components are heavily influenced by institutions. The BST does not approach the definition of Institution by Scott (1995). The literature on business systems categorises institutions into two categories.

- Background institutions (informal, cultural-cognitive)
- Proximate institutions (formal) (Whitley, 1992)

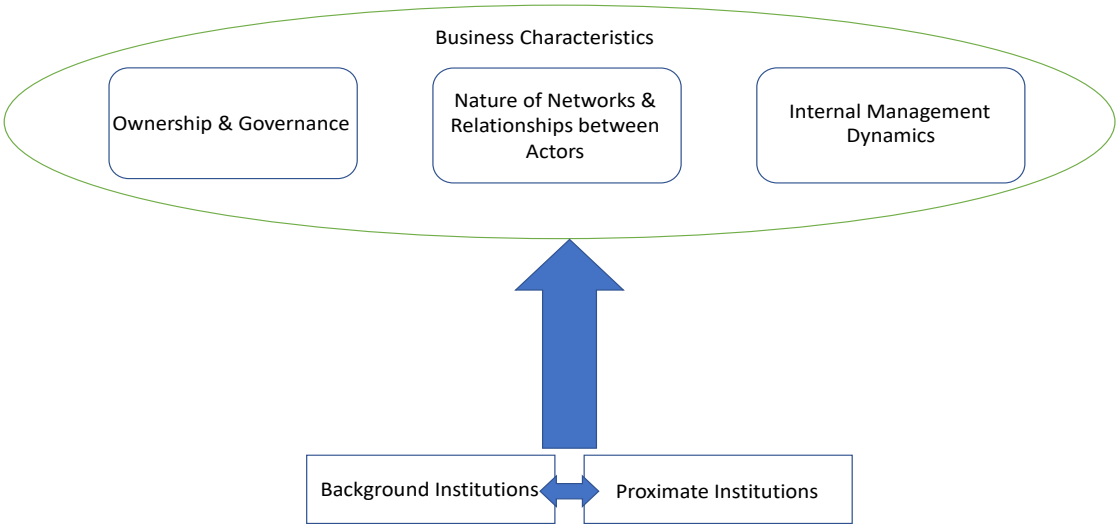


Figure 4: Business System Theory Framework including influencing institutions (developed by authors based on Whitley, 1992; Rana, 2014)

Background institutions are mostly shaped by culture and historical behavioural rules, while proximate institutions are driven by formal initiatives and background institutions (Whitley, 1992). Most of the time, changes in one of the two categories affect the other category as well in the process of complementarity. The complementarity mechanism is caused by the interactions between involved actors (Rana & Allen, 2018).

The benefit of using BST for analysing several topics in management studies is that it provides a framework that makes it possible to conduct comparative research across countries (Witt & Jackson, 2016), Denmark and the USA in our case. In addition, it takes the endogenous and exogenous factors of the organisation into account and uses a broad and deep perspective by seeing phenomena, processes, and change as constituting and constituent elements of institutional systems (Rana & Allen, 2018). Thus, we identified BST as a suitable framework to conduct the research question in this paper.

3.5 Entry mode to foreign markets

When a firm is pursuing new markets, one of the first questions sought to answer is what kind of market entry mode the firm is pursuing. This decision is widely seen as one of the most crucial strategic decisions a firm must take when entering new markets (Musteen et al., 2009). Root (1987) defines a firm's foreign market entry mode as "an institutional arrangement that makes possible the entry of a company's products, technology, human skills, management, or other resources into a foreign country. Cateora & Graham (2002) further emphasised the need for firms to specify their entry strategy and mode of market entry when considering entering new markets.

When discussing what kind of entry mode to pursue, International Business theory describes multiple entry modes. Each of which has consequences on the degree of risk a company is seeking, the degree of control they will have over the subsidiary or if they want to give away control, as well as the degree of commitment the company is willing to make.

Entry modes of internationalisation can be broadly categorised into two groups: (1) equity modes of internationalisation and (2) non-equity modes of internationalisation. On the equity side of the spectre, you will find Joint Venture and Wholly Owned Subsidiaries. On the non-equity mode spectre, you will find exports and contractual agreements. Within each of these modes, there are many aspects that can vary, and thus you could say that the opportunities for customised entry modes are endless (Sharma & Erramilli, 2004).
Whether a firm is pursuing an equity or non-equity mode of entry, there are advantages and disadvantages connected with every choice. Below we will go through some of these to understand the reasons behind the choice of entry mode.

3.5.1 Non-equity modes

Advantages: One of the key advantages of conducting a non-equity market entry is that it allows a firm to enter a foreign market with minimal investment. Decreasing the need for investment also decreases the overall risk for a firm. Also, non-equity modes may increase the time-to-market period, thus allowing firms to enter the market faster than an equity entry-form.

Disadvantages: One of the biggest hurdles when entering a new market through a non-equity mode is that the firm is being seen as an outsider, and thus the road to earning legitimacy in the market can be challenging. Also, if the firm does not have a physical presence in the market, customers could be sceptical towards the firm since it's not showing commitment to investing time, money, and efforts into the market. Furthermore, the fact that you only have a physical presence in another country might face exporters with challenges regarding high export taxes, as well as licensees will be faced with a lack of control over products and limitations that are within the scope of the licensing agreement (Erramilli et al., 2002; Nakos & Brouthers, 2002; Anderson & Gatignon, 1986).

3.5.2 Equity modes

Advantages: By approaching a foreign direct investment into a foreign market without a partner, the firm will typically allow the firm to keep some degree of direct control over its foreign operations. Bringing a local partner onboard – through, for example, a joint venture – it will allow the firm to leverage the knowledge of the local partner about the market and its experiences

Disadvantages: One of the largest disadvantages of pursuing an equity mode approach is that the necessary degree of investment might be quite high, which also increases the degree of risk. Furthermore, besides the need for a high degree of investment, an equity mode approach also raises the need for establishing relationships in the new market, where the knowledge might be lacking.

Going together with a local partner and establishing a joint venture will also make the firm give up a degree of control over the operations while establishing a subsidiary does not necessarily lead to a loss of control over the operations, depending on how it will be organised (Erramilli & Rao, 1993; Nakos & Brouthers, 2002; Agarwal & Ramaswami, 1992).

4 Empirical Evidence

This chapter will firstly describe the institutional characteristics of the Danish and the U.S. business systems, whilst secondly demonstrate how these institutional characteristics have shaped the business system characteristics of the case companies. Whitley (1992a, 1992b, 1999) proposed the approach of comparative business systems to be able to explain differences in organising economic activities that are developed because of institutional features in society. Rana & Morgan (2019) argue that MNCs develop their strategies by building on their home institutional context. In this chapter, we will therefore present institutional characteristics in Denmark and in the U.S. that we assess are having a dominant impact on AI-HC startups.

In order to be able to understand how the institutional characteristics of the U.S. market are potentially shaping the case companies' business system characteristics, it is important to show differences in the two markets. The institutional characteristics that we have identified for this paper can be divided into proximate and background institutional characteristics. The proximate institutions are the following: Regulations, Construction of the healthcare sector, and Institutions supporting AI development. In terms of the background institutions, we identified the attitude toward AI-driven healthcare products – divided into buyers, political and public attitudes – as being the most relevant ones to highlight. The identification of those factors originates from our preliminary research on the topic of the context of this paper, where we identified these characteristics as being some of the most crucial challenges for AI-HC startups to address when internationalising. Furthermore, our discussions with Christina Brinch Clark confirmed the validity of these challenges. Deloitte (2020) also identified four challenges that are very close to those we identified, namely: Data challenges, Legal and Regulatory challenges, Organisational and financial challenges, as well as social challenges.

Firstly, we will address the Danish institutional characteristics. As previously explained, we believe it is important to understand the home-institutional context of firms to be able to assess how foreign institutions shape-shifts in the firms' economic activities. Secondly, we will directly address the host-country institutional characteristics that can potentially shape, or already have shaped, the case companies after entering the U.S. market. Thirdly, we will summarise and compare the institutional characteristics in the two countries, whilst lastly, we will describe how the institutional characteristics of both countries shape the business system characteristics of the two case companies.

This will provide us with the necessary foundation for the comparative case analysis later on, where we will address how the Danish institutional environment has underpinned the internationalisation of the companies whilst also addressing how the firms are adjusting their activities when entering the U.S. market, as a result of the institutional characteristics

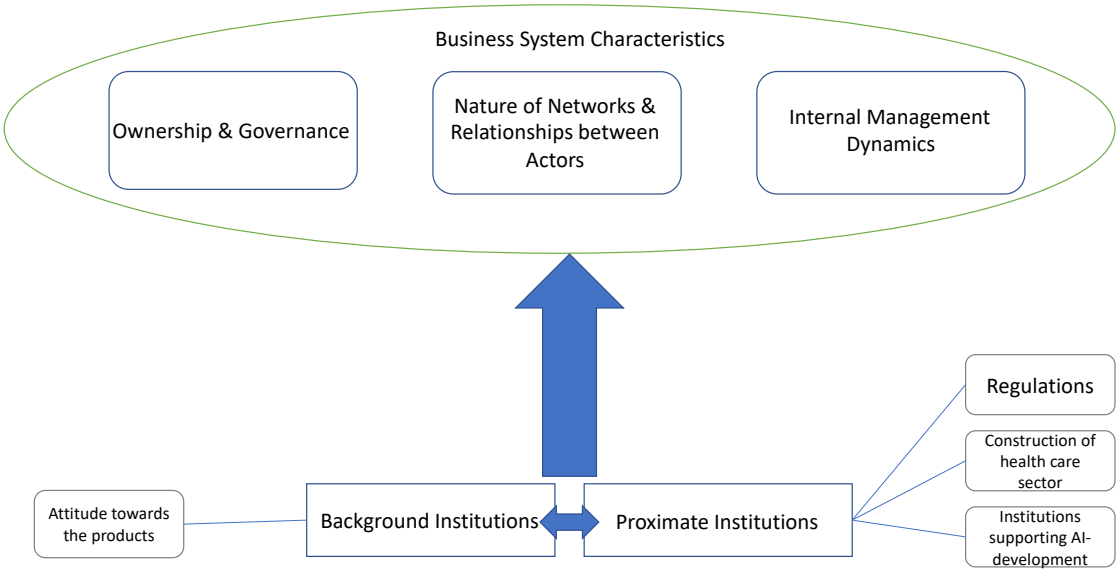


Figure 5: Business System Theory Framework including the institutional characteristics with major impact as we have identified (developed by authors based on Whitley, 1992; Rana, 2014)

4.1 Institutional Characteristics in Denmark

The aim of this section is to lay out and analyse the home institutional context of the Danish startups by describing the previously identified institutional characteristics that have shaped the emergence of the Danish AI-HC business system as well as being relevant to the context of how these characteristics have underpinned the internationalisation of the firms. Firstly, we will go through the proximate institutions, whilst secondly, we will address the background institutions.

4.1.1 Proximate Institutions

In the section on proximate institutions, we will lay out the already identified institutional characteristics that fall under the category of proximate institutions, namely: Regulations, the construction of the healthcare sector in Denmark, and institutions that are supporting AI development.

4.1.1.1 Regulations

When it comes to the regulative overseeing of the Danish market, we have identified the following two institutional characteristics as having a major influence on the market:

a) Approval of Medical Devices

b) Data protection regulations.

a) Approval of Medical Devices

In Denmark, it is the Lægemiddelstyrelsen, Danish Medical Agency (DMA), that oversees the approval and control of medicine and medical devices. In addition to that, DMA is also approving clinical trials, overseeing medicine side effects, deciding which medicines should receive appropriation, and overseeing all medical devices that are available in Denmark. As a part of the Danish Department of Health, DMA is a federal government agency that is also supporting the department's work in preparing new regulations (Lægemiddelstyrelsen, 2021).

However, as a member of the European Union (EU), Denmark's regulation within the area is based on European legislation and tight European cooperation. Member states are cooperating and collecting their competencies with regard to, e.g., approval of new medical devices. Here the member states exchange relevant knowledge and acknowledge other member states' inspections and laboratory controls. When it comes to AI-HC specifically, these technologies are primarily being categorised as medical devices. According to the DMA, medical devices are not being defined by which materials the medical devices are made of; instead, they are being defined by the means and purpose of the products. If the aim of the product is to work in diagnosing, prevention, monitoring, predicting, prognosis, or treatment of an individual, the product is being classified as a medical device (Lægemiddelstyrelsen, 2020).

To market medical devices in Europe, it is necessary to be CE-certified. The road to being CE-certified can vary. EU has put in place risk-classifications, which are based on the risk connected to the medical device, and the possible damage the medical device can cause. If the product is being classified as a low-risk product, the manufacturer can apply for a CE-certification by themselves if they can document that they are complying with necessary regulations.

If the product, on the other hand, is being classified as a high-risk product, it is necessary to cooperate with an authorised body to ensure that the device is living up to requirements related to quality, safety, and performance to receive the CE-certificate (Lægemiddelstyrelsen, 2022).

b) Data protection regulations

As a member of the European Union, Denmark is subject to the GDPR directive that the European Union has imposed on its member nations. The GDPR is a directive being put on all member states which covers all data that is being collected by a data processor or controller within the European Union. The directive further discusses the transfer of data to international organisations and cross-border transfer of data to third countries. According to the directive, consent management is a key aspect since the directive points out the role of the patient and the importance of the patient's consent for data processing. The directive further stresses that it is always the controller's responsibility to be able to demonstrate that the data subject has given consent to the processing operation (Larrucea et al., 2020).

As Phillips (2018) argues, cross border collaboration in developing AI technologies is based on large amounts of data. If barriers are being put in place, which will ultimately lead to resistance to sharing data with other countries, the continued development of research projects will likely be hindered.

4.1.1.2 Construction of the healthcare sector in Denmark

Since the construction of the healthcare sector varies between countries, it is essential to understand it and how it affects the actors within the healthcare sector. Being generally defined as a welfare state, in Denmark, welfare and public services such as healthcare and education are provided to citizens for free in return for a relatively high tax rate (Heckman & Landersø, 2021).

In Denmark, the hospitals are run and operated by the different regions which make up the entire country. There are a total of five regions in Denmark which decide and control the budget and operations of the hospitals within the regions.

As mentioned at the beginning of this section, Denmark is a welfare state where the expenses for healthcare are largely placed with the government and paid through the taxation system. However, there are also private hospitals where patients can pay for their services. Occasionally a public patient will be referred to a private hospital by the public system, and this is then covered through the public healthcare system as well (Sjølie, 2007).

The public hospitals in Denmark are managed by the different regions, and their advisories of 41 individuals. Every year the different regions use approx. DKK 30 bn on maintaining hospitals, buildings, departments, and equipment (Regioner, n.d.). This budget is the baseline for what the regions decide when equipment and healthcare services need to be upgraded.

The regions can purchase new equipment in different ways which presents different opportunities to the AI-HC companies. The potential partnerships or customer relationships between the hospitals and an AI-HC company can happen through a private agreement- if the company is the sole reasonable and most efficient provider of a solution, they can engage in a partnership. The regions also tend to utilise a different approach to gaining new business partners or distributors of medical equipment and tech – they can use a bidding approach where they outline the issue or proposal at hand, and AI-HC companies can bid with a solution and price for the issue or proposal. The bidding approach is also a way for the regions to find the best solution to the price, as they have the potential providers bid against each other, increasing the competition for the proposal. In 2018 the regions increased the proposals in the bidding model by 76 %, indicating a strong increase in this kind of partnership seeking (Regioner, 2018).

4.1.1.3 Institutions supporting AI-development

Looking at specific institutions in Denmark that are working towards supporting the development of AI-HC products, we have primarily identified what appears to be some strong public-private partnerships that help to underpin the development of the sector. Healthcare Denmark (n.d. a) argues that Denmark has a long tradition of strong public-private partnerships, where the public healthcare system and the industry work together to bring innovative medicines and solutions to patients. The aim of pursuing such public-private partnerships is to bring the expertise from the respective sectors together (Healthcare Denmark, n.d. a).

CAI-X: Denmark is continuously putting efforts in place to enhance the development of new AI-HC solutions. In December 2021, Odense University Hospital (OUH), together with the University of Southern Denmark (SDU), announced the establishment of a new Danish research centre named CAI-X. The centre will be a collaborative venue where doctors, engineers and companies will join forces in efforts to develop new smart AI solutions.
According to Bjarne Dahler-Eriksen, medical director at OUH, the ambition is that the centre shall be at the forefront of AI in the Danish healthcare system and ultimately become one of the world's leading in clinical AI. As of November 2021, 20 projects were ready to be carried out in the new centre (Syddansk Universitet, 2021).

Copenhagen Healthtech Cluster: Copenhagen Healthtech Cluster (CHC) is working towards connecting Danish regions, municipalities, and companies in order to bring them together to

develop and implement digital healthcare solutions. According to CHC, the necessary development within the healthcare sector will not happen by itself, and thus they believe it is important to work as a bridge keeper between the public and private sectors with regard to research, development, and innovation. Also, CHC wants to focus on the need for joint investments across municipalities since investments in digital technologies can be quite costly.

One of CHC's key initiatives is the partnership "Data Saves Lives", which is a partnership of public and private partners who work towards better use of Danish health data. The aim is to improve access to and usage of Danish health data for the benefit of citizens, patients, and communities. At the same time, the focus is also on enhancing and maintaining a high level of security around all data (Copenhagen Healthtech Cluster, 2018).

National Strategies: Danish Government has launched strategies with the aim of sustaining and developing the life science industry, as well as the AI industry specifically. Below, we will address these two initiatives.

The Danish government launched in 2019 a *National Strategy for the Development of AI in Denmark.* The vision behind the strategy is, "Denmark shall take the lead when it comes to responsible development and usage of AI". The goal is that Denmark should not simply imitate countries such as the U.S. and China in this development, but instead, the country should find its own path in which ethics and personal privacy are prioritised along with working on challenges that can be solved by the usage of AI. The strategy also has a strong focus on the responsible usage of AI in business models, and the Government is viewing this as a potential competition parameter both nationally as well as internationally. The government is also aiming to increase the access to data, the access to employees with digital competencies, as well as increase the research on the area of AI (Digitaliseringsstyrelsen, 2019).

In the *Danish Life Science Strategy* from 2021, the Danish Government is proposing a proactive approach toward diminishing entry barriers to markets with potential for Danish companies. The strategy suggests that this can be done through promoting regulatory cooperation, increasing the knowledge of practical and innovative Danish solutions, and working determined towards ensuring proper terms for the exports of Danish products, services, and solutions (Ministry of Industry, 2021).

Danish Trade Council: As a part of the Danish Foreign Ministry, Denmark has established a quite far-reaching network of Trade Council offices. The offices are located around the world,

typically at the Embassies of Denmark in the respective countries. The tasks that The Trade Council conducts for companies vary, from conducting initial research, to more concrete tasks, such as opening the doors to stakeholders in the foreign market. One of the major benefits of working together with The Trade Council is that since it is a governmental institution, coming from a country with quite a high reputation, being represented by this governmental institution can benefit by increasing its legitimacy.

4.1.2 Background Institutions

This section seeks to describe the background institutions which play a role in the Danish AI-HC startups. The background institutions described are public attitude, buyer's attitude, and political attitude.

4.1.2.1 Public attitude

Denmark is generally being seen as a highly digitalised country – in fact, in November 2021, Denmark was ranked an altogether 1st place on the Digital Society and Economy Index when it comes to being Europe's most digitalised country. The ranking is based on several parameters, out of which Denmark ranked 1st on connectivity, 2nd on digitalisation of the business environment and public sector, as well as a 4th place when it comes to digital skills. The EU commission highlighted that Denmark had launched several successful initiatives regarding the digital transition, thus indicating digitalisation-ready legislation (European Commission, 2021).

According to a study conducted by Microsoft Denmark and LEAD Agency, it appears that there is a generally positive attitude toward the implementation of AI technologies in Danish society. However, some experts worry that if not the public discussion of AI is being improved, the public discourse might change into a more sceptical attitude towards AI (LEAD Agency & Microsoft Denmark, 2018).

The study shows that 87% of the Danish population assess that AI can be expected to have a positive or very positive impact on the Danish society. At the same time, 78% believe that AI today is not being prioritised highly enough on the political agenda and thus assess that there is more potential in the technology than what is being exploited at this time. 85% of the respondents say that they do not think that political decision-makers have enough knowledge about potentials and challenges related to AI (LEAD Agency & Microsoft Denmark, 2018).

Despite the fact that these numbers indicate that the public attitude towards AI is positive, there are concerns that this attitude might change if the public discourse is not being elevated. In the report conducted by LEAD Agency & Microsoft Denmark (2018), Jan Damsgaard, professor and leader of the Department of Digitalisation at Copenhagen Business School, points out that his biggest concern with regard to the implementation of artificial intelligence into the Danish society is the public opinion on the matter. He is worried that if not AI is being addressed in the right way in the public eye, the public opinion discourse probably will be that AI will lead to increased monitoring of citizens, replace people's jobs, etc.

4.1.2.2 Buyers' attitude

In Denmark, it is primarily the Danish Regions and the respective hospitals that have the role of Buyers of AI-HC technologies. Although the members of the Danish Regions are elected, we will not define this as a political attitude towards AI-HC technologies but instead as the attitude of buyers. In section 4.1.2.3, we will assess the political attitude towards AI-HC technologies, which will be the attitude of politicians at a federal level.

The fact that the Danish healthcare sector is primarily public and being administered by the Regions opens up for public-private partnerships that appear to be very valuable for the emergence of the Danish AI-HC industry. Danish hospitals appear to have a quite open attitude towards early clinical testing of new technical medical solutions that can benefit the Danish society as a whole – this applies to AI-HC solutions as well. Examples of this are the hospitals in Bispebjerg and Frederiksberg, which are testing new evolving technologies from a Danish company called Human Bytes, which is working with using AI technologies for diagnostics (Medwatch, 2020).

Anders Kühnau, chairman of the Danish Regions, acknowledges the potential of using AI in the healthcare sector and sees the implementation of digitalisation and AI to support the work of the hospitals as essential for optimising the services that are being delivered (MedWatch, 2022).

However, for AI to really be adopted in the Danish healthcare systems, there needs to be uniformity among the decision-makers in the management of the hospitals, and this is where Denmark is lacking the speed of a privatised healthcare sector. The data and the digitalisation is ready, yet the will to get the AI implemented is lesser than that of the countries Denmark compares itself to within healthcare, e.g. USA, China, Singapore, Israel, etc. (EIT Health, 2020)

4.1.2.3 Political attitude

The national strategy for AI proves there is a strong political attitude towards AI adoption in the market. However, a study by McKinsey and The Innovation Fund Denmark from 2019 suggests Denmark is not yet ready to adopt the AI technology in the same grasp as other more AI advanced markets such as the U.S., thus putting Denmark in 8th place when it comes to readiness in the adoption of AI technology. The political attitude could be to improve this position with their aforementioned national strategy and ambitions for Danish AI. However the political attitude in the strategy suggests it is more in light of ensuring the public of a certain level of uniformity when it comes to ethicality and safety, as well as opening public centres and agreements with universities (Lindberg et al., 2019).

The Danish Digitalisation Agency is working towards giving Municipalities and Regions more experience with AI-driven solutions and has allocated 142,8 mio. from 2022 to 2025 in a new pool for specific projects to be tried out. Several of these projects are within the healthcare sector, where projects will be tried out at hospitals around Denmark. One project is using AI algorithms to improve the diagnosing of pregnant women, where the aim is to work towards decreasing the degree of premature births. The project will be implemented in Region Nord, Region Syd, Region Sjælland and Region Hovedstaden and will be organised by DTU Compute. Another project is concerning using AI for treatment support for eye patients, where the aim is to strengthen the treatment of age-related macular degeneration, which is a chronicle eye disease, and the most frequent reason for blindness in Denmark (Digitaliseringsstyrelsen, 2022).

4.2 Institutional Characteristics in the U.S.

This section aims to lay out the institutional environment of the AI-HC market in the U.S. We will follow the same structure as we did in Chapter 4.1 by dividing it into proximate and background institutions.

4.2.1 Proximate Institutions

In the section on proximate institutions, we will lay out the already identified institutional characteristics that fall under the category of proximate institutions, namely: regulations, the construction of the healthcare sector in the U.S, and institutions that are supporting AI development.

4.2.1.1 Regulations

In terms of the regulative overseeing of the U.S. market, we have identified the following institutional characteristics as having a major influence on the market:

a) Approval of Medical Devices
   - Approval of Software
   - Approval of AI-enabled software

b) Data protection regulations

a) Approval of Medical Devices

This section will first give an overview of the U.S. Food and Drug Administration (FDA) in general and its approval process for medical devices to provide an understanding of the approval process for AI-based software, as this is based on the same process. Following, specifications for software in the field of healthcare will be introduced and narrowed down to specifics that come along with AI-based software that is used in this field.

The FDA is responsible for ensuring the safety and effectiveness of new medical treatments but also for ensuring that these treatments reach the public as fast as possible to help patients and physicians. Over the last years, the approval process got more complex and stricter due to the increasing complexity of drugs and medical devices as well as the enormous growth of the pharmaceutical industry. Nowadays, the US has one of the strictest regulations regarding the medical device and drug development (Van Norman, 2016).

The process for FDA approval is usually costly and lengthy due to the regulations and the importance of only approving safe products. There are two different stages in the approval process: *FDA compliant* and *FDA approved*.

FDA compliance refers to meeting the product safety regulations defined by the FDA. It is essential to have a FDA compliant product in order to get the product to the market.
All FDA approved products are FDA compliant, but not all FDA compliant products are FDA approved (Krüger, 2020).

The process for FDA approval is different depending on the type of product that needs to be approved. The process consists, in general, of five steps that the company should know when

approval is needed for its product. Every step has a different time duration and is difficult to calculate beforehand.

1. Device classification: The FDA divides medical devices into three classes: class I, class II and class III. This classification is "based on the level of control necessary to assure the safety and effectiveness of the device" (U.S. Food and Drug Administration, 2020a). Thus, the classification of the device is risk-based as well as categorised by the intended use of the device. It can be difficult to categorise devices, especially if a subset of intended use arises. Usually, the intended use gets clear when looking at the device's labelling or when presenting the device. The classes relate to different requirements that need to be complied with (U.S. Food and Drug Administration, 2020a).

Class I only has a level of general controls since it includes medical devices with the lowest risk; class II has a level of general controls as well as special controls such as the 510(k) Premarket Notification that refers to the substantial equivalence to a device which is already present on the market to prove safety and effectiveness of the device; class III includes devices that can have an unreasonable risk of harm, but can have a huge positive impact on human life and health. Additionally, to the general and special controls of class II, it needs premarket approval, including clinical trials, due to the high level of risk.
When there is no comparable device in the market, an investigational device exemption (IDE) will be used to collect data about safety and effectiveness during clinical studies. The IDE usually supports the premarket approval to provide the FDA with data for their decision. General controls refer to all three classes and are the baseline requirements of the Federal Food, Drug and Cosmetic Act (FFDCA), which was first introduced in 1938 (U.S. Food and Drug Administration, 2020a; senetics healthcare group, 2022).

2. Prototype development: The company needs to build a prototype of the medical device they want to sell in the U.S. market or an early version of it for preclinical testing. The prototype is not for human use at this stage, and it is only used in controlled laboratory settings. This step is necessary in order to provide researchers with important data about the device and the lack it may still have. The process of creating a prototype attempts to reduce risk and increase the effectiveness of the device (U.S. Food and Drug Administration, 2020a).

3. Submission of the application for class II and class III devices: As part of the pre-market approval (PMA) or the 510(k) application, it is necessary to get an FDA verification and validation for the device. The FDA verification is necessary to ensure the fulfilment of all requirements made by the FDA, and it is about designing the device in the right way. The FDA validation ensures the fulfilment of the needs of the market and makes sure that the company is designing the right device for the market and customer needs (Krüger, 2020).

4. Waiting for FDA Review and Approval: The FDA review team will review the medical device and either approve or disapprove it in the time duration between one week up to eight months since the review process depends on the device class and a range of several other factors. The more complicated and risk associated with the device is, the longer the review process takes (Hetrick, 2021).

5. Maintain FDA Compliance: Getting FDA approval is an important step for selling the medical device in the US market, but it is still necessary to take FDA compliance into account to maintain the FDA approval. The FDA must ensure that medical devices available in the U.S. market meet the regulations regarding effectiveness and safety throughout their total product life cycle. Therefore, the FDA has established Quality System Regulations in order to ensure the right device design and validation as well as manufacturing practices that have proven to be effective (U.S. Food and Drug Administration, 2020b)

Approval of Software

This section will first describe how the process of FDA review changes when the medical device is or includes software. Due to the rapidly increasing possibilities, new technologies are bringing software to become an important part of the healthcare sector too. These products provided new opportunities in healthcare, for instance, when monitoring patients.

New types of products need to be regulated, and thus the FDA created a new approval process for software products related to medical devices.

There are three categories:

1. Software as a Medical Device: software that is a medical device on its own
2. Software related to Medical Devices: software that is embedded in a medical device
3. Software used in the manufacture or maintenance of a medical device: software that does not have a direct impact on the medical device and its functions (U.S. Food and Drug Administration, 2018)

The International Medical Device Regulators Forum (IMDRF) defines the term Software as Medical Device as "software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device" (International Medical Device Regulators Forum, 2013).

Since the use of Software as a Medical Device is possible in a broad range of technology platforms, the use of these products is increasing continuously. Previously, this type of software was called health software, medical device software, or also standalone software before the term Software as a Medical Device was introduced (U.S. Food and Drug Administration, 2018)

Approval of AI-enabled software

Even though the FDA categorised different types of software that are related to medical devices, AI-enabled products brought up new challenges regarding the review process. Many of these products modify more often compared to other products due to the ability to self-learning from real-world use and experience and, additionally, the ability to improve their performance (U.S. Food and Drug Administration, 2019a).

AI experienced a rapid increase in use and integration in a wide range of applications since it "offers substantial promise in addressing a number of critical issues – among others, expenditure growth, inefficient resource allocation, wait time, physician burnout, and missed diagnoses" (Harvey & Gowda, 2020). The former FDA Commissioner Scott Gottlieb acknowledged the potential of AI to transform healthcare but underlined the need for a regulative framework for it (U.S. Food and Drug Administration, 2019b). Since there was no separate review process for these products at this time, the FDA realised the need for a framework that regulates the FDA process for AI-enabled medical products.

In 2019, the FDA released the first proposal for a regulatory framework for modifications to AI-based software as a medical device. This framework recognises the uniqueness of AI-based software as a medical device and attempts to create an appropriate tailored regulatory oversight to ensure the safety and effectiveness of these products.

First, manufacturers need to submit a marketing application to the FDA, including the submission type and data requirements that are based on the level of risk of the device, before starting to distribute the medical device. This will be either the 510(k) notification, the De Novo request, or a premarket application. The Center for Devices and Radiological Health of the FDA has published a guide for changes in design, specifically in software, after it has been reviewed under a 510(k) notification. This guide should aid in deciding when a premarket submission is

required and when it is not. This guide applies to products that change their functions due to an improved algorithm, for instance.

Since the intended use of AI-enabled software varies, the IMDRF designed a framework that categorises the software in one of four risk classes depending on the intended use. Table 3 shows the four risk classes and the categories that are being used to identify the risk class.

State of healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

Table 3: Risk categorisation of AI-enabled Software as a Medical Device (U.S. Food and Drug Administration, 2019a)

Due to many possible modifications of AI-enabled software as a Medical Device, the FDA introduced a total product lifecycle regulatory approach. This approach aims to maintain the assurance of effectiveness and safety throughout the lifecycle of the product. The approach only applies to AI-based software as a Medical Device that requires a premarket submission.
It is based on four general principles:

1. Establish clear expectations on quality systems and good machine learning (ML) practices
2. Conduct a premarket review for that Software as a Medical Device that requires premarket submission to demonstrate reasonable assurance of safety and effectiveness and establish clear expectations for manufacturers of AI-based Software as a Medical Device to continually manage patient risks throughout the lifecycle
3. Expect manufacturers to monitor the AI device and incorporate a risk management approach and other necessary approaches in the validation, development, and execution of algorithm changes (Pre-Specifications and Algorithm Change Protocol)
4. Enable increased transparency to the FDA and users by using post-market real-world performance reporting in order to maintain assurance of effectiveness and safety (U.S. Food and Drug Administration, 2019a).

In 2021, the FDA released the Artificial Intelligence/Machine Learning Action Plan which included the feedback for the first proposal the FDA made in 2019 that was described before. It is a further development of the regulations regarding AI/ML-based software and shows that

these regulations are dynamically changing and adjusting. Some of the goals of the FDA for the further development of these AI/ML products are to support "the development of good machine learning practices to evaluate and improve machine learning algorithms" (U.S. Food and Drug Administration, 2021), to have a patient-centred approach that should create transparency to the users; develop "methods to evaluate and improve machine learning algorithms" (U.S. Food and Drug Administration, 2021) and to advance pilots that should monitor real-world performance (U.S. Food and Drug Administration, 2021).

The FDA recognises that the field of AI/ML software in the sector of healthcare is still evolving and regulations, standards, and best practices need to be adjusted to the evolvement. The FDA recommends stakeholders in this sector use ten principles in order to develop new practices and stick to current regulations:

1. Use of multidisciplinary expertise for the total product life cycle
2. Security practices and good software engineering should be implemented in the model design
3. Data sets and participants represent the intended patient population
4. Independency of training data sets and test sets
5. Reference data sets should be based upon the best available methods
6. Model design should be tailored to the available data and should reflect the intended use of the device
7. Performance of the human-AI team is prioritised
8. Tests should demonstrate the device's performance during clinically relevant conditions
9. Transparent information for the users
10. Retraining risks of deployed models are managed, and the models are monitored for performance. (Jercich, 2021)

The changes and adaptions regarding AI-enabled Software as a Medical Device the FDA made over the years show that the topic is still evolving, and the process of creating an updated version of the framework is still ongoing. Additionally, it shows the complexity of the topic and the challenges it brings along to finding suitable regulations.

b) Data protection regulations

In the U.S., there has been a legislative focus on AI for quite some years. During the Barack Obama presidency (2009-2017), the U.S. government's reports on AI emphasised the

application of AI in aspects such as fairness, safety, and governance. During the Donald J. Trump presidency (2017-2021), there appeared to be a shift in focus since it appeared as the focus went more towards ensuring a more free-market-oriented approach. This was done through working towards removing regulatory barriers to AI innovations, putting AI as one of the administration's top R&D budget priority areas for 2020, as well as launching the American AI Initiative. Not until January 2020 did the White House publish a draft with guidance for regulations that government agencies should consider when working with AI applications. These guidelines contained the need to include scientific integrity, risk assessment and management, as well as safety and security (Gerke et al., 2020). The Joseph R. Biden cabinet has continued this focus on AI by launching the National AI Research Resource Task Force, with the ambition of developing a roadmap to democratising access to research tools that will promote AI innovation and "fuel economic prosperity" (The White House, 2021).

HIPAA

The Health Insurance Portability and Accountability Act (HIPAA) is the most important regulation framework regarding data protection and the prevention of misuse of health data. Every company that deals with sensitive health data must ensure HIPAA compliance (Cohen & Mello, 2018; De Groot, 2022).

When it was first introduced, it was considered mainly as a framework of rules regarding data privacy and security to protect health information. After the HITECH Act that addressed challenges arising from electronic health records, HIPAA was being adjusted to these new challenges and proved to be extremely functional. The privacy rule, included in HIPAA, defines that patients need to give their written authorisation for disclosure before identifiable health information can be used by a third party, unless a specific exception, like an operation, applies. This rule is handled slightly different in health research. Researchers can use protected health information for research purposes without patient authorisation in case an institutional review board or privacy board gives its permission. The condition for the use is the exclusion of data that can be directly identified to the patient, e.g. medical record number, name, etc. (Cohen & Mello, 2018).

The evolving topic of big data brought up new challenges regarding this topic. Before universities and health systems had an interest in data for their research, due to the increasing importance of data in all sectors, private companies are interested in gathering data for their own research as well. The exemption rule that institutional review boards and privacy boards

can give permission for the use of personal deidentified data was not designed for this new case (Cohen & Mello, 2018).

It is a challenge to manage the potential of AI-based software, which requires a huge amount of data for the healthcare sector on the one hand and the need for the protection of individual data on the other hand. One adjustment of the HIPAA to the new challenges was a proposed change to the HIPAA privacy rule. It should strengthen the individuals' right to access their own health data, improve flexibility for disclosure in an emergency or threatening circumstances, and reduce administrative burdens on HIPAA covered healthcare providers and health plans while keeping the privacy interests of individuals in focus (U.S. Department of Health and Human Services, 2021).

The HIPAA regulations are dynamic due to the increasing importance of AI-based software in the health sector, and it is expected that the regulations will be adjusted regularly in order to ensure data privacy. It can be seen that there is a gap in HIPAA since it ensures data protection on the part of healthcare providers and healthcare systems, but it does not cover data that is generated outside of health entities, like data from mobile health applications or smart watches (Tom et al., 2020)

4.2.1.2 Construction of the healthcare sector in the U.S.

Since the U.S. has a different approach to providing healthcare than Denmark, by being mainly privatised, the construction of the sector is different. Therefore, it is fundamental to understand the construction of the U.S. healthcare sector, understand the reasons behind this approach, and how actors in the sector are affected by that.

The U.S. is a country which is built on the dreams of building your own fortune, taking care of yourself, and having a less centralised government. This way, the American people pay less tax to the state but at the same time receive fewer social services from the state in return as well, e.g., having to pay for their healthcare and education (Heckman & Landersø, 2021). Thus, every individual has to pay for needed healthcare him-/herself.

In the U.S., the healthcare market is mainly privatised which also means the decisions are made at a faster pace with less bureaucracy, and the hospital itself is often considered a private company entity rather than a public or non-revenue entity. The hospitals buy equipment based on what makes the most sense in a decision-making process, like most other companies investing in new equipment, to optimise and increase profit (Willis, 2004).

However, the decision-making process is also impacted by the various pricing models of the U.S. pricing model system. This system shows how the hospitals receive money for their treatments for patients, and this determines or paves the way for how the hospitals generate revenue. The healthcare system in the U.S. is starting to shift from a typical *fee-for-service* approach to a *value-based healthcare system* (Brown & Crapo, 2014).

Fee-for-service

This is the traditional terminology for the transaction a patient would give for the treatment at a hospital in the U.S. Fee-for-service refers to a patient paying for a specific treatment and following services provided by the hospital based on the treatment and number of services. By that definition, the prices are based on the quantity of the treatments and services and not their quality of them. This gives hospitals, seen as private companies, incentives to push for the most expensive and technological solutions for the patient and not necessarily the highest quality of the offered treatments. It is also incentivising the hospitals to have as many hospital beds filled as possible at any given time, as this means more services, treatments, and tests - which ultimately return higher reimbursements to the hospitals, again, disregarding and potentially even lowering the overall quality of the treatments, tests, and services due to overfilled hospitals and lack of healthcare employees (Ikegami, 2015).

The fee-for-service pricing model is therefore being criticised more and more by scholars, bloggers, physicians, and society in general as an outdated healthcare model (Meuse, 2020). Therefore, there is starting to happen a shift to a different pricing model within healthcare. This model is referred to as *value-based healthcare* and focuses more on the quality of the treatments and services rather than performing as many services and treatments to a patient as possible.

Value-based healthcare

The value-based healthcare model, which is gaining more and more traction across the United States, is a model where, as opposed to the fee-for-service, the hospitals get paid for the quality of the documented processes and treatment quality to the patient. The hospitals are therefore evaluated and reimbursed based on the patient outcome, incentivising to not necessarily offer the most expensive treatment and as much treatment as possible but instead focus on the quality of the treatment and process (NEJM Catalyst, 2017).

The hospitals and physicians are awarded based on the documentation of the treatment process as a whole, documenting the value they have brought to the patient along the way with the different steps in the treatment process. This is a different direction from the fee-for-service model and has a different impact on the decision makers' process of purchasing new equipment and treatments (NEJM Catalyst, 2017).

With this change, it is not necessarily the most expensive treatment the hospitals are going for, as this is not how they are reimbursed with the value-based healthcare model. With the new model, the hospitals could benefit more from new technology which helps document the treatment with every step and how it exactly helps and benefits the patient's unique health issue and recovery.

4.2.1.3 Institutions supporting AI-development

The development of new technologies to maximise value and growth is a major goal in many countries, also in the USA. Silicon Valley is known to be a global centre of innovation where the most known and successful companies like Apple and Google have their headquarters located. All over the USA, there are several regions where innovative companies of different sectors locate themselves, e.g. San Francisco for healthcare technology. Some of the supporting initiatives to increase the attractiveness of these regions are accelerator programs, incubators, and think tanks. These initiatives attract startups as well as bigger companies to use partnerships and expert groups across different companies to increase development. Additionally, it increases funding in this area and attracts venture capital firms to invest in some of the companies (Kamani, 2021). Younger and smaller companies get the chance to receive support in business growth, receiving financial support, entering and establishing in the U.S. market and establishing valuable partnerships, while bigger companies get the chance to find new partners and new innovations.

Horowitz et al. (2017) state that accelerators "will spark innovation around specific topics, challenges and populations, generate novel ideas […] maximise research quality and efficiency". The health sector in the U.S. realised the value of accelerators and started initiatives to increase development. More than 100 accelerator programs in healthcare are present in the US and show the increasing importance of new technologies in this sector. We will name and describe some of the accelerators to provide an understanding of the programs and the value it brings to participating companies (Horowitz et al.,2017).

Cedars-Sinai Accelerator is based in Los Angeles, California and is one of the most famous accelerators in the healthcare sector in the U.S. During a three-month program, it provides participating companies with funding of 100.000 USD. Additionally, it supports the companies by providing access to a broad network of entrepreneurs, investors, and relevant people for possible partnerships. It also gives the companies the possibility to use mentorship from world-leading experts, access to Cedars-Sinai's clinical expertise, and a fully equipped office. One of the key focus areas of this program is the topic of AI, Analytics, and ML (Cedars-Sinai, 2022).

The Texas Medical Center is one of the largest medical marketplaces worldwide and offers digital health and medical device startups an opportunity to join its accelerator program, TMCX, also known as TMC Innovation. This program focuses on clinical partnerships to improve the delivery and the outcome of healthcare by making sure that participating companies are connected with suitable mentors, clinical champions, service providers, and corporate partners. Each participating company receives a customised journey since the program ensures the connection with suitable partners and mentors that support them in several topics like clinical trials, fundraising, and regulatory strategy (Texas Medical Center, 2022).

The Mayo Clinic and *Arizona State University* (ASU) *Alliance for Health Care* set up the MedTech Accelerator to provide early-stage medical device and healthcare technology companies with tailored plans regarding business development and investment possibilities, as well as an entrepreneurial curriculum to gather the most important information for startups. Participating companies get access to the ecosystems of Mayo Clinic and ASU that support them with valuable knowledge and insights about the health sector. The MedTech Accelerator is located in Phoenix, Arizona, close to a thriving local MedTech community (Mayo Clinic and Arizona State University Alliance for Health Care, 2022).

These examples show the opportunities accelerators give startups in the health sector. It is highly valuable for companies that are new to the market to find and establish partnerships, as well as meet the regulations of the market.

4.2.2 Background institutions

In the following section, the public attitude, the buyers' attitude, which is mostly hospitals, and the political attitude towards the topic of AI in HC are described.

4.2.2.1 Public attitude

New technologies usually come with a critical attitude towards them because most people have concerns regarding the new technology. This can be, for instance, caused by a lack of understanding and therefore being reluctant to use it.

AI has the potential to change healthcare. Studies already show the proof of concept in various medical niche fields. The topic of healthcare deals with sensitive data and is a very private topic. Thus, it is essential to increase patients' understanding of AI to get acceptance of these products (Young et al., 2021).

Zhang & Dafoe (2019) conducted the attitude towards AI in the USA and found that there is mixed support for the development of AI in the country. Especially younger people such as college graduates, people with high incomes, and people with a background in computer science support the development of AI. At the same time, people with a less educational background and the low-income population are more critical regarding this topic. Major issues are the fear of privacy violation, misuse of data, and cyber-attacks. Thus, 82% of the Americans that were part of the survey think that AI-enabled products should be carefully managed. Many Americans are neutral towards this topic, but again, the majority supports the development of AI. It can be indicated that the lack of knowledge about this topic leads to people being critical of the topic (Zhang & Dafoe, 2019).

Usually, people hear about the topic of AI but not in connection with healthcare. Therefore, patients view AI with reservations, even when their attitude towards AI is positive. After using AI-enabled products in the intended clinical setting, patients' opinions changed positively since they were satisfied with the used AI-enabled tools (Young et al., 2021).

4.2.2.2 Buyers' attitude

Hospitals that have already worked with AI-enabled products before are more open to these products since they know how to implement them in their processes and the know-how to use them. They also know about the regulations and standards an AI-enabled product needs to meet and can therefore better decide if the product is suitable for the hospital. Due to the newness of these products, the organisational processes inside the buyers' organisation (usually hospitals) are often not adjusted yet, so it is not clear which department should make the decision whether to buy a product or not. This leads to uncertainty and being more critical of buying AI-enabled products.

Stine explains: "But what we see in the U.S. is that those if you're more likely to find a hospital that works with AI before so they at least know how to ask the right questions, they have gone

for an implementation process. They know what worked before, they know what all these ISO-standards and all of these things mean so that it's easier to go through. But you still have to show that your product brings value […] We find that we are going to the radiology department or you will go to the quality department or you will go to sort of a more average service department or the IT department. So that hasn't been formalised yet […]" (see appendix B).

4.2.2.3 ***Political attitude***

The USA is believed to be the leader in the topic of AI. In 2021, the *National AI Initiative Act of 2020* became law and got introduced to ensure leadership in AI research and development. As a result, the USA want to "lead the world in the development and use of trustworthy AI in the public and private sectors" (National Artificial Intelligence Initiative, 2022). Under this initiative, several committees and working groups were formed to ensure the right planning and coordination, as well as making recommendations. These groups and committees consist of some of the most senior R&D officials across the Federal agencies and experts from several AI-relevant disciplines (National Artificial Intelligence Initiative, 2022).

4.3 Summary of the Danish and the U.S. business system

In Table 4, we illustrate the differences in the institutional characteristics of Denmark and the U.S. We summarise our findings in sections 4.1 and 4.2 and divide them into categories of proximate institutions and background institutions. In addition, we want to point out how these institutional characteristics that are presented in the table are impacting AI-HC startups in the two markets.

Institutional differences between Denmark and the U.S.			
Country	**Institutional factors**	**Institution Type**	**Impact on AI-HC startups**
Denmark			
	GDPR regulations	Proximate	- Regulations the startups have to comply with
	Construction of health care	Proximate	- Changing value proposition of firms startups to fit optimization
	Public-private partnerships	Proximate	- Pushes for innovation and collaboration in the industry
	Political initiatives	Proximate	- International business network assistance - Plan to beomce leading in AI
	DMA	Proximate	- Regulative institute for approving the medical devices and solutions
	Public Attitude	Background	- Positive attitude from the public to adopt digitalization - Majority of public accepts AI in health care, but have concern
	Buyers' Attitude	Background	- Hospitals ready to try untested equipment and solutions - AI-HC startups have good posibilities of establishing pilot projects
	Political Attitude	Background	- Politicians pushes for AI solutions and sees the potential for Denmark to be a leader
USA			
	HIPAA regulations	Proximate	- Regulations the startups have to comply with
	FDA	Proximate	- Regulations the startups have to decide whether to comply with or not based on product
	Construction of health care	Proximate	- Changing value proposition of firms startups to fit revnue stream for the hospitals
	Accelerators	Proximate	- Helps with business networks and pilot projects in the American market
	Public Attitude	Background	- Positive attitude from the public to adopt digitalization - Majority of public accepts AI in health care, but have concerns for data and loss of workspace - Have digital cluster and digital giants in society already
	Buyers' Attitude	Background	- Hospitals who has tried it before are more open to adopting AI products
	Political Attitude	Background	- Is the leader within AI in the world - Initiatives implemented to maintain

Table 4: Institutional differences between Denmark and the U.S.

4.4 Case Companies in the context of the U.S.

This section will describe the case companies selected for this research paper first, in general, to provide an overview of their history and their products. Second, we will describe the activities of the companies in the U.S. Furthermore, it will illustrate how the companies' approached the U.S. market and explain how institutional characteristics in the U.S. business system have shaped the respective startups. This will lay the foundation for the later comparative-case analysis in the analysis section.

Lastly, we will describe the business system characteristics of the two case companies. As we have previously addressed in our Literature Review, the business system characteristics are made of three primary elements: (1) Ownership and Governance, (2) Relationships and Networks, and (3) Internal Dynamics. We will primarily focus on the two business system characteristics we assess are most relevant when discussing the internationalisation of the firms, namely Ownership and Governance and Relationships and Networks.

We want to describe if and how the Ownerships and Governance changed by entering the U.S. market. When entering a new market, companies are usually lacking market knowledge. In the context of the U.S., there are complicated regulations, like FDA, that can be challenging to deal with when being new to the market. Thus, we want to find out and describe if our case companies were willing to give away power and externalise activities.
Since Networks and Relationships play an essential role in economic markets, we want to describe how the case companies were seeking to find partnerships, establish valuable contact, and built up a network in the U.S.

4.4.1 Radiobotics

Radiobotics is a Danish startup company based in Copenhagen. As of February 2022, the company had 21 employees. As of 2021, the company is yet to have an annual positive return – every year since its establishment, the company has had a negative yearly result (Proff, n.d.).

Radiobotics' ownership structure is primarily distributed amongst the four co-founders – Mads Jarner Brevadt, CEO (33.34-49.99%), Stine Mølgaard Sørensen (5-9.99%), Pavel Lisouski (5-9.99%), and Martin Axelsen (5-9.99%). Besides the four co-founders, Innovations A/S holds 5-9.99% of the shares, InQvation ApS holds 5-9.99%, and Bjerg ApS holds 10-14.99% (Proff, n.d.).

Throughout Radiobotics' journey, they have received several grants along the way. This includes grants from Accelerace, Copenhagen Healthtech Cluster, Data Pitch - Innovation Programme, DTU - Danish Technical University, EIT Health, Eurostars, Innovations Fonden, EIC Accelerator, MEDTECH Innovation, and SME Instrument (Radiobotics, n.d.).

Radiobotics' product portfolio currently spans over two products – the descriptions below are described with inspiration from Healthcare Denmark (n.d. b):

1) RBknee™ is a CE-marked and FDA cleared clinical decision support tool for the radiology department. The product is built with AI, and the aim is to identify osteoarthritis (OA) in the knees based on a standing radiograph. The product will analyse the x-ray images and then provide clinicians with two decision support outputs: a) A structured analysis report that describes the OA conclusions and findings, and b) A capture where radiographic OA findings are highlighted. According to Radiobotics, one radiologist stated: "The reporting will become more consistent, structured and robust – this will, in the end, save us a lot of time". Furthermore, Healthcare Denmark describes the main benefits to radiologists by using RBknee™ products as (1) Improved outcome: structured reporting will reduce the changes of diagnostic errors, (2) Direct timesaving: when it comes to the routine reporting of knee OA, less time will be spent, and (3) Reduced cost for outsourcing: there will be less need for external assistance to describe medical images.

2) RBhip™ is also a clinical decision support tool built with AI, but instead of focusing on OA, RBhip™ is assisting orthopaedic surgeons when they evaluate hip radiographs. RBhip™ will analyse x-ray images and provide clinicians with outputs in the form of specific analysis and measurements which are being used in the day-to-day operations of an orthopaedic surgeon to evaluate the diagnosis of the patients. One orthopaedic surgeon stated: "The product has some unique features, and it will support the orthopaedic surgeon in making evidence-based decisions". Furthermore, Healthcare Denmark describes the main benefits of using RBhip™ as the following: (1) Direct timesaving: When it comes to evaluating and measuring pelvis radiographs, less time will be spent, (2) Increased patient satisfaction: The product will lead to faster diagnosis and treatment of patients, and (3) fewer follow-up appointments: since the right diagnosis can be received the first time.

The products are being marketed in Europe. As previously described in the Danish institutional environment section, it is necessary to be approved by a third-party notified body when the

products are being classified above low risk to receive the necessary CE-certificate. Radiobotics' products have been audited by the notified body, Tüv Süd (Radiobotics, n.d.).

4.4.1.1 Operations in the U.S.

On the 4th of February 2021, Radiobotics announced that they were expanding their operations to the U.S. market. This was done by establishing a wholly-owned subsidiary named Radiobotics Inc, with COO and Co-founder Stine Mølgaard Sørensen being named as President. However, the process of penetrating the U.S. market started in March 2020 when Radiobotics was chosen to take part in the Texas Medical Center's Accelerator program, TMCx. Through this program, Radiobotics in summer 2020 was introduced to a wide range of clinicians, specialists, and several of the other member institutions of TMC. In the announcement on the 4th of February 2021, Stine Mølgaard Sørensen described the participation at the TMCx as the following: " It has truly been a privilege to be part of last year's cohort, and this has really shown us that the US is a huge opportunity for us" (Sørensen, 2022).

After participating in the program, Radiobotics started to prepare for entering the market – which resulted in the establishment of Radiobotics Inc, established in Delaware, in February 2021. When asked specifically about which strategy the company pursued when Radiobotics entered the U.S. market, Stine Mølgaard Sørensen indicates that they pursued an approach where they chose to take a slow-paced approach, where they did not commit many financial resources from the beginning to the entry on the market.

Stine Mølgaard Sørensen explains: "when you [red. Interviewee] say strategy [red. as of asking about their choice of entry strategy], you sort of give us way too much credit. […] Sometimes, you just give it a try. We gave it six months to see how far we go" (full interview transcript is presented in appendix B).

In their efforts to increase their knowledge of this new market, Radiobotics have entered some local strategic partnership. One of these partnerships is with Virtual Radiologic (vRad). According to Radiobotics, vRad is a leading teleradiology practice in the U.S. which is working towards optimising and revolutionising the workflow of radiologists. The aim of Radiobotics when entering this partnership is that they believe it will strengthen Radiobotics' capability of being able to develop and validate algorithms within musculoskeletal at a higher pace.

Radiobotics has also entered a partnership with U.S. based Efferent Health. Efferent health is a provider of cloud-based hybrid systems for medical imaging and clinical operations

management. The aim of Radiobotics entering this partnership is to enable its products to be distributed through the channels of Efferent Health.

Besides entering these partnerships, Radiobotics have connected with advisors in the U.S. market – namely Ayse McCracken and Nicholas Pachua – both of whom have extensive experience within the U.S. healthcare market.

When asked why they chose the U.S. as a market for penetration, Stine Mølgaard Sørensen has primarily two main arguments. Firstly, the U.S. is the world's largest healthcare economy, and thus there is immense potential. Secondly, she argues that compared to Europe and UK, in the U.S., AI driven products are being implemented into the healthcare sector at a much higher pace and scale, and thus also provides an interesting opportunity (Sørensen, 2022).

4.4.1.2 Business System Characteristics in the U.S.

In this section, we will describe how business system characteristics of Radiobotics are in the U.S. market, as well as if it is likely that these will be adapted in the future as a result of pressures from the institutional characteristics. Firstly, we will address the Ownership & Governance aspect, whilst secondly, we will address the Relationships & Networks aspect.

Ownership and Governance

In this section, we will first address whether Radiobotics is considering changes in their ownership structures because of their entry into the U.S. market and assess if institutional characteristics are leading to these considerations. Secondly, we will discuss the governance aspect of Radiobotics and how their entry into the U.S. market has or will cause changes in their approach.

As of now, Radiobotics has not conducted changes in its base of shareholders as a result of its entry into the U.S. market. However, it appears as if they are open to entering into an equity-based partnership if the right opportunity arises. It appears that the primary motive for Radiobotics to enter such a partnership would be to gain access to specific market knowledge, expert knowledge, market experience, etc.

In our interview with Stine Mølgaard Sørensen, COO of Radiobotics, she appeared to be open to possible partnerships in the future. For example, a cooperation with Ascension, which is a large hospital group in the U.S.

She explained: “We also speak with some called Ascension and those sort of conversations is to have one large partnership or not. Like a bunch of small customers for the part, we already have here. And so we changed the strategy a little bit, so when we are ready with our next product, have at least someone with huge impact where we can start” (see appendix B).

Whether the nature of this partnership would be of an equity or non-equity character was not specifically mentioned, it appeared as Radiobotics would be open to both kinds of partnerships as long as the right opportunity would arise.

Moving on to the Governance aspect of Radiobotics, overall, there has not been made major changes in the Governance structures of the firm. This is primarily a result of the degree of commitment the company has pursued in the U.S. market, where they follow a quite incremental and slow-paced entry to the market whilst they are exploring their opportunities in the market. As of now, operational control and authority are placed in Denmark since the President of the U.S. operations (Radiobotics Inc.) is Stine Mølgaard Sørensen, who is the COO of the Danish operations. When the company opened its operations in the U.S., it was decided that the authority of the U.S. operations shall be operated through the Danish top-management of the firm. Originally, the plan was that the CEO and COO of the Danish operations would take three-month shifts in the U.S. Stine Mølgaard Sørensen explains: “So I'm the president of it and we sort of agreed on that we wanted to do like two, three months terms in the U.S., Mads who is the CEO and me” (see appendix B).
However, the company is working towards increasing its staffing at the U.S. office. Stine Mølgaard Sørensen explains: “I have been looking for hiring somebody full-time, sort of in a in a more senior role. It could sort of be our person there, so we don't have to go ourselves all time. We haven’t found that, it's extremely difficult to find anyone. So, we have sort of consultants. We also have our Chair of the board she's from Texas, lives in Houston, comes out of Texas Medical Center. And we have a part-time employee and then we have a consultant who comes from GE Healthcare, which is basically those that would be a partner in this and could be a reseller of our technology in this. Well, we don't have full-time person yet but I mean we are set up to do it and we're mostly running it (red. Radiobotics Inc.) as a commercial entity so we can invoice American companies” (see appendix B).

Relationships and Networks

The aim of this section is to describe if and how Radiobotics is seeking to establish contacts and get access to valuable networks in the U.S. market, and how establishing contacts and using networks leads to an increase in market knowledge and the optimisation of specific processes, like the FDA approval process, by externalising these.

After entering the U.S. market, Radiobotics decided to externalise some operations. The process of applying for the FDA clearance is a process that can be very thorough and demanding and expert knowledge about requirements. For this, Radiobotics decided to externalise the operation of the application process to external consultants. However, finding the right consultants for this task was also challenging. In our interview, Stine Mølgaard Sørensen explained that the first round of FDA approval failed because of not hiring fitting consultants. After the first try, they found new consultants, and this time it smoothened the process quite a bit, according to Stine Mølgaard Sørensen:

"I wouldn't say it [Red. applying for FDA approval] is the biggest barrier, it is just a different barrier. I mean first we failed with our first FDA but that was because we hired the wrong consultants. Once you hire the right consultants it goes relatively smoothly but you also must pay more" (see appendix B).

As of now, most of Radiobotics' other activities are internalised. As previously mentioned, Radiobotics have only received an FDA clearance for one of their products; RBknee™. However, according to Stine Mølgaard Sørensen, the plan is eventually, when other products have gained FDA clearance, to externalise some elements of the downstream value chain, specifically the sales channels:

"So, we will eventually do partnerships like that and resellers and all those agreements as soon as we have a more fully built product. So, to say because that's all, that's the only way you can scale, but at the first couple of years it's too early to do those things because you still developing your product right "(see appendix B).

Now we will describe how Radiobotics tries to establish contacts within the U.S. market and if and how they are seeking to get access to health networks within the country.

Radiobotics had the opportunity to meet several stakeholders and establish contacts within the U.S. healthcare sector by being a part of the TMCx program. They got introduced to several potential buyers, valuable experts, and other stakeholders as a part of the program. Furthermore,

Stine Mølgaard Sørensen also travelled to Silicon Valley, Boston, and Minneapolis in order to establish contacts there and get access to these networks.

4.4.2 Teton.ai

This section aims to provide an overview of Teton.ai, one of the case companies of this paper. First, we will give an overview of the company, its journey, and the products they are offering to provide an understanding of these topics. Following, we will lay out the business system characteristics of Teton.ai in the U.S., what their approach to these is and if they are open to adjustments or already have a straightforward strategy to enter the U.S. market successfully.

Teton.ai is a Danish startup formally established and founded in Copenhagen in 2020. It is still operating its business from Copenhagen, and the team consists of 13 employees. The startup is developing an AI and computer system that shall be able to mimic the human understanding of events and behaviour. This shall be done by introducing an intelligent assistant to health professionals. According to Teton.ai, they look toward revolutionising the hospital experience, and their first product, Nightingale, is the first generation of a contactless patient monitoring system using deep learning and computer vision technology – boiled down, the aim of the product is to be a "digital nurse", monitoring patients when the nurses cannot (Teton.ai, n.d.).

Initially, the company was started by the two study colleagues, Mikkel Wad Thorsen and Esben Klint Thorius. During their studies at the Technical University of Denmark (DTU) in 2017, they started working together on the project and received grants from DTU to produce a prototype and to work on the product alongside their studies. Later, they received grants from *Innovationsfonden* which led to an acceleration of the process. In 2018 they received a legatee from the *Alexander Foss Industrifond*, which also included a one-year membership of *Dansk Industri* – which is Denmark's largest employer and business organisation, representing over 19.000 small and large companies from virtually all branches of the Danish business community.

The two founders own 80,2% of the shares altogether, whilst the existing 19,8% of shares are divided between Fashion Records ApS and Preseed Ventures Tech Fund I K/S.

As previously described, as of now, Nightingale is Teton.ai's first product on the market. Nightingale is a tool for care staff that is fundamentally new. It can monitor all patients in rooms

that are equipped with the device. By using sensors, all activities can be tracked and analysed. Nightingale recognises the activities and can understand and categorise these. This is done by using AI-based technology, deep learning, and computer vision, which means that the cameras are equipped with a small computer that recognises and analyses every activity and communicates this information to the staff. Nightingale's technology enables it to measure and analyse all things that can happen in a patient's room and thus makes it possible to only use one device instead of having many specific devices.

The tool can be integrated into already existing devices within the hospital or the ward and provides the staff with the opportunity to get an overview of the activities of all patients and prevent high-risk situations, like falls, by quickly reacting to possible risky situations that Nightingale recognises.

4.4.2.1 Teton.ai in the USA

Teton.ai decided to explore the U.S. market due to the huge possibilities of earning money and scaling really fast. Mikkel argued that he had and still has some good connections in the Austin medical community as well as in the Ensign group, a huge group of businesses operating in the healthcare sector. Thus, they chose Austin as their landing place in the U.S. Right now, they are still in talks with the Ensign Group. The plan is to set up a deal where Ensign Group will collect funds from 16 different facilities, the product will be tested in one facility, and if the tests are going well and the results are valuable, Teton.ai can expand its business in the U.S (full interview transcript is presented in appendix C).

4.4.2.2 Business System Characteristics in the U.S.

In this section, we will describe how the business system characteristics of Teton.ai are in the U.S. market, as well as if it is likely that these will be adapted in the future as a result of pressures from the institutional characteristics. Firstly, we will address the Ownership & Governance aspect, whilst secondly, we will address the Relationships & Networks aspect.

Ownership and Governance

In this section, we will first address whether Teton.ai is considering changes in its ownership structures because of its entry into the U.S. market and assess if institutional characteristics are leading to these considerations. Secondly, we will discuss the governance aspect of Teton.ai and how their entry to the U.S. market has or will cause changes in their approach.

Teton.ai appears to be quite reluctant to consider changes in the ownership structures of the firm by giving away power and entering formal partnerships. Although Mikkel Wad Thorsen, CEO of Teton.ai, acknowledges the possibilities a partnership could lead to, he is primarily concerned about losing control of the U.S. market.
Mikkel Wad Thorsen explained: “I don't like distributors that much. I don't like affiliates. I don't like to give away power unless it's a really good deal and you don't wanna be in the country yourselves. I mean, it's all about ambition level, I think because you can probably make a lot of money having someone take the entire market for you and if you have a really good product, there's a chance that you make a lot of money, right? But you also lose a lot on the top end. I like to keep control. I think the brain is very important. I like to keep control of the experience that the customer has” (see appendix C).

It is especially in markets that Teton.ai values as high potential, where they are concerned about losing control of the operations. Strategically, Teton.ai perceives the U.S. as a significant market, whereas they, on the other hand, for example, viewed the German market as of less importance and thus would be willing to discuss entering partnerships in Germany. Mikkel Wad Thorsen explained: “[...] I think the US is a good market for us. So I'm not gonna give that up, but I might give up Germany or kind of Benelux country, for example. That might not be as big of an opportunity, but the hurdle to get into is the same for us” (see appendix C).

After describing the Ownership structure and attitude towards making changes by getting new shareholders on board, we will now describe the Governance structures of the company in the U.S.

Teton.ai is currently based and operated in Copenhagen, Denmark. For now, it is not planned to be physically present in the U.S. market. Mikkel Wad Thorsten went to the U.S. a few times to make connections, but he does not see this as the way to go. He perceives this as a huge barrier for them since they are not physically present and do not have a reputation in the country yet.

“But you have nothing in the U.S., and you can't really go there because I mean, we are based in Copenhagen. So I was in the US a month ago, but it's just not really feasible for me to be there all the time and make those connections. So that's a big, big barrier” (see appendix C).

The plan is to keep R&D in Denmark since the company has a solid R&D team in Denmark already and does not want to move or outsource this topic to the U.S. because of the high prices for developers in the U.S. Right now, the company does not have people for different departments, like sales. Mikkel is doing sales, development, and other organisational topics since the company are small at this moment. If Teton.ai can successfully enter the U.S. market and the market has proven to be profitable for the company, they want to set up a sales department in the market, as well as probably set up customer support and other activities related to customers, but operational control and authority is planned to stay in Denmark (see appendix C).

Relationships and Networks

Teton.ai pursues to use one strategy for all countries the company wants to enter. Mikkel states that the goal is to first "find a base or a home" (see appendix C) in the target market before any operations will be moved to the country. The priority is to first find a partner that can be valuable for Teton.ai and is interested in the products and the company's vision. Thus, the approach is to first find out if there is a demand for the product in the market and how it can provide value to potential buyers and users, setting up a valuable partnership - and if these steps are completed, it is a possibility to move operations to the target market. Even the regulative environment, like FDA or HIPAA, is not a priority first. Before looking at the regulatory environment and trying to understand and meet the regulations regarding the product, Teton.ai wants to see if the product is valuable for the market and if they can find a suitable partner.

In the U.S., Austin is the starting point for Teton.ai because they have some good contacts in the Austin medical community and in the Ensign group (see appendix C).

The company is currently not focusing on partnerships with distributors or something similar. It keeps the focus on selling directly to hospitals, care homes and other potential buyers to make direct sales without using a middleman. Right now, the company is trying to set up a deal with Ensign Group. This deal provides a good opportunity to scale rapidly in the U.S. market.

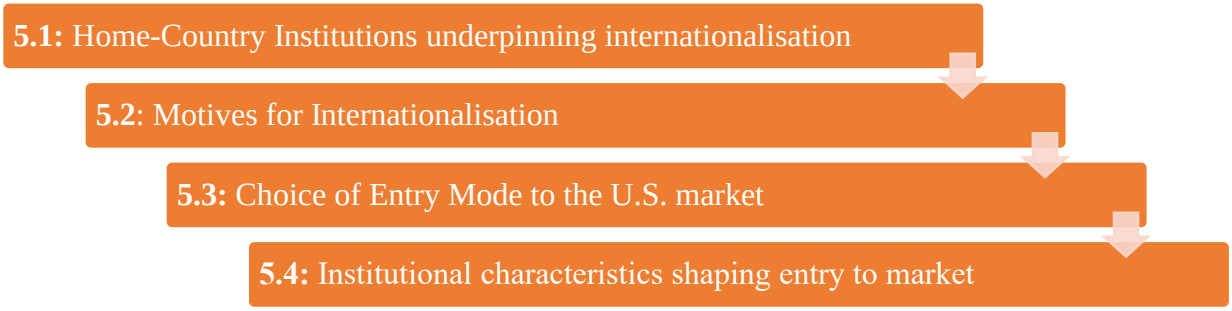
Mikkel Wad Thorsen comments on this: "So we are in talks with a company called Ensign Group, for example, they have 35,000 patients at all times, which is basically equivalent to all of Denmark and all of Sweden within both hospital and like nursing homes, dementia care. […] it can scale probably within a year to what would be the equivalent of two whole countries" (see appendix C).

5 Analysis

The aim of this analysis is through a comparative case study to draw some analytical generalisations, as well as present diversities in how institutional characteristics have shaped the two case companies that are being examined in this paper, and thus to assess how institutional characteristics both in the home- and host country have shaped and adapted the internationalisation approach of the examined companies.

By using the Business System Theory approach as the foundation for our research, we will lay out how institutional characteristics have shaped the internationalisation processes of the companies in question. This will be done through a structure where we identify specific institutional characteristics and how the companies explicitly have handled these institutional characteristics.

The structure of the analysis will be the following:



By following this structure, it gives a natural flow to the analysis by first assessing how or if Danish institutions are underpinning internationalisation and then moving on to examining motives for choosing the U.S. as a market of interest. Thirdly, we will examine the choice of entry mode into the U.S. market and examine how institutional characteristics have shaped the entry mode approach taken by the companies. Finally, we will examine how institutional characteristics otherwise have shaped the overall strategy of the firms when entering the market.

In the Literature Review, we found that Rana & Morgan (2015) define four core dimensions that the BST presents. The analysis will focus mainly on one of them, how companies' strategies, structures, and entrepreneurial dynamics are being shaped by the institutional environment of a certain country, Denmark and the U.S., in our context.

5.1 Home-Country institutions underpinning internationalisation

In chapter 4, we identified institutional characteristics that have shaped the emergence of the AI-HC field in Denmark. It appears that some of these institutional characteristics have

encouraged and motivated the internationalisation of startups within the sector. The aim of this section is to assess how these institutional characteristics have shaped or even underpinned the internationalisation of Danish AI-HC companies in general, as well as the case companies directly.

The Danish Government has, in recent years, taken a proactive approach towards developing the AI-HC industry in Denmark. Besides formulating two strategies in place that identify the focus and goals of Denmark when it comes to AI-HC, the Government has also allocated a substantial degree of funding for AI projects at hospitals. Access to clinical testing is crucial for startups since it is very significant for their products to be clinically tested. Mikkel Wad Thorsen emphasised the importance for Teton.ai to get access to being able to conduct clinical testing as crucial. He explained: "We've implemented our prototype in a hospital without it working basically at all and just started working on it in the hospital, that you can't do that in the US, liabilities are way to high they are way too scared of that entire thing. So I think you probably like you have to be a more professional company to navigate in the US and you have to do in Denmark which makes Denmark a pretty nice place to start out because I think I think you can, you can hit a fairly good like revenue in Denmark and then use the muscle that you gain from that and the experience you gain from that to enter the US market" (see appendix C). By having a continuous focus on increasing access to conduct clinical testing – as the Danish Government is currently suggesting – might in the future have a major impact on how the industry emerges in Denmark, as well as it could potentially lead to firms taking international steps.

In the Life Science Strategy, the Danish Government is proposing a more proactive approach towards internationalisation of Danish firms and obliges to work towards diminishing existing barriers that prevent Danish companies from being successful in their internationalisation. We have previously identified what we see as the major institutional challenges when entering the U.S. market, and we have also identified that the Danish Government has undertaken actions towards making it smoother for companies to apply for FDA approvals in the U.S. since the Danish Medicines Agency (Lægemiddelbestyrelsen) established a cooperation with the U.S. Food and Drug Administration (FDA) for mutual drug control in 2018, which enables authorities from both parts of the agreement to work on and build on the works of the opposite authorities. This cooperation can ultimately save time and money for companies applying for FDA approvals (Sundhedsministeriet, 2018).

As a part of Denmark's efforts through many years to have a proactive approach towards internationalisation, the Danish Foreign Ministry has established a quite far-reaching network of Trade Council offices. The offices are located around the world, typically at the Embassies of Denmark in the respective countries. The companies that have been examined in this paper have all been working together with the Danish Trade Council through the Consulate in Houston. The tasks that the Trade Council conducts for companies vary, from conducting initial research, to more concrete tasks, such as opening the doors to stakeholders in the foreign market. One of the major benefits of working together with the Trade Council is that since it is a governmental institution, coming from a country with quite a high reputation, being represented by this governmental institution can benefit by increasing its legitimacy.

Further initiatives taken between Denmark and the U.S. has been the 'biobridge'. The biobridge is a collaboration between Denmark and the Texas Medical Center, the largest medical city in the world. The purpose of the collaboration is to promote innovation & research, and education between the two parties. These initiatives help Danish companies with gaining knowledge and be relevant to the U.S. healthcare market (Texas Medical Center, 2019).

Additionally, Denmark attracts many startups operating in the technology sector since the country is perceived as a good market to start and get products ready for the market. This can be argued as a result of the level of digitalisation of the country, as well as the huge amount of available data and the increasing cooperation between startups within the AI-HC industry and hospitals/clinics. This can likely lead to an increasing wish for growth after establishing products and the company itself in the Danish market. Thus, it can be argued that companies consider entering foreign markets in order to grow and explore new potentials (see appendix C).

It can be summed up that the mentioned home-country institutional characteristics are underpinning the internationalisation of Danish startups by diminishing entry barriers, providing local support in the foreign market, and showing Danish companies the opportunities that entering foreign markets brings.

5.2 Motives for Internationalisation

"When you are doing healthcare technology, I guess you always have the U.S. on the radar, I mean if you are not aware that the U.S. is the largest healthcare economy in the entire world, I guess you have been a little bit ignorant when starting your company. […] you can also see the penetration of adopting new AI technology happens in the U.S. on a much faster scale than in Europe for instance. […] there is an opportunity to make money on a faster scale and the adoption makes it attractive" (see appendix B).

Mikkel Wad Thorsen also sees the potential of the U.S. market for AI-HC because he thinks that "you can scale really, really fast within large organizations" (see appendix C).
The case companies confirm the attractivity of the U.S. healthcare market because of being the largest healthcare economy in the world and perceive the U.S. as highly attractive regarding new technologies, like AI. Therefore, they chose to enter the market to exploit the potential within it and profit from the high potential within it.

5.3 Choices of Entry Mode

When conducting strategic choices of companies in business systems, it is essential to understand why companies decide to enter the market in a specific way. It is necessary to understand the choice of entry mode. In addition to that, it needs to be understood how the internationalisation process went, what ideas and strategies were behind it and did the approach changed due to unforeseen barriers. Furthermore, it is essential to conduct how the institutional conditions of the market context shape the choice of entry mode and the process of internationalisation (Rana, 2014).

When examining the choice of Entry Mode of the two companies, it appears that they all have chosen quite similar approaches. All the companies chose an approach that very deliberately aimed towards diminishing risks and saw their efforts in the U.S. more as a way to explore the market and to figure out if there was potential for their products on the market.

However, there were some differences in their approaches. Below, we will introduce the approaches of the companies, whilst we finally will make general comments about the differences in their approaches.

5.3.1 Radiobotics

As previously mentioned, Radiobotics decided to pursue their U.S. ventures without establishing any formal contact with a partner on the market. However, there were some very specific institutional characteristics that had an impact on how Radiobotics decided to enter the market. Firstly, for Radiobotics, it was important to get access to one specific accelerator program to gain an initial understanding of the U.S. market and thus slowly start their penetration of the U.S. market. Secondly, the proximate institutions in the U.S. had a direct impact on how the operations in the U.S. were established.

5.3.1.1 Accelerator access dominant for timing

Radiobotics had identified a quite specific trigger for the preliminary expansion of their operation to the U.S. market. The company believed that the previously mentioned TMCx accelerator program that the Texas Medical Center in Houston is conducting could be an ideal start to their initial entry into the market.

Stine Mølgaard Sørensen states: "We saw that the Texas Medical Center has an accelerator program. And when you see the landscape of the accelerator program where you can actually find a way where you can learn more about the inside of the economy. We put that on our radar, and if we get into that, there will also be a validation that what we do is something that is needed" (see appendix B).

Radiobotics applied for the program twice and got accepted to it with their second try. According to Stine Mølgaard Sørensen, admission to the program also had a confirmative effect on Radiobotics, which made them more confident that the product had potential in the market. However, the primary goal of entering the program was to increase their level of knowledge about the market and establish valuable contacts.

Stine Mølgaard Sørensen, COO, explains: "So, it was really deciding that there is a market opportunity, going for an accelerator program that represents hospital systems […] that is teaching you everything about reimbursement rates, hospital systems and all important things. And you really get to meet all the people there and they have more than hundreds of advisors connected to the program […] if we hadn't done it that we wouldn't have been able to get a foot as fast into the market" (see appendix B).

However, Radiobotics also examined other options for the case their application for the TMCx wouldn't get approved. They were looking towards entering partnerships of a more formal character. Stine Mølgaard Sørensen explained in our interview that she spent time travelling around the U.S. to assess other options, where she, e.g. spent time in Silicon Valley, Boston and Minneapolis to learn more about additional Health Tech Clusters and to establish contact with these. They were also trying to establish contact with Mayo Clinic, which is a large hospital with an extensive ecosystem in Minneapolis (see appendix B).

5.3.1.2 Proximate Institutional impact on entry mode

After their preliminary examinations of the U.S. market through the TMCx accelerator, Radiobotics decided to pursue their operations and decided on taking active steps towards entering the market. One of the initial steps was to establish a subsidiary in Delaware. This was a direct consequence of the FDA regulations since it is a requirement to have an U.S. located office to gain the necessary FDA clearance (see appendix B).

Because of the low risk and relatively low commitment to entry into the U.S. market, Radiobotics decided to pursue a direct sales approach. These operations are basically being driven from the Danish office since the CEO and COO are switching to taking shifts in the U.S., where they are out discussing sales opportunities with potential buyers.

5.3.2 Teton.ai

As previously mentioned, there are similarities in the entry mode undertaken by Radiobotics and Teton.ai when they approached the U.S. market. However, the aim of this section is to go through two variables that have a decisive impact on how specifically Teton.ai have approached the U.S. market. Firstly, Teton.ai appeared constrained about entering partnerships in the U.S., whilst it appears that institutional characteristics had a direct how they chose to initially address the market.

5.3.2.1 Constrained attitude towards partnerships

What we witnessed in our assessment of Teton.ai was a difference in mindset compared to Radiobotics. Radiobotics, on the one hand, appeared to be very open to the idea of entering partnerships that somehow could accelerate their penetration of the U.S. market. On the other hand, Teton.ai indicated quite some concern about relieving control of the company, which

could be necessary if entering a formal partnership with a U.S. business partner. Mikkel Wad Thorsen explained:

"I don't like distributors that much. I don't like affiliates. I don't like to give away power unless it's a really good deal and you don't wanna be in the country yourselves. […] I like to keep control. I think the brain is very important. I like to keep control of the experience that the customer has. And I think the U.S. is a good market for us. So I'm not gonna give that up" (see appendix C).

5.3.2.2 Proximate Institutional impact on physical subsidiary

As previously mentioned, Radiobotics, in their efforts to gain an FDA clearance, had to establish a U.S. based office. However, Teton.ai has pursued a very deliberate product development strategy that made it possible for them to steer outside of the territory that the FDA covers. At the same time, this also had the consequence that it was not necessary for Teton.ai to establish a U.S. based office. This approach allows them to conduct direct sales, also being driven by employees in Denmark, that then take trips to the U.S.

Mikkel Wad Thorsen explained: "So I think we made a conscious decision of trying to be the least regulated company we could be. So we also make kind of product choices with that in mind" (see appendix C).

However, Teton.ai appears to be quite conscious about *how* and *when* they would like to increase their presence in the U.S. market. As of now, they are out there, incrementally trying to establish contacts, and the trigger for increasing commitment to the U.S. market, is, according to Mikkel Wad Thorsen, CEO, when they have established more contracts.

"If we end up making a deal with Ensign, and a nice pipeline, where it can grow inside there, there are plenty of companies like Ensign. Ensign is the fifth largest in the U.S., so there are a bunch that are a little smaller. If that model works, we'll start approaching all the other companies. If we do deals with, say, four or five of those companies, then it makes sense to set up an office to support that. And then the goal is to basically grow those channels, see if we can scale, use that model to scale inside there" (see appendix C).

5.4 Institutional characteristics shaping strategical approach

The aim of this section is to examine the differences in the institutional characteristics in the business systems in Denmark and the U.S. Below, we will go through institutional characteristics that we have identified as having shaped the business characteristics of the examined companies – both by examining the difference in the two business systems that are being examined, whilst secondly how the institutional differences specifically have shaped the operations of the case companies that are being examined.

5.4.1 Proximate Institutions

First, we will focus on proximate institutions to understand the differences between Denmark and the U.S. and their impacts on the companies operating in the mentioned industry and how these differences can lead to a shape of the companies' strategic approach toward the market and also towards possible future markets. We will do so by applying the case companies to the proximate institutions and analysing the findings of the conducted interviews to see how the two case companies were shaped by proximate institutional factors and how they approached challenges.

5.4.1.1 Medical Device Regulations

When discussing the healthcare industry in general, one of the most dominant challenges for companies operating in this industry is to operate accordingly with regulations that are in place to ensure that products and services being offered to patients are safe and responsible.
Looking at the context of this paper, we can conclude that there is quite a difference in the regulative sphere in the two countries that are being examined – Denmark and the U.S.

The regulative standards for companies in the U.S. for companies that are developing medical devices for the healthcare industry typically fall within the scope of FDA regulations. The process of getting a product FDA approved is quite a complicated process that can take years to comprehend. For many companies, the step of gaining FDA approval is a massive barrier to being able to market their products.

Denmark, however, as a member of the European Union, is following European standards when it comes to the certification of medical devices. To be able to market medical devices in Europe, it is necessary to receive a CE-certification. The CE-certificate verifies that the product meets

all regulatory requirements regarding health, safety, and environmental protection in the European Area.

For companies that are planning to expand their operations from Denmark to the U.S. market, the shift in regulative requirements can serve as a great challenge, especially for startups, which are being examined in this paper, since they might lack the necessary resources and capabilities for being able to navigate in a complex regulative environment.

However, the companies that have been examined for this Thesis paper appeared to have found their way through this challenge – both companies in each their own way. Radiobotics did so by hiring external consultants to be responsible for the application process, whilst Teton.ai have pursued a product development strategy that deliberately was focused on developing the products, so they didn't fall within the scope of FDA regulations and thus did not even need an FDA clearance to operate.

Since Radiobotics externalised the process of navigating through the regulation process, the COO of Radiobotics, Stine Mølgaard Sørensen, didn't see this process as a major challenge. However, for them, the challenge was rather to find the right consultants to conduct the application process since they, in their first efforts, hired consultants with whom they did not have a good experience, and thus their first efforts to gain FDA clearance were unsuccessful:
"I wouldn't say it is the biggest barrier, it is just a different barrier. I mean first of all, we failed with our first FDA but that was because we hired the wrong consultants. Once you hire the right consultants it goes relatively smoothly but you also have to pay more. So FDA is incentivised by money" (see appendix B).

For a startup that perhaps is not having the financial backing as Radiobotics has, this process, without a doubt, could prove to be significantly more challenging and could also work as a barrier when entering the U.S. market.

Although Radiobotics hired FDA consultants, the strict FDA clearance regulations made them adapt their strategy to market. Instead of pushing both their products to market, they decided to slow down the pace and incrementally penetrate by initially pushing one of their products into the market. Whilst in Europe, the application processes for the separate products were quite similar, in the U.S., the application processes were different since they were categorised in

different classifications. They set the focus more on trauma, which resulted in getting into a slightly different FDA approval process since the product was now categorised in acute and emergency care. There is no difference between this in Europe, but in the U.S., it is. Therefore, they chose to change the focus a bit. Stine Mølgaard Sørensen explains that the analysis of their product was more retrospective, and they decided to change the focus on trauma so it "is more on the spot in the clinic" (see appendix B).

As of today, Radiobotics is working towards gaining FDA approval for their second product. However, there are some challenges, as there is a requirement for conducting a clinical study, which according to Stine Mølgaard Sørensen, is quite more challenging because it has a difficult design of protocols, and the company needs to hire people to "validate your technology" (see appendix B), which can prove to be costly.

Another fact that needs to be considered when going to the U.S. and having a product that meets the requirements of needing FDA approval is the fact that it is necessary to officially register as a company in the U.S. Radiobotics set up a Delaware company with a licence to Texas in order to be able to get the FDA approval because they need to have something officially registered in the U.S. otherwise it is not possible to assign the approval to the company (see appendix B).

Another possibility to deal with this barrier is the approach of Teton.ai to this challenge. They try to stay outside the FDA regulations, so they do not need to get FDA approval for their product.
Mikkel Wad Thorsen states: "So I think we made a conscious decision of trying to be the least regulated company we could be. So we also make kind of product choices with that in mind" (see appendix C).

Teton.ai designed the product features in a way that they are not categorised as a medical device to prevent it from falling under the FDA approvement regulation. This is how they have done it in Denmark as well, trying to be the least regulated they can. They have not gotten any pushback from clients in Denmark yet, therefore, they are continuing with this approach. But Mikkel Wad Thorsen is aware of the fact that this can potentially become a problem in the U.S., but "time will tell" (see appendix C).

5.4.1.2 Data protection and Data Access regulations

When it comes to Data Protection and Data Access regulations within AI-HC products, there are also different standards in the two business systems. Here, Denmark, again, is following European standards, and thus companies operating in the Danish business system need to comply with the General Data Protection Regulation (GDPR), whilst companies in the U.S. must comply primarily with the HIPAA standards.

However, our findings indicate that within this context, this could prove to be a benefit for Danish companies since the European countries have a relatively high standard when it comes to data protection through the GDPR regulations.

Stine Mølgaard Sørensen, COO of Radiobotics, argued: "Yes but the HIPAA compliance is much easier than the GDPR and they have a general interpretation of the HIPAA compliance whereas in Europe there are maybe millions of different interpretations of the GDPR rules. So that is not a barrier, it is actually relatively easy to go for a process to state that you are fully HIPAA compliant" (see appendix B).

Teton.ai, on the other hand, had not prepared intensively on data regulations. Instead, they had decided to deal with it when the issue would come up. Even though he does not know much about HIPAA, he thinks they will not have problems with it.

Mikkel Wad Thorsen explains: "But I think like HIPAA is not that different from GDPR, we have designed some data protection stuff into the product at the root of the product. So my thought is that it would take us a couple of months to become compliant in that space and then we can deal with that when we get there" (see appendix C).

The differences between the approaches the companies take to deal with several challenges are interesting. On the one hand, Radiobotics has a proactive approach towards solving these challenges by already understanding the topic fairly and already making actions or having plans on how to deal with these challenges. On the other hand, Teton.ai perceives a more reactive approach and does not want to dive too deep into regulations before they want to deal with it when the topic comes up.

Even though the data protection regulation in the U.S. may be less strict than in Europe, in Denmark, in our context, the topic is very important in the healthcare industry because the data within this industry is highly sensitive.

Christina Brinch Clark, Life Science Advisor at the Danish Consulate in Houston, stated that she experienced the data protection topic as a highly relevant topic when selling products to potential buyers, like hospitals, for instance. One of the first things they want to know is if the product meets HIPAA compliance (full interview transcript presented in appendix A). Therefore, it is essential for foreign companies to ensure that their products are HIPAA conform. As mentioned before, the case companies do not perceive the data protection regulations as a challenge but as an important factor to consider for startups that want to enter the AI-HC market in the U.S.

Access to data

At the very heart of AI-HC products lies access to data. Access to data is pivotal for companies that are developing AI driven products, and thus it is essential for each business system that wants to underpin the development of this emerging industry, to work towards the liberalisation of data.

As a country, Denmark has massive amounts of high-quality data. This is primarily because Denmark is a very digitised country, as well as has a relatively long history of digital health records. However, getting access to data in Denmark appears to be quite challenging and can work as a prohibiting force in the development of the industry in Denmark.

Christina Brinch Clark says: "We're (red. Denmark) still not as far as other countries in terms of allowing that data to be used. Countries like Israel, for example, are much further along, allowed access to data much, much sooner than we (red. Denmark) have" (see appendix A).

However, despite the struggle to gain access to data in Denmark, it appears that Denmark has an institutional environment in place that is quite open and constructive towards conducting clinical trials. Mikkel Wad Thorsen explained how they gained direct access to conducting clinical trials at a Danish hospital at a very early stage:

"We've implemented our prototype in a hospital without it working basically at all and just started working on it in the hospital" (see appendix C).

Although Danish companies, if given access, can develop products with high-quality data, as well as conduct successful clinical trials, this is necessarily not enough for buyers in the U.S. market since many of them are demanding a product that relies on U.S. based data.

In overcoming this challenge, Radiobotics entered a partnership with vRad to conduct clinical testing and to test the technology in the U.S.:
Stine Mølgaard Sørensen says: "The more local it (red. the data) can be, the better it is but we are very fortunate that we have trained part or almost all of our technology on US data because we have a massive data partnership with vRad which is US largest teleradiology company. […] So we've been very fortunate to have that so that gives the security that it works on clinics in the U.S." (see appendix B).

It appears that Teton.ai is working towards overcoming this barrier in a similar way. They are working on making an agreement with Ensign Group about testing their devices in one of their facilities so that the Ensign Group can get a feeling about the product, whilst Teton.ai can use the data collected for further research.

Another possibility to overcome this challenge is to work together or hire a company that assists you in gathering data sets; this is done in radiology, for example (see appendix A). The challenge regarding this topic can be mostly eliminated by these options, but time and resources are needed to gather this data. This is something entering startups need to consider when going to the U.S.

5.4.1.3 Construction of healthcare sectors impacting value propositions

There is a fundamental difference in the construction of the healthcare sectors in Denmark and in the U.S. This has a major impact on how a Danish company needs to pursue changes in its strategy when entering the U.S. market. The aim of this section is thus to illustrate the differences between the two business systems and thus how the changes have shaped the business characteristics of the examined companies.

Public contra private healthcare sector

The fundamental difference between the two healthcare sectors is that in Denmark, the healthcare sector is constructed as a public sector, meaning all citizens have equal access to healthcare services, whilst in the U.S., the healthcare sector is being driven by private corporations. Besides having a structural impact on the construction of the respective sectors, the primary goal and purpose of these two sectors vary. In Denmark, the goal is to ensure a public healthcare sector that is centred around creating a healthcare system that is taking well care of patients and working towards a more effective and optimised treatment of patients for

the patient's own well-being. In the U.S., this is naturally also of importance, but however, since the sector is being run by a private corporation, the maximisation of profit goal is of dominant importance.

Leading to a shift in proposed value-proposition

In our examinations of the two case companies, we noticed that the fundamental differences between the two healthcare sectors have led to making strategic adjustments to the value propositions of the two companies. Mikkel Wad Thorsen, CEO of Teton.ai, argued that in Denmark, the value proposition that is being sold to potential buyers is the possibility to save nurses' work time, which can release them of their duties, and thus give better care to patients instead of a constant hectic work environment:

"I think probably our best selling feature is gonna be, we're working on something we call an auto documentation, so where our system does the documentation for the nurse. In Denmark that maybe saves a nurse 10% of her work time, which is great. […] So it's all about quality. So you raise the quality because she can do other stuff instead of doing the documentation" (see appendix C).

In the U.S., however, they noticed that this value proposition did not convince buyers. Therefore it was necessary for them to adjust their value proposition. What they discovered was that the proposition of easing the process of conducting documentation for reimbursements showed potential. It is important to document everything regarding healthcare in order to get reimbursement for provided services in the U.S. It often happens that the hospital staff gets into stressful situations, for example, when an emergency occurs, and they eventually forget to document activities. A feature that does auto documentation could therefore ensure the right documentation and the reimbursement of several activities and treatments. So, the value proposition, in this case, is focused on ensuring the right documentation and, thus, the increase of the financial revenue. The product can be used in the same way as in Denmark, but the focus of the value proposition needs to be shifted.

Mikkel Wad Thorsen explains: "In the U.S., this value proposition does basically nothing. I mean it's fine, but it's not gonna move the needle. But what the product can do is that, if we can do more consistent correct documentation and we don't forget to do it and it's timely, you can get reimbursement for all the things that we document. […] That also increases the

quality and although the metrics that they're trying to figure out. So it's the same product, but the value proposition is wildly different, just because of the system" (see appendix C).

For Radiobotics, it was also necessary to adjust the Value Proposition they pursued in the U.S. market. Stine Mølgaard Sørensen explained how they realised it is furthermore necessary to differentiate the value propositions they proposed to different potential buyers:

"So if you go to the payers, the insurance companies, they're very keen to hear about this (red. minimising CT scans) because that's exactly what they want, but then you go to a smaller radiology department and an imaging department, so to they are there to make money. Then you talk about the efficiency so you little bit choose your value proposition of who you speak to" (see appendix B).

It is an interesting finding that there is even a difference in the value proposition that needs to be presented to convince the buyers, depending on the audience you are speaking to. It can still be possible that the product has the same value proposition as in Denmark if it is the right audience that needs to be convinced. But it can also appear that the startups need to adjust the value proposition that their product has in Denmark to the U.S. market, and after that, they may need to change it again depending on the target group of buyers they are perceiving.

5.4.2 Background Institutions

As we have previously covered, new emerging technologies, such as AI, that are expected to have a fundamental impact on a wide range of societal functions can come with a certain degree of scepticism and lack of trust in societies. When examining the public's opinions about AI technology, it appears that Danish citizens, in general, are more open to these technologies compared to citizens in the U.S. The reasons for this are the relatively high degree of digital literacy in the Danish Society, having citizens that have been quite educated in digital technologies, as well as generally being very digitalised. This has, without a doubt, shaped the attitude of Danish citizens to be open to new technologies. However, it appears that U.S. citizens are more critical - especially less educated people, and the older generation is sceptical towards AI (see chapter 4.2.2.1.). This is a more general challenge for all companies operating within the field of AI and not only one for startups entering the U.S. The scepticism and lack of trust usually result from a lack of understanding of these technologies in the society. This can also be seen inside the hospitals in the U.S. Hospitals that already have experience with AI-

based products are more towards these products because they know how to implement them in the existing processes, they know the value this technology and its products can bring, and they know what factors need to be considered when buying it (e.g. data protection rules). Hospitals without having experience with AI-based products are often more reluctant to buy these products. They do not know how to implement the products in their existing processes, and they do not know who is responsible for it - if it is the IT department or the doctors and is therefore sceptical and insecure about how to deal with these products.

Stine Mølgaard Sørensen evaluates: "But what we see in the U.S. is that those, if you're more likely to find a hospital that work with AI before so they at least know how to ask the right questions, they have gone for an implementation process. They know what worked before, they know what all these ISO-standards and all of these things mean so that it's easier to go through. […] We find that we are going to the radiology department or you will go to the quality department or you will go to sort of a more average service department or the IT department" (see appendix B).

Another factor that increases the lack of trust is the non-standardised regulations regarding AI. The government set up initiatives and expert groups to work on the topic and how to deal with it, finding the right regulations (see chapter empirical evidence). Thus, the utilisation of AI technology within healthcare is slowed down because of a lack of understanding and trust, but it can be expected that the regulative environment of the AI-HC industry will stay dynamic, and companies operating in this industry need to be reactive to possible changes regarding existing or new regulations.

An important factor in the U.S. market is the reputation of a company, especially when operating within the field of AI, due to the lack of trust and general scepticism. A startup entering the AI-HC market in the U.S. is usually unknown and has no reputation in the market, while it probably already has a reputation in Denmark due to already working with hospitals. Therefore, it is difficult to establish themselves and build up a good reputation. Only with good reputations, the distrust regarding foreign startups will be removed. Since the deals in healthcare are usually quite huge and have a long runtime, the hospitals do not want to risk a deal with an unknown foreign startup. Building up a reputation is perceived as a huge challenge for foreign companies, especially for small companies like startups. These startups need to provide much better products than the already established companies in order to get attention from larger

potential buyers, like huge hospitals. But there are companies that are willing to set up deals with startup companies, like Ensign Group with Teton.ai (see appendix C).

Mikkel Wad Thorsen says: “Alright, one thing is that nobody knows who you are, right? So you have zero reputation in the U.S. Even when you don’t have any cases in the U.S., it’s really hard because whenever we do something in Denmark, the hospital always calls the hospitals that we are working with, […] and you get a recommendation from them. But you have nothing in the U.S. […] So that’s a big, big barrier” (see appendix C).

Especially in the healthcare industry, Mikkel Wad Thorsen perceives the hurdle to get into the industry as high since he sees the healthcare industry as one of the most sticky and hardest to get into. He also adds that a lot of larger hospitals do not take them into consideration as a potential partner because they perceive it as too risky to work with a small Danish company

He states: “So that’s definitely a big hurdle and I think we probably get passed by a lot of larger hospital organisations just because the thought of working with a small Danish company is terrifying for them because then a lot of other risk factors appear” (see appendix C).

These risk factors could be, what will happen when the Danish company leaves the U.S. market and what will happen if this small Danish startup will not succeed and needs to shut down its business. When working with larger companies, it can be assumed that the trust is usually higher due to the expectation of having a solid business and financial resources.
But as already mentioned before, there are larger hospital organisations that are willing to work with smaller foreign companies if they see their product as valuable. This is the case with Teton.ai and Ensign group.

Mikkel Wad Thorsen comments on this possible deal: “For example, the deal that I’m trying to structure here with Ensign Group is that pull together some funds from 16 different facilities and we test it in one facility and if the results are good there we can then expand. So it’s a fairly low risk deal for them and it has high potential for us. […] we prove the values there” (see appendix C).

But the big hospitals, like Houston Methodist, want to get the product and do not want to have to test it first, get needed approvals and these things. To do deals with these big hospitals, Teton.ai lacks credibility and reputation at this point.
If Teton.ai can close the deal with Ensign Group, it will most likely improve Teton's reputation, and they potentially get access to other potential buyers since Ensign Group is huge, and many other companies will possibly draw their attention to the Danish startup that is selling their product to a huge healthcare group like Ensign.

This challenge was not as huge for Radiobotics because of their participation in the TMCx program. This program is done by the Texas Medical Center, which has a good reputation in the U.S. and thus, participants get on the radar of other companies in the U.S. that are looking for new products within healthcare. Only 5-6 companies get the chance to participate in the program that chooses new participants every six months, and more than 500 companies apply for it. Therefore, it was prestigious for Radiobotics to get accepted by it. The program gives participating companies the chance to meet partners, advisors and all people you need to know to start your business in the U.S. Thus, it can be concluded that Radiobotics did not have the big hurdle of earning reputation and credibility as Teton.ai had.

The findings of our analysis enable us to adjust the figure we used in the previous sections in order to provide an illustration of the most impacting institutional characteristics of the groups of proximate and background institutions and the effect they have on the companies. Thus, Figure 6 presents the institutional characteristics that we identified as being most relevant and that the group of background and proximate institutions are shaping the two business system characteristics of focus of the two case companies.

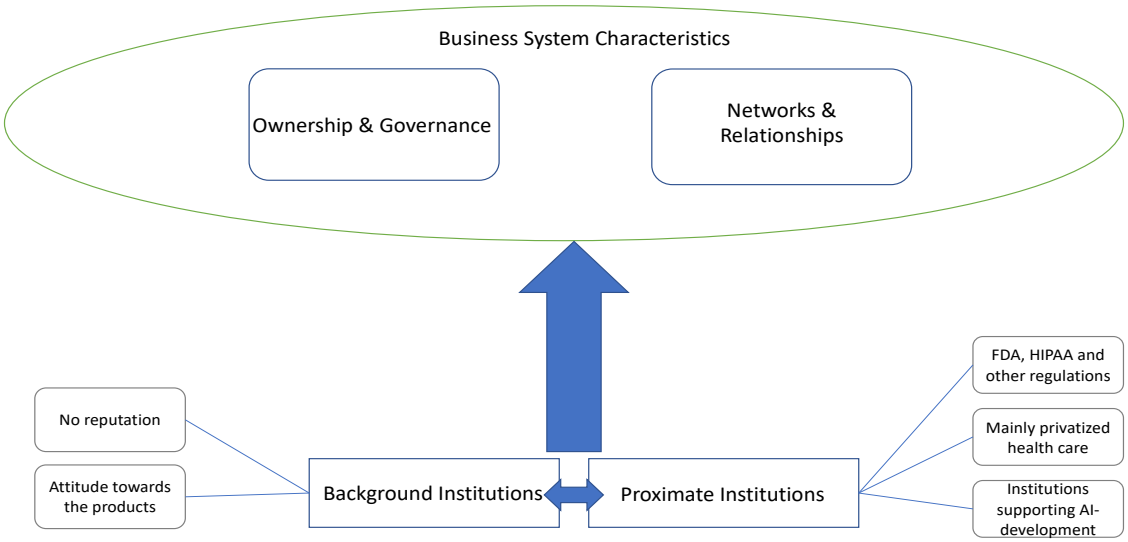


Figure 6: Institutional characteristics we identified with major impact that shape the companies' selected business characteristics (developed by authors based on Whitley, 1992; Rana, 2014)

6 Discussion

The aim of the discussion is to put the findings of the paper into a theoretical context and to further demonstrate our contributions to what we have identified as a gap in the literature, namely the lack of research within the field of internationalisation of AI-driven healthcare startups. We will discuss if our findings of the analysis of the two case companies, in connection with the rest of our findings in this paper, are applicable for the whole category of startups or if these are individually shaped results. This is important in order to evaluate the answer to the research question and find out if further research is needed in order to draw a conclusion for the whole group of startups entering new foreign markets within the same conditions as the ones examined in this paper.

The literature on Business System Theory suggests that firms from the same home country will act similar to a certain degree when entering new markets (Whitley, 1992). Our findings, however suggest that this hypothesis can be partly refused for the two case companies we analysed.

6.1 Institutional Characteristics in Denmark shaping the emerging AI-HC sector

As mentioned above, Whitley (1992) states that companies from the same home-country act similar to a certain degree when they enter new markets. As a result of this, it can be assumed that institutional characteristics of the home-country influence the companies and their approach towards internationalisation. Thus, we want to discuss the impact of institutional characteristics on the home-country context in general and how institutions are underpinning internationalisation in particular in order to be able to give an answer to our first sub-research question. We will do so by wrapping up our findings of how the institutional characteristics in Denmark shaped the two case companies and if any of the institutional characteristics underpinned them in their wish to enter foreign markets. This will help us to understand to which extent the two case companies reacted differently to institutional characteristics in Denmark and if and how several institutional characteristics underpinned the approach of internationalisation of the two case companies.

As the Literature Review shows, the institutional context of the home country and the host country is perceived as a critical market condition for economic growth and development for companies operating within these and have an impact on the companies' strategy (Glückler, 2020; Feng & Genna, 2003). Therefore, we want to first discuss the impact of the home-country institutions in Denmark in general, as well as in particular on our case companies.

Regulations, as a part of proximate institutions, are setting the regulatory frame for companies that operate within a market. These regulations can put pressure on the companies to adjust their strategical approach and/or products to meet several regulations. Some regulations are essential to meet in order to be able to market the product in the country. We identified the data protection regulations, GDPR, and the European CE mark as important regulations for operating in Denmark. Companies are taking different approaches to these regulations; some are pursuing a proactive approach by developing their products and adjusting them in order to meet these regulations, whilst other companies are taking a more reactive approach by developing their products in a certain way to stay outside of these regulations. Our two case companies show these different approaches, Radiobotics' products meet the regulations, while Teton.ai designed their product in a way to stay outside of these regulations and try to be as less regulated as possible.

Furthermore, institutions in Denmark that support AI-Development, like the Danish strategy regarding AI development launched by the Danish government or institutions like the Copenhagen HealthTech Cluster, are shaping proximate institutions and are indirectly influencing and supporting Danish healthcare startups by pushing the development and establishment of AI-driven products in general, as well as specifically in the healthcare sector, and providing the companies with opportunities to develop and test their products in a real-life clinical context.

Teton.ai had the possibility to develop and test their product *Nightingale* in a clinical environment without it working at all. This was a perfect opportunity for the company to develop and adjust its product to clinical challenges that may appear in daily use. It can be argued that this opportunity was indirectly pushed by the initiatives the Danish government set up to push the development of AI-driven products.

By getting this opportunity, the company was able to develop its product and get it ready for foreign markets. The governmental support for the development of AI-based products increases the pace of AI development, attracts companies to start doing business in Denmark, and helps companies to further develop their products. This leads to an establishment of the companies in the market, and it can be argued that this increases the wish to enter foreign markets because of the validation of the value proposition of the products and establishing their business and products, which is likely to lead to an increasing wish of further growth.

This leads to another institutional characteristic that has been shaping the two case companies. The structure of the healthcare sector in Denmark. Healthcare is provided for free to all citizens by the Danish government, indirectly paid by the citizens by the relatively high tax rate. The healthcare system is mainly organised by the five regions of Denmark. These regions are responsible for decisions and control of the budget within hospitals of their region. There are also hospitals and clinics that are privatised and do not fall under the category of free healthcare. At these locations, the patient has to pay him-/herself for the services.

Since the hospitals and clinics that fall under the category of free healthcare are not dependent on making as much profit as they can, the quality of healthcare and optimisation of products and processes is the main priority.

Teton.ai is a good example to show what is meant by that. Since the product has a feature that is doing auto-documentation, the nurses do not need to do that anymore, and it saves their work time that can be used to do other things, for example, treatments. This leads to an increase in the quality of the nurses' work and, thus, an increase in the quality of healthcare.

The need and wish for products that can optimise current processes and increase the quality of healthcare are highly wanted in Denmark. This can lead to a shape of companies' approach in the Danish market. Danish startups that are developing their product in Denmark want to meet these needs and wishes in order to establish themselves within the Danish healthcare market and be successful. Therefore, the value proposition of the developed products will mainly be to optimise processes and increase the quality of healthcare.

Our findings in chapter 4.2.2 show that the general attitude, public and political, towards new technologies, AI in our case, is positive. Since Denmark is one the most digitised countries worldwide, Danes are used to digitalising processes, and the government's initiatives towards pushing new technologies like AI are strengthening the trust in the potential of the field. Even though the attitude is mostly characterised as positive towards AI, studies indicate that the discussion of this topic should be improved to ensure this general attitude. Experts are worried that the general attitude could change and drift more into a sceptical attitude if the public discussion is not improved. For now, the overall positive public attitude results in Denmark being highly attractive for companies that are operating within the field of AI. The general attitude towards new technologies plays an essential role since it can regulate the demand for types of products within this field. This is seen as an institutional characteristic that has a positive impact on our case companies and pushes them to further develop and establish their startup companies, as well as explore new markets after establishing and being successful in the Danish market.

To sum it up, it can be seen that there are several institutional characteristics that are shaping the companies within the market. Some characteristics, like institutions that support AI development or the general attitude towards AI, influenced the two case companies in the same way by strengthening the institutional environment of the country. Other characteristics, like regulations in the market, shaped our two case companies differently. While Radiobotics developed their products in a way that met regulations regarding data protection and got approved by the CE mark, Teton.ai tried to stay outside of these regulations and developed their product in a way that is as less regulated as it can be. Here the two case companies reacted differently to the institutional characteristics. Even though we see similarities in the shape of the two case companies by institutional characteristics, we also see differences. The approach of Teton.ai is fundamentally different from Radiobotics' one towards regulations, and it can

therefore be argued that they are not acting similar to some degree, they are acting completely different in this case.

6.2 Home-country institutions underpinning internationalisation

To answer the sub research question of how home-country institutional characteristics underpin internationalisation, we will sum up and discuss our findings in chapters 4.1 and 5.1.

The Danish Life Science strategy aims to support the internationalisation of Danish companies. One of the goals of this strategy is to diminish existing barriers that are stopping Danish companies from entering a foreign market and establishing themselves there. In the empirical evidence chapter, we identified four primary barriers that are typical for AI-HC companies internationalising: legal and regulatory challenges, data challenges, organisational and financial challenges, and social challenges (Deloitte, 2020). These barriers can also be seen in the U.S. market; one of them is the FDA regulations. The Danish Medicines Agency, *Lægemiddelbestyrelsen,* established cooperation for mutual drug control with the U.S. Food and Drug Administration, FDA. This cooperation allows both parties to build on the works of each other and can therefore save time and resources in the process of FDA application for Danish companies. Since we identified the FDA approval process to be quite complicated, time-consuming and potentially expensive, this cooperation can lead to a decrease in the barrier that the FDA approval is building and can enhance Danish companies that were concerned about the approval process to take the initiative and start entering the U.S. market.

Another goal of this strategy is to have a more proactive approach towards internationalisation. The Danish Government is supporting Danish companies to internationalise by setting up a wide international network of Trade council offices located all over the world. These are offering local support in foreign countries for Danish companies entering a foreign market by providing valuable information about regulations, connecting them with potential stakeholders, as well as increasing the companies' reputation in the foreign market.

Another positive aspect that Denmark is offering is the opportunities to develop AI-driven products in the healthcare sector. As one of our interviewees, Mikkel Wad Thorsen, explains, Denmark is a good country to start your business (see appendix C). His company, Teton.ai, got the opportunity to develop its prototype further in a hospital, without it working at all. That

provides value for the company since they can test their product in a clinical environment and adapt it to challenges that appear in the daily use in practice.

The first sub-research question of home-country institutional characteristics underpinning internationalisation of Danish startups can be answered by concluding: We found strong evidence for institutional characteristics underpinning internationalisation by providing local support in the foreign market and the aim to diminish existing market entry barriers.

6.3 Institutional characteristics are shaping the choice of entry mode

The previously conducted analysis identified similarities and differences in the approaches undertaken by the examined companies when entering the U.S. market. Both companies pursued a slow-paced penetration, where they chose to keep the degree of risk and commitment as low as possible whilst exploring the market opportunities in the market. However, our findings indicate that the institutional characteristics in the U.S. lead to some similarities in the approaches of the companies. The most dominant difference was that one of the companies chose to establish a physical presence on the market, whilst the second company decided to only pursue operations from the headquarters in Denmark without a physical presence in the U.S. This difference is a direct consequence of the FDA regulations since the products of the companies falls within different classifications when entering the U.S. market. For firms developing products that fall within the scope of FDA regulations, it is necessary to have a physical presence in the U.S. market to go through with the application process. However, if pursuing a product strategy where the company is deliberately pursuing to develop products that do not need an FDA approval, you can slow down the pace even further and explore the market without having the necessity to establish a physical presence whilst exploring the market and take initial contact to potential buyers.

Our findings also identified a difference in attitude towards entering partnerships in the U.S. market, as well as the necessity of gaining access to local knowledge of the market. Whilst both companies appeared to be quite open to establishing contacts in the U.S. that could increase their knowledge of the market, the concern of one firm to losing ownership appeared to lead to an attitude that made them more reluctant towards entering partnerships.

Radiobotics showed quite an interest in entering partnerships – and did not appear to be that concerned about potentially losing ownership shares if the right partner came along. This company also recruited American people with distinctive insights into the U.S. healthcare

industry into the Board of Directors. However, Teton.ai appeared to be quite constrained regarding the possibility of entering partnerships – although they seemed to be open to the thought of using partnerships to increase their knowledge of the market, they appeared to be very negative about potentially losing ownership to enter such a partnership. As a startup with limited financial resources, it can be challenging otherwise to persuade potential partnerships.
The literature we have reviewed in this paper indicates that startups entering new markets are facing multiple challenges. Amongst the challenges startups face, we see the lack of trust by clinical stakeholders towards startups and their sufficient clinical credibility (Young, 2022) as a major challenge. Here, we believe that entering a partnership with a company that is embedded in the U.S. business system definitely could help to increase the reputation of Teton.ai and open up opportunities that would be difficult to pursue otherwise.
By being a startup that is reluctant to have a physical appearance until they have explored the market opportunities very closely and the market has proved too profitable, as well as having a negative attitude towards entering equity-based partnerships, we believe Teton.ai is decreasing its possibilities of success.

Besides our findings regarding institutional characteristics that have shaped the physical presence of the firms, as well as attitude towards partnerships, our findings also indicate that in the case of Radiobotics, an accelerator program was crucial to the timing of market entry for the firm – not only was the accelerator program crucial for timing, but it appeared as this accelerator program gave the startup the final push to believe in their product and decide to pursue their U.S. adventure.

Overall, it can be said, the entry modes of the firms have similarities regarding the degree of pace, risk and commitment to the U.S. market. However, there are specific institutional characteristics in the U.S. market that did lead to differences in their entry – specifically regarding the physical presence, timing, gaining knowledge of the market, as well as attitude towards partnerships.

6.4 Host-country institutional characteristics shaping strategical approach

Our third sub research question aims to identify how host-country institutions are leading to adaptations of the strategical approach of foreign companies. Our findings show that there are several institutions that are putting pressure on entering companies and shaping their strategic approach.

When foreign companies enter a new market, they need to deal with a new institutional environment consisting of various factors. The findings of our paper show that companies are dealing and adapting differently to these pressures.

We identified several institutional characteristics that are shaping the companies' strategical approach: regulations, especially FDA and HIPAA; the construction of the healthcare sector in the U.S. (mainly privatised); institutions supporting AI-development within the country; and the attitude (public, buyers' and political) towards AI.

We will discuss how the two case companies of our paper got shaped by these institutional characteristics and how they adapted their strategical approach as a response to these institutions.

Regarding regulations, the main regulative pressures are caused by FDA and HIPAA, and the two case companies chose different approaches. In general, there are two ways of dealing with this topic, while these ways can vary in detail. One of them is taking a proactive approach by informing about the regulations and how to meet them in order to get the products approved. One of our case companies even hired consultants that help them with this topic by making sure the approval process will work, and all needed documents and adjustments of the product are in place. This could be a problem for other startups that may not have the financial resources to hire consultants since good consultants usually demand high prices in the U.S. Additionally, they have to make small adjustments to their product in order to meet the demands of an FDA categorisation for the specific FDA classification process.

The other option is to take a more reactive approach and deal with these regulations when they occur as a problem. Additionally, some companies, like one of our case companies, may develop their product in a way to stay outside of these regulations. This is usually done for the home market but can appear as a problem when they enter foreign markets.

Another institutional characteristic that can lead to adaptations of the companies' strategic approach is the construction of the healthcare sector in the U.S. Since the sector is mainly privatised, healthcare providers, like hospitals and clinics, are reliant on making a profit. Thus, these providers want a different kind of value proposition than in public healthcare sectors, like in Denmark. This can lead to a change of the intended use of the product, adaptations of the product, or only the presentation of the value proposition of the companies to potential buyers. Our findings show that the case companies reacted differently to this pressure. One of them only had to change the presentation of the value proposition, while the feature of the product stayed exactly the same as in the home country. The other company made small adjustments to

their product in order to stay inside a product category and meet a demand for products that are used in clinics and hospitals and not mainly in research.
Our findings imply that the adaptation of the value proposition to the differences in the construction of the healthcare and the resulting change in the value demand can be quite easy to deal with by making changes in the presentation of the value proposition - but can also be more challenging if adjustments of the products are necessary in order to create a suitable value proposition for the foreign market.

We found that there are institutions that are supporting AI development in both countries. In chapter 6.2, we have already evaluated the Danish institutional characteristics that underpin internationalisation. Here we will focus on the impact of institutions that are supporting AI development within the U.S. and if and how they are impacting the companies operating in the market.
The U.S. is known to be the base for many big and well-known technology companies, like Facebook. Silicon Valley is probably one of the most famous areas for technological development. The U.S. also has several regions where many health companies are based and created a community. These communities are providing foreign companies with a good opportunity to establish contacts and get access to a valuable network. Additionally, these communities, also called clusters, are increasing the pace of development by working and supporting each other.
Other factors that are supporting the development of AI are accelerator programs and Think Tanks. Accelerator programs provide foreign companies, as well as domestic companies, with a good opportunity to get access to market knowledge, make their products ready for the market, establish valuable contacts, as well as get consultancy regarding different topics.
Our analysis shows that these institutions can shape the strategic approach the entering companies are pursuing by impacting factors like the entry mode, the access to market knowledge, and the timing of the market entry. Therefore, these institutional characteristics should be taken into account when pursuing a market entry into the U.S.

The last institutional characteristic we are discussing to answer the sub research question is the background institutions. As covered in this paper, new emerging technologies usually come with a certain degree of scepticism and a lack of trust in societies. Companies and their products that use emerging technologies, like AI, can be affected by the public and politics towards the technology.

Our analysis of the background institutions in the U.S. shows that U.S. citizens perceive AI more critically than Danes. For example, hospitals that did not work with AI-based products before do not know what factors need to be considered, how they will be implemented in the current processes and who is responsible for it. Non-standardised regulations additionally lead to insecurity within the society. This can be a barrier for foreign countries entering the market when the society does not even trust domestic companies within this sector. The Danish and the U.S. Government are addressing this challenge in their countries by their publication of strategies that aim to support the development of AI and increase the acceptance of AI-based products in the countries.

Another critical factor is the lack of reputation of foreign companies within the market, especially for startups. The case of Teton.ai shows that they perceive this to be a big barrier for them because nobody knows them in the foreign market, and nobody can recommend you and give you a reputation in order to convince potential buyers. Even though there are many hospitals that may not take small foreign companies as potential partners into account, there are big companies that are willing to work together with these, like Ensign Group is negotiating with Teton.ai.

When overcoming the barrier of lacking reputation, foreign companies build the basis of establishing and being successful in the market.

7 Conclusion, Limitations, and Future research

In the last section of our paper, we want to draw a conclusion on our findings by providing a fundamental answer to our research question. Furthermore, we want to describe the limitations this paper had to deal with that needed to be taken into account, and lastly, we want to point out how future research can use the findings of this paper in order to increase the amount of research in the context our paper conducted, and what possible topics future research could try to cover.

7.1 Conclusion

When we began working on this Thesis, we wanted to explore the internationalisation of AI-driven healthcare startups. The motivation was quite simple – navigating in a complex business environment within a highly regulated industry was something we found interesting and thus wanted to explore. Specifically, we wanted to assess the impact of institutional characteristics and *how* or *if* they are leading to shifts in strategy when these startups are entering new markets. Through a comparative case study, we examined how two Danish startups were influenced by institutional characteristics in their adaptions to the U.S. market.

To provide a structured and valuable answer to our research question, we decomposed the research question into three sub research questions: Firstly, our aim was to assess if Danish institutional characteristics were underpinning the internationalisation of AI-HC startups. Secondly, to assess if host-country institutions are impacting the choice of entry mode, whilst thirdly, whether host-country institutions are leading to adaptations of the strategical approach.

Our findings overwhelmingly suggest that host-country institutional characteristics shaped both the choice of entry mode of the examined firms as well as it led to adaptations of their strategical approach.

Furthermore, we found evidence for Danish institutional characteristics underpinning internationalisation. There is a focus in Denmark on developing the AI-HC industry, and there has been strong progress within this area over the past years. We found Danish institutions directly underpinning the internationalisation of Danish startups by the Danish government putting efforts and strategies in place to encourage companies to internationalise – this is being done by the federal government directly working towards diminishing entry barriers to foreign markets, as well as establishing a strong network of Trade Councils that are represented at Danish Embassies and Consulates around the world, that are offering local support for Danish companies when entering these markets.

Our examination of the impact of host-country institutional characteristics on the choice of entry mode and strategical approach of the companies in the U.S. shows that host-country institutional characteristics led to shifts in the approach for Danish companies entering the U.S. market.

The analysis of our two case companies resulted in showing similarities in the approach of choosing the entry mode by focussing on pursuing a low degree of risk, commitment, and pace to the U.S. market. However, we found that there are specific institutional characteristics in the U.S. that had a direct impact on the choice of entry mode. Specific FDA regulations demand a physical presence in the U.S. to be able to receive FDA approval for products. In addition to that, other factors of the market entry like timing, access to market knowledge and the attitude towards partnerships vary in our results of the two case companies because of the different levels these companies were shaped by institutional characteristics of the U.S. market.

In addition to that, our findings show that several institutional characteristics of the U.S. market are shaping the strategical approach of foreign startups when entering and establishing the market. Our results identified four categories of institutional characteristics that are having the most impact on the foreign companies' strategical approach to the U.S. market: regulations, primarily FDA and HIPAA; the construction of the healthcare sector; Institutions supporting AI-development; and the general (public, political, buyers') attitude towards AI technology.

Regulations led to adjustments of the products' features in order to get into a specific category of products that results in a different approval process for the FDA. The complicated FDA approval process additionally led to a shift of the strategical approach to overcome this barrier by hiring expensive consultants that provide support in the FDA approval process.
Although the strict GDPR regulations that the startups already were compliant with in Europe made the startups well prepared to handle the HIPAA regulations in the U.S., our findings indicate that it was necessary to conduct minor shifts in the attributes and features of the companies' products to meet data protection regulations in the U.S.

In addition to that, the construction of the U.S. healthcare industry forced the Danish companies to shift their products' value proposition to meet the buyers' needs. The privatised healthcare industry in the U.S. demands most healthcare providers generate profit. Thus, their main goal is to increase their profit by buying new products and not only increasing the quality of

healthcare, as is the goal in Denmark. This led to slight adjustments to the intended use of the product, as well as a change in presenting the products' value proposition to the audience of potential buyers in the U.S.

Furthermore, we found that there are institutions that are supporting AI development and influencing the companies' strategic approach to the U.S. market.
The U.S. has a strong reputation regarding health-tech development, and several health-tech communities are based in the country. This provides an opportunity for foreign companies to establish valuable contacts and become part of a network, resulting in a faster adaptation to the market and establishment within the industry.
Other factors that are supporting the development of AI are, for example, accelerator programs. These provide foreign companies, as well as domestic companies, with a good opportunity to get access to market knowledge, make their products ready for the market, establish valuable contacts, as well as get consultancy regarding different topics.
Our analysis shows that these institutions can shape the strategic approach the entering companies are pursuing by impacting factors like the entry mode, the access to market knowledge, and the timing of the market entry. Therefore, these institutional characteristics should be taken into account when pursuing a market entry into the U.S.

Lastly, our findings indicate that the attitude (public, political, buyers') toward AI-enabled products shapes the companies' approach to the market. The attitude towards AI-enabled products influences the determination to use these products and thus has an impact on the market interest in the products.
Emerging technologies like AI are especially connected with a degree of scepticism – which is why this needs to be addressed to improve the attitude towards these products.

Our findings further demonstrated that it could become a challenge for the examined Danish startups to win over their first potential clients – we identified that there is some constraint in the healthcare community in the U.S. towards even domestic startups, who question whether the startups' solution has sufficient clinical credibility. We, therefore, believe it is important for Danish companies to enter partnerships in the U.S. to increase the degree of trust and reputation of the firms.

7.2 Limitations

The research has encountered limitations in regards to methodology and data collection which is important to address as it can have an impact on the ultimate validity of the conclusion. Firstly, the amount of cases available for the data collection is notable. Even though a conclusion has been possible to draw, a deeper and more valid conclusion could have been made with more case companies to analyse. It is important to obtain enough cases and data for our study as we are trying to make a generalisation of the impact the host countries' institutions have on the Danish AI-HC startups. In the beginning, the study would have consisted of at least three interviews with Danish AI-HC startups and one with the sector expert; however, due to illness and circumstances outside of our control, the third company had to cancel the interview and has then been left out of the study.

Secondly, another limitation has been time – time is a constraint as there has been a deadline for the study to be completed within. The time constraint played its part when reaching out to potential case companies as some could not make it in a reasonable time of the deadline to assist with data for our paper. Having more time would have made it possible to increase the data for our analysis, and make it possible to propose a more valid answer to our research question.

Thirdly, the limitations of our selected case startups come into play as they are all from the same domestic market. This limits the validation of our findings to be relevant for Danish AI-HC startups and startups from markets similar to the Danish. Having AI-HC startups from other domestic markets could help generalise a broader aspect of the research question. The impact of the institutional characteristics could be different for AI-HC start-ups from other countries or when trying to enter less established markets. The research would therefore benefit from further research with more cases from different markets, e.g. emerging, developed, etc.

7.3 Future Research

For future researchers, it could be interesting to further validate the results of our study with even more case studies and implement cases from different markets, both domestic markets of origin and foreign markets as destinations.

In our initial research on the topic of how institutional characteristics shaped AI-HC startups' internationalisation process, we identified a gap in the literature on this matter. Although research has been conducted on these topics individually, we found that there has been conducted a very limited amount of research that involves all these concepts. Our aim has thus

been to facilitate a starting point for this research topic, which can function as a foundation for further research on this topic in the future. Although our research was based on two startups, we believe that we have been able to make some generalisations and show some trends that are contributing to this area of research. Future research needs to include more startups, as well as other institutional settings, to gain a bigger picture of this topic. Since the BST literature suggests that companies with origins from the same home-institutional environment behave in similar ways, it would be interesting to conduct an analysis with countries from various home-country institutional settings and assess if these startups are acting in similar ways in the U.S. market. Furthermore, we believe the U.S. economy can be defined as a developed economy. It would also be interesting to expand the research into emerging markets and assess if there are similarities.

8 References and Appendices

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8.2 Content of Appendices

Appendix A-C: *List of interviews*

List of interviews				
Interview	**Company**	**Type**	**Date & Venue**	**Appendix**
Christina Brinch Clark	Danish Trade Council	Prelimenary study	March 31 - Microsoft Teams	A
Stine Mølgaard Sørensen	Radiobotics	Case company	April 29 - Google Meets	B
Mikkel Wad Thorsen	Teton.ai	Case company	April 25 - Microsoft Teams	C

Appendix D: *Template of interview guide for preliminary interview with Christina Brinch Clark*

Appendix E: *Template of interview guide for case companies*