Ahead of the curve - healthcare AI start-ups:

Changemakers for adoption and normalization of AI in the healthcare industry

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Abstract:

This thesis investigates healthcare AI start-ups as changemakers to build adoption for AI in healthcare. Most industry observers agree – the benefits of AI are large in healthcare, but adoption thus far is slower than in other industries. Why is this the case?

Research questions: which challenges do healthcare AI start-ups face as they attempt to develop and create adoption for their products? Why do these challenges occur? How and why do the challenges change over time?

Findings: Healthcare AI start-ups face challenges with (1) *product-market fit, (2) data and technology, (3) regulation management, (4) organization and talent, (5) low customer readiness for AI*. These challenges occur at different stages of the product development process. These challenges occur because AI is a new practice that has not been normalized in healthcare operations. Medical professionals and other decision-makers struggle to understand what AI is, the benefits it can create, and how to implement AI in their operations).

Keywords: healthcare, artificial intelligence, start-ups, diffusion of innovation, normalization

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1. Introduction

1.1. Artificial Intelligence start-ups: changemakers for the healthcare industry

Artificial Intelligence (AI) is a growing technology bringing big changes across industries. AI promises big improvements for the healthcare industry; however, adoption is slower than many other industries despite healthcare seeing large investments into AI start-ups. We set out to explore this occurrence by looking at healthcare AI start-ups – a group of small nimble companies that build AI software for healthcare. What challenges do they face as they try to build a business and create adoption across the healthcare industry?

1.2. Artificial intelligence in a nutshell:

AI are mathematical/statistical models that learn how to predict outcomes based on training data. The applications of AI include visual recognition (e.g., used in manufacturing to automatically detect faulty products), natural language processing (e.g., reading text and predicting the sentiment – positive or negative – in media articles), and machine learning (e.g., training on data to predict potential illness)

Between 2011 and 2019, funding for AI start-ups worldwide increased from near zero to nearly $30 billion and is estimated to grow (Venture Scanner, 2020). According to McKinsey Global Institute, $26-39 billion was invested in AI in 2016, which tripled compared to 2013. (Bughin et al., 2019) Sweden had 183 AI start-ups in 2020, ranked number one out of the Nordic countries (Tracxn Technologies, 2020).

In 2020, Swedish people believe that work efficiency, improvement in social services quality, and everyday services (shopping and transport) are the top 3 positive effects that AI has created.

16% of 256 decision-makers in companies surveyed in 2018 perceive AI-based business models and services to be the most important topic in AI.

One industry where AI will have a significant impact is healthcare. In Sweden, 18% out of 1000 respondents reported using healthcare apps daily (Statista, 2018). Worldwide in 2019, there were 386 deals where AI healthcare companies received funding, up from 121 in 2015 (Statista, 2019). 96% of experts questioned by McKinsey in October 2017 identify healthcare and wellness as an industry where AI will have a large impact – ranking first before any other industries.

70% of life sciences companies – surveyed by the Healthcare Financial Management Association, HFMA – have implemented an AI strategy. For healthcare employers at large, 58% have implemented an AI strategy. According to HFMA, healthcare organizations are now starting to build AI literacy with their staff. (HFMA, 2020).

1.3. Applications of AI in healthcare

The idea behind AI is to provide each patient with highly tailored medicine and care based on their health data. (Toews, 2020). Patients are now seen as consumers. (Americas, Richter, & Atreja, 2017). Big data and AI enable tech companies to build medical software that can perform clinical image analysis, diagnosing for medical illnesses, predicting illness based on genetics, or suggesting treatment for illness based on a patient's health data. AI is a flexible technology with many uses – both for business-to-consumer (B2C) markets for patients and business-to-business (B2B) markets, e.g., health professionals, insurance companies, or research institutions.

AI is an umbrella term for different technologies including (Reim, Åström, & Eriksson, 2020) natural - language processing (the application of computational algorithms to analyze text and speech) and machine learning and deep learning (training algorithmic models to detect patterns in data and predict outcomes, e.g., the likelihood of cancer tumors based on radiology images of a patient).

The nature of the technologies makes them applicable to healthcare and makes healthcare smarter and more cost-efficient.

In clinical practices, AI can be used e.g. (Miotto, Wang, Wang, Jiang, & Dudley, 2017) on **clinical imaging** (such as analyzing x-ray scans to look for tumors), **electronic health records,** to predict risk for readmission of addict patients or to diagnose patients based on their health data**, and mobile monitoring of patients' health condition** via their smartphones or other wearables and predicting their health situation.

Bhardwaj et. al. (2017) mention four different sectors of healthcare provision that can make use of AI:

Preventive: analyzing big data about patients to predict which patients are likely to get a certain illness and take steps to prevent this. Surgeri.ai performs analytics as a service and can for example help hospitals and authorities analyze covid-related data.

Diagnostic: analyzing big data about patients to predict which illness a patient has based on their symptoms or analyzing medical imaging to determine if there are signs of e.g., tumors, or Alzheimer's plaques. There is a shift towards evidence-based medicine, where data analysis using AI can help practitioners make better diagnoses and treatment decisions, (Bhardwaj et al., 2017). Thermaiscan (2020) has a diagnostic service that helps women self-scan for breast cancer using their smartphones.

Remedial: analyzing big data about patients to predict which treatment would be the most effective given certain symptoms/diagnoses. Droice Labs (2021) has this type of service, which matches patients to the most effective remedies.

Therapeutic: analyzing big data about patients to predict and give advice on which therapies work the best for a specific patient – given their biometric data. Qinematic (2021) and Paindrainer (2021)are examples of this type of company.

AI can help clinicians make decisions based on models that are trained on aggregated data from clinical trials and electronic health records. This can lead to improved health outcomes for patients (Miotto et al., 2017).

The opportunities that come with AI in healthcare include **improved health outcomes**, **direct efficiency cost savings** and that **human capital** can be redeployed to more value-creating tasks (HFMA, 2020). Bhardwaj, Nambiar, & Dutta (2017) describes increasing costs in healthcare as a major reason why AI is growing in importance in healthcare. The authors argue that technological innovation in healthcare can be a fix to the rising costs.

In Garbuio & Lin (2019)'s framework, healthcare AI start-ups can niche on creating value for either patient-focus or provider/payer-focus. For example, patient-focused products usually help with increasing healthcare accessibility and behavioral management, improved patient satisfaction, and patient safety. While provider/payer-focused products are used to increase operational efficiencies of healthcare organizations, help increase the financial and administrative performance of providers/payers(insurance companies).

With AI technology, there's a shift to patient-centered care in healthcare, where consumers as patients have higher control of information and their care delivery (McColl-Kennedy, Vargo, Dagger, Sweeney, & van Kasteren, 2012; Osei-Frimpong, Wilson, & Lemke, 2018; Sandström, Edvardsson, Kristensson, & Magnusson, 2008), whereby AI – through wearables and mobile apps can be used to reduce the information asymmetry between patients and providers, and give patients more influence. (Bhardwaj et al., 2017). In healthcare, the patients' participation helps themselves get better care and treatment and help the system acquire data to further develop the AI software. (Leone, Schiavone, Appio, & Chiao, 2020).

Most observers argue that AI in healthcare has a large potential to improve health outcomes and reduce costs of healthcare. However, AI in healthcare has a far way to go before it can deliver on its promises. According to academic research and business text, the deployment of AI in healthcare has not yet reached full maturity (PwC, 2020; Seneviratne, Shah, & Chu, 2020). Ada, a healthcare AI start-up writes that the "uptake of AI into healthcare settings is too slow to meet ever-growing demands" (Ada, 2020). PwC writes, "AI applications for healthcare are largely in their feasibility assessment stages" (PwC, 2020). Thus, there appears to be consensus in business, academic, and start-up writings that adoption for AI in healthcare is low, but on the rise.

PwC cites low interoperability between data systems as one reason why it is difficult to adopt AI in healthcare. There are many different sources of data, and the coordination between them is low according to PwC. Multiple sources confirm the view that investments into AI in healthcare are growing, but the actual implementation in healthcare appears much slower, for example, Gartner (Deloitte, 2019) who show **that investments in healthcare AI are vast**, and McKinsey (2020) who reversely show that **adoption of AI in healthcare is low.**

It is also difficult to understand what the models are doing, the models are seldom traceable – especially not to an untrained person, professionals do not trust that AI models are accurate – these are just some of the problems regarding AI from a technological point of view (Reim et al., 2020; Seneviratne et al., 2020).

Further, challenges also include strict regulation and clinical effectiveness, and safety demands (Higgins & Madai, 2020). Lacking infrastructure, and low talent availability also make it difficult – especially for small start-up companies to develop. We were interested in further investigating these challenges from a start-up perspective.

Investigating the landscape for AI in healthcare, we have found that an important actor for AI in healthcare is start-ups who build AI to solve a specific clinical problem. There is a similar pattern here as in other industries, where small nimble companies founded on the idea to solve a specific problem are becoming increasingly important drivers of AI in healthcare. This observation made us interested in understanding more about these start-ups and investigating them more closely. We wanted to understand which challenges AI healthcare start-ups perceive as they try to create adoption for AI products in healthcare and to gain some insight into why these challenges occur.

2. Problem formulation

AI is being adopted slowly in the healthcare industry. We are interested in understanding which challenges healthcare AI start-ups – important market drivers for AI in healthcare – face as they attempt to increase adoption.

We choose to focus on start-ups because the conditions for start-ups are different from that of established firms. A start-up is defined as an organization searching for a scalable, repeatable business model. Start-ups tend to focus their resources on fewer, niched products/services, compare Ericsson to Boneprox (2021) for example. Start-ups can use their small scale and agility to pivot to new problems and solutions as necessary (Eisenmann, Ries, & Dillard, 2018). We have identified a vast ecosystem of start-ups focused on solving healthcare problems with AI (DataRoot Labs, 2020), this made us interested in seeing what role these companies have – which could be different from that of large organizations such as Google or IBM who are also developing AI.

Another reason to focus on AI start-ups is the explosion of investments (VentureScanner & Statista, 2020) made into AI start-ups between 2011 (almost 0) to 2019 (almost 30 billion dollars). This indicates that there is a great interest in AI start-ups across industries, thus increasing the relevance of research into start-ups in this field:

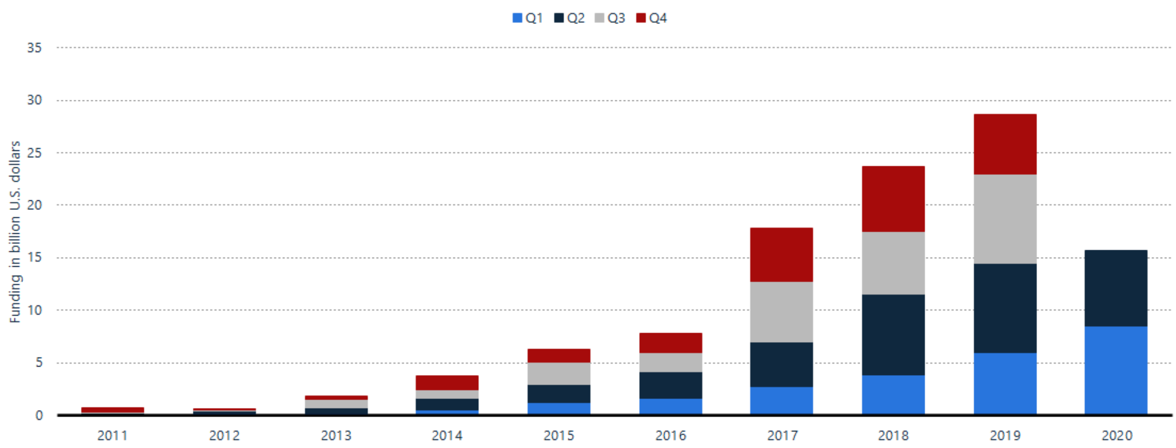


CHART 1 – VENTURE SCANNER & STATISTA TOTAL AI START-UP FUNDING WORLDWIDE

The reason we choose to focus on the healthcare industry is that compared to AI start-ups in other industries such as industrial or telecommunication, is that we see despite big investments being made into healthcare AI start-ups, the adoption of AI in the healthcare industry is the lowest if we compare across industries (McKinsey & Company, 2020):

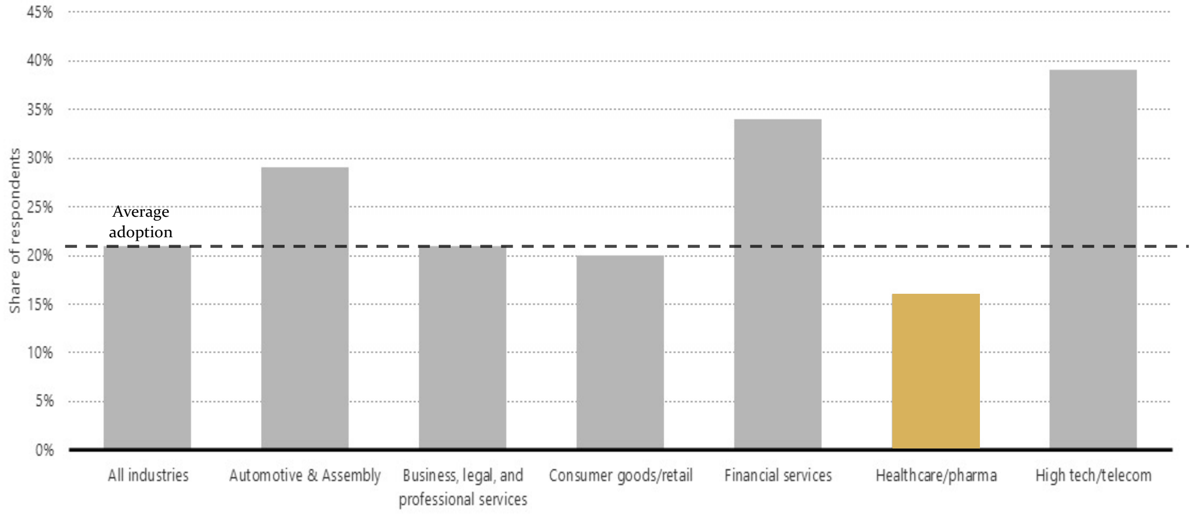


CHART 2 - MCKINSEY'S EVALUATION OF AI ADOPTION ACROSS INDUSTRIES

Using (Robertson, 1967; Rogers, 1995), we can conceptualize AI as being in the very early stages of adoption, with low cumulative adoption, around "early adopters". That would mean, most healthcare providers are just starting to implement AI in their operations.

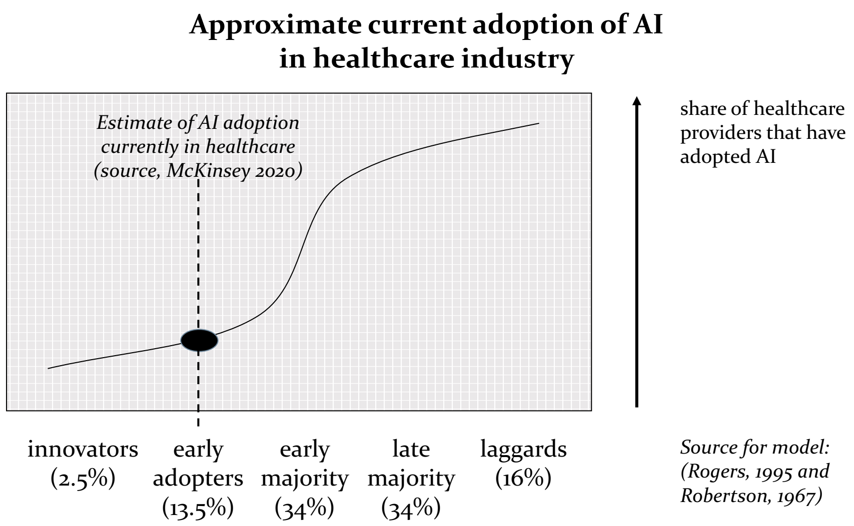


FIGURE 1 - PLOTTING ADOPTION OF AI ON ROGERS' DIFFUSION CURVE

According to Deloitte/Gartner (Deloitte, 2019), investments into healthcare AI ranked #5 across 17 surveyed industries. These numbers beg the question: despite the comparably large vast investments into healthcare AI start-ups, why is the adoption of healthcare AI products lower than comparable industries? Here we have found a problem that justifies the research.

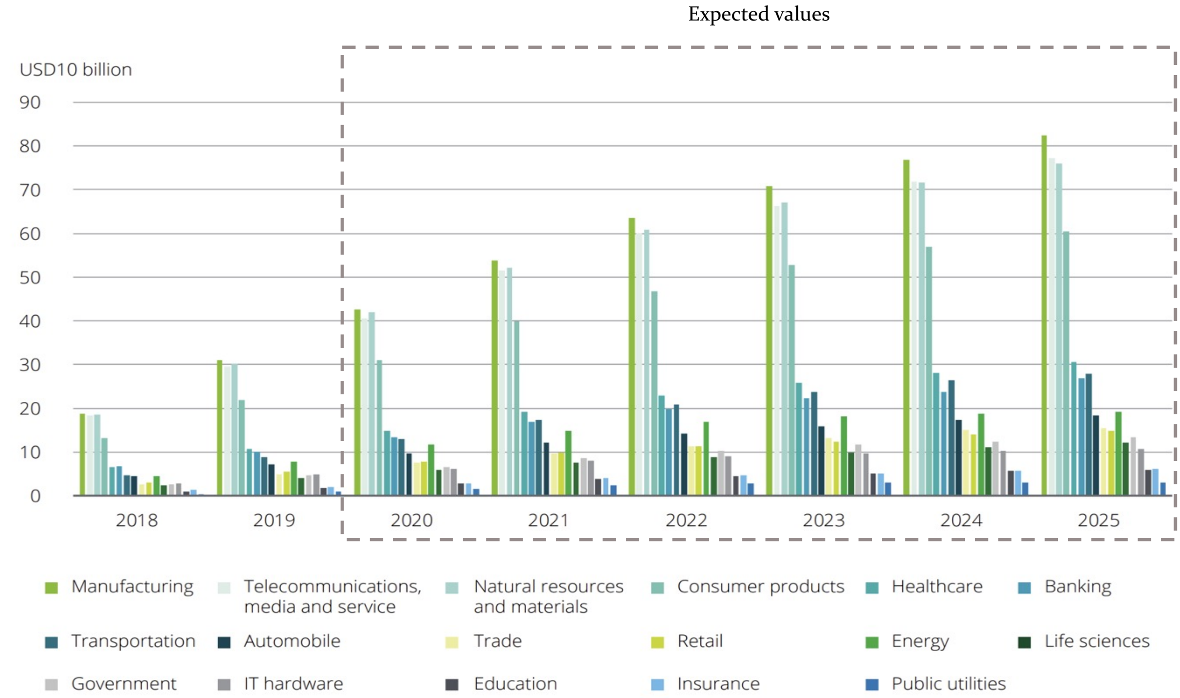


CHART 3 - CHART FROM DELOITTE SHOWING INVESTMENTS INTO AI ACROSS DIFFERENT INDUSTRIES (PROJECTIONS AFTER 2019)

We find that the business and academic literature for AI in healthcare provides a description of which challenges there are to adopting AI in healthcare, and processual models for how new medical products are developed and launched. However, there is a gap in literature focused on understanding why the adoption is quite slow **and the role of AI start-ups – that we have identified as important changemakers in the healthcare system – remains mostly unexplored.**

Furthermore, we have observed in the literature about healthcare AI start-ups that **challenges appear to be dynamic and changing over time** – as a company develops from early formation through to launch of products and beyond (Higgins & Madai, 2020). Therefore, we want to investigate **how the challenges change** over time, **which challenges are dominant at certain stages**, and gain some insight into **why the challenges change.**

2.1. Purpose, aim, and intended contribution

Healthcare AI is seeing large investments, but adoption is still comparably low. Why is this occurring?

By researching which challenges healthcare AI start-ups face, we expect to gain some insights into the specific challenges of creating adoption for AI in the healthcare sector, and why these challenges occur.

2.2. Research questions

- Which challenges do healthcare AI start-ups face as they develop their business?
- Why do the challenges occur?
- How and why do the challenges change over time?

2.3. Delimitations

- As the number of healthcare start-ups is very limited – we have not delimited ourselves to a particular geographic focus.
- General-purpose AI start-ups are eliminated as they are not specifically focused on healthcare topics.
- We only draw conclusions about B2B healthcare AI start-ups. While some of our interviewees are a hybrid between B2C and B2B, they are all B2B, and a majority are B2B only. Therefore, we cannot make any claims about B2C.
- The profit model is viewed as sensitive and confidential information by some interviewees, and thus we have not been able to discuss it with interviewees. We, therefore, exclude it in our analysis.

2.4. Structure of the paper

First, we do a **review into the existing literature** around AI in healthcare, innovation, and business models, then we discuss our **methodology**, after which we focus on **empirics**. We then have a section for **interpretation/analysis of the findings** and a **discussion** about theoretical and practical contribution, after which we end with our **conclusions**.

3. Literature review

This literature review will investigate:

- **Described challenges of implementing AI in the healthcare industry.** What have other researchers given as an explanation for slow adoption in healthcare?

- **What is the process of developing an AI product in the healthcare industry?** To provide insight into the unique challenges that go into developing and marketing an AI product in healthcare, which could give insight into why the challenges exist for start-ups.
- **The process of implementing innovation.** AI can be thought of as technological innovation. **What can prior literature tell us about the process of adopting new technological innovations?** This can give insight as to why challenges occur for start-ups.
- **What is a business model?** To give insight into how challenges can be organized into different internal components of a business.

3.1. Challenges of implementing AI in healthcare

The following table provides an overview of the challenges other studies have described for implementing AI in healthcare:

Article	Challenges	Description
Seneviratne (2020)	Actionability Safety Utility	Machine learning difficult to provide follow-up actions, hard to understand whether a model is correct, and data is accurate, difficulty assessing utility versus the cost of machine learning
Reim (2020)	Transparency, Trust, Data acquisition, Understanding of AI, Revenue	Models must be transparent and traceable, people in organizations do not trust AI, it is a challenge to design a good data acquisition model, people in organizations don't understand AI, it is challenging to create revenue from AI (B2C, B2B, B2G)
Miotto (2017)	Data volume, Data quality, Temporality, Domain Complexity, Interpretability	Big dataset volume, the accuracy of training data, diseases changing all the time, diseases complex nature, black-box problem - low interpretability hard to convince professionals that model is accurate
Quan & Sanderson (2018)	Regulatory concerns	Healthcare is slow to adopt AI because of regulatory concerns

Higgins & Madai (2020)	Clinical, regulatory, data/data strategy, model development	Products must improve health or lower costs, products must fulfill regulations, products must have access to proper datasets and understand the data structure, products must prove that prediction is accurate
Hwang & Christensen (2008)	Fragmented IT systems, Regulatory battles	Low IT coordination in healthcare limits implementation of AI, restrictions on which cost-cutting measures are allowed due to ethics and regulation
Bhardwaj (2017)	Unstructured data,	80% of healthcare data is unstructured
HFMA (2020)	Cybersecurity, privacy, deployment options	Privacy and security of data, companies want all-in-one solutions
Leone (2020)	Support Education Maintenance of customers Building of networks and ecosystems	Companies must successfully overcome the described challenges to succeed with AI

TABLE 1 - OVERVIEW OF ARTICLES DETAILING BUSINESS MODEL CHALLENGES FOR IMPLEMENTING AI IN HEALTHCARE

Summarizing these challenges, we can say that they are largely connected to a couple of key areas:

- **Technical challenges:** e.g., how the organization accesses data and ensures high validity of AI/ML models, ensuring good quality and structure of data.
- **Strategic challenges:** e.g., overcoming problems with fragmented IT systems, which deployment options to use, managing the business ecosystem, managing clinical trials, and certification.
- **Security challenges:** e.g., how to ensure the integrity of data, how to ensure that model predictions are correct to avoid harm to individuals (for example faulty predictions which could lead to misdiagnoses), how to ensure compliance with regulations.
- **Customer challenges:** e.g., how to build trust for the models, how to build understanding for what the models do and the outcomes of predictions (reducing

perceived complexity of AI), supporting and educating customers, maintain customer relationships.

It is important to note – these are challenges in the implementation of AI in healthcare operations, **not business challenges faced by healthcare AI start-ups.**

It appears from our review that major challenges are connected to the product development of AI in healthcare. Therefore, we will now review what has been written about developing AI healthcare products.

3.2. Developing an AI healthcare product is a temporal activity

For the sake of clarity, our definition of AI healthcare product: software that uses data to make healthcare-related predictions. **AI product thus is a software – not a tangible good.**

For AI healthcare product, the product development cycle includes four major domains (Higgins & Madai, 2020)**:**

- **Clinical proof-points:** the products must prove that they either **increase health outcomes or decrease costs for healthcare providers,**
- **Regulatory fulfillment:** products must prove that they **fulfill all applicable regulations**, for example regarding **patient data integrity**,
- **Data/data strategy:** AI products must have **access to high-quality datasets** and companies must prove that they **understand the data structure**
- **Model accuracy:** products must prove that the **model prediction is accurate and predicts what it should predict.**

There are three phases in the AI healthcare product development cycle: form, build and launch (Higgins & Madai, 2020).

At Form Stage, a small team identifies a clinical need and tries to develop a basic solution to it. Then a bigger team works together for a longer time- approximately 1 to 2 years at Build Stage. The team needs to produce a basic code that works form a clinical and regulatory perspective at this stage. Eventually, when it comes to Launch Stage, the products must pass medical device certification and clinical validation. There must be clinical studies demonstrating the efficacy of products to make sure the products can be deployed in a live clinical setting.

Previous research describes AI as a technology that can create a shift to patient-centered care in healthcare, where consumers as patients have higher control of information and their care delivery (McColl-Kennedy et al., 2012; Osei-Frimpong et al., 2018; Sandström et al., 2008), whereby AI – through wearables and mobile apps can be used to reduce the information asymmetry between patients and providers, and give patients more influence (Bhardwaj et al., 2017). In healthcare, the patients' participation helps themselves get better care and treatment and help the system acquire data to further develop the AI software (Leone et al., 2020).

3.3. Implementing new technologies and practices in healthcare

Authors	Description
(May & Finch, 2009)	**Normalization process theory** explains how individuals collectively understand a new technological practice and engage themselves in implementing it and how these practices become embedded into every day of work. Eventually, the goal is to make the technological innovation fully integrated – at which point no one talks about it anymore as an innovation. It has then become "invisible" in the organization. Normalization requires consensus about: • **Coherence:** what work is to be done? • **Cognitive participation:** who enrolls and commits themselves to the implementation? • **Collective action:** how does the work get done? beliefs and behaviors that define and organize work • **Reflexive monitoring:** how to understand the benefits and drawbacks of the new practice? Once organizations have an understanding of these criteria, then they are ready to implement the practice.
(Rogers, 1995)	Diffusion of an innovation across industry or society can happen fast or slowly due to certain "accelerating factors", perceived: • **Relative advantage** of innovation over status quo • **Compatibility** with existing technology, beliefs, or other systems in organizations • **Complexity** of implementing and using the innovation • **Trialability** of the innovation in a limited part of an organization • **Observability** of results of adopting innovation
(Davis, 1989)	Acceptance of a technological innovation depends on two factors: 1. **Perceived benefits** 2. **Ease of use**
(Omachonu & Einspruch, 2010)	Innovation in healthcare is driven by different stakeholders including (patients, government agencies, healthcare professionals, healthcare providers, consumer advocacy groups.

	Because of the complexity of AI technology, it is usually hard and costly for healthcare providers to develop the technology in-house. **The development and adoption of AI in healthcare are driven by the needs of stakehol**ders – **which is external to the innovation companies themselves (e.g., healthcare AI start-ups).**
(Dietzenbacher & Los, 2002)	**Disembodied innovation:** ideas and understanding of R&D can be a positive externality as investments from one competitor can be of benefit to others.

The theory that we believe has the most applicability to explain how the implementation of a new innovation occurs is (May & Finch, 2009), which explains how organizations form a common understanding of an innovation and how they subsequently integrate it into their daily work routine.

3.3.1.Normalization of a practice

Innovation companies can facilitate implementation on an organizational level by helping stakeholders normalize the new practice into their work routine. Innovation companies can do this by helping stakeholders understand (May & Finch, 2009):

1. Coherence: **what work is to be done to facilitate the implementation?**
2. Cognitive participation: **who is to do the work of implementation?**
3. Collective action: **how does the work get done?**
4. Reflexive monitoring: **what are the benefits and drawbacks of the implementation?**

Innovation companies must interact with the various stakeholders to raise understanding of AI and enable stakeholders to implement it. Eventually, the theories predict that adoption will increase as the understanding of AI increases in the industry and within the organizations of healthcare providers.

AI in healthcare is a relatively new technology. AI will continue to be a new technology until it has reached a broad adoption in healthcare. Part of the answer to why healthcare companies face certain challenges may be explained by the theory that aims to understand how the implementation of a new technology occurs. Normalization process theory could provide an explanation for the "external" factors, such as why customers may have low readiness for AI and provide guidance to understand why customers are slow to adopt AI.

Now we have reviewed literature describing challenges in healthcare, developing AI products in healthcare, implementing new innovations/practices – it is also necessary to turn attention to the internal perspective of the business. **We need a theory to understand the challenges from the start-up perspective.**

3.4. Definition of a Business Model

As an internal conceptual understanding of a business – **the business model helps understand how a start-up works and how it can grow from an internal perspective.** The business model can be used to organize and understand which part of the business affects/is affected by different challenges. A business model is a conceptual tool to explain how companies create, deliver and capture value. (Osterwalder, Pigneur, & Tucci, 2005). There are several ways to conceptualize a business model, the most common ones being:

- **Business model canvas:** 9 elements including value proposition, customer segments, activities, key resources, revenue, and cost (Osterwalder & Pigneur, 2010).
- **Lean start-up:** an adaptation of business model canvas which includes the elements of: **problem, solution, unfair advantage, key metrics** (Eisenmann et al., 2018).
- How organizations **create, deliver, and capture value** in business relationships with customers and other stakeholders (Teece, 2010)
- **Value proposition to customers, revenue model, and cost model** (Schön, 2012)
- **Value proposition to customers, resources, profit formula, and process** (Christensen & Johnson, 2009)

What all these have in common are:

- **Value-proposition:** what the organization offers customers
- **Customer:** who the organization offers value to
- **Key activities:** what the organization does to deliver value
- **Key resources:** assets that companies use to create value
- **Profit-model:** how the organization creates profit

3.5. Gaps in the literature

Prior studies describe general challenges of implementing AI in healthcare – mostly from a provider perspective. But very little literature examines the challenges from the perspective of healthcare AI start-ups. **We see a potential gap that we can fill by studying and mapping out which are the challenges of start-ups.**

Theory also doesn't really explain the connection between the challenges and the business model and which challenges are most important in which stage of product development. **Our research can help explain why challenges change over time, and what the connection to the business model is.**

Existing healthcare AI literature also largely fails to give an explanation for why the challenges exist. **Our research can help explain why the challenges occur.**

3.6. Theoretical framework

The products and services developed and sold by AI companies are a central part of developing a business model in this field. Developing a business model is a temporal activity, and therefore, we have identified the two frameworks of business models (Eisenmann et al., 2018; Osterwalder & Pigneur, 2010; Schön, 2012) and product development (Higgins & Madai, 2020) as being connected to each other. Furthermore, we see that the external reality of AI (a new technology, and as a new practice) also has implications on why certain challenges would occur for start-ups. Therefore, we distinguish these different views, the internal factors of the business that they themselves can affect **(for example the business model, the process of developing a healthcare AI product),** and the **external factors (AI as a new practice in healthcare, AI as a technological innovation).** We theorize that the following framework can help structure and organize the challenges into the relevant questions to be answered, and provide a theoretical lens to help answer these questions:

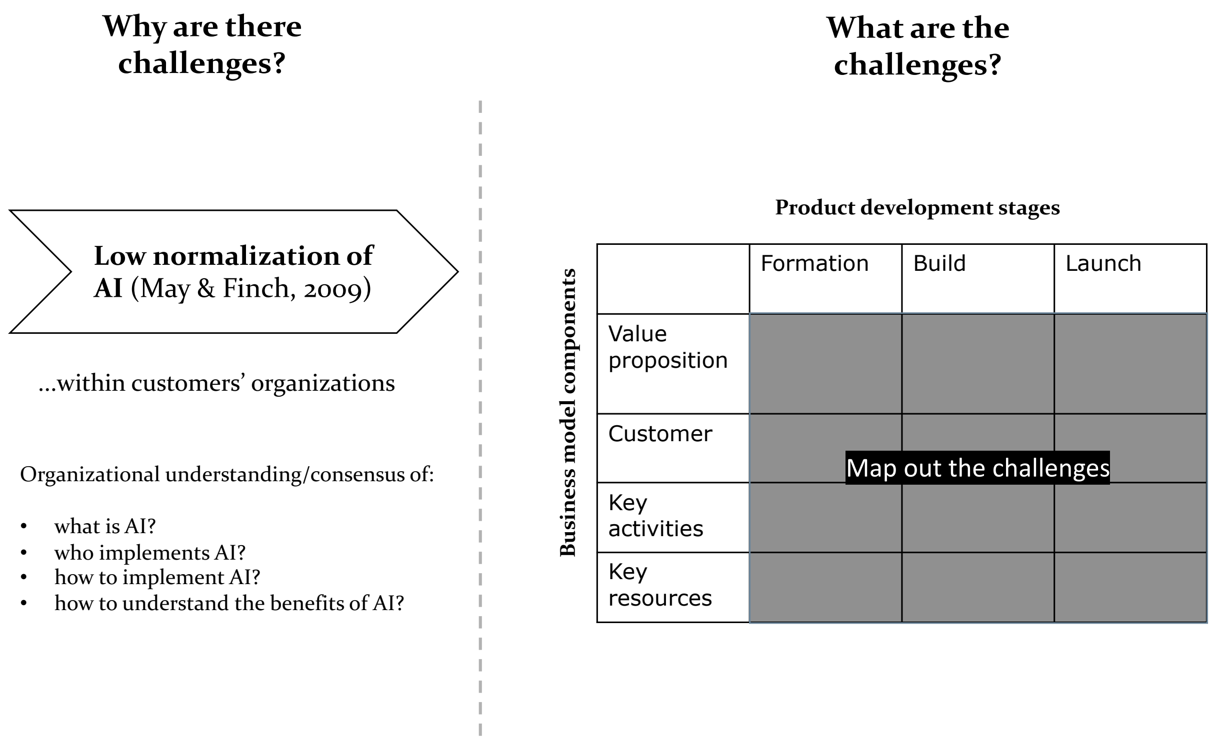


FIGURE 2 - MODEL SHOWING PREDICTED CAUSALITY BETWEEN ADOPTION RATE IN INDUSTRY AND BUSINESS CHALLENGES FACED BY AI START-UPS AS THEY DEVELOP THEIR BUSINESS MODEL

The picture illustrates how we theorize that the industry characteristics affect start-ups and lead to challenges they must overcome to develop a strong business model.

3.6.1. *Key components of the model*

Low normalization: The low adoption in the healthcare industry means that the normalization of AI within healthcare provider organizations is low. Normalization is the process an organization goes through when implementing a new practice to understand: (**coherence**) what to do with it, (**cognitive participation**) who will do it, (**collective action**) how to do it, and (**reflexive monitoring**) how to understand the benefits and drawbacks of AI (May & Finch, 2009). Low normalization would cause challenges to occur for healthcare AI start-ups as they develop. The low normalization in healthcare providers' operations means they are not ready to implement AI. Healthcare AI start-ups are forced to help customers normalize healthcare as a new practice.

Challenges: theory does provide a good overview of the challenges of implementing AI as a practice – however, these are described as general challenges for the system as a whole – not for innovation companies (healthcare AI start-ups) specifically. The theory, therefore, gives a hint towards which challenges may be important barriers from healthcare providers' point of view – but we are interested in understanding which challenges this creates for the start-ups. Therefore, theory suggests that challenges are related to strategy, technology, security, and customer – but **discovering which challenges start-ups face and mapping them out in the model will be a major part of our empirical collection**

Business model components: start-ups aspire to develop a strong and coherent business model by overcoming the business challenges. The business model components that a start-up must develop are *value proposition, customers, key activities, and key resources – as described by business model theory.*

4. Methodology

4.1. Research paradigm

Our study focuses on the subjective experience of healthcare AI start-up executives. They are treated as subjects, and the questions are of the type e.g., "what were the challenges?" which is an interpretivist question, or e.g., "why do you think healthcare is a good industry for AI?", e.g., "how do you perceive the level of readiness for AI among your customer-base?"

As seen from our research question, we have targeted companies in the category "healthcare" + "AI" + "start-ups" – this is our screening for companies to reach. That assumes that there are in fact such company categories from the first place.

We are also making an interpretation and some form of subjective classification of these companies into this group. We are screening companies based on our own perception of whether or not they fit into this category. For example, we have chosen to eliminate "general purpose" AI companies from the study, because we don't consider them as part of the category "healthcare AI start-ups", despite the fact that they may sell their services to e.g., healthcare providers or clinicians. Therefore, we are interpreting what should be considered part of that category and not. Further, the nature of our questions allows the employees to answer from their interpretation. The interviewees are not just observing the problem we are researching – they are actively participating in developing the business models of healthcare AI start-ups. Therefore, their reality is constructed by themselves (Bryman & Bell, 2015; Guba & Lincoln, 1994). Our questions are formulated to understand the subjects' interpretation of the issues we are asking about – therefore, we are not making predictions that can be observed as scientific truths or trying to prove some hypothesis.

The nature of the questions allows the interviewees to speak for their own experience and background. The answers are highly contextual to which growth stage their businesses are, what challenges or opportunities they are having at the time when they are taking the interview, and to their personal experience at the moment of the interview. That is, they are interpreting reality as they see it (Bryman & Bell, 2015; Kvale & Brinkmann, 2009). These factors indicate that our study is more interpretive.

Concerning ontology, we do not believe there is an objective reality as to the challenges a start-up goes through. We are asking interviewees for their experiences and opinions about their perceived challenges when they have developed their business. The focus is on their subjective experience and their story. Hence – while we develop a theory to explain our findings – our research does not try to prove or disprove any hypotheses about reality. Reality is socially constructed (Bryman & Bell, 2015) as start-up executives interact with other stakeholders and learn how to run their business.

4.2. Study approach

Our study approach is primarily inductive (Bryman & Bell, 2015). We started with a research question, and the research question informed the questions that we chose to ask interviewees. The questions that we asked interviewees and the research question then informed what kind of theory we collected. We predominantly let the research question guide our theory collection towards strands of literature about business model innovation, start-up ecosystems, and technological implementations. There was not one theory from the beginning that we wanted to specifically use for analysis.

4.3. Selection

4.3.1. *Representability*

To understand what different challenges AI healthcare start-up companies face at different stages of their business model development and how they work to solve them, we interviewed the people – healthcare AI start-up executives – that actively participate in shaping the market for this type of products/services, and the business ecosystem that they are part of. As our study is interpretive, we are focused on understanding the way they have experienced these challenges, as that could inform executives in other healthcare AI start-ups the experiences they might have in their organizations or inform other stakeholders in this ecosystem how these executives view their companies' existence.

Executives in these healthcare AI start-ups, are part of a social context that includes other people in these companies, other companies in the same business ecosystem, and other stakeholders in the relevant industry (healthcare). This social context will influence how they interpret their reality and the challenges they experience (Alvesson & Sköldberg, 2007; Weick, Sutcliffe, & Obstfeld, 2005).

4.3.2. *Strength of selection*

A crucial question to answer is whether or not executives in our sample accurately represent other executives in other healthcare AI start-ups. Furthermore, given how small the healthcare AI start-up category of firms is – as we define it, based on our criteria – our sample of executives is big enough to constitute a large chunk of the total number of executives working in this category of companies. The field is nascent, and we estimate there are only a few hundred companies that qualify into our classification. Therefore, patterns identified among these executives exist across a large proportion of our target population – this indicates the external validity of this study (Bryman & Bell, 2015).

By asking the people who – many co-founders – of the companies, we believe we can get an accurate view of what we are trying to measure. That is the perceived challenges by the people who established and managed these companies throughout their growth trajectory. We conclude that the study measures what it is supposed to measure, therefore internal validity is high because of a good selection.

4.3.3. Weakness of selection

In order to figure out the reason behind the low adoption of AI in healthcare, it might be insightful to include the customers (e.g., healthcare providers, healthcare professionals, patients…) **into the research**, since they are the ones making the decisions to implement AI or not. Such a study could potentially give more specific insight into why healthcare providers are slow to implement AI in their operations. Bringing these other stakeholders into the research might provide a broader view from several sides.

We are interested in understanding how start-ups build a business under the specific conditions that low AI adoption creates. We primarily want to focus on the challenges of AI healthcare start-ups. We feel that the existing literature provides an exhaustive description of the challenges healthcare providers experience of implementing AI in healthcare. Therefore, interviewing healthcare providers would not add anything that isn't already known and would dilute the focus on the start-up business element of AI in healthcare.

4.4. Sampling

4.4.1. Definition of sample criteria

In our screening of interviewees, we have three criteria/keywords:

- Healthcare: the organized provision of medical care to individuals or a community (National Center for biotechnology information, 2009).
- Artificial Intelligence: the application and training of algorithmic models to make predictions based on large datasets (Lee, Suh, Roy, & Baucus, 2019; Quan & Sanderson, 2018).
- Start-up: "a start-up is an organization formed to search for a repeatable and scalable business model", as defined by Steve Blank (2010). This is a definition of "start-up" that

is commonly applied by researchers investigating start-ups, and therefore we will use this as our definition.

To qualify, a company must fulfill all three criteria.

4.4.2. Sampling method

Our sampling method was purposive (Bryman & Bell, 2015). We approached companies that fulfilled the following criteria:

- The company has a page on LinkedIn (as the leading professional networking social media, we used their catalog to screen companies).
- Companies that fulfill the three criteria mentioned previously.

A second sampling method was also employed where we searched LinkedIn for people self-described as:

- Having prior/current employment in a company fulfilling the three criteria mentioned previously.

or

- Self-described as an expert or academic researcher on companies fulfilling the three criteria.

Another sampling method used was to screen companies that were included in lists such as the following picture:

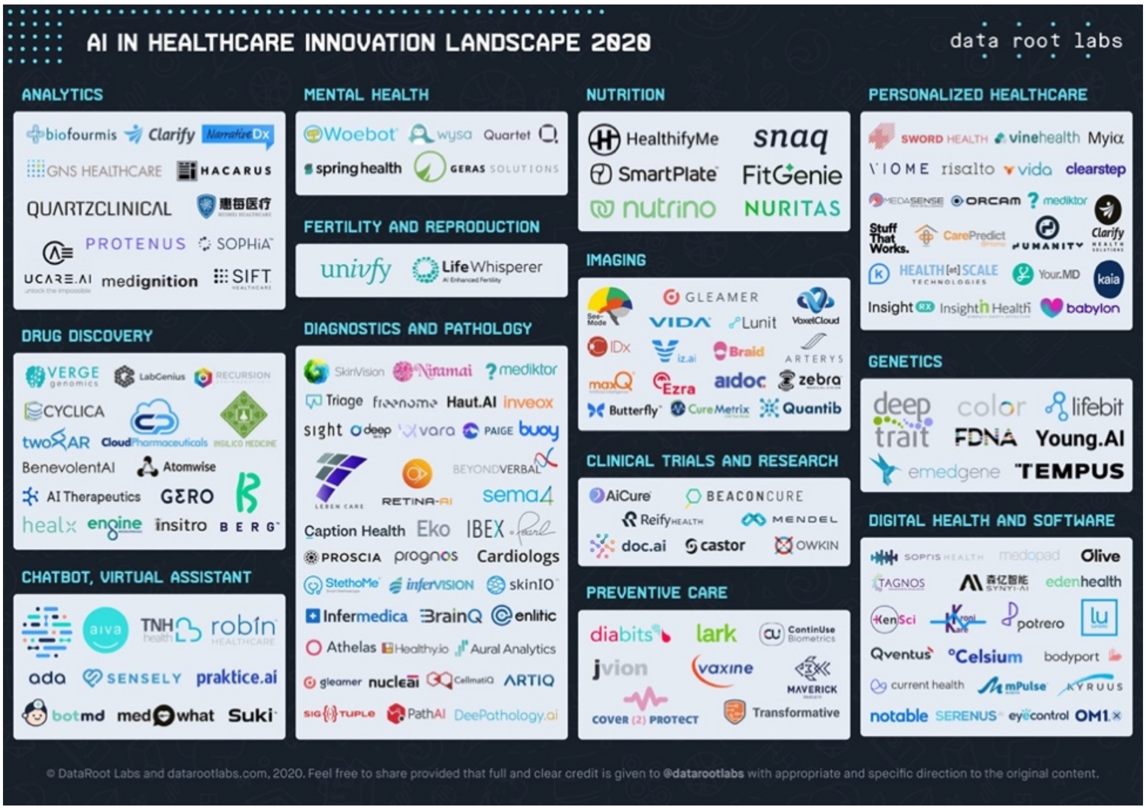


FIGURE 3 - DATAROOT LABS LIST OF HEALTHCARE AI STARTUPS 2020 (DataRoot Labs, 2020)

Such online lists gave an overview of the companies to look for, and then we screened those companies based on the aforementioned sampling criteria.

Our interviewees are experts or researchers (one academic journal editor) and leading decision-makers in their respective companies or have previously been such, and therefore have a broad overview of the business activities in these firms. We believed that these people could help give an externally and internally valid answer to our research question. We have included experts or researchers that do not have direct start-up experience, to gain a more nuanced perspective.

Our sampling resulted in 248 companies that we approached for interviews, of which 17 responded and proceeded to have an interview. The following charts give an overview of the companies in the sample:

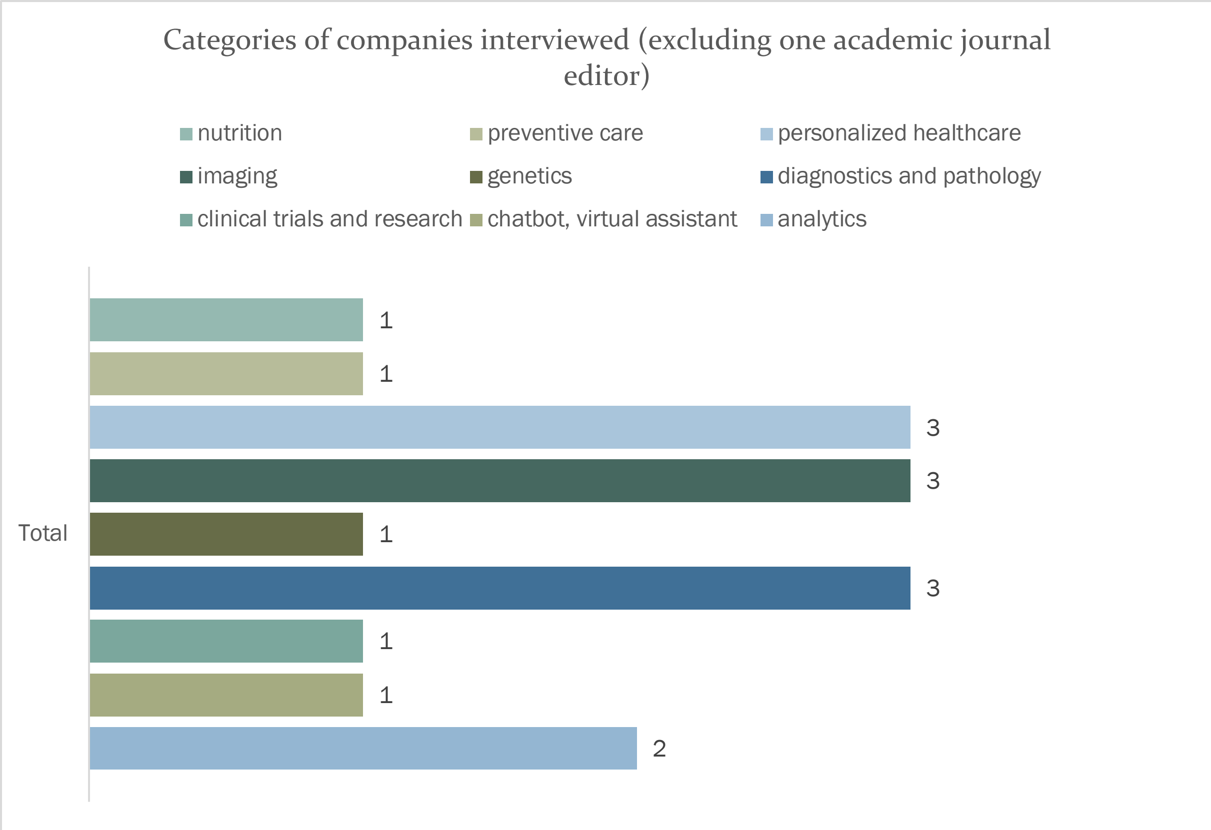


CHART 4 - INTERVIEWEE OVERVIEW BY DESCRIPTION CATEGORY

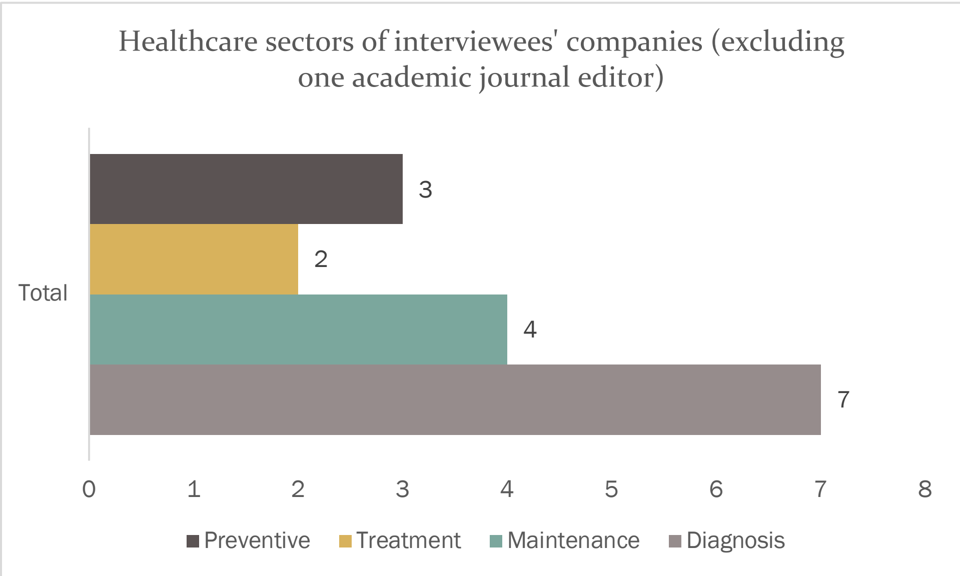


CHART 5 - INTERVIEWEE OVERVIEW BY COMPANY HEALTHCARE PARADIGM

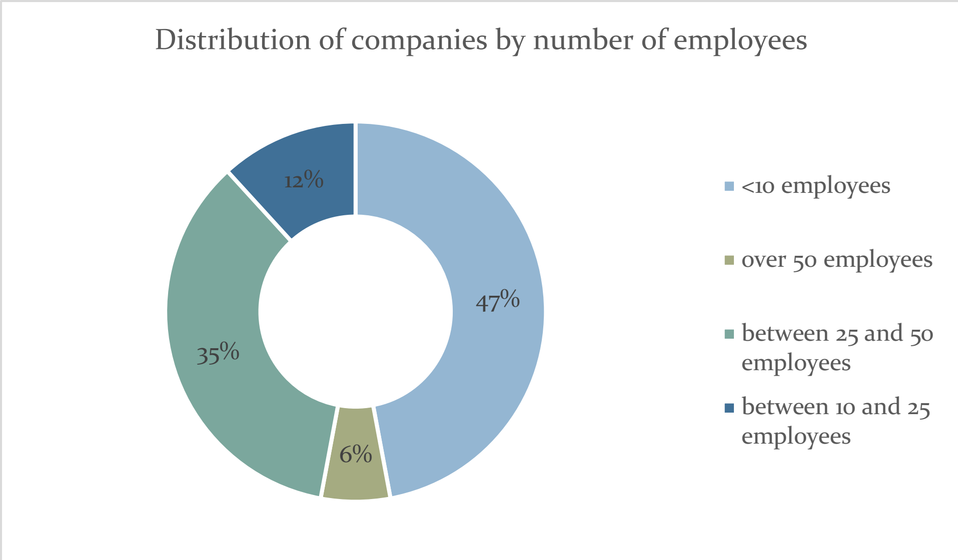


CHART 6 - DISTRIBUTION OF COMPANIES BY NUMBER OF EMPLOYEES

4.4.3. Data collection

Semi-structured interviews provided room for the interviewees' subjective experiences and left room for new topics to emerge – which was highly beneficial to our study. We used the semi-structured interview method with a basic script of questions that are similar across interviewees, and we included follow-up questions when a new interesting topic was brought up, for example, "you mentioned technology as a challenge, in what way is technology a challenge?". These kinds of questions help elaborate further on how the interviewees experience things qualitatively. This type of semi-structured interview is suitable because the experience of interviewees is highly subjective, abstract, and intangible (Bryman & Bell, 2015; Kvale & Brinkmann, 2009). It served both the exploratory and explanatory nature of the interviews. The interviews have not only explained the framework we developed from the literature review, but also brought up topics that are not yet researched in the field, for example, the key decision-maker from the clients during the sales. The flexibility encouraged the interviewees to express unexpected insights and topics (Bryman & Bell, 2015; Kvale & Brinkmann, 2009).

4.5. Literature search

4.5.1. Keywords / databases

We have used the SSE library to screen leading research databases including Business Premier, Science Direct, Scopus, Web of Science, Taylor & Francis Online, and used Google Scholar to find articles that are related to our topic.

The keywords we used were “healthcare”, “AI”, “artificial intelligence”, “start-ups”, “machine learning”, “deep learning”, “business models”, “business model innovation”, “health technology”, “digital start-ups”, “medical technology” and “digitalization”, “innovation”, “technology”, “implementation”.

We used different combinations of these keywords and downloaded articles based on their relevance – as judged by the database algorithm. For example, “artificial intelligence + healthcare + start-ups” or “artificial intelligence start-up business models”.

We read the article abstracts and downloaded all the articles we perceived relevant based on the abstracts. Then we read everything in-depth that we thought was relevant.

This method of literature collection was intended to give a broad overview of the available research with a purposive focus on the research question (Bryman & Bell, 2015).

4.5.2. Analysis procedure

To eliminate the bias in the answers, we first screened the transcript and eliminate potential leading questions in order to remove the personal perspective of us as researchers.

We subdivided quotes from the interviews into different categories. Categories were inductively derived from the interviews, and classified under keywords for example “infrastructure”, “customer ai readiness” or “product-market fit” based on what the interviewee talked about.

In the empirics section, we have put a bar chart showing the number of quotes classified into different categories compared to the average number of quotes in each category.

In our analysis, we chose to use the 6 most commonly discussed categories – to ensure we focus on the things our interviewees mentioned the most.

4.5.3. Ethical considerations

We have anonymized the participants in the study. We have only provided details to their role in their respective companies – as it provides context to the study and the number of employees in the company. We do not believe the study gets any value from including identifying information about participants, and in this way, we can negate any potential damage to interviewees from participating in the study.

4.5.4. Reflexive / self-critical concerns

We are aware of the influence our personal position poses on the research. Through the course of this study, we have made choices that may induce researcher bias. For example, we selected participant companies, we decided which questions to ask interviewees, we inductively classified categories of the interview scripts, we decided the way to interpret the materials. All these are decisions where a researcher must make a choice. Our own beliefs, judgment, and practices are brought to the study. It creates dilemmas and challenges for us, especially during the interpretation of the interviews.

In this study, neither of us has any experience or connection with the companies that we've interviewed, which makes us objective toward all of them. We decide to use a semi-structured interview guide so that the interviewees received similar questions without bias on the questions. During the interpretation of the materials, we identify the most discussed topics with the frequency of the keywords. As another safeguard, we have revised our analysis several times to make sure that the findings and analysis accurately represent what was discussed in interviews.

5. Findings

In this section, we are going to share the main findings of the study. We first demonstrate the key categories of challenges that have been discussed in the interviews. Then the six most mentioned categories would be discussed in detailed quotes.

Below is a chart showing the number of quotes in each category we developed for the empirical material. Categories are compared to an average dotted line.

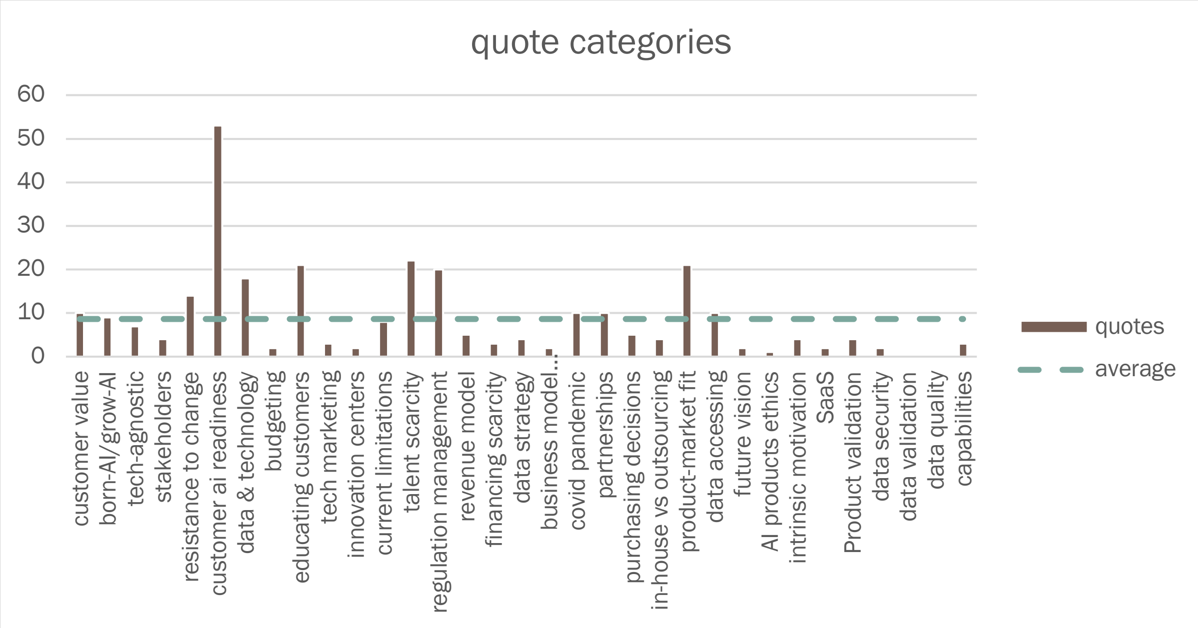


CHART 7 - EMPIRICAL CATEGORIES

Below we show a chart that includes only the 6 most mentioned categories in the empirical material, indicating which business model challenges are most important amongst the most commonly mentioned:

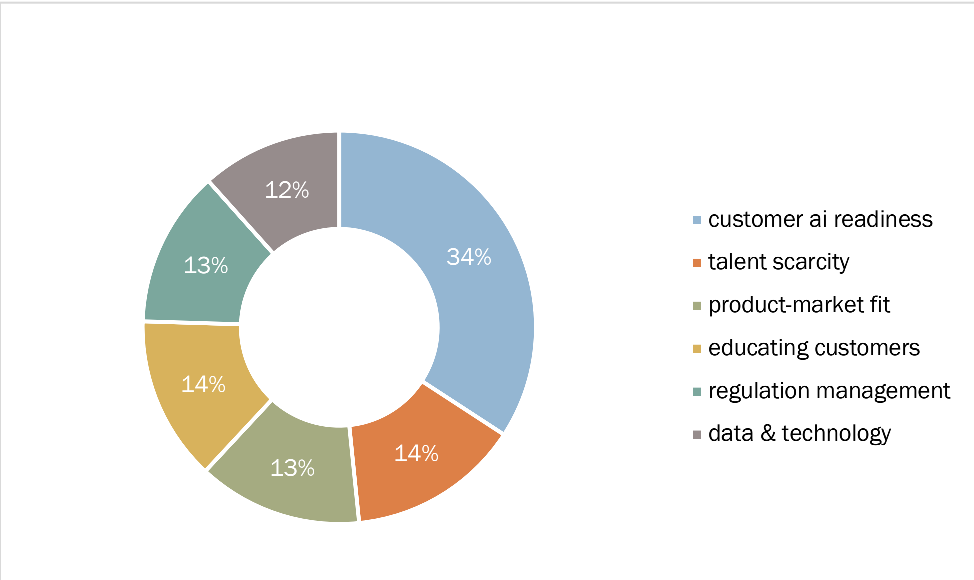


CHART 8 - MOST COMMON CATEGORIES OF EMPIRICAL QUOTES

The split within the categories shows that customer AI readiness is significantly more frequently discussed in our interviews than in the other categories.

5.1. Challenges

5.1.1. Product-market fit

PRODUCT-MARKET FIT

During the interviews, interviewees mentioned product-market fit as a common challenge when talking about the early stage of product development. Most of the start-ups started their business by identifying problems in the healthcare sector that they could solve with AI technologies. Therefore, the businesses were more focused on what the market needs instead of on the use of AI itself.

"It's really important when you're looking for product-market fit. To go and talk to your market...That you should listen to the customer. If he says he doesn't care, we should just understand that he doesn't care and look for something he cares about and say , 'OK, you don't care about having diabetes. But do you know that if you continue with this lifestyle in a few months, you won't have abs anymore? If you have abs now...' - Things that people care; people think about." – ***management trainee, healthcare information company in remedial sector***

When forming and early in product development, many start-ups usually notice more than one problem that they could solve. A significant challenge is to find the specific problem that they could help with, and they should dedicate their time to. Interviewees mentioned:

"One of the problems that we ran into which is a good problem to have is that we found a lot of use cases for what we're doing. So, one of the hardest things was thinking the very specific things that we were going to dedicate our time to because there are only so many hours in a day, and if you don't develop, you know one or two things extensively enough, then you have no product thing that you can take to a customer. So one of these challenges is finding what we were going to work on." – ***co-founder, clinical trials company in preventive sector***

VALUE PROPOSITION

The value proposition is one of the topics that are brought up the most during the interviews. Start-ups face a challenge to create a strong value proposition, developing an offering that can fix certain needs (such as AI to organize information sources for doctors), creates certain gains (such as giving doctors a second opinion in diagnoses), or alleviate certain pains (such as helping radiologists reduce workload by AI that can analyze images) for healthcare professionals.

"If you are a patient, I think you would want to know what works for you. That's it. That's all we do. We tell you: you have a prescription in your hand from one doctor. Is that really the right prescription? Are you sure? A doctor is not sure. The system is not sure. We spend two minutes with you and had to go with what terabytes of data around you and made a call because we saw somebody last week who looked like you and had the same symptoms. Are you sure you want to take that? That's it. Very simple. That's all we do. Personalized healthcare. This is the future we envision for every single person. 'Tell me what is good for me'." – ***CEO, diagnostics and pathology company in remedial sector***

A large part of building a strong value proposition is to prove to the market the clinical benefit of the product, and showing them that it works:

"I'm selling a product, or we are selling a product. That is a cost, not an opportunity for revenue. The benefits have to be strong in other areas because they are not economically driven."- ***VP of business development, imaging company in diagnosis sector***

"You need to bring the solution to the market and make sure that people understand and see the value of that, so they are willing to sign a contract." - ***VP of business development, imaging company in diagnosis sector***

"We constantly work with clinical organizations that look into our solution and evaluate the results that they're getting there so as to finally come to some sort of validation." – ***Business Developer, diagnostics and pathology company in diagnosis sector***

"The only way to do it is to make sure that you work towards that accuracy and towards that reliability." – ***Business developer, diagnostics and pathology company in preventive sector***

Ways to show the benefit of AI and building a strong value proposition include having an experienced team, and testimonials and case studies that show the value of the offering:

"There's a part of it where it's about convincing and getting the trust of the partners to sort of commit to this … showing that you have the background experience and the capabilities. If it's doctors, researchers, Ph.D.'s that are coming out of this space in setting something up, then you have done quite a bit of work for the credibility parts. The other part is about getting to a point where you have testimonials and case studies and ways that you can approve that other companies have gotten value from interacting with you as quickly as possible."- ***Business Developer, analysis company in preventive sector***

5.1.2. Data & technology

MODEL TRANSPARENCY

AI healthcare products are often considered a black box by customers – it is difficult for them to understand what the product does. Therefore, maintaining and demonstrating model transparency can be a challenge for healthcare AI start-ups when developing the product. Transparency is important to eliminate biases that could otherwise skew the predictions.

"I think it's now less about the technology. The technology is there, it's more about the ethical deployment of AI and it not being a black box. Now the trend is towards explainable AI and transparency. So, you can't just sell algorithms under the hood, or it being a black box. Explainable AI, unbiased, unprejudiced, AI and AI that you can say see what's happening A-Z – end to end. That's more important now, especially in the European Union, I think." – ***Co-founder, genetic analyzing company in preventive sector***

DATA ACQUISITION AND STRUCTURE

Interviewees said that the way healthcare professionals acquire, and structure data is a key concern. Most interviewees said they did not have their own datasets, but instead relied on their customers (usually hospitals or smaller clinics) to provide input data for the AI models. AI and ML models require structured data – but most healthcare data is unstructured. For start-ups, the way to deal with this is to train customers to acquire data in a more structured way (for example, as figures/scales instead of free text)

"There's a lot of data in medical records, but it's unstructured." – ***Co-founder, genetic analyzing company in preventive sector***

"Standardizing our data acquisition methodology has been our biggest challenge for AI development. Health and fitness workers are used to having more flexibility in the way they capture data. In fact, they are quite undisciplined in the way they measure, compared to what an engineer is used to. Our system tries to keep the data acquisition as controlled as possible by design, which can be frustrating for the clinician who is used to the more freestyle assessment methods that we are trying to replace or complement. That affects the product-market fit cycle and requires us to spend considerable time educating the market about the need for validity and reliability, and standardization to feed the AI with useful data."- ***CEO, personalized healthcare in therapeutics sector***

"Big data wants it in a way that you can use tools, or you can manipulate that they change such a way that you can then plug it into certain machine learning frameworks and then get some output that is relevant to a problem that you're solving. A lot of these people might have the best algorithms, but then the data they are using might not be clean or are labeled as good that they can make it useful." – ***Co-founder, genetic analyzing company in preventive sector***

DATA VOLUME

Especially in the early stages of product development, interviewees described access to the high volume of data as a key challenge – which would become less of an issue once the start-up is past product development.

"The biggest challenge is the data because the AI is as good as the data that is trained on. So, if it's a new start-up company, they may not have huge datasets because a lot of patient data is not publicly available" – ***Journal editor, academic***

"I think a huge thing is access to data. Without having huge amounts of data, the predictability isn't that great. And good labeled data. So, the biggest issue with AI and machine learning is if your data is labeled properly. If it's clean, if it's pre-processed. In a way such that you can extract useful information from it." - ***Co-founder, genetic analyzing company in preventive***

DATA QUALITY AND INCLUSIVENESS

Data is one of the most important things in product development for healthcare AI start-ups. To make the products effective and applicable, interviewees have mentioned the challenge of having high-quality inclusive data.

"The datasets need to be inclusive. Because oftentimes it so happens to start-ups, they start developing in training their model on whatever data set they have, and they predict outcomes, but as soon as they applied on the patient population, depending on the diversity of the patient, that population the AI models can just drastically fail." – ***Journal editor, academic***

To access good quality data, start-ups often must rely on partnerships with healthcare providers. A challenge is to grow these partnerships.

"I think the collaboration is still happening at the higher level with big hospitals that are seeing a higher influx of patients and who have the infrastructure to support these data. Because in a small setting, oftentimes they don't even have the infrastructure to support the data." – ***Journal editor, academic***

5.1.3.Regulation management

GOVERNMENT SPENDING REGULATION

AI healthcare start-ups face a common challenge of regulation, given the healthcare industry is highly regulated and heavy on ethical concerns.

Regulation especially influences the revenue model for AI start-ups in the public healthcare system, as healthcare is subject to strict rules about purchasing.

"Regulation does affect a lot in terms of the payment model, reimbursement market. Who will pay for what and why? That is heavily affected by regulation because it's a big government spending in healthcare. So even in the US, their regulation does form limitations sometimes because most of the market wants to be compliant." – ***CEO, digital analytics company in remedial sector***

DATA ETHICS AND INTEGRITY

Start-ups must not only follow the government purchasing regulations but also pay extra attention to ethical considerations. Data security and transparency are vital for AI healthcare start-ups (Miotto et al., 2017). As start-ups would use data from patients, they have to be responsible when accessing, processing, and using the data.

"Validation of your security model is a big challenge. So, in the US there are multiple regulatory authorities who you have to get some certification to say my system is secure. In Europe it's different in Australia is different and in Southeast Asia, it's almost non-existent," – ***co-founder of analytics company, preventive sector***

"Really regulation is pretty strict on how to use patient records. For instance, anonymized aggregated datasets are how AI companies approach data." – ***Co-founder genetics company, preventive sector***

For AI healthcare start-ups that operate internationally, the regulations in different countries can be another challenge. Regulations differ all over the world on data accessing, product validation, certificates, verification, etc. Start-ups must invest more time and resources into regulation management if they operate in many different geographical markets.

"Our biggest challenge is international data management. As SaaS, we can service people all over the world, but the world has not yet decided how to manage its data. Anonymizing data for analysis is great and serves us well today. However, we see so much potential benefit from data flowing internationally in real-time, without so many restrictions. Online consultations across borders, in different time zones, and comparing population-specific data could add so much value to data insights and customer utility." – ***CEO of digital health company in therapeutics sector***

"The regulatory environment. A company like ours and our competitors all want to be considered a global partner, a global provider of services. So, we have the USFDA. We have European CE marketing. And then we have groups like the FDA in China, many other KFDA in Korea. Understanding the regulatory environment and then developing your products so that you can meet the requirements of those regulatory bodies in a way that also allows you to then meet the needs of the market." – ***VP of business development, imaging company in diagnosis sector***

Most of the start-ups have the vision that the regulation on AI healthcare would be stricter in the future, as more companies enter this industry and there are more AI healthcare products in all fields of clinical practices. For start-ups, this could mean that it can be harder for them to access data and requires more investment in regulation management.

"I think it will be much, much tougher for AI companies that are doing something in medicine. It will come AI regulations in each big area. China has its own, Europe has its own. North America has its own and also here we're lucky that we're starting before these regulations go into effect because it would be much, much harder to collect the data and more regulations." – ***Chief product officer of imaging company***

CLINICAL STUDIES & CERTIFICATION

To be able to convince customers to buy their product, start-ups must pass clinical trials. This can be an expensive and time-consuming process.

"Well, because we are a medical device class one, we need to have CE certification and we need to have clinical evidence so there's much work around those criteria, and now we have our first clinical studies finished." – ***CEO, personalized healthcare company in therapeutics sector***

5.1.4. Organization & talent

TALENT RECRUITMENT FOR R&D

Companies always struggle to find talent. Talent scarcity is an issue throughout the development of the interviewed companies. There is a large scarcity, especially for premium talent (AI developers and AI strategists):

"Think about data strategy. How many people can do a healthcare data strategy? With the technical side and the strategy side in one? How many people are there in the world? Very few. Because nobody has seen this data. Large corporations don't understand this data and don't know what to do with it." – ***CEO, digital health company, remedial sector***

For specialized talents such as ML and AI developers, the talent pool is fragmented globally. A global talent pool means that companies must accept recruiting staff to work remotely.

"Today is very significant in growing talent because bright students are coming out of undergrad and graduate programs all over the world from, from the Americas to Europe to Asia so no, I add because it's a global community where you don't have to move from, you know Mumbai to San Diego to work for companies. Right, I mean the work is a virtual community… You can work virtually, so the talent pool, is global." – ***VP of business development, imaging company in diagnosis sector***

Interviewees said that a problem for start-ups compared to established organizations is that big companies have access to the existing talent pool – which can be an incentive in itself for talented individuals to come work for them (e.g., Google). Start-ups with an existing talent pool will be more likely to succeed in attracting more talent.

"Talent attracts talent, that's number one. Talent recruitment strategy is its own thing. You have to have your network. You have to know where this talent comes from. You need to understand how this is groomed. You also need to give them this growth opportunity and you need to compete for it." – ***CEO of diagnostics and pathology company in remedial sector***

Finding good talent is also challenging because there is limited data available to be used for healthcare AI. This makes it difficult for people to learn AI.

"Talent is not scarce - it's like non-existent because healthcare data is not available. When you make this data available, a lot of people can train themselves to be an expert… AI is that field, you can only learn by doing. That's where talent is extremely scarce – at least the premium talent, the talent that matters is extremely scarce." – ***CEO of diagnostics and pathology company in remedial sector***

PURPOSE AND VISION OF THE START-UP

When finding talents, start-ups rely on their cause and vision to attract talent with intrinsic motivation to work. Motivators to work that start-ups can offer can include such things as job satisfaction (interesting data and use cases), autonomy, achievement, and growth opportunities (Herzberg, Mausner, & Bloch Snyderman, 1959; Malek, Sarin, & Haon, 2020). Start-ups must continuously strive to develop the motivators that are attractive to top talent.

"There has to be something in your company that you can really say is doing something different or they have something unique about it that pulls the right type of people. If you are aiming high enough and you are basically selling your vision. The right type of people will come to you. If you can show them the problem, you will attract people." – ***Co-founder genetics company, preventive sector***

"So, you have to find people who are motivated by the actual work that's being done by the company, I think if they're driven purely by money in pay-checks they're probably just going to work for Google or Amazon or something. It seems that you really have to find people who are engaged with the company and believe in the idea to draw them in." ***– Co-founder, clinical trials and research company in preventive sector***

TALENT RECRUITMENT FOR SALES, LEGAL AND OTHER ADMIN ROLES

Interviewees described the talent need as changing throughout the product development process. In the launch and post-launch of product - sales, finance, legal, and operations competence becomes more important. At that stage, the organization will largely maintain its R&D team and focus on developing new skills more related to marketing and managing regulations.

"I mean we have all the competencies for the breast cancer product, but I mean we need legal experts in our team because there are different regulations in different areas, we need to understand them and how to adapt the technology or solution to that. I think that's what we need now, but of course, now we grow, we need more people, more engineers, more business and product-oriented marketing so. It's more business and legal. And economy finance that we need to focus on recruiting." – ***Chief product officer, imaging company in diagnosis sector***

"Because challenges are you need to build a sales force who can sell this concept, they have not sold something like this in the past, so they don't understand how to sell an analytics product. Traditional software sales are different than clear selling analytics products. And then because the sales force is difficult to build, that also means that the customer is not well educated to learn about." – ***Co-founder, analytics company in preventive sector***

5.1.5. Increasing customer AI readiness

DECISION-MAKERS – WHO MAKE PURCHASING DECISIONS?

Many stakeholders can influence the purchasing decisions, which means healthcare AI start-ups cannot limit their sales efforts to just one avenue. They have to focus their efforts on the relevant medical staff, technical staff, business managers as well as executive leadership.

"To only give you a summary of the various stakeholders that would be either influencers or potential detractors and then ultimately the decision-maker. So, it depends on who the customer is. Let's take an average hospital, for example, stakeholders would be the mammography technologist to operate the machine. The radiologist who interprets the exam, the administrator, or business manager who has to reconcile cost and benefit, the executive leadership at the hospital level that approves budgets." – ***VP of business development, imaging company in diagnosis***

AI in healthcare is mainly driven by demand from healthcare professionals. AI can create large efficiency gains, and that is perhaps the greatest driver for adopting AI.

"It's really by the diagnostician, so by the health care provider. They know that they are missing cancers. They need help with that. They know that their recall rate from a screening patient. Let's say you screen 1000 women for breast cancer with mammography. They typically recall about 10% of those patients. The recall rate is about 10%. So, in addition to your normal caseload of screening memo patients, you're now putting 10% of them back into the system. Every day so they need help managing. And so, they are the ones turning to AI for help." – ***VP of business development, imaging company in diagnosis***

But healthcare AI start-ups must convince medical professionals of the utility of AI.

"Typically, the radiologist is going to be key in the decision making because they have so many choices. And they have to feel confident that your product is superior to the others. Or represents a benefit that ultimately drives him or her in your direction. So, in many cases, it's the radiologist that makes that decision." – ***VP of business development, imaging company in diagnosis***

Interviewees also noted a trend in the industry that most hospitals have developed innovation offices. High-ranking people of those teams are considered highly relevant targets for healthcare AI start-up sales efforts. This is because innovation offices – while they usually do not make the final decision (this is done by the hospital board or steering committee) – they have significant input into which technologies are brought up for discussion, and they actively look for new technologies to use.

"Most hospitals now have innovation offices. And they have a chief innovation officer or an in-house guy who's responsible for implementing innovation. For instance, when we wanted their patients to use our product, the hospital could recommend the product and we went through their innovation Office, head of innovation. I think hospitals would have those departments, and AI health tech companies would engage with those guys and then try to see if there could be a collaboration. "- ***Co-founder genetics company, preventive sector***

OVERCOMING *RESISTANCE*

Interviewees have mentioned resistance to change in client organizations as a potential concern for healthcare AI start-ups.

"Some of our insights challenge the status quo, and this can be met with resistance from some health workers, researchers, and educators, and puts quite a lot of pressure on us to seek independent validation of new ideas. This is expensive and time-consuming, not to mention out of scope for most traditional clinical trials. We probably have more in common with people in robotics than in medicine and allied health, even though most of our non-tech team have a clinical background." – ***CEO personalized healthcare company in maintenance/therapeutics sector***

The users of AI healthcare products are mainly doctors/pathologists. They have received traditional medical training for many years, which makes some of them have low trust in AI. Therefore, validation of the training data and the algorithm is important when communicating with the doctors.

"Digital technology's readiness is significantly high. People are ready to work with digital technology. But for AI and machine learning I think it is far, far behind. Simply because these technologies, as cool and nice that they look, are still unproven and they are looking for more verification from the market." – ***Co-founder, analytics platform in preventive sector***

While AI in healthcare can create higher accuracy of readings, AI is not yet replacing medical professionals. AI in the future can replace human professionals – and this may be a reason why medical professionals have some resistance towards AI.

"So we build tools that allow doctors to be faster and better and make decisions in a quicker manner. But we're not looking to replace them, but we're looking to enable them, and that's sort of how we tend to position it with our clients." – ***Business development, analytics company in diagnosis sector***

RAISING *AWARENESS AND READINESS FOR AI*

The lack of knowledge is one of the reasons for a resistance from customers. Since AI is a relatively new and complicated technology, customers (e.g., healthcare professionals) usually don't have enough experience with it. This requires AI healthcare start-ups to have the ability to educate their customers with proper strategies.

"On the business side, with anything related to artificial intelligence and machine learning, I think the adoption is always the biggest challenge. I would say the initial adoption because of lack of awareness and lack of knowledge of the majority of people that you would deal with in that sort of setting is probably one of the biggest challenges." – ***business development, clinical trials and research company in preventive sector***

"We offer tutorials and workshops for customers, to help them understand how our service enhances their work, and the value, the measurement, and analysis brings to their work and the benefit for their clients." - ***CEO personalized healthcare company in maintenance/therapeutics***

Education to the customers on AI technology and specific knowledge of the product can be costly for start-ups. Although some start-ups try to educate with workshops and tutorials, most of the start-ups choose to solve this problem with proper communication strategies.

"I don't think you have to educate customers about the technology. Data science is not the trade of a pharma or even a health system." – ***CEO diagnostics and pathology company in remedial sector***

"Say I had 100 conversations. I would say maybe 5 of those people had enough understanding to ask slightly more in-depth questions about what was going on and how we were approaching it and things like that, so not a whole lot." – ***clinical trials and research company in preventive sector***

Most companies choose to skip the technical terms to directly communicate the usage of the product and benefit of it. While some try to explain the technology with language the customers are more familiar with. The advantage of these approaches is that it is easier to explain how the product works and ignores the part that customers think is difficult to grasp: the technology.

"We just don't talk about AI, we talk about the problem, about the solution "the problem, this is why it matters to you" this is all they care about, AI or BI [business intelligence]. A good tech should be transparent." - ***CEO diagnostics and pathology company in remedial sector***

Customer readiness also differs in different parts of the world. We have noticed that the level of acceptance of AI healthcare products is higher in the US, compared to Europe. AI healthcare start-ups in the US and the UK have experienced less resistance from customers than European companies. Some interviewees have mentioned that customers in Europe tend to ask more questions about the technology and the products. While in the US, healthcare professionals and patients ask fewer questions as long as they know the benefit that the products could bring.

"Technology readiness level in allied health and fitness is very low, especially in Sweden. Australia and the US are more advanced with technology in clinics and gyms. Surgeons and sports medicine practitioners are better equipped to understand what we do, as they have had more exposure to technology. But this is changing very quickly due to the pandemic, with remote consultations and the necessity to become familiar with IT." - ***CEO personalized healthcare company in maintenance/therapeutics sector***

"If people don't have familiarity with the types of techniques that you're using or what you're trying to accomplish because of their background, it can be very, very difficult to get people to wrap their head around the fact that you can do it, let alone whether it is even possible in the first place because they just don't have a good understanding of it." – business development, ***clinical trials and research company in preventive sector***

CLINICAL VALIDATION

When talking about sales, interviewees mentioned clinical validation as another challenge. In most cases, there is a lack of knowledge from the customers, and it is hard and costly to fully educate the customers on the technologies. Start-ups find it tricky to prove to the customers the validity and safety of the products:

"It is more attitude I think here in Sweden. The attitude towards us or technology or innovation from the beginning makes it not interesting for them. They said, "but we don't need this without even understanding what it actually does." But in developing countries, the attitude has been different. They see it like 'OK, we don't have any tools. This can help us to detect in the early stage. This is interesting. It's an affordable and comfortable solution.' I think it's a bit about education that they [hospitals in developed countries] don't know actually what thermal technology is and what it can do." – ***Chief product officer, imaging company in diagnosis sector***

6. Analysis

AI products are very versatile and as described by Garbuio & Lin (2019), these technologies can be applied in a wide range of settings. In our empirical material, we have a sample of companies from a wide range of specializations (preventive sector, diagnosis, remedial, and therapeutics). These companies fulfill many different types of services (imaging, pathology, digital health companions, genetics to name a few examples). **Our empirical material shows that AI can be used for a wide range of applications.** Start-ups who can capitalize on this can create new strong market positions in which to grow.

The overarching story detailed by interviewees is that there are certain challenges they face throughout developing their company and business model. Interviewees broadly detail three themes:

1. Start-up companies face certain challenges as they develop.
2. The challenges arise due to the need to fulfill the five business model criteria (value proposition, customer, key resources, key activities, and profit model).
3. Formation of a business is a temporal activity – thus different activities/capabilities are more or less crucial in different stages of business development.

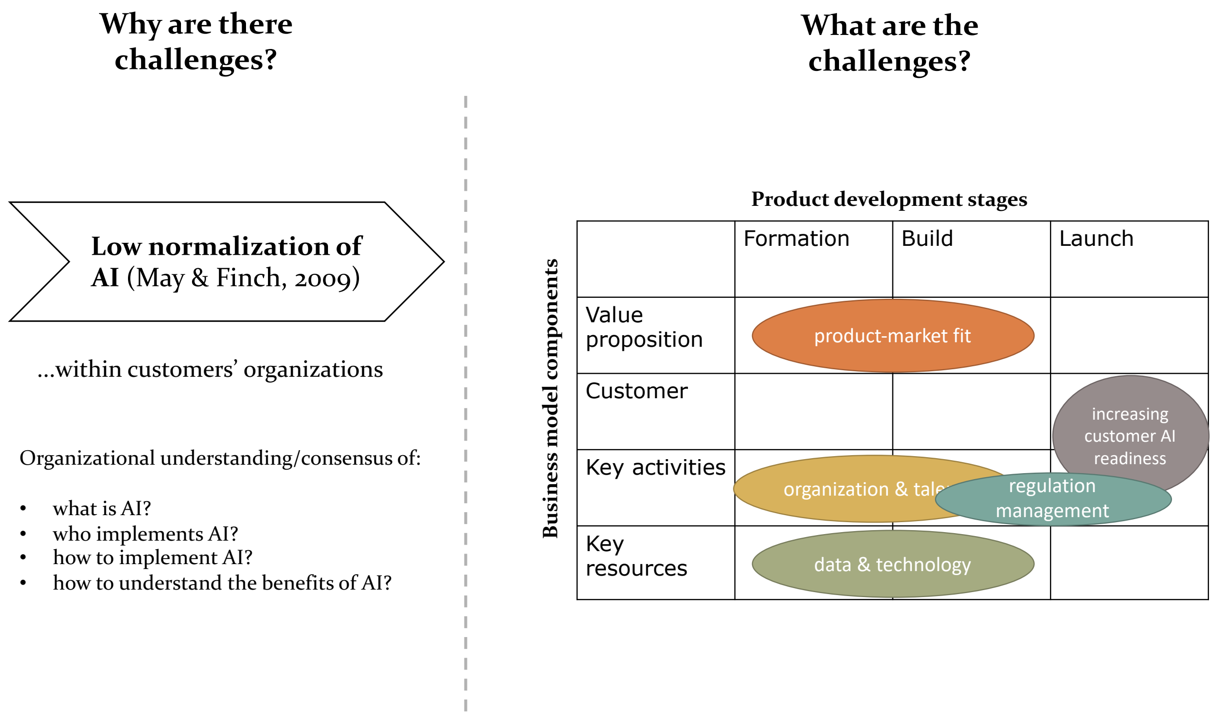


FIGURE 4 – MODEL FOR WHICH CHALLENGES HEALTHCARE AI START-UPS FACE, HOW THEY CHANGE OVER TIME, AND WHY THEY EXIST AT DIFFERENT STAGES.

With the challenges discovered from the empirics, we have improved the theoretical framework as above. The challenges we found from the empirics show a temporal pattern. We have also plotted out the relationships between challenges and business model components based on empirics and our analysis.

6.1. Challenges differ from our empirics and that of previous literature

We find that challenges described by interviewees are largely similar to those described in the literature review, which we summarized as technical, strategic, security, and customer challenges. The major differences are connected to

Product-market fit: previous literature largely misses the element of product-market fit. Product-market fit and value propositions are a fundamental concept to business model theory (Eisenmann et al., 2018; Osterwalder & Pigneur, 2010). As AI is in the early stages of adoption in the healthcare industry, interviewees were much more focused on product-market fit and value propositions as a challenge than previous literature has described. That is a potential contribution of our empirical material: our empirics indicate that start-ups find it challenging to find a fit between their product and the market. This appears to be mostly because of a gap in customer comprehension of what AI is, how to implement it and what the benefits are. Interviewees said there were many problems to fix – but customer comprehension for AI was not big enough to fully capitalize on that.

Customer AI readiness: Other articles have looked into capabilities such as relationship management and industry co-creation (Leone et al., 2020; Sheth, 2019). Prior research has not discussed customer readiness, while interviewees in our study have described customer readiness as the most crucial business challenge. Interviewees have said that customer AI readiness also influences the other challenges such as product-market fit as customers do not understand the benefits of the products, and data & technology because customers cannot accurately collect data for the AI models.

Talent & organization: Previous literature does not mention talent as a major challenge. Here is an important difference between our empirics to previous literature. Interviewees described talent as very important – and that the shortage of talent was not limited to developer talent. Other types of talent are also needed (e.g., software sales, operations/implementation, legal, and finance) who have competence in AI. Because AI is low adoption in healthcare, this talent pool is very limited. Our empirical material provides further insight into how start-ups view talent and indicates that there is a major challenge to find developer talent for AI in healthcare.

Challenges are dynamic – not static: Previous literature does not distinguish the fact that challenges may differ over time as a start-up develops, except for (Higgins & Madai, 2020) in their model for product development – which our research builds on. Our empirics and analysis have shown that the challenges are dynamic and change in importance over time as start-ups manage and seek coherence in their business model. The following sections will detail how and why the challenges exist and change across the different stages - form, build and launch.

6.2. Formation

6.2.1. Product-market fit

As described in (Higgins & Madai, 2020), when a healthcare AI start-up forms, its initial goal is to find a clinical need and to build a "proof-of-concept" solution to that need. The goal of the company is to build an initial **value proposition**. What is it that the start-up aims to deliver to customers? The value proposition is a central issue early on during formation. In interviews, we could clearly distinguish a themeless mature company that was more focused on challenges relating to finding product-market fit. This is certainly what general business model theory would expect (Blank, 2010; Osterwalder et al., 2005). Early on in development, companies focus on developing a value proposition – discovering who the customer is and what needs they have.

As mentioned by interviewees, conducting customer discovery (Blank, 2010) is the way to achieve product-market fit. Ensuring that the company is building something the customer is interested in. That requires having an extensive network of prospective customers that start-ups can collaborate with (Lee et al., 2019) to gain insight into the customers' most pressing needs. This is one of the reasons why a large portion of healthcare AI start-ups are providing customized solutions to the customers. They actively communicate with potential customers about how AI technology could help and adjust the products according to specific needs/demands from the customers.

AI is highly flexible and there are plenty of problems that AI can help fix as described by interviewees and theory (Miotto et al., 2017). Some interviewees said their company had so many potential problems they could fix (because the healthcare system is so fragmented) that they struggled to choose one and focus their effort on a specific problem. Because the development process is quite complex (with software development, clinical trials, and certification), start-ups must focus all their resources on one problem – or they would not be able to successfully develop through to launch their product on the market (Higgins & Madai, 2020).

AI is a highly complex technology, that customers have little knowledge about. When start-ups form their value proposition, they must take these characteristics into consideration. To develop a proper product-market fit and data strategy, start-ups must make sure that healthcare providers invest comprehension in reflexive monitoring to understand the benefits of AI in their operations (May & Finch, 2009). AI start-ups can facilitate this comprehension. For example, start-ups should choose a problem where AI has a large enough relative advantage to make it clear to the customer why they should implement the finished product in their operations. An example of a company that did this very well is an imaging company that we interviewed. They identified that the current technology had a cost of ca $30-40 per scan, whereas their technology could perform scans at a cost of around $6. They were able to select a problem in which their solution can observably create benefits, and where the relative advantage of AI over current technology is significant. When the cost reduction over the current technology has been demonstrated to prospective customers, they comprehend the benefits of the new practice.

Healthcare AI start-ups with B2B model are trying to find problems in healthcare providers' practices, instead of patients' direct needs. From previous studies, we noticed that some researchers believe that AI technology creates a shift to patient-focused healthcare. Yet we found that it depends on the business model of the healthcare AI start-ups. As we only focused on the start-ups that have a B2B model, it seems that AI healthcare products/solutions are more provider-focused. The start-ups are trying to increase the operational efficiencies and clinical accuracy of the healthcare providers. The products/solutions create benefits to the patients indirectly in terms of, for example, waiting time, result accuracy, etc. Yet B2B healthcare AI start-ups' primary focus is on healthcare providers' problems.

6.2.2. Data & technology

Another key challenge that appears to be very constricting for healthcare AI start-ups information is **access to large volumes of processed data for training models** (Higgins & Madai, 2020; Miotto et al., 2017; Reim et al., 2020)**.** In this challenge, theory suggests several possible pitfalls of forming start-ups:

The objectives in the early formation stage are to acquire access to an initial data set, understanding the structure of this data, determining whether it can be appropriately used to solve the clinical need, and also to predict which data is needed in later stages (Higgins & Madai, 2020). The accuracy and quality of the data, transparency of the models, and dealing with the temporality of diseases, domain complexity, and ensuring high interpretability of the models are all key challenges that occur already during formation (Miotto et al., 2017).

Data and technology can be viewed as belonging to the "key resources" business model component that the healthcare AI start-ups must develop (Osterwalder et al., 2005). Actively building access to high volume, quality, and structure of data, and ensuring interpretability and transparency of models will **help build a strong key resource** that the healthcare AI start-up will need in later stages of its product development. In this way, we can see dependencies across time.

Because normalization and adoption for AI are low in healthcare, there is little access to relevant datasets for AI start-ups to work with. Many of our interviewees mentioned data access as a severely constricting factor. In the future – when AI normalization is greater, more healthcare providers will know how to coordinate datasets in the right way (May & Finch, 2009) so that they can be shared with start-ups who build AI. Data is the most crucial in the formation and build stages – when start-ups build their initial codebase, which is why access to big datasets is a challenge. Interviewees indicated they see a change occurring in some parts of healthcare now because of covid-19, where healthcare providers are building capabilities to share datasets with researchers and innovation companies. Interviewees indicated they believe that in only a few years access to data will be far better – thus, as AI becomes normalized in the work routine of healthcare providers (May & Finch, 2009), healthcare providers will become better at producing datasets for AI, and these datasets can be used by start-ups who are in formation stage.

6.2.3. Organization & talent

Another challenge in formation is organization and talent – more specifically with a focus on recruiting R&D talent. The organization is just getting started with building its initial codebase – therefore, lack of access to premium AI developer talent would be a severely constricting challenge at this stage. **Start-ups must – as a key activity – learn how to recruit talent, which is especially difficult in all AI-related fields because developer talent is currently very restricted.**

Surprisingly, in our literature review, we did not find much theory suggesting that lack of developer talent would be a concern. Interviews painted a different picture with most interviewees suggesting that access to developer talent is a crucial challenge early on. A reason why this is perhaps not mentioned in previous research is that most start-ups that try to form around AI would be founded by someone with AI capabilities. Without R&D talent – there would be no way to form a company at all. That is perhaps why talent is not mentioned in prior research as a crucial challenge.

As mentioned, the market for AI talent is severely constricted currently, which is another symptom of the low normalization of AI. Interviewees described seeing growth in the talent pool for AI now, as more students graduate from computer science and AI programs from universities. As AI becomes normalized (May & Finch, 2009) into healthcare providers, other partners in the ecosystem will develop and integrate AI into their practices (for example universities or large tech firms). The industry will collectively decide, who builds this talent and how do you effectively build it? When AI is integrated fully into the ecosystem, there will not be a lack of talent. As one interviewee put it "throw a coin and there will be software engineers – but AI talent is severely restricted". As it stands now, the low normalization is an external factor to the start-ups that causes them to perceive a challenge with talent scarcity.

6.3. Build

At the build stage, the team works on producing a product that works in clinical practices and follows regulatory requirements (Higgins & Madai, 2020).

As the products are the center of the business for healthcare AI start-ups, the build stage has been discussed a lot during the interviews. Start-ups usually spend 1-2 years or longer to develop the products (Higgins & Madai, 2020). At the same time, they must be aware of the regulations in the regions that they operate. Internally, the large need for talent creates challenges as well.

6.3.1. Product-market fit

In the build stage, a major challenge is to ensure that products are fulfilling the needs of the customers. **There are tight linkages between product-market fit, regulation management, and customer readiness for AI.** This is because customers, healthcare providers/professionals are concerned with regulation, and must learn and understand how the AI tools work and how they are used.

What is slightly different from AI in healthcare compared to other types of start-ups and compared to start-ups not in healthcare, is that healthcare start-ups must fulfill certain proof-points that are healthcare specific. These proof points become more crucial during the build stage because the goal of the build stage is to build a product that can pass clinical validation. Customers of healthcare AI start-ups are typically hospitals where a board/commission usually makes all purchasing decisions of these types of products. Any products they purchase must prove demonstrably to reduce cost or increase health outcomes, and products must pass clinical certification to even be considered by the hospitals (Higgins & Madai, 2020). Therefore, at the Build stage, healthcare AI start-ups must lower the complexity of the technology for healthcare professionals to understand the usefulness and safety of the technology. (Rogers, 1995).

6.3.2. Data & technology

As product development is one of the key activities at the build stage, data and technology is one of the challenges that start-ups mentioned the most. We noticed that they mostly talk about this in relation to activities that closely match the "build stage" as described by (Higgins & Madai, 2020). During the build, healthcare AI companies want to grow bigger datasets so they can achieve greater validity of their models. However, because of regulatory issues related to data – the more they grow in terms of data, the bigger their challenges to manage regulations.

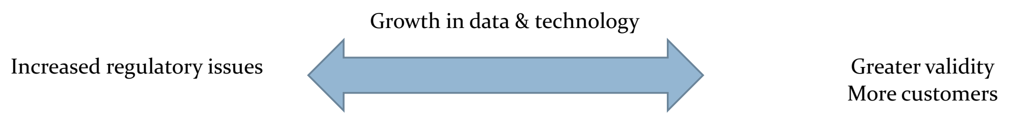


FIGURE 5 - TENSION BETWEEN GROWTH IN DATA & TECHNOLOGY VERSUS REGULATION MANAGEMENT

At this early stage of AI adoption, healthcare providers struggle to provide healthcare AI start-ups with high-quality data. To provide customized products, many healthcare AI start-ups choose to build their products with customer data. However, at the early stage of the normalization, data management is a new practice to the customers (May & Finch, 2009). There is no standardized way, experience, or guidelines to do it in the industry. Many customers don't have a clear understanding of what types of data to collect, who should collect this data, and how to make sure the data is inclusive, diverse, and unbiased. Healthcare providers have not yet developed a structured practice for how to organize datasets. They have little knowledge about how the way they collect, and store data influences the accuracy of the AI product. We have learned from the interviews that it has happened to healthcare AI start-ups that the products are not accurate because of biased data from healthcare providers. As the adoption grows and AI is normalized in healthcare practices, healthcare providers will have more knowledge and experience on data collection, and healthcare AI start-ups can leverage the data to build more accurate models.

6.3.3. *Organization & talent*

As the company grows and starts developing the foundation for fruitful customer relationships, it becomes more difficult to fulfill the needs of customers. During formation, a company usually has a foundational idea for a clinical need to solve, and how to solve it. But we have learned from interviews that AI is a very customized industry. Each provider has different needs, and AI companies in the build stage thus must build their software to match the needs of healthcare providers.

At the Build stage, healthcare AI startups try to create a relative advantage of their product over status quo of the customers (Rogers, 1995). To develop products that not only help with customers' specific situation but also compatible with their existing technologies and systems, start-ups need a large amount of experienced technical talent, given the technological complexity of AI healthcare products.

The flexibility of AI products gives start-ups more opportunities and a larger customer base, yet it also severely limits the talent pool and worsens the challenge of scarcity for developer talent.

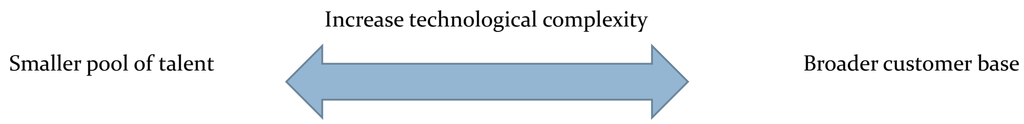


FIGURE 6 – TENSION BETWEEN TECHNOLOGICAL COMPLEXITY TO REACH A BROADER CUSTOMER BASE AND SMALLER TALENT POOL

6.3.4. *Regulation management*

At the build stage, healthcare AI start-ups get their hands on bigger patient datasets and build medical devices that are going to influence patients' life, which gives them little room for error in managing security. For example, a misdiagnosis could have severe consequences for a patient. **Therefore, compared to AI start-ups in other industries, AI healthcare start-ups would have to go through more validation and verification procedures.** We see the pattern from what interviewees said that regulation management is a challenge that becomes more important during the build stage. At formation, the company is finding a problem to fix and designing a prototype, but in the build stage, they must build a working product. And at this stage, regulatory concerns become important, because as a healthcare service provider you must be compliant with strict regulations about data integrity and safety.

This requires start-ups to develop knowledge about regulations for data, medical products/devices, and certification during the build stage. Validation and verification are important steps before the launch of the product. If you are not compliant and lack the relevant certifications – you will not sell anything in the healthcare market. It is not only required by regulators but also by healthcare providers to purchase the product.

Low normalization makes regulation challenging in the build and launch stage to manage because regulators have not been able to implement AI in their practices yet. As the normalization of AI in healthcare increases, external stakeholders such as regulators and customers will form a consensus into which regulations are necessary around AI, and how to manage those regulations. But at this point, existing regulations regarding medical products and data security are not very well designed to fit with AI. One reason is that AI is not a traditional medical product – such as an MRI scanner or a ventilator**.** AI is an analytical product – not a tangible machine. Therefore, AI does not directly fit into existing regulations. And regarding data security – there is also low normalization for regulations regarding data security. Our empirics indicate that low normalization of data security and regulations for AI as medical products are causing challenges for healthcare AI start-ups how to manage data and regulations.

6.4. Launch

At the launch stage, the goal according to theory is (Higgins & Madai, 2020)

- Pass medical device certification and clinical validation
- Have clinical studies showing the efficacy of products
- Products should now be possible to deploy in a live clinical setting

In our interviews, we find that interviewees largely talk about these issues as well. However, going beyond the theory – we conclude that there is also a great deal of effort that goes into customer-related activities, raising awareness of AI benefits and educating customers how to use the products. In launch, regulation management is a big challenge for those start-ups who sell in different geographical markets.

6.4.1. Customer AI readiness

As explained by (Miotto et al., 2017) and interviewees AI readiness is a big challenge in the launch phase. The AI service must be interpretable to healthcare professionals who use the service – otherwise, the start-ups would not be able to sell. There is a lack of trust in AI among medical professionals. Interviewees in certain fields believed the technological readiness is higher for their customers because they have learned to use similar technologies in the past.

Increasing AI readiness is one of the key activities at Launch from a business model perspective. Increasing understanding, trust, and familiarity for AI could make stakeholders more likely to apply the right data acquisition methods and use the service in the most effective way – and that can create improved health outcomes or efficiencies.

In the launch phase, there is also the element of targeting and processing the key decision-makers. The consensus among interviewees is that the key decision-makers are the operational staff – e.g., doctors, radiologists, and others who use the software daily. AI start-ups must reduce any resistance toward AI in these groups, and that is a key activity that entails continuous communication with stakeholders, educating and supporting customers on how to use the product (Leone et al., 2020).

Many healthcare professionals are also concerned about whether AI technology is going to replace human jobs. This requires healthcare AI startups during the launch stage to change medical professionals' beliefs about AI and convince them that AI will help them work more efficiently and not replace them (May & Finch, 2009).

Another important decision-maker that interviewees repeatedly mentioned are "innovation-centers" at hospitals. Innovation centers at hospitals consist of teams specifically focused on finding new technologies to apply to the operations. Therefore, a challenge for AI start-ups is to develop partnerships with innovation centers and raise their understanding of AI products.

The flexibility that makes AI useful in a wide range of settings also creates a downside. As flexible as AI is, it also introduces technological complexity, which according to (Davis, 1989; Rogers, 1995) will slow down the adoption of AI. High technological complexity makes AI difficult to understand.

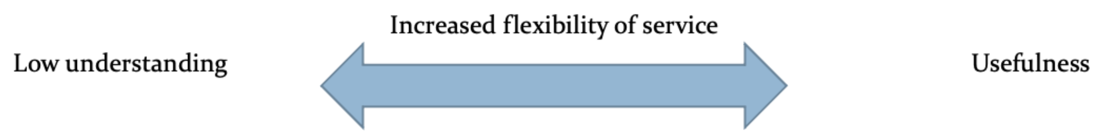


FIGURE 7 - TENSION BETWEEN INCREASING THE USEFULNESS OF THE PRODUCT AND CUSTOMER UNDERSTANDING OF THE PRODUCT

This introduces problems of adopting AI for customers and reduces their understanding of what AI is, how to implement it and what the benefits are. This creates a low readiness to implement AI as a new practice (May & Finch, 2009). The technology acceptance model (Davis, 1989) dictates that people will weigh the perceived utility of innovation against the perceived ease of use when they decide whether or not to implement new technology. Increased perceived technological complexity would therefore be expected to have a negative impact on the intention of healthcare providers to implement AI.

This makes it a big challenge for AI start-ups to increase AI readiness. Some strategies that interviewees mentioned to increase AI readiness at the launch stage include**:**

- **Educating customers** (for example doing workshops with them to teach them how to record and structure data in a good way).
- **Marketing the problem and the solution – not the technology**: focusing on the benefits and applications of AI – increasing relative advantage and observability (Rogers, 1995) – and putting less emphasis on the technology itself – reducing complexity (Davis, 1989).

- **Standardizing the products and reducing the technological complexity** – for example, make it "no-code" to allow medical professionals (at their level of readiness and their understanding of IT environments) to use it.

Healthcare AI start-ups must help medical professionals achieve an increased readiness for AI by normalizing it as a new practice in healthcare providers' operations. But as described by May & Finch (May & Finch, 2009), this normalization process comes at the cost of investing meaning, commitment, effort, and comprehension in the process. Interviewees described this trade-off, where they strive to maintain a balance between the investments that they make into this normalization process (which will increase their available market), and the cost thereof.

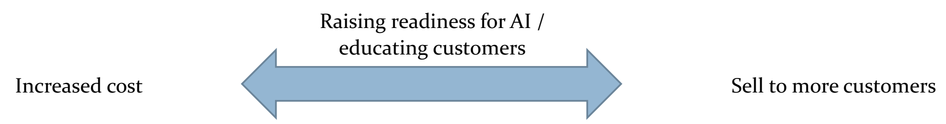


FIGURE 8 - TENSION BETWEEN INCREASING CUSTOMER READINESS FOR AI AND THE COST THEREOF

Normalization becomes a more important external driver in the launch stage of challenges related to readiness for AI. This is because the launch stage brings an increasing focus on managing customer relationships, sales, and marketing. **Low normalization of AI practices creates the perceived challenge of low readiness that interviewees described.** As expected based on (Reim et al., 2020), we see a pattern from interviews: when employees of customer organizations understand, trust, and are familiar with using the AI product, they will be more positive towards implementing it in the operations.

6.4.2. Regulation management

Another issue that becomes much larger in the launch phase is regulation management. When organizations have a product that is functional from the build stage, they now must manage highly fragmented regulation. Especially for companies that are operating multi-nationally. The regulation varies drastically between countries because of several reasons.

For example, an imaging company operating in a public healthcare system who develops a software that helps radiologists prioritize which cases they should work on first (to diagnose for cancers) will mainly sell to hospitals – because those hospitals are the ones who are large enough to afford the software and who have a problem managing their workload (due to fragmented IT systems, which a smaller clinic would not have the same problem with). This makes the purchasing process more complicated because there are more regulations to follow. That leads to a challenge with regulation management. Here, the choice of product and the geographical market largely dictates who the customer is – which in turn creates a regulation problem. This example shows that by extension the business model choices of a start-up can create challenges for the start-up.

Growth into new markets introduces more regulatory complexity for healthcare AI start-ups. Here is yet another tension. Organizations want to grow into new markets to serve more customers, and to spread the adoption of the innovation (Rogers, 1995) – but because of how fragmented regulation is regarding healthcare (each country has its own healthcare systems and specific regulations) – growth into new markets create a challenge for healthcare AI start-ups to manage regulations.

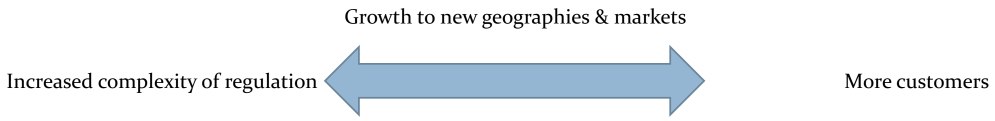


FIGURE 9 - TENSION BETWEEN GROWTH TO NEW MARKETS AND INCREASED COMPLEXITY OF REGULATIONS

One reason that interviewees described was the level of development of the healthcare systems. Their experience was that developing countries have much less regulation to manage. In certain markets, there is virtually no regulation applicable to AI according to interviewees. However, in other markets like the EU, interviewees said there is far more regulation to manage.

Another reason why regulation management is a key activity in the launch is that many of the healthcare AI start-ups sell in markets with a public healthcare system. In a public healthcare system, healthcare is government spending. Therefore, there is much regulation about how governments are allowed to spend money. Our interviewees described this distinction, as they said that hospitals are more willing to spend money in a private system – if you can demonstrate a clinical improvement. Whereas public healthcare systems are more difficult to navigate, and you need to convince more people of the benefits.

As mentioned during the build stage, because AI is early in normalization (May & Finch, 2009) of healthcare providers' practices and adoption (Rogers, 1995) across the healthcare industry, regulators and other stakeholders have not yet reached a clear understanding of how regulations for AI should best be managed in healthcare – certainly not between different markets. Regulators' lack of experience causes challenges of regulation management for AI healthcare start-ups – especially those who are active across different geographical markets because regulations are different.

6.4.3. *Organization & talent*

Talent recruitment is still a challenge during the launch stage. However, now the focus of organizations is to increase the AI readiness of healthcare providers to drive sales. This introduces a need to find salespeople who understand the products and to find operations people who can help deploy the software within customers' operations.

Because AI is early in normalization, finding operational and sales talent who can understand and generate sales of AI products is highly challenging. Few people have the relevant strategic and technical skills to understand healthcare AI strategy: what to do with AI in healthcare, who needs to do what, how that is done and what the benefits are of deploying AI in healthcare operations (May & Finch, 2009). To sell an advanced analytics product like AI, staff would need to have competence in these different topics and be able to distribute that knowledge to healthcare providers and medical professionals. But because AI is not yet normalized across the industry, the talent pool for people with all that different expertise is constricted – the industry has not yet built enough experience selling and implementing those products to know how it is done. Furthermore, because regulation management is a key issue in the launch stage, recruiting relevant legal expertise to manage AI becomes another major challenge.

6.5. Post-launch

After launch, we have found in our empirics that the overall focus of the organization largely shifts. From being a developer organization with a focus on building good models, data access, and managing regulations – a start-up that is beyond the launch stage of development would now focus more on sales, marketing. Looking at adjacent theories such as the business model (Blank, 2010; Osterwalder et al., 2005) and lean start-up methodology (Eisenmann et al., 2018), we can explain this change as the organization now has found its maturity. Beyond this stage, the organization would cease to be a start-up, instead of becoming an established organization. The organization has now found a scalable business model.

6.6. Final remarks of analysis

Gradually, as we see AI being implemented via pilot studies and experiments across healthcare operations as proposed by (Lee et al., 2019), AI will become increasingly normalized. Interviewees described a future where this is likely to occur. One interviewee said, "In a few years, no one will talk about AI, just as we don't talk about the internet anymore". In NPT terms, AI will by then have become embedded, normalized, and fully integrated into the work routine of the healthcare industry. Think about electronic medical records (in Sweden). This innovation has been implemented widely across the Swedish healthcare system, and now all patients can access their journals electronically. That has become integrated into the healthcare system and in the way that medical professionals work. According to our research, we are likely to see the same trajectory for AI.

Normalization is the process by which individuals inside organizations collectively learn how to implement a new practice. Over time as staff shift employers and job roles, this experience is distributed across the industry, at which point there is a greater understanding of what AI is and how it works. There will be a greater understanding of who implements it (e.g., innovation companies, implementation partners such as consultants, or the healthcare providers themselves in-house). There will be a general process and experience of how to implement AI in healthcare and greater knowledge of what advantages and disadvantages AI can create in healthcare operations.

Normalization of AI will happen over time but will require investment of effort, commitment, and comprehension of healthcare providers (May & Finch, 2009)**.** Healthcare AI start-ups have a crucial role to play, by facilitating this process. They will do this by finding relevant problems to solve, building products that fit the needs of medical professionals, regulations, and by educating and facilitating medical professionals' and hospitals' implementation of AI.

An interesting observation is that healthcare AI start-ups' business models are like "elastic bands". The story we interpret from interviews is that start-ups strive to facilitate the normalization of AI in customer organizations, but that comes at cost of effort, commitment, and comprehension. Thus, start-ups choices about value proposition (e.g., flexible versus simple to use), customer segments and relationships (e.g., large versus small organizations, how much effort spent to educate customers), key activities (e.g., growth into new markets), key resources (e.g., which talent to recruit) can influence the severity of the challenges.

7. Discussion

7.1. Contribution to practice

Our research has investigated healthcare AI start-ups, as changemakers in the healthcare industry, they face several challenges as they develop their business. These challenges occur because of their business model choices, but also because of AI being in the early stages of industry adoption and implementation as a new practice in healthcare organizations. Our research is an attempt to provide understanding as to why healthcare is seeing slower adoption of AI than other industries.

Our research provides insight into:

- Which challenges AI healthcare start-ups face throughout business development, and how they change as they progress toward becoming an established organization.
- Why they face these challenges – as a developing industry, early in adoption AI has yet to reach broad normalization as a new practice, so medical professionals know what to do with it, how to do it, who will do it and to understand the benefits and drawbacks of AI.

This knowledge may be useful for entrepreneurs in the AI healthcare field to understand which challenges they need to navigate to successfully launch their product to market and provide a theory for why these challenges occur specifically in the field of AI.

7.1.1. Slow diffusion of AI brings opportunities and challenges

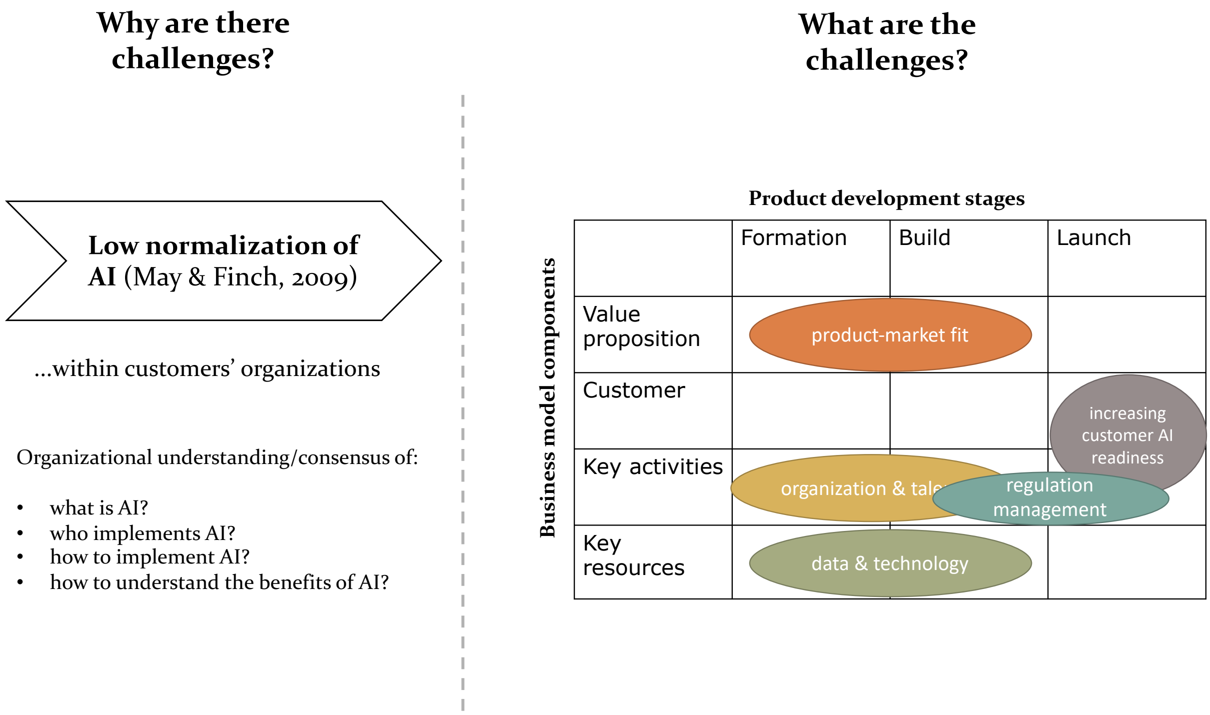
Our research indicates that healthcare AI start-ups must take relative advantage, ease of use, compatibility, trialability, and observability into account when they develop their products. We have demonstrated that the development of AI in healthcare can be viewed as technological innovation and that characteristics of AI such as the ease of use and relative advantage of AI over current practices greatly influence start-up's ability to find product-market fit. Our analysis shows that none of the facilitating product characteristics are present for AI in healthcare and thus could explain why AI start-ups in healthcare face challenges as they try to develop their business. The product characteristics are more important during the form and build stages – as the company focuses on building their product offering.

7.1.2. AI readiness as a positive externality

Investments into AI readiness can be seen as a "positive externality" (Dietzenbacher & Los, 2002) from healthcare AI start-ups, which may limit their ability to invest in it. If we view AI in healthcare as a "disembodied innovation" – that is, a transmission of ideas, knowledge, and expertise of how to use AI and how to understand it. Then, according to (Dietzenbacher & Los, 2002) theory of positive externalities, increasing AI readiness will create benefits for the whole industry and society at large – those early pioneers such as AI healthcare start-ups currently must bear the costs. Healthcare AI start-ups operating now at this early stage of the normalization of the technology would have to bear more cost in raising the AI readiness of healthcare providers than start-ups that will join when the technology is fully normalized.

A relevant thought is whether healthcare AI start-ups are fit to take this role or whether other stakeholders (research institutions, government agencies, big tech companies) could and should do more to increase the diffusion and normalization of AI in healthcare? We have identified low readiness for AI as one of the most important constricting factors to AI adoption. With a promise of large health benefits and operational efficiencies from increasing AI readiness, other stakeholders have an interest in investing in it.

7.2. Theoretical contribution



7.2.1. Challenges of healthcare AI start-ups are dynamic

Our research has shown that certain challenges for healthcare AI start-ups are more or less dominant in different phases of product development. Our research shows that challenges change as the organization shifts from focusing on developing products to marketing and sales.

7.2.2. Low normalization is an explanation for the challenges

Our research can be seen as a case application of May & Finch's (2009) normalization theory. Our research shows the importance of technological advancements in an industry – and that companies must skillfully manage their customer relationships, partnerships, and ecosystem participation to help grow the readiness across the industry for a technological innovation.

Our research shows that healthcare start-ups face large challenges because AI has not been normalized in the practice of start-ups' customers: healthcare providers, and within their teams of medical professionals. The limited knowledge the customers and market have, and the technological complexity of AI technology have negatively influenced the normalization of the products in healthcare. **This requires healthcare AI start-ups to invest resources, effort, and commitment to facilitate the normalization of AI within customers' organizations.**

Our research provides further insight into how organizations create technological acceptance (Davis, 1989) and that it is important for B2B companies in high-tech sectors to not only adapt their products to the needs of customers – but also actively educate customers to a higher level of understanding of the new technology and practice.

7.2.3. Business model choices can affect the challenges of start-ups

We find that the choices start-ups make about their business model influence the severity of the challenges. For example, organizations that focus on reducing the technological complexity of products reduce the flexibility of the products – but may in the process reduce the challenge of customer AI readiness. In reverse, an increased technological complexity may attract more competent staff, but would reduce the available talent pool and most likely reduce customer readiness. In this way, we see that start-ups are not completely in the hands of external market forces. Their choices about business model components: value proposition, customer segments/relationships, key activities, and key resources can affect the severity of challenges.

7.2.4. Filling in the gap of challenges specific to healthcare AI startups

As we noticed from the literature review, there are very few studies on challenges specific to healthcare AI start-ups. Most of the previous studies are focused on healthcare providers or bigger med-tech companies. By interviewing executives from healthcare AI start-ups, we get insight from the supplier-side of the AI adoption in healthcare, which demonstrates the internal and external challenges that healthcare AI start-ups have as increasingly important innovators in the healthcare industry.

7.2.5. *Summary of theoretical contributions*

We conclude that the challenges healthcare AI start-ups face are influenced by:

- The stage they are at in the product development process
- Choices about business model components
- Normalization of AI in customer organizations
- Relationships and tensions between the challenges

7.3. Further research

MANAGING TALENT FOR HEALTHCARE AI

In our empirics, we see a big business model challenge is talent scarcity. Future research could delve deeper into this specific business model challenge. Examples of research questions include:

- How do healthcare AI start-ups overcome the talent scarcity for AI developers?
- How is the new talent pool for AI forming?

In our empirics, we see that there are several different categories of talent that AI start-ups need, and that this type of talent would be different across the business model development stages.

Our empirics also indicate that intrinsic motivation is very important to this rare talent. Research into this topic could explore which factors AI healthcare start-ups must focus on to win the battle for talent. As one interviewee said: "finding the right talent is half the battle" – this indicates that healthcare AI start-ups have a big business challenge in this area.

WHO BUYS AI?

Another possibility is to do further research regarding who makes purchasing decisions for AI solutions. Interviewees in our empirics repeatedly mention "innovation offices" as a key avenue for selling AI solutions to hospitals. Innovation offices of the hospitals are responsible for finding and implementing new technology. Interviewees mention that other people who make decisions are board/commission members of hospitals. Possible research questions:

- What do innovation centers look for?
- How do they make decisions?

Further research could investigate for instance via interviews what motivates key stakeholders' purchasing decisions.

WHAT IS THE ROLE OF TECH CONSULTANTS IN AI ADOPTION?

We know from similar technological innovations in the past, e.g., ERP systems (SAP, Oracle) and RPA (Blue Prism, UiPath) **that technological consultants (e.g., Deloitte, PwC, EY) play a significant role in the implementation of technological advancements in various industries.** Further research could be needed to understand what role these professional services providers play in the implementation of AI in the healthcare industry. Such research could explore the partnerships and relational ecosystems formed between software providers in healthcare AI and technology consultants who implement their software. What is the role of tech consultants in the diffusion of AI in healthcare?

CHALLENGES IN DIFFERENT HEALTHCARE SECTORS

In the study, we have included healthcare AI start-ups in all healthcare sectors - preventive sector, diagnosis, remedial, and maintenance/therapeutics. We did not find significant differences in the challenges of companies in the different sectors. Reasons for this may be that

- they have similar customer segments: healthcare providers
- under the hood, many AI products are very similar: it is just mathematical algorithms that do predictions

The uses for AI can be drastically different in the different sectors. For example, the diagnostics sector has many use cases within image analysis, whereas the therapeutics sector has a lot of use cases for digital apps for patients to track their conditions. We do not see that the healthcare sector has a major influence on the challenges that start-ups face.

However, it is still a relevant question. What are the differences in challenges between different sectors? Certainly, the vast difference in use cases could create certain challenges. Such research could be relevant to explain which sector is the easiest to enter, and that in extension could explain potential differences between the adoption of AI in different healthcare sectors.

WHAT WERE THE CHALLENGES OF START-UPS THAT FAILED?

Start-ups in our research are still operating. We only make claims about the challenges of start-ups who successfully handled their challenges. Further research could explore defunct start-ups, what are the challenges that defeated them? How did they handle the challenges? What could they have done differently to survive? Such research could help explain the failing factors of healthcare AI start-ups and what approaches to avoid when handling the challenges.

7.4. Limitations

AI IN HEALTHCARE WILL MATURE

AI healthcare is a relatively new group of technology that is still growing and changing rapidly. We see more and more AI start-ups entering the healthcare industry. With the changes in the healthcare sector happening rapidly worldwide, the future of the industry is unknown. Therefore, this research is focused on AI healthcare start-ups that operate now, but in five or ten years the conditions for AI start-ups may be completely different. From the literature and interviews, we could also tell that people believe this industry is growing and changing, which also requires the participants to have the ability to meet future challenges and develop capabilities to mitigate them.

GEOGRAPHIC DIFFERENCES

Many of the companies we interviewed sell predominantly to markets with a "privatized healthcare system" such as the US – where hospitals are run as private companies. We partially discuss the differences between markets – but there is a potential limitation here, as companies predominantly selling products and services in a public healthcare system would focus more of their efforts on selling to public health officials as opposed to direct to hospitals. The purchasing motivation for the public healthcare system is also different. Interviewees said budgets are less tight in a private healthcare setting. If healthcare executives believe the product will have a positive effect, they are more likely willing to buy it. Because any investments made in a public healthcare system are made directly from tax money – spending is more controlled.

DIFFERENT TYPES OF PRODUCTS

We didn't see a clear difference in the kinds of answers we get depending on which problem in the healthcare value chain that start-ups work to solve (Higgins & Madai, 2020), however, we hypothesize that different types of AI products would have different kinds of business model challenges. For example, a company developing a software to do self-scanning via your smartphone ("specialized diagnostic", see Garbuio & Lin, 2019) may have more of an "engineering dimension" than a company developing AI for electronic health record systems ("aggregator", see Garbuio & Lin, 2019). That would require different types of talent and different ways of educating customers.

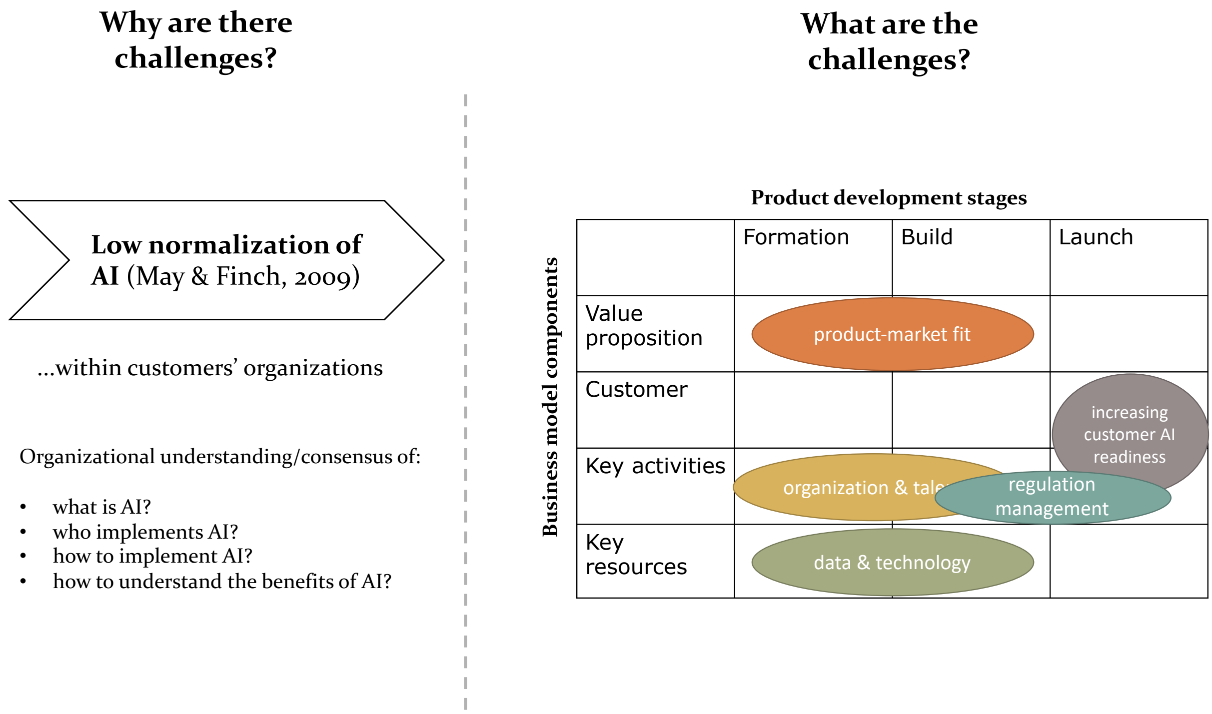
DIFFERENT STAGE OF DEVELOPMENT

The start-ups we interviewed are at different stages of their business development. Some start-ups have already launched their product for a few years and the product is mature. While some of the start-ups are still in the product development phase. Start-ups at different stages of business development tend to emphasize different types of challenges during the interview. Start-ups currently at the product development stage are more focused on the challenges of data-related issues. While start-ups at the Launch stage talked more about customers and partnerships. Even when these start-ups talking about their past experience during product development, they tend not to see that as a big problem since they have successfully solved it.

START-UP FUNDING AS A CHALLENGE?

We are aware that funding is a major hurdle for start-ups. The reason we have not mentioned it as a major challenge is that the interviewees did not bring it up very much. A potential reason for this is because – as we mentioned in the introduction – healthcare AI start-ups receive a lot of funding (Deloitte, 2019). Therefore, the companies in our sample might not have experienced funding as a problem. We hypothesize that they take funding for granted as a constant challenge throughout their journey. As the interviewees did not mention it to a great extent – there is no basis to bring it up in the study. However, perhaps the topic of funding is an issue we could have asked more questions about – how to overcome that challenge, what are the strategies to do it. Investigating funding for healthcare AI start-ups can be a relevant topic for future studies.

8. Conclusion



8.1. What challenges do healthcare AI start-ups face as they develop their business?

Healthcare AI start-ups face challenges of (1) **building product-market fit**, (2) **developing data & technology**, (3) **managing regulations**, (4) **accessing competent talent to develop and market the products**, and (5) **helping customers overcome low readiness for AI**. These challenges occur over time throughout the formation, build and launch (Higgins & Madai, 2020) of the products.

8.2. Why do the challenges occur?

Healthcare AI can be seen as a **normalization process of a new practice (organizational level, in customers' organizations).** AI is a new practice that needs implementation – which indicates that the healthcare system must learn what to do with AI, who implements it, how to implement it, and the benefits of implementing it. Normalization also spreads experience across organizations and industries, which increases adoption of the innovation in the whole industry.

To sell their products, AI healthcare start-ups must help their customers (medical professionals and hospitals) to normalize AI as a practice in their operations. Normalization is a more important driver for challenges during build and launch, the later stages of product development as the company shifts its focus to marketing and deploying its product in healthcare operations.

Normalization process theory (May & Finch, 2009) provides a lens through which to view the difficulties of implementing AI in healthcare and understand **why start-ups face certain challenges.** There's a lack of knowledge and understanding of how to implement AI within healthcare organizations (low normalization) – that leads to a low readiness for AI in the industry and creates the described challenges for start-ups as they develop their business.

Because the normalization of AI is low within customer organizations, we find that healthcare AI start-ups' choices about business models create trade-offs they must balance. The impact of challenges can be increased or decreased by start-ups' choices about business models (e.g., simple to use versus flexible product) and the challenges influence each other (e.g., low customer AI readiness makes it harder to find product-market fit).

8.3. How and why do the challenges change over time?

Our research shows that the big challenges in each stage are:

- **Formation:** product-market fit, talent & organization, and data & technology
- **Build:** product-market fit, regulation management, talent & organization, and data & technology
- **Launch:** customer AI readiness, regulation management, and talent & organization

The challenges change over time from "development-focused" challenges related to developing the initial business model and product, toward "marketing-focused" challenges, related to selling the product and managing the healthcare ecosystem and associated regulations. As start-ups learn how to manage the challenges – they cease to be as big challenges, and the business model solidifies around the **business model components (product-market fit, customer, key activities, key resources).**

8.5. The end

We would like to end our report by repeating a quote from one of our interviewees that nicely illustrates the promise of healthcare AI:

"If you are a patient, I think you would want to know what works for you. That's it. That's all we do. We tell you: you have a prescription in your hand from one doctor, is that really the right prescription? Are you sure? The doctor is not sure. The system is not sure. We spend two minutes with you and had to go with what terabytes of data around you and made a call because we saw somebody last week who looked like you and had the same symptoms. Are you sure you want to take that? That's it. Very simple. That's all we do. Personalized healthcare. This is the future we envision for every single person. 'Tell me what is good for me'."

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9. Appendices

Exhibit 1 - Questionnaire for interviews

The following questions were discussed with interviewees. The subsequent discussions also opened up to probing questions. However, mostly, the interviews centered on the following questions quite rigorously:

- How does «Company» create value for your stakeholders?
- Was «Company»'s business model 1. always centered around Artificial Intelligence or 2. has your business model evolved into applying Artificial Intelligence?
- Why do you think healthcare is a good industry to adopt AI?
- What have been «Company»'s challenges when implementing AI into your business model?
- Which resources did «Company» need to implement your AI-driven business model?
- What are «Company»'s current struggles/limitations related to AI that you must overcome to reach your business/other goals?
- How does «Company» reach out to potential customers?
- How do you perceive the level of readiness for AI among your customer base?
- Have you experienced any challenges when it comes to the adoption of your products?

Interviewee number	Role in company	Company healthcare sector	Company category	# Employees of the company
1	Co-founder, CEO	Remedial	diagnostics and pathology	36
2	Ex co-founder	Preventive	genetics	0 (defunct)
3	Co-founder	Preventive	clinical trials and research	7
4	Co-founder, CEO	Therapeutics	personalized healthcare	6
5	Co-founder, Chief product officer	Diagnosis	imaging	4
6	Co-founder	Preventive	analytics	9
7	Trainee	Remedial	personalized healthcare	47
8	Co-founder, CEO	Therapeutics	personalized healthcare	12
9	Journal Director	Academic	academia	1
10	Co-founder, CEO	Diagnosis	chatbot, virtual assistant	9
11	VP, Business Development	Diagnosis	imaging	41
12	Business Developer	Diagnosis	diagnostics and pathology	20
13	Business Development	Diagnosis	analytics	47
14	Business Development Manager	Diagnosis	imaging	107
15	Global partnerships manager	Diagnosis	preventive care	33
16	Co-founder	Therapeutics	nutrition	4
17	Business development manager	Diagnosis	diagnostics and pathology	26

EXHIBIT 2 - INTERVIEWEE OVERVIEW

10. References

Ada. (2020). Putting AI to work: How can we overcome barriers to AI adoption in healthcare?

Alvesson, M., & Sköldberg, K. (2007). *Tolkning och reflektion. Vetenskapsfilosofi och kvalitativ metod* (Second edi). Lund: Studentlitteratur AB.

Americas, M. H., Richter, M., & Atreja, A. (2017). *" In the future , hopefully there will be fewer drugs , or there will be drugs that prevent you from getting sick in the first place ."* (June).

Bhardwaj, R., Nambiar, A. R., & Dutta, D. (2017). A Study of Machine Learning in Healthcare. *Proceedings - International Computer Software and Applications Conference*, *2*, 236–241. https://doi.org/10.1109/COMPSAC.2017.164

Blank, S. (2010). What's a startup? First principles. Retrieved March 18, 2021, from https://steveblank.com/2010/01/25/whats-a-startup-first-principles/

Boneprox. (2021). Boneprox website. Retrieved February 25, 2021, from https://boneprox.com/

Bryman, A., & Bell, E. (2015). *Business Research Methods* (Fourth edi). Oxford University Press.

Bughin, B. J., Hazan, E., Ramaswamy, S., Chui, M., Allas, T., & Henke, N. (2019). How artificial intelligence can deliver real value to companies.

Christensen, C. M., & Johnson, M. W. (2009). What Are Business Models , and How Are They Built ? *Harvard Business Review*, *44*(0), 1–11.

DataRoot Labs. (2020). *AI in healthcare innovation landscape 2020*.

Davis, F. D. (1989). Perceived Usefulness, Perceived Ease of Use and User Acceptance of Information Technology. *Information Systems Journal*, *Vol. 13*(September), 319–340. Retrieved from http://www.jstor.org/stable/10.2307/249008

Deloitte. (2019). Global Artificial Intelligence Industry Whitepaper. *Deloitte*, 1–110.

Dietzenbacher, E., & Los, B. (2002). Externalities of R and D expenditures. *Economic Systems Research*, *14*(4), 407–425. https://doi.org/10.1080/0953531022000024860

Droice Labs. (2021). https://www.droicelabs.com/.

Eisenmann, T., Ries, E., & Dillard, S. (2018). *Hypothesis-Driven Entrepreneurship : The Lean*

Startup. (January), 1–26.

Garbuio, M., & Lin, N. (2019). Artificial intelligence as a growth engine for health care startups: Emerging business models. *California Management Review*, *61*(2), 59–83. https://doi.org/10.1177/0008125618811931

Guba, E. G., & Lincoln, Y. S. (1994). Competing Paradigms in Qualitative Research. In *Handbook of qualitative research*. https://doi.org/http://www.uncg.edu/hdf/facultystaff/Tudge/Guba%20&%20Lincoln%20 1994.pdf

Herzberg, F., Mausner, B., & Bloch Snyderman, B. (1959). *The Motivation to work*.

HFMA. (2020). *How investment in AI for healthcare organizations has changed due to the pandemic*. (November), 13–18.

Higgins, D., & Madai, V. I. (2020). From bit to bedside: A practical framework for artificial intelligence product development in healthcare. *ArXiv*, *2000052*. https://doi.org/10.1002/aisy.202000052

Kvale, S., & Brinkmann, S. (2009). *Den kvalitativa forskningsintervjun* (Second edi). Lund: Studentlitteratur AB.

Lee, J., Suh, T., Roy, D., & Baucus, M. (2019). Emerging technology and business model innovation: The case of artificial intelligence. *Journal of Open Innovation: Technology, Market, and Complexity*, *5*(3). https://doi.org/10.3390/joitmc5030044

Leone, D., Schiavone, F., Appio, F. P., & Chiao, B. (2020). How does artificial intelligence enable and enhance value co-creation in industrial markets? An exploratory case study in the healthcare ecosystem. *Journal of Business Research*, (September). https://doi.org/10.1016/j.jbusres.2020.11.008

Malek, S. L., Sarin, S., & Haon, C. (2020). Extrinsic Rewards, Intrinsic Motivation, and New Product Development Performance. *Journal of Product Innovation Management*, *37*(6), 528–551. https://doi.org/10.1111/jpim.12554

May, C., & Finch, T. (2009). Implementing, embedding, and integrating practices: An outline of normalization process theory. *Sociology*, *43*(3), 535–554. https://doi.org/10.1177/0038038509103208

McColl-Kennedy, J. R., Vargo, S. L., Dagger, T. S., Sweeney, J. C., & van Kasteren, Y. (2012). Health Care Customer Value Cocreation Practice Styles. *Journal of Service Research*, *15*(4), 370–389. https://doi.org/10.1177/1094670512442806

McKinsey & Company. (2020). *AI adoption in organizations worldwide 2020, by industry and function*.

Miotto, R., Wang, F., Wang, S., Jiang, X., & Dudley, J. T. (2017). Deep learning for healthcare: Review, opportunities and challenges. *Briefings in Bioinformatics*, *19*(6), 1236–1246. https://doi.org/10.1093/bib/bbx044

National Center for biotechnology information. (2009). Appendix 1: Definitions of health-care settings and other related terms.

Omachonu, V. K., & Einspruch, N. G. (2010). Innovation in healthcare delivery systems: A conceptual framework. *Innovation Journal*, *15*(1), 1–20.

Osei-Frimpong, K., Wilson, A., & Lemke, F. (2018). Patient co-creation activities in healthcare service delivery at the micro level: The influence of online access to healthcare information. *Technological Forecasting and Social Change*, *126*, 14–27. https://doi.org/10.1016/j.techfore.2016.04.009

Osterwalder, A., & Pigneur, Y. (2010). *Business Model Generation*.

Osterwalder, A., Pigneur, Y., & Tucci, C. (2005). *Clarifying business models: Origins, present, and future of the concept*. *6*(1), 7–29. https://doi.org/10.1016/S0046-8177(75)80107-9

Paindrainer. (2021). https://paindrainer.com/.

PwC. (2020). *AI adoption challenges for healthcare in the*. (January).

Qinematic. (2021). https://www.qinematic.com/home.

Quan, X. I., & Sanderson, J. (2018). Understanding the artificial intelligence business ecosystem. *IEEE Engineering Management Review*, *46*(4), 22–25. https://doi.org/10.1109/EMR.2018.2882430

Reim, W., Åström, J., & Eriksson, O. (2020). Implementation of Artificial Intelligence (AI): A Roadmap for Business Model Innovation. *Ai*, *1*(2), 180–191. https://doi.org/10.3390/ai1020011

Robertson, T. S. (1967). The Process of Innovation and the Diffusion of Innovation. *Journal of*

Marketing, *31*(1), 14. https://doi.org/10.2307/1249295

Rogers, E. M. (1995). *The Diffusion of Innovations* (pp. 1–26). pp. 1–26.

Sandström, S., Edvardsson, B., Kristensson, P., & Magnusson, P. (2008). Value in use through service experience. *Managing Service Quality: An International Journal*, *18*(2), 112–126. https://doi.org/10.1108/09604520810859184

Schön, O. (2012). Business Model Modularity - A Way to Gain Strategic Flexibility? *Controlling & Management*.

Seneviratne, M. G., Shah, N. H., & Chu, L. (2020). Bridging the implementation gap of machine learning in healthcare. *BMJ Innovations*, *6*(2), 45–47. https://doi.org/10.1136/bmjinnov-2019-000359

Sheth, J. N. (2019). Customer value propositions: Value co-creation. *Industrial Marketing Management.*

Teece, D. J. (2010). Business models, business strategy and innovation. *Long Range Planning*, *43*(2–3), 172–194. https://doi.org/10.1016/j.lrp.2009.07.003

Thermaiscan. (2021). https://thermaiscan.com/.

Toews, R. (2020). These Are The Startups Applying AI To Transform Healthcare. *Forbes*, 1–16. Retrieved from https://www.forbes.com/sites/robtoews/2020/08/26/ai-will-revolutionize-healthcare-the-transformation-has-already-begun/?sh=19ef3694722f%0Ahttps://www.forbes.com/sites/robtoews/2020/08/26/ai-will-revolutionize-healthcare-the-transformation-has-already-begu

VentureScanner, & Statista. (2020). *Artificial intelligence (AI) startup funding worldwide from 2011 to 2020 (in billion U.S. dollars), by quarter*.

Weick, K. E., Sutcliffe, K. M., & Obstfeld, D. (2005). Organizing and the Process of Sensemaking. *Organization Science*, *16*(4), 409–421. https://doi.org/10.1287/orsc.1050.0133