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Exploring the pre-scaleup development of Healthtech startups: the case of Dutch healthtech startups

TU Delft

Delft University of Technology

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This Master thesis is submitted to Delft University of Technology in partial fulfilment of the requirements for the degree of

Master of Science

in Management of Technology
Faculty of Technology Policy and Management

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Acknowledgements

This thesis marks a significant milestone in my academic journey as I conclude my Management of Technology Master's degree at TU Delft. The journey that led me to this point has been one of intense dedication, persistent inquiry, and the unyielding pursuit of knowledge. As I look back on the countless hours spent delving into research, crafting arguments, and refining my ideas, I am struck by the immense growth I've experienced both academically and personally. This thesis has not only deepened my understanding of my chosen field but has also honed my critical thinking skills, resilience, and ability to navigate the challenges inherent in such a significant undertaking. This accomplishment would not have been possible without the dedicated individuals who have played pivotal roles in my growth and learning. It is with immense gratitude that I extend my heartfelt thanks to the following people:

Firstly to my first supervisor, Dr. Pieter Vandekerckhove, your expertise and guidance have been invaluable. Your insightful feedback and encouragement have been instrumental in shaping my research and enhancing the quality of my work. I value the health-specific knowledge you shared with me and the time and effort you sacrificed to help me throughout the thesis journey. Secondly, I would like to express my gratitude to my second supervisor, Dr. Hanieh Khodaei. Your meticulous attention to detail and your commitment to pushing the boundaries of my research have been truly motivating. Your suggestions have helped me refine my ideas and develop a deeper understanding of the subject matter. Your academic experience and previous research inspired me to study the startup journey and played a significant role in driving my thesis forwards. Prof.dr. Sabine Roeser, my chair, your leadership and expertise have guided me through the administrative aspects of the thesis process. Your insightful input during discussions has enriched my understanding and perspectives, and I am grateful for your kindness throughout our meetings together.

Moreover, I want to give special thanks to Priyanka, for your unwavering support, and your invaluable insights have been a beacon of light throughout my thesis. Your guidance has helped me navigate challenges and has enriched my academic experience in countless ways.

I would also like to extend my gratitude to my friends who have been a constant source of motivation and joy throughout the rigorous masters program. Nikki, Julia, Renzo, Marleen, Masa, Ellen, Stanley, Thomas, Fin, Felix - the fun memories and shared experiences have made these past two years truly memorable and fulfilling. Irene, Evelyn, Chun - I am grateful for your unending support and willingness to listen at any time of the day, and your guidance and motivating words throughout my thesis journey.

To my family in South Africa, I am profoundly thankful for your unwavering support, encouragement, and understanding. Your sacrifices and belief in me have been my driving force, and I am humbled to have your love as my foundation. To my sister, Jemma, I thank you for helping me always take a step back and see things from another perspective. To my mother, Kitty, I am forever grateful for your constant support and kind ear, and I cannot express my gratitude for the sacrifices you have made and the love that has helped me become the women I am today. Lastly, I want to dedicate a special mention to my late father. Though he is not here to witness this accomplishment, his unwavering belief in my potential has been a guiding light in every step I have taken. I carry his spirit with me, and this achievement is a tribute to his love and support.

In closing, I am honoured to have had the privilege to learn, grow, and thrive under the guidance of

such remarkable individuals. This achievement signifies not only my hard work but also the collective effort of all those who have been part of my journey. I am excited to embark on the next phase of my life, equipped with the knowledge and experiences gained during this master's program.

Executive Summary

Health systems globally, currently face many multi-faceted and dynamic challenges. There is a growing demand for quality healthcare, shifting expectations towards more responsibility for patients in their own health journey, an evolving role of technologies within society, and external pressures to decrease costs and improve sustainability in a directive towards more preventative healthcare. In response to these challenges, many innovative technologies have been developed and applied for example to improve medical devices, enable virtual health services, manage patient and health system data and for other applications throughout the value-chain of health systems. There is a continually growing need for such innovations to be developed and implemented, despite the uncertainty characterising the ever-evolving health system landscape.

In the attempt to address the need for innovative health technologies, there has been an explosion of firms, entrepreneurs, and innovation hubs shifting their focus to developing and implementing new health technologies. Healthtech innovation and start-ups are vital to improve the quality and capacity of available healthcare, relieve overburdened health systems, and match shifting needs and expectations within the health industry. However, it has been observed that many start-ups are failing to grow to a point where their innovations can make an impact and have sustainable success in the health system. The downfall of many startups focusing on developing health technologies (healthtech startups) occurs most frequently in the time before they manage to start selling their health technologies to customers, or what is termed "scaling-up". Although there are many aspects or factors that play a role in the failure of these healthtech startups, there is one palpable observation; the development journey experienced by healthtech startups before scaling-up is distinctly unique and misunderstood. This observation calls for research to create a better understanding of the complex and unique development required of healthtech startups - to facilitate their ability in scaling-up, selling and implementing their health technologies.

In line with addressing this need, this thesis begins by conducted a literature study focused on technology and health technology startup development, aiming to explore the existing knowledge concerning the pre-scaleup phase in healthtech startups. The literature study consisted of a two-stage review process, beginning with a scoping review of literature pertaining to the technology startups and their early development, and proceeding with a rapid review of literature related to specifically healthtech startups in their early development phases. This examination revealed a recurrent tendency in the literature to discuss this startup phase through several key themes. Drawing from this discovery, the subsequent step involved characterising available literature information into nine defining themes: regulation, network, development processes, financing, capabilities, performance metrics, solution, system and market context, and social aspects; which collectively define the pre-scaleup development of healthtech startups. The literature study emphasised the distinctiveness of healthtech startups in their pre-scaleup journey, underscoring the imperative to investigate how this distinctiveness could be effectively represented.

Consequently, the thesis advanced to exploring models that could represent the unique nature of the early development of healthtech startups. Existing models geared towards representing and guiding early startup development were critically evaluated accruing to their limitations in comprehensively capturing the distinctive aspects specific to the pre-scaleup development phase within the healthtech sector. This evaluation culminated in a synthesis of insights derived from both the reviewed models and the themes identified from literature. This synthesis aimed to clarify the distinct attributes intrinsic to healthtech startups, ultimately culminating in the formulation of a bespoke theoretical model tailored to effectively

represent the pre-scaleup progression of healthtech startups. The model incorporates elements from existing literature models to construct a developmental framework delineating stages and pivotal points that encapsulate the fundamental activities undertaken during healthtech startup evolution. It also spotlights the essential challenges that demand resolution to propel a startup to subsequent developmental phases. Built with adaptability and collaboration in mind, the model allows for iterative processes and the seamless exchange of feedback across successive stages. The theoretical model captures the pre-scaleup journey of a healthtech startup within five distinct developmental stages: (1) concept development, (2) opportunity framing, (3) clinical validation, (4) pre-organisation, and finally, (5) scale-up. These stages are demarcated by a set of critical barriers termed 'critical junctures'. Comprising four such junctures - (1) problem-solution fit, (2) commitment, (3) credibility, and (4) scale-readiness - these represent the essential obstacles that must be surmounted for a healthtech startup to forge ahead in its growth trajectory.

Furthermore, the thesis introduced and implemented an approach to gather supplementary data, thereby enriching the insights and comprehension of healthtech startups and their pre-scaleup development. This involved conducting a series of interviews with individuals possessing various perspectives, expertise and practical experiences in the pre-scaleup phase of healthtech startups in the Netherlands. The conducted interviews, coupled with their subsequent inductive coding analysis, yielded a range of valuable insights that were categorised into themes, providing a characterisation of the pre-scaleup progression of healthtech startups. Moreover, these interviews yielded information that resonated with the previously established theoretical model.

Upon recognising the emergence of consistent themes in both literature and the interview data, a subsequent comparison was conducted to compare these two research approaches. The culmination of this comparison led to the formulation of a definitive catalogue consisting of four key and four lesser "characteristics of the pre-scaleup development of healthtech startups" that effectively encapsulate the pre-scaleup journey of healthtech startups, enhancing the characterisation, definition, and comprehension of this development phase. The resulting four key characteristics are; (1) the network and people involved, (2) the development processes carried out, (3) the financing methods used to support the development journey, and (4) the applicable regulations of the health technology being developed and how the healthtech startup conforms to them. The four lesser characteristics capture (1) the social considerations to be accounted for, (2) the characteristics of the health solution that must be prioritised, (3) the capabilities that are essential within the development of a healthtech startups, and (4) the influence of the context of the health system and market on the development journey of healthtech startups.

Furthermore, the insights garnered from the interviews provided substantial input relevant to the theoretical model. These inputs subsequently generated several recommendations for prospective research endeavours, aimed at assessing the practical viability of a model akin to the theoretical construct developed in this thesis. It is recommended that the model be tested or applied in case studies to gauge the practical applicability of the model. Moreover, the interviews also revealed an unexplored linkage between deliverable, evidence levels, and critical junctures. Future research efforts should explore the incorporation of measurable outcomes that correlate to the relevant development stage or critical juncture in the model. Additionally, it was found that processes, evidence requirements, and activities may significantly differ based on the type of health technology being developed. While the theoretical model's overall structure might suit diverse healthtech startups, it may fail to represent the specific activities and barriers for medical devices, biotechnology, and electronic health technologies. The model holds potential

as a guiding tool for comprehending and directing healthtech startup pre-scaleup development. However, it requires refinement to address gaps, ideally through extensive case studies, broader expert input, and collaboration with process modelling experts. Ultimately, the model lays a foundation for future research aimed at producing a more accurate representation of the unique challenges posed by healthtech startup pre-scaleup development.

Finally, some key observations are discussed and several recommendations are made for future related research. There is a major emphasis placed on 'user-centred' development of health technologies during the interviews and in literature. One of the most popular methods of user-centred development in literature, called Participatory Design, demonstrates that the active involvement of users from early in the development of a health technology facilitates trust, shared understanding, and ultimately helps develop a solution that satisfies the needs of all its stakeholders and encourages its successful adoption in the health system. Furthermore, there are several social and ethical considerations that healthtech startups should consider throughout their development. Both the analysis of existing literature and interviews with industry professionals highlighted the fragmented nature of information concerning the responsibility for upholding ethical and socially responsible practices in the pre-scaleup development of healthtech startups. Key stakeholders emerged from the literature search, including startups, regulatory bodies like the FDA and EMA, healthcare professionals, ethics committees, industry organisations, data protection agencies, patient advocacy groups, and academic institutions. These stakeholders collectively share the responsibility for ensuring patient safety, data privacy, and ethical considerations throughout the development and use of health technologies. Further research is necessary to explore the allocation and sharing of these ethical responsibilities among stakeholders in the healthtech sector.

Having explored the unique journey that healthtech startups experience in their aspiration to develop valuable and sustainable solutions for health systems, is it evident that there are in fact many misunderstood and overlooked aspects, challenges and factors that make their mission more difficult than expected. This thesis presents a first attempt to better understand the unique experience that healthtech startups have in their pre-scaleup development, and the findings of this thesis should become a starting platform for future research into this unexplored matter.

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List of Abbreviations

BML Build-Measure-Learn

DMU Decision making unit

HREC Human Research and Ethics Committee

KPI Key Performance Indicator

KOL Key Opinion Leader

MVP Minimal viable product

PoC Proof of Concept

PoP Proof of Principle

QDA Qualitative data analysis

TA Thematic analysis

TRL Technical Readiness Level

1 Chapter 1: Introduction

1.1 Research motive

There is a significant growth of businesses starting up in the world of health technologies - especially given the rising demand for high-quality healthcare, increasing burden on healthcare providers, and parallel progression of clever technologies that can address these issues.(OECD, 2019; Vasanth & Sbert, 2014) These new companies that focus on inventing, developing, and selling technologies to health-related applications are called healthtech startups. In basic terms, healthtech startups are a type of technology startups, but in actual fact they are much more complicated than that.

In an attempt to jump on the trend for health technologies, many technology startups such as Google and Microsoft have tried get involved in the healthtech space. (Young, 2022) They either adapted their technologies to suit an application within a health setting, pivoted their tech for health purposes, or tried to develop their own health technology or healthtech startup. During this scramble for finding a place in the rise of healthtech , an interesting phenomenon became apparent: strangely, these experienced and successful tech startups or tech innovation organisations struggled to make the move to developing a successful health technology or healthtech startup. In fact, many of them failed outright despite their many previous successes in the technological development space. (S. Khan, 2023; Smilow, Lynn, Serwetz, & Blank, 2020; Zavala, 2018)
This brought about the idea that something about the development of a healthtech startup may require something quite different to the well-practised development of a new technology or technology startup.

Furthermore, the failure of these tech startups in attempting to transition to healthtech occurred most frequently in the time period prior to the company being able to "scale-up", or in other words, make their first customer sale. This period of pre-scaleup development of a health technology (healthtech) startup - similar to all other technology startups - is characterised by many multi-faceted challenges, complex activities, fast-paced changes and conflicting interests. (Atun, 2012) However, there is apparently a unique twist to the pre-scaleup development of specifically a healthtech startup, since even experienced tech startups struggled in this phase.

There is evidently a problem being experienced in the practice of healthtech startups that has not yet been sufficiently addressed on a larger scale. Healthtech startups have noticed that they cannot approach their pre-scaleup development the same as other technology startups do, but have not yet figured out the best alternative approach to adopt (S. Khan, 2023; Zavala, 2018). Therefore, there is significant relevance in addressing this gap in practice. Moreover, there is an opportunity to fill a theoretical gap by contributing to literature addressing healthtech startups and their subsequent struggles and development.

1.2 Study background

In the study of healthtech startups and their pre-scaleup development, is is essential to understand the basis of what is meant by a technology startups, a healthtech startups and their pre-scaleup development.

1.2.1 Technology startups

A technology startup or venture refers to a newly established business that focuses on developing innovative technological products, services, or solutions. These startups often leverage technology advancements and aim to disrupt existing industries or create new markets. They typically have high-growth potential and are driven by entrepreneurial individuals or teams with a vision to bring their technological ideas to the market. (Bailetti, 2012; Cockayne, 2019)

The emergence and relevance of technology startups have been driven by several factors. Firstly, rapid advancements in technologies such as artificial intelligence, internet of things, block-chain, and biotechnology have created new opportunities for entrepreneurs to develop innovative solutions and disrupt existing industries. Second, the availability of affordable and accessible technology infrastructure, open-source software, cloud computing, and online platforms has reduced the barriers to starting a technology-based venture. This has empowered individuals and small teams to turn their ideas into reality. Thirdly, increasing customer expectations and market demand for innovative products and services have created a favourable environment for technology startups to thrive. These startups often focus on addressing unmet needs or solving complex problems with their technological solutions. Finally, the growth of venture capital funding and the development of supportive startup ecosystems, including incubators, accelerators, and networking communities, have provided the necessary resources, mentorship, and networks for technology startups to grow and scale. (Audretsch & Caiazza, 2016; Chesbrough, 2004)

The relevance of technology entrepreneurship and startups lies in their potential to drive economic growth, job creation, and societal impact. These startups often introduce disruptive technologies and business models, challenging established players and fostering competition. They contribute to technological advancements, create employment opportunities, attract investments, and stimulate innovation in various sectors.(Audretsch & Caiazza, 2016)

The relevance of technology startups to this research, is based on the assumption that healthtech startups are essentially a type of technology startup and therefore exhibit many of the same characteristics of a technology startup. However, there are a few factors that make healthtech startups unique, especially because of the nature of the health system in which they exist.

1.2.2 Healthtech and healthtech startups

Health systems are extremely complex and dynamic ecosystems containing many interacting actors, interrelationships, technologies, and their underlying norms and values. Moreover, the healthcare industry is interlinked with the macro-environment of societies, economies, and the natural environment – with any changes in these areas having a knock-on effect and requiring adaption of health systems. (Andersen et al., 2018; Atun, 2012) Moreover, healthcare is currently facing many challenges that are multi-faceted and dynamic - continually increasing the burden and complexity of health systems. There is a growing demand for quality healthcare, shifting expectations towards more responsibility for patients in their own health journey, an evolving role of technologies within society, and external pressures to decrease costs and improve sustainability in a directive towards more preventative healthcare. (Marques, Pitarma, M. Garcia, & Pombo, 2019;

OECD, 2019; Vasanth & Sbert, 2014) These shifts and challenges have significant and uncertain impacts on the traditional workings of the health system, requiring changes in the relationships patients have with health professionals, the management of patient monitoring, medicating and other health services, and the entire value chain involved in the delivery of healthcare. (Marques et al., 2019)

In response to the challenges and needs present in the health system, many innovative technologies have been developed and applied for example to improve medical devices, enable virtual health services, manage patient and health system data and for other applications throughout the value-chain of health systems (Singhal & Carlton, 2019). There is a continually growing need for such innovations to be developed and implemented, despite the uncertainty characterising the ever-evolving health system landscape (Suennen, 2014). This is what "healthtech" startups focus on.

1.2.3 Pre-scaleup development

The exact definition of the "scaling up" of a tech startup varies from source to source, but the most comprehensive definition views it as the point at which a startup achieves significant market penetration. What is meant by *significant* market penetration is also unclear, but literature views it to be aligned with a startup's purposeful intention to start selling their technology to customers on a large-scale to make a profit. (Duruflé, Hellmann, & Wilson, 2017; Marullo et al., 2018) Therefore, the development of a tech startup prior to scaling is the period of time from when an idea is conceived for a new technology, to point before the startup launches their technology into the market on a large scale.

1.3 Problem Definition

A large portion of the literature covering the topic of the pre-scaleup development of healthtech startups, focus on studying the development of a particular startup (Young, 2022), or one type of health technology (Chakraborty, Vigneswara Ilavarasan, & Edirippulige, 2022; Vasanth & Sbert, 2014), or a particular phase in the development of health tech startups (eg. as prototyping) (Fearis & Petrie, 2017). Many studies focus on the barriers or success factors of healthtech startup development (Zorba, 2010), or propose strategies for healthtech startups to adopt in overcoming barriers in their growth journey (Walsh & Rumsfeld, 2017). Also, there are many studies that focus on a particular challenge experienced by healthtech startups and how to overcome such a challenge; such as funding of healthtech startups (Stafinski, Menon, Philippon, & McCabe, 2011), or communication between health systems and startups (Dhainaut et al., 2020).
However, there are no studies that consider specifically the pre-scaleup phase of development, despite this phase being where most healthtech startups fail due to the heightened uncertainty and complexity in this phase of development. (Atun, 2012) There is also little to no literature regarding the pre-scaleup development of healthtech startups, and how this period of development may be unique for healthtech startups compared to that of other technology startups. Therefore, there is a need to better understand this period for specifically healthtech startups by taking on a exploratory approach as to avoid narrowing the analysis of this period of development to a single type of health technology, health system application, or healthtech startup case study. Within the need to take on an exploratory approach to studying the pre-scaleup development of healthtech startups, there is a need to define this period of development by a set of characteristics or themes so that the knowledge acquired during this study can be translated to practice.

Moreover, in relation to understanding the development of startups, there is an abundance of literature that suggest, applies and presents models to guide or represent the development of startups (Bhave, 1994; Griva, Kotsopoulos, Karagiannaki, & Zamani, 2023; Täuscher & Abdelkafi, 2016), but there is no literature that considers how a model for the pre-scaleup development of specifically healthtech startups may differ due to the unique challenges they experience in their development. There is hereby a gap in literature to investigate the implications that the unique characteristics of the pre-scaleup development of healthtech startups have on current models that exist to guide or represent the early or pre-scaleup development of healthtech startups in practice.

1.4 Research questions and objectives

Based on the problem definition, there is a need to answer the following main research question:

"How can the pre-scaleup development of healthtech startups be characterised?"

In posing this question, this thesis aims to formulate a better understanding of the pre-scaleup development of specifically healthtech startups using an exploratory approach instead of focusing on a specific case or health technology. Answering the main research question requires two investigations, as highlighted already in the problem definition. It is first necessary to address the gap in literature related to better understanding the pre-scaleup development of healthtech startups; for which the thesis will develop a list of characteristics that can be used to define the unique nature of the pre-scaleup development of healthtech startups. Then, the second investigation of the pre-scaleup development of healthtech startups involves considering the implications that the unique characteristics of the pre-scaleup development of healthtech startups have on a theoretical model to represent this period of development, and how such a model may have relevance in practice.

These two investigations related to the main research questions are summarised by two sub-research questions as follows:

(a) *What are the unique characteristics of the pre-scaleup development of specifically healthtech startups?*

(b) *What implications does the uniqueness of healthtech startups have on a model to represent the pre-scaleup development of specifically healthtech startups?*

In addressing these questions the thesis has the objective to produce research with both theoretical and practical relevance.

Theoretical relevance: As part of answering the main research question, a review of current literature must be conducted to construct a consolidated view of the existing gap of literature - to (a) characterise and (b) model the pre-scale development of specifically healthtech startup. The research aims to produce a list of characteristics to define the pre-scaleup development of healthtech startups and construct a theoretical model to represent this period of development for healthtech startups - both feats that have not yet been achieved in

existing literature. Therefore, by studying this topic, this research will contribute to these gaps in literature and will produce outcomes that can be developed further by future research.

Practical relevance: A list of characteristics to define the pre-scaleup development of healthtech startups has practical relevance to many healthtech startups and their stakeholders to better understand their own development process, prepare for challenges and guide their subsequent development activities. Moreover, a theoretical model of the pre-scaleup development of specifically healthtech startups can serve as a guiding framework in for example; new startups aiming to specialise in health technologies, organisations wanting to support healthtech startups, or companies that are struggling or have previously failed to progress to a stage where they can scale-up their health technology.

Moreover, in a general sense, this thesis aims to achieve the following objectives:
I. To contribute to creating a better understanding of the pre-scaleup development of specifically healthtech startups
II. To develop novel theoretical insights related to developing a model to represent and/or guide the pre-scaleup development of healthtech startups in practice
III. To propose recommendation for future research into understanding, modelling, and guiding the pre-scaleup development of healthtech startups

These objectives, along with the research questions will guide the research to follow and will be reflected upon at the end of the thesis.

1.5 Research outline

The research to address the research questions posed above, will be conducted in a step-wise manner as follows:

Step 1: Study the existing literature covering the topic of the pre-scaleup development of healthtech startups to create a better understanding and definition of this period of development for specifically healthtech startups (Chapter 2)
Step 2: Study current models used to represent and/or guide the development of startups, consider the applicability of these models to represent the pre-scaleup development of specifically healthtech startups, and theorise a model that accounts for the unique characteristics of the pre-scaleup development of healthtech startups (Chapter 3)
Step 3: Conduct data collection and analysis to gather supplementary insights related to better understanding and defining the pre-scaleup development of healthtech startups (Chapter 4-5)
Step 4: Critically reflect on the findings from Chapters 2-5. Compare the results of the analysis of literature and the results of the data collection and analysis and generate a final list of characteristics to define the pre-scaleup development of healthtech startups. Reflect on the implications of the theoretical model constructed in Chapter 3 to represent and/or guide the pre-scale development of healthtech startups in practice. Finally, reflect on the research process and formulate recommendations for future research.

The steps listed above are linked to the objectives for this research as shown in Figure 1.

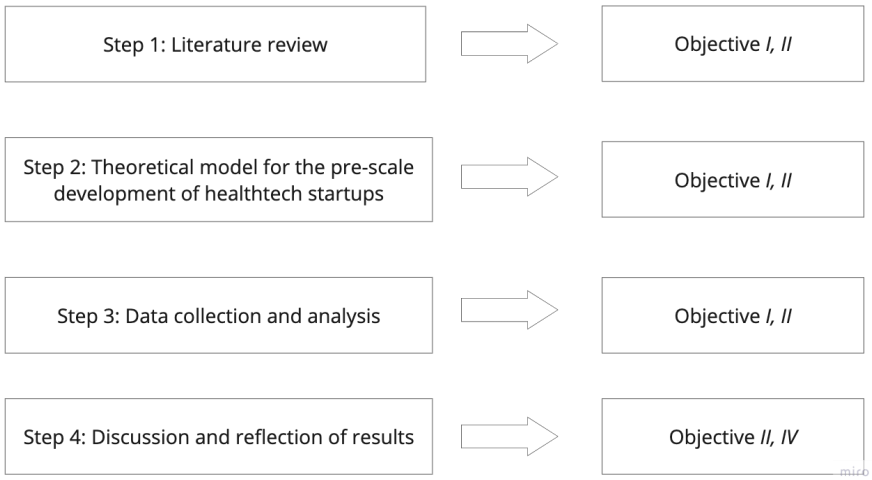

Figure 1: Research steps to be executed in this thesis and the objectives they contribute to

2 Chapter 2: Literature study of the pre-scaleup development of healthtech startups

2.1 Chapter introduction

Chapter 2 conducts a literature study of the key concepts and definitions used throughout this thesis. This involves creating a baseline understanding of the current theory relating to technology startups, healthtech startups, and their pre-scale development. A key objective of this chapter is to take an exploratory approach to the theory existing on tech startups, healthtech startups, and their pre-scale development - and characterise the unique challenges and activities experienced by healthtech startups during this development period - partially addressing sub-research question (a): "*What are the unique characteristics of the pre-scaleup development of specifically healthtech startups?*" . The chapter also gathers high-level insights on the type of literature existing in the domain of interest, the key themes emerging within this literature, and obvious gaps.

2.2 Methods

The literature study chapter will conduct a two-stage rapid review process as defined and demonstrated by Wilson et al. (2021) This type of two-stage rapid review process is desirable in cases where there is a limited body of literature to be found via traditional literature search means - as is the case with literature addressing the pre-scaleup development of healthtech startups. The literature search approach of Wilson et al. (2021) has been specifically designed for addressing questions related to complex health policies and systems within a time-constrained literature study - due to the underdeveloped body of literature within this topic. (Wilson et al., 2021)

The two-stage rapid review process of Wilson et al. (2021) was applied to this research as follows:

Stage 1 Scoping review

A scoping review was conducted as per recommendation by Wilson et al. (Wilson et al., 2021) for addressing research questions relating to complex health system issues. Scoping reviews produce high-level insights in a time-efficient manner(Tricco et al., 2018) - a suitable technique for studying the expansive set of literature on technology startups and their early development since this is not the main focus of this research and only aims to inform the subsequent literature review that addresses healthtech-specific literature. The scoping review aims to identify the key concepts, sources, and gaps in research related to a specific topic, rather than focusing on the quality or validity of individual studies. (Tricco et al., 2018) In this research, the "Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) Checklist" was used to guide and inform the scoping review procedure. (*PRISMA*, NaN)

The online databases; Science Direct, Google Scholar, and Directory of Open Access Journals (DOAJ); were used to search for literature published in the past 10 years, between 2013-2023, on technology startups and their pre-scaleup development. This time frame was used because technology and technology startups

are known to experience rapid changes; therefore it was assumed that literature older than 10 years would be irrelevant.

Publications were gathered using a key word search related the topic of interest, and searching for articles in the databases that contained the chosen keywords in their title or keyword list. The following Boolean search was used: (technology) AND (startup OR venture) AND (early OR pre-startup) AND (development OR process OR growth). Synonyms for key words were also used to account for studies that used different terms to those used within this research. The key word search returned in total 116 records, of which 6 were duplicates and were removed. Then from the remaining 110 records; 12 encyclopedia, conference abstracts, discussion, news, or other type records were excluded. Next, 10 articles were manually removed since they were not accessible without purchasing the article or their main focus was not on technology startups or their pre-scaleup development. That finally resulted in 88 articles that were included in the scoping review. This search and exclusion procedure is summarised using a PRISMA flow diagram seen on the left of Figure 2. (*PRISMA*, NaN)

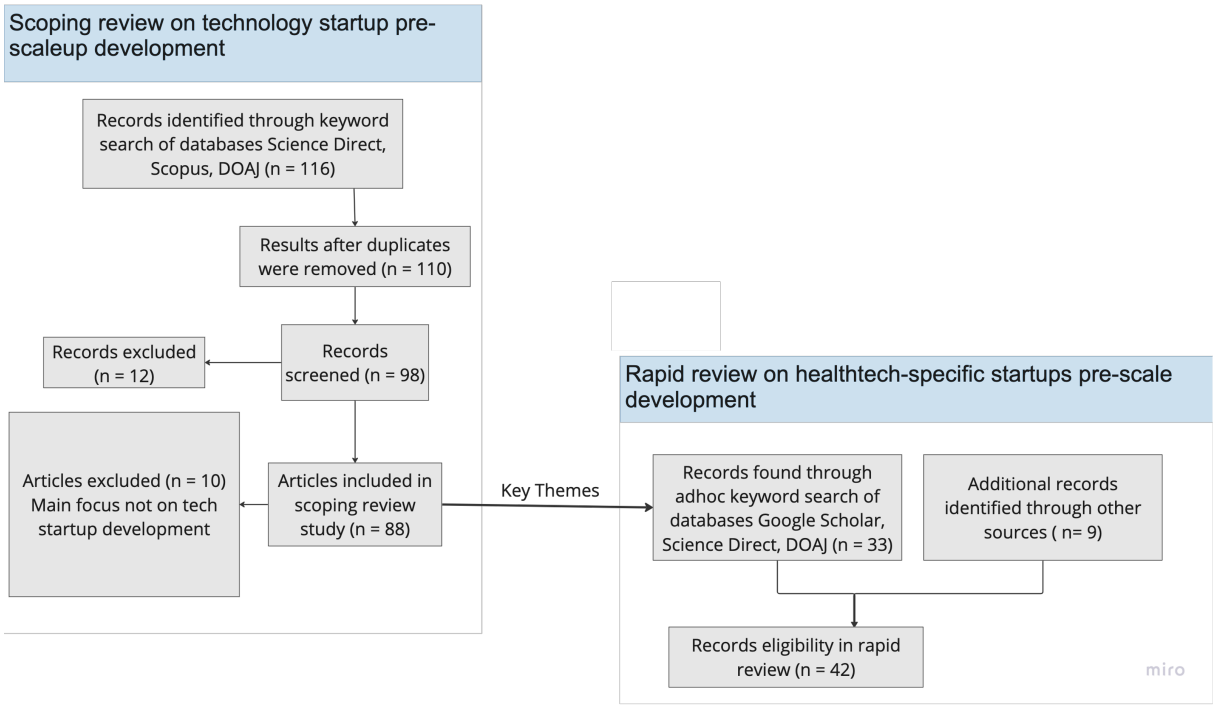

Figure 2: PRISMA flow diagram of the two-stage rapid review conducted in this chapter

As per the method of a scoping review, the 88 articles that were included were analysed. The key words and concepts were recorded to take note of common themes occurring within the subset of literature - later presented in the results section **??** of this chapter. The scoping review identified several key themes in literature related to the early development of technology startups. Based on the initial assumption made that healthtech startups are a type of technology startup, the themes found in the Stage 1 scoping review are used to guide the next stage of Wilson et al.'s two-stage review - the rapid review (Wilson et al., 2021).

Stage 2: Rapid literature search of healthtech-specific startup pre-scaleup development

Since the scoping review in stage 1 produced a set of key themes, the Stage 2 rapid review was conducted via a thematic summary rapid review format. This thematic summary rapid review was suitable due to the time constraint of the research and the variety of sources that study healthtech startups and their pre-scaleup development. A thematic summary often utilises various sources of evidence, including existing systematic reviews, or primary studies (through targeted searches of a small number of databases or re-analysis of primary studies from existing systematic reviews). The resulting output of a thematic summery rapid review, produced within a short time frame, often consists of organised tables or diagrams, accompanied by a narrative highlighting key findings and themes. (Wilson et al., 2021)

The thematic summary involved a rapid search of literature related to healthtech startup pre-scale development within each of the themes identified during the scoping review. The rapid search per theme drew from both primary studies from database Science Direct, and from additional online sources. The inclusion of online sources was essential for the particular focus of this rapid review because there was a large portion of crucial information related to healthtech startups and their development that had not yet been studied in academic or research literature, and therefore only appears online.

For the rapid search from the databases, a keyword search was carried out on an adhoc basis using the keywords: (health OR healthtech) AND (startup OR venture) AND (development OR process OR growth) and the additional inclusion of the keyword for theme "n". For example, the rapid search within the theme of "regulation" searched for (health OR healthtech) AND (startup OR venture) AND (development OR process OR growth) AND (regulation). Literature from the past 10 years was included because of the scarcity of literature returned from the keyword search. Within the returned records per theme search, many duplicates were found due to articles addressing more than one theme. These duplicates were removed as to only include these records once in the study.
Then for the online sources, a similar search was conducted using the keywords (health OR healthtech) AND (startup OR venture) AND (development OR process OR growth) and the additional inclusion of the keyword for theme "n". However, to maintain accuracy of the information included, only credible online sources were included in the rapid search. For example, only online sources published by national organisations or academic institutes were included.

In the selection of sources for the rapid search, the most relevant sources had to be manually selected since many of the search results were irrelevant to the research question. For example, many records returned by a keyword search of the databases were focused on health technologies themselves or biological developments in science, and did not present any useful findings for studying the pre-scaleup development of healthtech startups. This search strategy is summarised according to a PRISMA search method flow diagram guidelines in the right-hand side of Figure 2. (Tricco et al., 2018) The rapid review thematic summary resulted in 42 number of records (33 articles, and 9 online sources) included in the thematic study. A full list of these records included for each theme is attached in Appendix A, Table 8. As seen in Figure 2, the key themes exiting from the Stage 1 scoping review were used to guide the Stage 2 rapid review. The findings of this

review are presented in the results section of this chapter in **??**.

2.3 Results

The detailed results of the scoping review are summarised in Table 7 in Appendix A which shows the analysis of each included article by their author, date, key words and concepts. This preliminary analysis showed that there were many studies that focused on the same topics surrounding technology startup development in its early stages, from which the topics could be grouped into overarching themes. In finality, the scoping review produced a list of nine distinct themes that were found most commonly in the literature related to the early development of technology startups. These themes were; (1) Regulation, (2) Network, (3) Financing, (4) Development process, (5) Capability, (6) System and market context, (7) Solution, (8) Measures of performance, and (9) Social aspects.

Based on these themes, the Stage 2 rapid review gathered 42 relevant articles, from which each theme was studied specifically relating to healthtech startups and their pre-scaleup development. A summary of the 9 themes and the key concepts found, is presented in Table 1.

Theme	**Key concepts within each theme**
Regulation	(1) device classification, (2) conformity assessment, (3) technical documentation, (4) quality management system, (5) notified body involvement, (6) CE marking, (7) Unique Device Identification (UDI), (8) EU database on Medical devices
Network	(1) Clinical stakeholders, (2) reimbursement agencies, (3) public services, (4) specialised healthtech support mechanisms
Development process	(1) quality management system, (2) plan and execution of clinical trails or evidence study, (3) user-centred design approach, (4) inclusion of reimbursement agencies
Financing	(1) cost of clinical trials an regulatory compliance, (2) cost of longer development cycle, (3) different investor profiles, (4) health-specific funding opportunities available
Capabilities	(1) Clinical expertise, (2) Knowledge of regulatory process, (3) medical speciality knowledge, (4) specific development capabilities (eg., conducting clinical trials), (4) data security
Measures of performance	(1) Health outcomes, (2) Clinical Metrics, (3) Cost and Efficiency Metrics (4) Patient Engagement and User Experience
Solution	(1) interoperability, (2) problem/solution fit, (3) regulatory compliance, (4) usability , (5) performance
System and Market context	(1) competition with dominant market players, (2) market size trends, (3) employment trends, (4) technological lock-in effects in health systems, (5) health system workflows, (6) external events
Social aspects	(1) equity & access, (2) inclusivity diversity, (3) ethical use

Table 1: The key themes of the pre-scaleup development of healthtech startups, and related concepts

The themes are each described in more detail as follows.

Regulation

The largest reported difference regarding the pre-scaleup development of healthtech startups compared to other startups is the set of heavy regulations that govern the realm of health technologies, their development, and implementation.

There are a mass of regulatory bodies responsible for medicinal product approval, medicine device certification and clinical investigation approval. In the EU a few of these include the CE - Conformitè Europëenne, CMDh - Co-ordination Group for Mutual Recognition and Decentralised Procedures–human, CS case study, EC European Council, EMA - European Medicines Agency, EU - European Union, GCP - Good Clinical Practice, MDSW - medical device software, MS - multiple sclerosis, NB - Notified Body, NCA - National Competent Authority, SV95C - Stride Velocity 95th Centile. (Colloud et al., 2023)

The agencies and regulation activities that need to be involved in a healthtech startup's development will depend on the type and medical class of technology that they are developing. Here is an overview of the required activities to comply with the regulatory requirement for medical devices:

1. *Determine the Applicable Regulations*: Identify the relevant European Union (EU) regulations that apply to the medical device. The main regulations include the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR). (Council of European Union, 2014a, 2017)

2. *Device Classification*: Determine the classification of the medical device based on its intended purpose, potential risks, and duration of contact with the human body. Medical devices are classified into different risk classes: Class I (non-sterile, non-measuring), Class I (sterile, measuring), Class IIa, Class IIb, or Class III - or in vitro diagnostic devices: Class A (low individual and public health risk), Class B (moderate individual risk and/or low public health risk), Class C (high individual risk and/or moderate public health risk), and Class D (high individual and public health risk) (Council of European Union, 2014a, 2017)

3. *Conformity Assessment*: Prepare a "Declaration of Conformity" to demonstrate that the device meets the essential requirements outlined in the regulations. This assessment involves evaluating the device's design, manufacturing process, and documentation. The level of assessment required depends on the device's classification, and often requires the involvement of a notified body. (*Europe's IVD regulatory approval process MDRC*, 2023; *Europe's regulatory process for medical devices MDRC*, 2023)

4. *Technical Documentation*: Prepare technical documentation that provides comprehensive information about the design, manufacturing, and performance of the medical device. The documentation should include details such as device description, risk assessment, labelling, instructions for use, and clinical

data (if applicable). (*Europe's IVD regulatory approval process MDRC*, 2023; *Europe's regulatory process for medical devices MDRC*, 2023)

5. *Quality Management System*: Establish a Quality Management System (QMS) that complies with the requirements of the regulations. Most manufacturers choose to implement ISO 13485, an internationally recognised standard for medical device quality management. (*ISO - ISO 13485 — Medical devices*, NaN)

6. *Notified Body Involvement*: For certain classes of medical devices, involvement of a notified body is required. Notified bodies are independent organisations designated by EU member states to assess conformity of medical devices. They review technical documentation, conduct audits, and issue certificates of conformity. (Council of European Union, 2014a, 2017)

7. *CE Marking*: Once successfully completing the conformity assessment and all regulatory requirements are met, acquire the CE marking on the medical device. The CE marking indicates compliance with applicable EU regulations and allows the device to be placed on the European market. A CE Certificate (issued by a Notified Body) is not applicable to Class I, non-sterile, non-measuring devices and Class A devices since manufacturers will self-declare conformity with the Regulation EC 2017/745 (Council of European Union, 2017; *Europe's IVD regulatory approval process MDRC*, 2023; *Europe's regulatory process for medical devices MDRC*, 2023).

8. *Post-Market Surveillance*: After placing the device on the market, monitor its performance and address any reported issues or adverse events. Implement post-market surveillance activities, such as collecting and analysing feedback from users, conducting post-market clinical follow-up, and reporting any incidents to the competent authorities. The MDR and IVDR mandates the use of a Unique Device Identification (UDI) system, where each device is assigned a unique identifier. This system enhances traceability, facilitates recalls, and improves post-market surveillance. (Bianchini & Mayer, 2022)

9. *Vigilance and Reporting*: Comply with vigilance requirements by promptly reporting any incidents, field safety corrective actions, or updates to the competent authorities and relevant stakeholders. Maintain a system for monitoring and evaluating the safety and performance of the medical device throughout its life cycle. Improved transparency is achieved through the establishment of a comprehensive EU database on medical devices called EUDAMED, with certain parts accessible to the public. (Bianchini & Mayer, 2022; Colloud et al., 2023)

To further complicate the medical device development process, Class III devices as well as active implantable devices, are likely to require substantial clinical trial data - conducted via clinical trials. Undergoing clinical trials introduces many more regulatory requirements for healthtech startups to comply with as stipulates in the Clinical Trials Regulation (Regulation (EU) No 536/2014) (Council of European Union, 2014b). Clinical trials conducted in Europe must be pre-approved by a Competent Authority and all data must be reviewed and approved by a Notified Body. (*Research and development | European Medicines Agency*, 27/05/2023)

Moreover, there is another complication related to any development of digital health technologies (commonly known as e-health). In addition to the Medical Devices Regulation, these e-health technologies must also

conform with additional regulations such as the Data Governance Act, EU Directive 2011/24 on Cross-border Health Care, Privacy protection Directive 95/46/EC, Arts. 8-12, and eCommerce Directive (den Exter, n.d.).

It is evident that the regulatory process for health technologies is highly complicated; involving many difference regulation agencies, requiring multiple documentation procedures, frequent revisions and even implementing specific systems (eg., a Quality Management System) in compliance with quality and safety regulations. It is obvious that healthtech startups should consult the official regulations and seek guidance from experts or regulatory consultants to ensure compliance with the specific requirements applicable to their technology. (Chakraborty, Ilavarasan, & Edirippulige, 2021)

Network

Many studies in literature emphasise the importance of securing a place in a strong network of relevant stakeholders, supporters, and other actors. This literature highlights that tech startups should initiate and maintain strong connections with stakeholders of their technology such as users, complementary product providers, support firms, potential users, and other technology and innovation stakeholders. (Andries, Clarysse, & Costa, 2021; Isenberg & Onyemah, 2016)
However, for healthtech startups it is essential not only that they are part of such a network, but that they connect themselves to a network with specific orientation to the health system.

Within aim of understanding the unique network for health startups, it is helpful to first understand the existing network within the health systems that healthtech startups aim to operate and compete within. A healthcare system comprises of many actors - some of the most obvious being patients, physicians, clinicians, patient organisations, and insurance providers (Atun, 2012). These actors would become stakeholders of any new health technology introduced into the health system, and therefore they should become part of a healthtech startup's network.
One of the unique issues attached to health system networks is related to the tensions that arise due to the multiple and ever-changing roles, priorities, needs and values of the stakeholders in the network. Anderson et al. (2018) reports an inherent tension in the priorities of patients versus clinicians that negatively affects the adoption of healthtech innovations: patients are often concerned about how the care that they experience affects their personal quality of life, whereas clinicians prioritise maintaining a professional standard of care and adhering to medical guidelines.(Andersen et al., 2018) Many other relevant articles also report differing perceptions of healthcare, health innovations, and the health system. (Agarwal, Brem, & Grottke, 2018; Atun, 2012) Therefore, it is vital that healthtech startups engage with stakeholders in health systems from early in their development process in order to understand the various requirements for their technology, manage stakeholders' expectations, and create a shared understanding of the health system's needs and how health technologies are beneficial to all the stakeholders involved. (Chakraborty et al., 2021; Tuan, Thanh, & Tuan, 2019) These clinical stakeholders will ultimately determine if the launch of a health technology is successful or not. (Young, 2022)

Secondly, it is wise for healthtech startups to connect with the potential users of their technology. Many

studies advocate for participatory programs such as bio-design, live-in laboratories or patient-led design which involve the patients, physicians or other end users already during the design of the health technology. Such programs have had significantly successful outcomes; with better adoption, user acceptance and smoother implementation of these health technologies due to the refined design process.(Augustin et al., 2020; Reddy et al., 2019) Although this extent of user involvement is not always required, it emphasises how important it is to engage with end-users from early on in a healthtech startup's development process. However; actually making contact with patients, physicians or other end users is very difficult in practice due to strict doctor-patient privacy laws, patient protection organisations and the multiple layers of specialisation within health systems. (Young, 2022)

Thirdly, healthtech startups need to take into consideration that the payment structure for health solutions is very different to that of other technologies. Often in healthcare, a third-party such as national health institutions or private health insurance providers will be the sponsor of health technologies. It is therefore vital that healthtech startups develop their business model with this in mind and have good knowledge of the reimbursement procedures and policies. (Dhainaut et al., 2020; Young, 2022)

Also, healthtech startups have to pay special attention to the stakeholders that will influence the adoption of their technology. Clinical stakeholders such as physicians and other health professionals will often question if healthtech startups and their solutions possess adequate clinical credibility, since their technologies have been developed externally to a health setting. (Young, 2022) This is why it is crucial to have a good relationship with these clinical stakeholders so that they will support the adoption and implementation of the startup's health technology. Moreover, good integration with existing healthcare systems and workflows is essential to lower the barriers to adoption. Seamless interoperability, data exchange, and integration with healthcare IT infrastructure are important considerations during the development process. (Dixon, Zafar, McGowan, & Grannis, 2013)

On a final note, many publications in literature discuss the involvement of supporting mechanisms or intermediaries in the early stages (pre-scaleup development) of healthtech startups. Such mechanisms include incubators, venture builders, or consultants for example. A significant consideration for healthtech startups is deciding whether to seek support from one of these services, especially to tap into the specialised expertise, connection or experience of such a support service in the realm of health systems, technologies and innovation. An incubator for example, will be helpful to a healthtech startup if the incubator itself is connected within a network of clinical stakeholders, has expertise in the regulatory pathway for medical devices and can provide support in specific health technology development challenges. It is therefore beneficial for healthtech startups, if they require it, to reach out to support mechanisms specialised in the field of health or medical innovation. (Ostrovsky & Barnett, 2014; H. P. Silva, Lehoux, & Sabio, 2022) The European Medicines Agency (EMA) for example, offers support to small businesses starting up in the space of health technologies and medical devices and can guide healthtech startups on how to plan and run their clinical trials and meet compliance standards. (*Research and development | European Medicines Agency*, 27/05/2023)

Development process

A major topic of focus in literature is the creation and theorising of models or strategies to represent and guide the path of growth or development of startups. However many of the models for startup development are not fully applicable to the pre-scaleup development of healthtech startups because of a few unique activities that a healthtech startup is required to perform.

Firstly, there is a larger need in healthtech startups to take on a design thinking or human-centred approach due to the nature of their technologies often being in close contact with patients and being responsible for saving lives. (Augustin et al., 2020; Reddy et al., 2019) This user-centred approach helps ensure that the final product addresses the specific pain points and provides value to patients, healthcare providers, and other stakeholders in the healthcare ecosystem. However, such an approach requires that healthtech startups make an active effort to involve and consult healthcare professionals and patients throughout their development process. (Koskinen & Ihamäki, 2018; Plattner, Meinel, & Leifer, 2020) Therefore the pre-scaleup development process of healthtech startups must have specific adaptions to achieve this.

Second, due to the unique regulatory requirements for health technologies as described in 2.3, the development process for a healthtech startup has to make special considerations for these regulations. These adaptions include; (1) designing and implementing a quality management system in compliance with ISO 13485 (*ISO - ISO 13485 — Medical devices*, NaN), (2) conducting clinical studies, trials, or real-world evidence generation to demonstrate the effectiveness of their solution according to strict study protocols, and (3) implementing robust data protection measures, ensuring patient consent, and addressing data interoperability and security considerations if the health technology aims to handle patient sensitive data (Fernández-Alemán, Señor, Lozoya, & Toval, 2013; Ienca et al., 2018).

Finally, healthtech startups need to align their product development and evidence generation processes with the requirements of reimbursement agencies - since these stakeholders are often partly responsible for the success of the adopting of a health technology. Involving the reimbursement agencies early in the development process can also enhance the health technology's value proposition for reimbursement. (Sorenson, Drummond, & Bhuiyan Khan, 2013).

Financing

The funding of health startups can differ from funding for other startups in several ways.

The first major difference in the financing health technologies, is in the payment structure for when health technologies enter the health system. Unlike many other technologies, health technologies often require reimbursement from insurance providers or government healthcare systems to be widely adopted. Demonstrating the value and cost-effectiveness of the technology is crucial for securing reimbursement. . (Levaggi, Moretto, & Pertile, 2014)
Secondly, healthtech startups experience much higher capital intensity in the pre-scaleup development - requiring significant capital investments due to the complex and regulated nature of the healthcare indus-

try. Developing medical devices, conducting clinical trials, obtaining regulatory approvals, and establishing healthcare infrastructure can be costly. This higher capital intensity can affect the funding requirements and investment expectations for healthtech startups. (Nyikos et al., 2019)
Thirdly, healthtech startups typically have longer development cycles compared to other startups. The need for rigorous clinical testing, regulatory compliance, and market validation in the healthcare sector can prolong the time it takes to bring a product or service to market. Investors considering funding a health startup should be prepared for longer-term investments and potential delays in achieving revenue generation. (Stafinski et al., 2011)

Then, shifting the focus to the typology of investors interested in funding healthtech startups; their requirements and expectations can differ from typical investors in other startups. Investors in the healthcare sector may seek founders or teams with a deep understanding of medical science, healthcare systems, and the regulatory processes. This expertise can be a crucial factor in evaluating the feasibility and potential success of healthtech startups. (Kang, 2018)

Finally, healthtech startups have access to unique grants, funding programs and other financial instruments positioned specifically for firms developing within the health sector. For example, the EU Research and Innovation programme - Horizon 2020 - had €1 600 000 000 of funding available in their Eurotam 2 year program specifically designed for innovation in Health and similar scientific areas. (Nyikos et al., 2019) The grants, programs, and funds available differ per country, innovation areas and other factors.

Capabilities

Capabilities of tech and healthtech startups refer to for example; the talent of their team and founders, their available resources, and the accumulation of knowledge that enables the startup to make appropriate decisions.

One crucial difference between the capabilities required for a healthtech versus tech startup in their pre-scaleup phase is related to the skills, expertise and knowledge of the team involved. Healthtech startups need a particular set of skills and expertise in the healthcare domain. Healthtech startups should have a deep understanding of the healthcare industry, including knowledge of clinical workflows, regulatory frameworks, privacy and security regulations, and healthcare reimbursement models. (Chakraborty et al., 2021; Dhainaut et al., 2020; Sorenson et al., 2013) This expertise is essential for developing solutions that align with healthcare needs and navigating the complex healthcare landscape.

Moreover, often healthtech startups may be addressing a problem in a specialised medical field and will require deep knowledge within that specialisation. Each medical speciality requires profound expertise and familiarity with the workflows and intricacies that front line providers typically acquire. (Young, 2022) For example, a startup developing a technology aimed at addressing heart failure should have in-depth knowledge of the technologies, procedures, biological details and other concerns within the domain of cardiology.

Healthtech startups also need to have the capability to comply with the strict regulatory standards and requirements specific to the healthcare industry. They need the resources, skills, and organisational capacity to implement robust data privacy and security measures, conduct clinical validation and evidence gathering procedures, and implement other measures in compliance with the health regulations described in 2.3. (Fernández-Alemán et al., 2013; Ienca et al., 2018)

Measures of performance

Another topic appearing quite frequently in literature is the debate of how to measure their performance or success.

The development or growth of startups has been frequently defined in literature. Griva et al. (2023) reviewed many different definitions of startup development and found that two common themes emerged. There was a stream of literature that considered successful startup growth or development to be characterised by the accumulation of human and financial capital; i.e., the number of employees, sales and turnover. However, another stream of literature viewed the development of startups as more than these objective measures, including non-financial dimensions such as skills, startup capabilities, processes and routines. In combination, an all-encompassing definition of startup development considers the accumulation of tangible and non-tangible resources over time. (Griva et al., 2023) It is emphasised that there is no concrete best practice for what a technology startup should look like, how to measure their success, or how they should develop or grow - an unsurprising fact given that these startups operate in a extremely variable and uncertain landscape. (Isenberg & Onyemah, 2016; P. H. Kim, Kotha, Fourné, & Coussement, 2019)

However, the measurement of performance in health startups can differ from other startups due to the unique nature of the healthcare industry and its specific challenges and goals. Some unique measures of the performance of healthtech startups include:

1. Health Outcome Metrics: Healthtech startups often focus on improving health outcomes and patient well-being. Performance measurements in this context may involve tracking metrics such as patient satisfaction, reduction in disease burden, improved treatment adherence, or health-related quality of life measures (HRQoL) (Mantas et al., 2012; Stange et al., 2014)

2. Clinical Metrics: Healthtech startups that develop medical devices, diagnostics, or therapeutics may use clinical metrics to measure performance. These metrics can include clinical trial outcomes, efficacy rates, safety profiles, and regulatory compliance (Semler, Rice, & Ehrenfeld, 2015).

3. Cost and Efficiency Metrics: Given the rising healthcare costs, healthtech startups often aim to deliver cost-effective solutions. Performance measurements in this area can involve metrics such as reduction in healthcare expenditure, cost savings, or improved resource utilisation. (Mantas et al., 2012; Vasanth & Sbert, 2014)

4. Patient Engagement and User Experience: Healthtech startups may prioritise patient engagement and user experience as important performance indicators. Metrics could include user adoption rates, patient

engagement levels, user satisfaction surveys, or app engagement analytics. (Mantas et al., 2012; Vedlūga & Mikulskienė, 2017)

These performance measures become the Key Performance Indicators (Key Performance Indicator (KPI)s) that healthtech startups will use to periodically assess their performance and set goals. (Mantas et al., 2012)

Solution

A fundamental aspect of a technology startup, is the technology itself that is being developed. The research and development of the technology go hand-in-hand with the development of the startup - no technology means no startup. (Verbovskiia, Poletae, & Chayka, 2014)

For health technologies, a few specific characteristics are reported to significantly affect the success of their acceptance and impact within health systems, and the success of the startup developing them.

Interoperability: Health technologies need to be compatible with current technologies and workflows in the health system to create a seamless-as-possible transition when adopting health technologies into the system. (Chakraborty et al., 2021; Marques et al., 2019)
Problem/solution fit: it is important that a health technology addresses a validated problem from the perspective of the health professionals or patients adopting it. Often, health technologies are introduced that are not actually needed in the health system, but instead were thought to be of value by designers or engineers external to the health system. (Semler et al., 2015; Young, 2022)
Regulatory Compliance: Health technologies must comply with regulatory requirements, such as data protection laws and medical device regulations (see 2.3. Compliance ensures patient safety, data integrity, and ethical use of technology in healthcare. (Fearis & Petrie, 2017; Marques et al., 2019)
Usability and User Experience: Health technologies should be designed with a focus on usability and user experience to facilitate adoption by healthcare professionals. Intuitive interfaces, streamlined workflows, and efficient data entry methods are essential for smooth integration into clinical workflows. (Fearis & Petrie, 2017; Marques et al., 2019; Reddy et al., 2019)
Scalability and Performance: Specific to digital health technologies, it is important that these technologies should be capable of scaling up to accommodate growing user bases and provide reliable performance to support critical healthcare operations. Healthcare systems often deal with large volumes of data and require scalability to handle increasing demands. (Marques et al., 2019)

System and Market context

Another aspect that has a major influence on the success of technology or healthtech startups - especially in their pre-scaleup or early phases - is the state of and trends in the market and system in which they are developing. The external environment in which these startups plan to launch into can determine if they succeed or fail.

The health system and market are known to have many barriers to the entry of new solutions for the

following reasons:

1. Health systems interact with external events happening in the socio- technical, political, or economic environment. For example, the growth of populations, economic disparities, changing governance structure and legislation, and even abnormal events (e.g. wars, Covid-19 pandemic) have a significant effect on health system and require that the system makes adaptions (Agarwal et al., 2018; Ross, Stevenson, Lau, & Murray, 2016).

2. There are technological lock-in effects in health systems - many existing workflows or technological infrastructure in health systems have been used for a very long time, and are often outdated or not compatible with new health technologies. Therefore, the adoption of new health solutions is often resisted by members of the health system since it requires a change to their routines. (Chakraborty et al., 2021; Ross et al., 2016)

3. The health market is dominated by large, well-known medical solution corporations such as MedTronic, Phillips, Novardis, and Siemans Healthineers to name a few.(Madan, 2022) These big companies have been supplying high-quality medical solutions of many years and have long-standing relationships with and the trust of influential members in the health system. Also, these big firms have the organisational capabilities and financial capital to overcome many of the challenges of operating within the health industry. Therefore, it is often difficult for healthtech startups to out-compete these firms in the market. (Barros, Brouwer, Thomson, & Varkevisser, 2015)

Other market trends will also influence the success of a healthtech startup's success. Recent market trends reported by MedTech Europe (Europe, 2022) include for example that over the past two decades, the number of European Patent Office (EPO) filings in medical technology has nearly tripled, whereas patent applications in pharma and biotech have remained relatively stagnant. Moreover, the medical technology industry in Europe provides direct employment to over 800,000 individuals. Germany has the highest number of employees in the medical technology sector, while Ireland and Switzerland have the highest number of medical technology employees per capita. In comparison, the European pharmaceutical industry employs approximately 840,000 people.The jobs created by the medical technology industry contribute to around 0.3% of total employment in Europe. The European medical device market is estimated to make up 27.3% of the global market - the second largest medical device market after the US (43.5%) (Europe, 2022)

Social aspects

Finally, there are also many social aspects that can affect the pre-scaleup development of tech and healthtech startups. Tech startups have experienced issues with technology literacy becoming a barrier in the adoption of their solutions, or cultural norms clashing with the adoption of their technology. (Kirchberger & Pohl, 2016)

For health technologies; there are additional social, cultural and ethical considerations that come into play because these technologies often address critical healthcare challenges and have a direct impact on patients' lives. These factors help ensure that the technologies are aligned with societal values, promote equity, protect patient rights, and address potential ethical dilemmas. Here are some important considerations in this regard:

Equity and Access: Health technologies should aim to reduce health disparities and promote equitable access to healthcare services. Developers need to consider how their technologies may impact under-served populations, address healthcare access barriers, and ensure affordability and availability of their solutions.(Felber, Tian, Pageau, Elger, & Wangmo, 2023)
Inclusivity and Diversity: It is crucial to consider the diverse needs of individuals and communities when developing health technologies. This involves understanding cultural norms, language barriers, and accessibility requirements to ensure that the technologies are inclusive and can be effectively used by diverse populations. (Mahlich, Dilokthornsakul, Sruamsiri, & Chaiyakunapruk, 2018)
Ethical Use of Technology: Health technologies should adhere to ethical principles such as beneficence, non-maleficence, autonomy, and justice. Developers should consider the potential risks and unintended consequences of their technologies, including issues related to algorithm bias, discrimination, and potential harm to patients. (Bellemare et al., 2018)

These considerations are essential for fostering public trust, ensuring responsible innovation, and maximising the societal benefits of health technologies. As already emphasised in 2.3 and 2.3; it is essential for healthtech startups to engage in ongoing dialogue with patients, healthcare professionals, policymakers, and ethicists, to address these considerations effectively.

2.4 Chapter conclusion

Chapter 2 conducted a literature study in line with addressing sub-research question (a): " *What are the unique characteristics of the pre-scaleup development of specifically healthtech startups?*". A scoping review was conducted on literature related to the early development of technology startups, which subsequently guided a rapid review of nine key themes related to the pre-scaleup development of healthtech startups. These themes are; (1) regulation, (2) network, (3) development processes, (4) financing, (5) capabilities, (6) measures of performance, (7) solution, (8) system and market context, and (9) social aspects; and were described and defined according to relevant literature. Also, a key observation from the literature was that regulation is a key determinant of the success of a health technology. Moreover, it was apparent that the network that a healthtech startup embeds themselves into has a crucial role in helping the startup overcome many of its barriers related to financing, regulation, adoption, and other challenges. These themes and observations are indicative of the unique characteristics of the pre-scaleup development of healthtech startups, and will be re-visited in Chapter 6 to produce a final list of characteristics to fully answer sub-research question (a).

3 Chapter 3: A theoretical model to represent the pre-scaleup development of healthtech startups

3.1 Introduction

The problem definition in 1 highlighted that there is currently no comprehensive research addressing how the pre-scaleup development of healthtech startups is unique, and consequently, how a model of this period of development may differ from models of the early development of other types of startups. This chapter aims to address this gap and therefore is directed at answering sub-research question (b): " *What implications does the uniqueness of healthtech startups have on a model to represent the pre-scaleup development of specifically healthtech startups?*"

Chapter 2 identified several themes by which to characterise the uniqueness of healthtech startups in their pre-scaleup development. Based on these findings, and a brief analysis of current models of the startups; Chapter 3 will construct a theoretical model adapted for the pre-scaleup development of specifically healthtech startups.

3.2 Current models used to represent startup development

There are many attempts in literature to conceptually model the development, process, growth or journeys of startups - appearing in studies related to venture creation, entrepreneurial activity or other similar terms. Many of these studies base their work on case studies or specific contextual settings, and many variations, techniques and theories have emerged. Most models build on a variety of approaches, a prominent commonality between many of the models is that they are temporal in nature - representing the development of startups in relation to time (van Gelderen et al., 2005).

The main approaches used to model (parts of) venture creation/ startup development or entrepreneurial activity normally follow one or a combination of three main approaches: a stage-gate, interactive, or iterative modelling approach.

Stage-gate models

Many of the models proposed in literature follow a linear-type structure; meaning that they represent the development process of tech startups as a sequential process which proceeds from phase to phase over time, where as one phase ends the next begins - similar to the stage-gate innovation model of Cooper (2006). (du Preez & Louw, 2008) Such models represent the development of a startup as a linear process of stages consisting of a number of activities; and gates that consist of a barriers that must be overcome for the startup to progress to the next stage of development. (du Preez & Louw, 2008)

There is an abundance of theoretical work that models various aspects of the pre-scaleup development process. Examples of this conceptual work include studies shown in Table 2. It is evident that different studies focused on different parts of the startup development process . Those that predominantly study the period

Reference	Stages of Development					
Bhave (1994)		Opportunity	Technology setup	Organisation Creation	Exchange	
van Gelderen et al. (2005)	Intention	Opportunity recognition	Organisation establishment		Exchange	
Yoon-Jun (2010)			Incubation		Growing	Maturing
Mueller et al. (2012)			Startup		Growth	
Bocken (2015)			Seed	Young	Growing	Mature
Salamzadeh & Kesim (2015)	Bootstrapping		Seed		Creation	
Santisteban (2017)			Seed	Early	Growth	Expansion
Picken (2017)		Startup		Transition	Scaling	Exit
Marullo et al. (2018)	Intention		Organisation creation		Startup	
Startupcommons (2018)	Ideation	Concepting	Commitment	Validation	Scaling	Establishing
Vohora et al. (2004)	Research		Opportunity framing	Pre-organisation	Re-orientation	Sustainable returns

Table 2: Stage-gate models of startup development in literature and their stages of development (Bhave, 1994; Marullo et al., 2018; Mueller, 2023; Picken, 2017; Salamzadeh & Kesim, 2015; Santisteban & Mauricio, 2017; Startupcommons, 2018; van Gelderen et al., 2005; Vohora et al., 2004)

before a startup launches its product or service into market were of more interest for this research since this coincides with pre-scaleup development.(Bhave, 1994; Khodaei, Scholten, Wubben, & Omta, 2022; Marullo et al., 2018; Salamzadeh & Kesim, 2015; Startupcommons, 2018; van Gelderen et al., 2005) These studies modelled the pre-scaleup development of a startup in various ways. In Bhave's (1994) model of venture creation, startup development is divided into three main phases, separated by natural transition points. The sequence starts with *opportunity recognition*, driven by both internal and external factors, leading to the identification of a business concept . This is followed by the *commitment* to start, which represents a clear transition point between the previously process and the next one. As a result, the events in venture creation up to this point are grouped into the opportunity stage, with the business concept representing its core variable.

After the commitment to physical creation, entrepreneurs gather resources and utilise them for technology setup, organisation creation, and marketing. This stage is the most visible in venture creation and concludes when a product ready for customers is created for the first time. Given that the setup of production technology is central to this sub-process, it is selected as the core variable representing the stage of *organisation creation and production technology setup*.

Once an idea is transformed into a product and sold to customers for the first time, completing the entrepreneurial loop, customers directly evaluate the product and provide feedback, both strategically and operationally. The marketing efforts in venture creation, along with initial customer feedback and corrective action, are all grouped into the *exchange stage*. The product itself becomes the core variable representing

this stage. (Bhave, 1994)

Gelderen (2005) made a attempt to combine various models and noticed that typically, four phases are commonly discussed. The first phase involves the development of an *intention* to start a business. The second phase entails the *recognition* of an entrepreneurial opportunity and the formulation of a business concept. In the third phase, resources are gathered, and the *organisation* is established. Finally, in the fourth phase, the organisation begins to engage in *exchanges* with the market.(van Gelderen et al., 2005)

Another study, by Salamzadeh (2015) models the development of a startup as a life-cycle, from a holistic perspective. In the initial phase known as the *bootstrapping stage*, the entrepreneur takes the initiative to transform their idea into a profitable business. However, this stage involves higher risks and uncertainties. The entrepreneur continues to work on the new venture idea, forms a team, utilises personal funds, and seeks investments from family and friends. The purpose of this stage is to position the venture for growth by demonstrating product feasibility, effective cash management, team building and management skills, and gaining customer acceptance. Following the bootstrapping stage, the founder enters the *seed stage*. This stage is characterised by teamwork, prototype development, market entry, venture valuation, and the search for support mechanisms such as accelerators and incubators. Typically, the seed stage is considered highly uncertain and challenging for most startups. It involves initial capital investment for the product and/or service development. Founders often seek support from accelerators, incubators, and other support mechanisms to aid the process. Many startups fail at this stage due to the inability to find adequate support. Valuation is typically conducted at the conclusion of this stage. Last is the *creation stage*. The creation stage occurs when the company starts selling its products, enters the market, and hires its first employees. (ie. scaleup) At the end of this stage, the organisation or firm is established, and corporate finance becomes the primary choice for financing the firm. Venture capital can play a facilitating role in the creation stage by providing funding for the venture. (Salamzadeh & Kesim, 2015)

Marullo (2018) attempted to consolidate some of the other models in literature and summarised the development of startups into three broad phases: (1) Intention - this phase involves recognising opportunities, developing the business concept, and defining the requirements for implementation;(2) Organisation Creation: During this phase, the entrepreneur focuses on technology development, acquiring and managing resources, and assembling and maintaining a team in the pre-startup stage; (3) Startup: This phase encompasses the entry process into the market and the interaction with the external environment. (Marullo et al., 2018)

Then, Startup Commons - a provider of open-source frameworks, innovation entrepreneurship education and training, and ecosystem development consulting - published the "Startup Development Phases" model in 2012 and has been revising it ever since with new industry knowledge and learnings. The Startup Development Phases model shows the path of a startup from having an initial idea, to building a product around that idea, to scaling it into a viable and sustainable business. The model identifies key milestones in a startup's growth journey: Problem/Solution fit, Vision/Founders fit, Product/Market fit, and Business Model/Market fit; and the activities required to achieve these milestones: Ideating, Concepting, Committing, Validating, Scaling, and Establishing. (Startupcommons, 2018)

Interactive models

In this type of modelling, the tech startup goes through a series of consequential phases similar to that of the linear model; but instead of a purely linear process, the phases do not necessarily have to end before the next phase begins and can instead run in parallel. This type of modelling more accurately represents the practical development process of tech startups which can have many phases running simultaneously. (du Preez & Louw, 2008)

The most well-known interactive model is the Waterfall model. The waterfall model is a project management approach that organises activities into sequential phases, where each phase depends on the completion of the previous one. (Petersen, Wohlin, & Baca, 2009) This model is commonly used in engineering design and, to some extent, in software development. However, it is considered less flexible and iterative compared to other approaches. The progression in the waterfall model follows a linear path, moving from conception to maintenance, without revisiting previous phases. This model was one of the earliest approaches used in software development. The origins of the waterfall model can be traced back to industries like manufacturing and construction, where making design changes later in the process became costly. When the model was first applied to software development, there were limited alternatives available for managing knowledge-based creative work. The waterfall model, has been used to model innovation processes and startup development - but has received criticism for not providing the sufficient flexibility required to create creativity in the innovation process and respond to changes in the realm of startup development.

To overcome the perceived limitations of the traditional waterfall model, various modified waterfall models have been introduced, such as "Sashimi (Waterfall with Overlapping Phases)," "Waterfall with Subprojects," and "Waterfall with Risk Reduction." These "incremental waterfall models", introduce some allowance for feedback within the process but still remain quite inflexible. (McConnell, 1993)

Iterative models

The concept behind iterative models of startup development is to divide the development process into smaller cycles, called iterations, where each iteration works to develop an increment of the bigger system (startup development process). Each iteration enables the incorporation of learning and feedback from previous iterations; providing opportunities for continuous improvement and refinement. Therefore, unlike the the linear or interactive models, iterative development models allow for flexibility and adaptation throughout the development process. They emphasise the importance of continuous feedback, collaboration, and the ability to incorporate changes based on user and stakeholder input. (Larman & Basili, 2003)

Originally, iterative models were introduced for software development where it is relatively quick and cheap to repeat development processes and produce workable "units" of software per iteration to incrementally build up to a final version. The first major project to use such iterative development methods was during the NASA Project Mercury in the 1960s for the development of NASA's space shuttle software. (Larman &

Basili, 2003) Then, another iterative-type software development practice called Agile software development, gained significant attention when it was published in 2001 as a consolidation of many other famous iterative software development methods such as Kanban and Scrum, in the Manifesto for Agile Software Development. (Beck et al., 2001) It is from the idea of Agile Software Development, or "Agile practices" as it has since been termed - that many of the more recent iterative models for startup development rose.

Another important concept is that of the **Minimal Viable product**, first defined in 2011 by Frank Robinson and since then gained popularity through its use in other iterative models. Again first applied in product development; a minimum viable product (Minimal viable product (MVP)) is a version of a product that includes only essential features, allowing early customers to use it and provide feedback for future development. Emphasising the release of an MVP helps developers avoid unnecessary work and instead focus on iterative improvements based on feedback. However, MVP's have also since been applied in a startup development context since it is similar to the scientific method of experimentation, applied to validate business hypotheses and determine the viability and profitability of a business idea. This approach is beneficial for new or startup companies seeking to identify potential business opportunities and validate market needs for a product. Additionally, it can be used for incremental enhancements of an existing product or business model. (Brikman, NaN; Ries, 2009)

The first appearance of a iterative-type model relating to venture creation instead of software development - was in "The Theory of Economic Development" of Schumpeter in 1912 and 1934. (Schumpeter et al., 1939) Schumpeter viewed new venture creation (or startup development) as the cycle of an entrepreneur recognising an opportunity to create technological change which disturbs the market equilibrium, creating further opportunities to be recognised and restart the cycle. This model of Schumpeter's is focused on the role of new venture creation as an engine for economic development, and therefore does not offer insight into the actual process of new venture creation. (Salamzadeh & Kesim, 2015)

The first popular iterative model that focused more on startup development instead of software or product development, was the Steve Blank's Customer Development model from the 1990s. Blank's model describes a process directed towards "building a customer". Blank noticed that the traditional product development process of his time often failed to include the customer and often resulted in products being developed that customers did not want or need. So, Blank proposed a customer development process consisting of four iterative phases - (1) Customer Discovery, (2) Customer Validation, (3) Customer Creation, and (4) Company Building. The idea behind Blank's model is to create a continuous customer feedback loop in parallel to product development activities - to solve nine problems with the traditional product development model that Blank identified. The model is iterative in two ways; each phase can by repeated before moving to the next phase, and cycle between phase (2) back to (1) is possible and is called a **pivot**. (Blank & Dorf, 2005)

Next, based on concepts from Blank's model came the "Lean Startup" methodology - currently considered as one of the most influential methods for startups today. (Blank & Eckhardt, 2023) The lean startup methodology is a business and product development approach that aims to accelerate the product development process and determine the viability of a proposed business model. It achieves this through a com-

bination of business-hypothesis-driven experimentation, iterative product releases, and validated learning. (Täuscher & Abdelkafi, 2016) The lean startup approach helps entrepreneurs in validating assumptions and eliminating wasteful activities that do not contribute to value creation, such as activities that customers do not demand (Täuscher & Abdelkafi, 2016). The methodology emphasises a learning process for business model innovation known as "validated learning." This process involves engaging in a **Build-Measure-Learn (Build-Measure-Learn (BML)) loop**, as outlined by Ries (Ries, 2011). Within this loop, the method advocates for a systematic approach consisting of testable hypotheses that are evaluated through early versions of the product (MVPs). These quasi-scientific experiments incorporate customer feedback, helping entrepreneurs determine whether to persevere with the existing business model, abandon it entirely, or "pivot" by retaining features approved by customers while adjusting elements that were rejected. (Geoffrey Russell Archer, 2018; York & Danes, 2014)

The underlying premise of this methodology is that entrepreneurs should embrace the concept of "failing fast"; learning from failures as quickly as possible, and avoiding persistence in misguided ideas that can deplete valuable resources (Ries, 2011). Despite its apparent simplicity, the lean startup method draws inspiration from scientific method - using performance indicators and metrics to continuously measure business development (**?**). Also, similar to Blank's customer development model, lean startup emphasises customer feedback, adaptability, and flexibility. (York & Danes, 2014)The lean startup methodology emphasises that "lean" is not about the amount of funding a company raises, but rather focuses on understanding and meeting consumer demands with the most efficient use of resources.(Blank & Eckhardt, 2023)

Since its introduction in 2008, the lean startup philosophy has gained global attention and has literature has since focused on developing effective tools to incorporate Lean Startup principles into entrepreneurial practice. However, there remains a scarcity of academic research and validation of the Lean Startup principles and propositions (e.g., (Bosch, Olsson, Björk, & Ljungblad, 2013)), and it has been reported that the lean startup methodology has been difficult to implement in practice (D. S. Silva, Ghezzi, de Aguiar, Cortimiglia, & ten Caten, 2020).

This lead to the final iterative model that i worth mentioning - the "running lean" process model, first introduced by Ash Maurya in 2010 (Maurya, 2012). Running Lean is a systematic process model that combines three fundamental methodologies; Blank's Customer Development model and Ries's Lean Startup already described, and "Bootstrapping" - a collection of financing methods used to minimise the amount of external debt or funding needed from banks or investors to finance startup development. Maurya claims that Running Lean is specifically applicable for developing startups under extreme uncertainty, and improves the works of Blank and Ries by providing a disciplined, rapid process that still enables the flexibility of other iterative models.(Maurya, 2012)

The Running Lean process outlines a three stage systematic process: (1) Problem/Solution Fit, (2) Product/Market Fit, and (3) Scale. Throughout the process, Maurya instructs that a startup initiated build-measure-learn loops to create measurable feedback, validated learning and the opportunity to refine parts of the startup's business model - similar to Ries's Lean Startup (Ries, 2011) . However, the focus of the

BML loops change between the second and third stage; the first two stages focus on validating parts of the business model and pivoting until a sufficient plan is found, and the third stage is focused on creating efficiency by refining and optimising the existing business plan to stimulate accelerating growth. (Maurya, 2012)

Vohora et al. (2004) made an invaluable contribution to literature and expanded the traditional stage-gate like models of startup development. They incorporated a similar level of flexibility and learning that Ries and Blank had in their iterative models, as well as drew from the theory of interactive model methodologies that encourages simultaneous activities within different stages of development. (Blank & Dorf, 2005; McConnell, 1993; Ries, 2011)

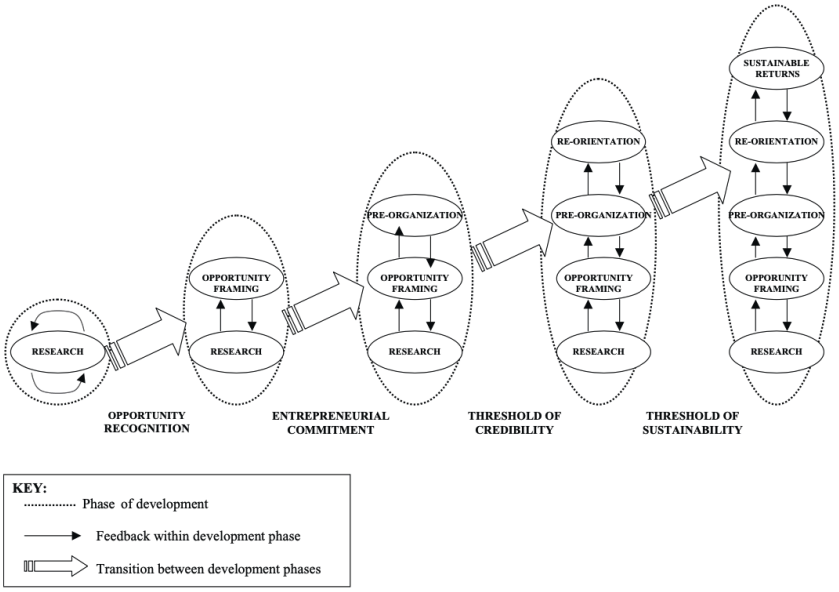

Figure 3: Vohora et al.'s model of the development phases and critical junctures of university spin-out companies (Vohora et al., 2004)

In their study of university spinout companies, they noticed that startups seem to not follow discrete stages of growth but instead experience non-linear phases of development, punctuated by critical junctures as seen in Figure 3. Their findings also highlighted the existence of "critical junctures" that must be successfully navigated to transition from one development phase to the next. Recognising these critical junctures is reported to be essential as they represent inherent conflicts within a venture that hinders progress. Thirdly, they discovered qualitative differences in terms of a startup's resources, capabilities, and social capital before and after each critical juncture - indicating that startups do not follow discrete stages of growth but instead experience non-linear phases of development, punctuated by critical junctures. (Vohora et al., 2004)

3.3 Construction of a model specifically for the pre-scaleup development of healthtech startups

Creating a pilot model to represent and/or guide the pre-scaleup development of healthtech startups draws on the theory studied in 3.2 on the types of models previously used for tech-startup development, and the challenges found in Chapter 2 that characterise development of healthtech startups. Moreover, since it is evident that the pre-scaleup development process in startups constitutes inherent uncertainty, the pilot model needs to incorporate an appropriate level of flexibility (Bosch et al., 2013). Furthermore, it is crucial that the model have practical relevance and can be a potential guiding model for healthtech startups in planning and executing their pre-scaleup development process. Therefore, the pilot model should also reflect the health-specific characteristics that were studied in Chapter 2 to describe the pre-scaleup development of healthtech startups. These characteristics appeared within the nine main themes- (1) regulation, (2) network, (3) development processes, (4) financing, (5) capabilities, (6) measures of performance, (7) solution, (8) system and market context, and (9) social aspects - which will be used to describe the development stages and critical junctures experienced in the pre-scaleup development of startups.

Development stages and critical junctures

Following the proposed model of Vohora et al. (Vohora et al., 2004), the growth or development of high-tech startups can be summarised as a non-linear number of development stages that are focused around overcoming a number of key barriers, or as Vohora et al. called them, critical junctures. This same logic will be used to model the pre-scaleup development of healthtech startups; as an accumulation of non-linear development stages, separated by critical junctures that represent a number of key barriers that must be overcome for healthtech startups to progress to their next stage of development.

Healthtech startups, similar to other startups, begin their development journey when there is a defining "moment of intention" by either the entrepreneur, inventor, or small startup team, to pursue an recognised opportunity. (Marullo et al., 2018; van Gelderen et al., 2005) This can be named the *Concept stage* since the primary focus at this stage of development is on forming ideas, a conceptual solution or technology from these ideas, and conceptualising how the solution may address a verified problem. The opportunity recognition in this stage occurs when a verified need or gap is identified and there is a technically and commercially feasible solution that can be developed to address this need. (Bhave, 1994; van Gelderen et al., 2005) The more detailed activities that are often carried out in the Concept stage are described in Table 3. The overarching objective within the Concept stage is to find a feasible solution to a verified problem - in other words to find a problem-solution fit.

This introduces the first critical juncture of the pilot model - the *Problem-Solution fit juncture*. The problem-solution fit juncture represents the barriers experienced when trying to find a good match between a verified problem in the health system, and a feasible solution to this problem. This challenge has often been experienced in healthtech startups: many of these startups either produced a technology that does not address any actual problem, or they struggle to develop a health technology that adequately solves a problem due to various reasons such as technical, resource or capability constraints. A major reason for this is the misalign-

ment between the healthcare industry and those involved in designing and developing health technologies. (Semler et al., 2015; Young, 2022) Related, there is lack of consensus and shared understanding on how best to approach public health issues, limited knowledge of health workflows and patient experiences, and little communication between health professionals and technical designers or engineers. (Andersen et al., 2018; Young, 2022) Other contributing barriers experienced within the Problem-Solution fit juncture are listed in Table 4

Once the Problem-Solution fit juncture is passed, the next stage - the *Opportunity Framing stage* begins. The Opportunity Framing stage is focused on making a measurable commitment to pursuing the opportunity identified in the Concept stage, by laying down resources, financial capital and time to further develop the solution. This aligns with the "technology setup" stage (Bhave, 1994), the "opportunity framing" stage (Vohora et al., 2004) or "commitment" phase (Startupcommons, 2018) of the models in Table 2. During this phase, the focus is on the transition from recognising an opportunity (done in the Concept phase) to taking the initial steps in creating a new technology-based startup (committing resources). Also, the Opportunity Framing stage aims to assess whether the identified opportunity has sufficient value to justify further efforts in pursuing commercialisation. This evaluation process begins with scrutinising the technology to ensure its functionality and its potential for applications beyond a testing environment. This involves developing the underlying concept of the technology proposed during the previous stage, and working on creating a MVP, testing it and prototyping within a laboratory environment. (CIMIT, n.d.; Vohora et al., 2004). Once the technological validity and performance of the opportunity have been evaluated, the next step is to "frame" it within a commercial context - trying to identify alternative markets, determine which applications of the technology to develop for those markets, and devise strategies to first reach out to potential customers and involve their preliminary feedback in the development and prototyping activities. (Startupcommons, 2018; Vohora et al., 2004). Then in terms of funding, the Opportunity Framing stage often relies on government grants to fund the MVP development activities, but this stage is also a essential opportunity for healthtech startups to make contact with angel investors and early-stage startup support firms to showcase the first version of their product and capture interest of potential investors to fund the following stages of development. (Startupcommons, 2018)

Challenges arise in the Opportunity Framing stage due difficulties securing the sufficient commitment from the founders, initial startup team and external shareholders to provide the resources required for the startup's product development activities, and other needs to continue its growth journey. This is marked by the *Commitment juncture*. Many of the difficulties in appropriately securing and allocating resources during this stage stem from a lack of commercial and health-specific expertise within healthtech startups. (Chakraborty et al., 2022) The opportunity framing stage also involves connecting and acquiring new stakeholders but there is a challenge to bridge the gap between well-developed technologies and the requirements of potential investors interested in healthtech and reimbursement agencies whose support is essential for the future commercialisation of the health technology.(Sorenson et al., 2013; Vohora et al., 2004; Young, 2022) Within the Commitment juncture, a lack of internal commitment in the healthtech startup can arise. This often stems from a reluctance from the founders and team to commit to actively pursuing the development of a health technology, especially given the high level of uncertainty so early in the development process. There is often

also a difficulty to frame the opportunity clearly due to the uncertainties and complexity that is inherent to the very early startup development stages. This can lead to inability to make decisions to move ahead with development. (Vohora et al., 2004)

Next under consideration, is one of the most prominent obstacles for starting up a healthtech venture - the complex regulatory landscape that causes many health technologies to remain in development and testing for much longer than other technologies. The regulatory challenge of generating clinical evidence, clinically approving health technologies, and constructing compliant quality management and reporting systems results in a large time delay to progress health technologies from an idea to actually reaching the first customer. This time lag also requires a higher financial intensity, specialised capabilities and support network, and specific characteristics to be incorporated into a startup's technology and development process. These specialised considerations are not represented in other models of startup development (Bhave, 1994; Startupcommons, 2018; van Gelderen et al., 2005; Vohora et al., 2004) but is crucial for the pre-scaleup development of healthtech startups. Therefore, there is a need to represent this time delay in the model of healthtech startups development - as an additional stage called *Clinical Validation* - see Figure 4. This extra Clinical Validation stage is focused on developing clinical evidence, conducting clinical trials if necessary, and planning and implementing systems to meet the regulatory requirements for the health technology under development. This stage aims to gain validation from clinical stakeholder such as reimbursement agencies, regulatory bodies, physicians, patient organisations and specialised clinicians. (Sorenson et al., 2013; Young, 2022) It must happen after the commitment juncture since the Clinical Validation stage requires a significant investment of funds, capabilities and resources (Nyikos et al., 2019; Stafinski et al., 2011). Also, the Clinical Validation stage occurs before the startup can begin preparing for scale-up and growing their capacity as an organisation; they must first get regulatory approval and successfully progress through the clinical trials and other compliance activities during the Clinical Validation stage. At the end of the Clinical Validation stage, the health technology has shown to be effective in a clinical setting, and there is evidence of its value for its stakeholders since it has passed the regulatory requirements and may progress to being produced, marketed and launched to customers on a large scale (scaleup). (CIMIT, n.d.)

However, progressing through the Clinical Validation stage has a number of critical barriers. The largest obstacle involves gaining the support and credibility for the health technology amongst clinical stakeholders, the health system, and the larger ecosystem of health technologies and other corporations, to fund, support and approve of the health technology being developed. (Ostrovsky & Barnett, 2014; Young, 2022) Therefore, the following critical juncture is called the *Credibility* juncture. Another barrier experienced in the Credibility juncture is the lack of knowledge, process capabilities, or financing to meet the regulatory requirements to continue developing and commercialising a health technology (Chakraborty et al., 2022; Fearis & Petrie, 2017). Moreover, there is often a lack of engagement with clinical stakeholders and others within the health system who can be come distrustful of external technologies they are not familiar with. (Reddy et al., 2019; Semler et al., 2015). The Credibility juncture represents all the barriers that healthtech startups face within their efforts to achieve regulatory compliance, acceptance for their technology within the health systems, and the support of a network and investors.

For any startup; it is only once they have defined ("framed") the opportunity which they want to pursue, and have committed resources and capabilities to pursuing the opportunity; that the startup can start implementing strategic plans to officially develop specific resources or capability further, plan to acquire new resources and/or knowledge, and decide how to access such resources. (Vohora et al., 2004) This can be called the *Pre-Organisation* stage, similarly names the organisation creation, organisation establishment or transition stage by other models in literature, (Bhave, 1994; Marullo et al., 2018; Picken, 2017; Vohora et al., 2004) and it entails similar activities whether an organisation is being built around a consumer product or health technology. However, the largest difference for a healthtech startups; is that the start of the Pre-Organisation stage is also reliant on first complying with the complex regulations for health technologies before they can begin strategically building their organisation. (Colloud et al., 2023; Fernández-Alemán et al., 2013; Sorenson et al., 2013) The Pre-Organisation stage consists of the gathering and allocation of resources and capabilities directed towards creating an organisational structure, growing a skilled team, attracting and connecting with an initial market, linking to a support network, building up and attracting new investors, and adjusting the business model to market and network requirements. (Bhave, 1994; Vohora et al., 2004) In a healthtech startup, this also involves planning and implementing manufacturing processes and quality control measures to ensure the consistent production of safe and effective medical devices in compliance with medical device regulations and health safety legislation. This includes selecting appropriate materials, establishing production facilities, implementing quality management systems according to regulatory guidelines. (Fernández-Alemán et al., 2013; *ISO - ISO 13485 — Medical devices*, NaN) Another aspect of the Pre-Organisation stage is the shift to more long-term financing partners such as venture capitalists, business angels and stock options. (Kang, 2018)

These activities to be carried out during the Pre-Organisation stage have the common goal to address the challenge of gathering and organising the startup's capabilities, finances and resources and putting these to work in finding and addressing a fit between the startup's health technology, and the requirements of the health system and market. (Maurya, 2012; Startupcommons, 2018) This final juncture in the pre-scaleup development of a healthtech startup is therefore called the *Scale-readiness* juncture. The Scale-readiness juncture consists of the barriers related to making contact with the right stakeholders (e.g., reimbursement agencies, health professionals) in the health systems that will encourage acceptance of the health technology (Andries et al., 2021; Dhainaut et al., 2020; Young, 2022). Also, within the Pre-Organisation stage, startups often find it difficult to choose their first target market, the right application of their technology, the best marketing approach and other similar decisions to be made under uncertainty (Vohora et al., 2004). Moreover, at this stage of their development, healthtech startups have to take extra care to ensure that their health technology can be accepted and implemented as seamlessly into the existing workflows and infrastructure in health systems. Although these interoperability features of their health technology should have already have been developed in earlier development processes, its at this stage of development that the interoperability and level of acceptance will be put to the test in practice (Dixon et al., 2013). The Scale-readiness juncture represent the final set of barriers before a healthtech startup can scale-up, or begin producing and selling their health technology on a large scale. Therefore, another challenge experienced within this juncture is related to implementing and organising the logistical, manufacturing quality management and other operational activities necessary for the startup to scale-up.

A startup able to navigate these barriers indicates that the startup is geared to commence with launching their product into the market an a large scale - or in other words, to scaleup (Startupcommons, 2018) This marks the end of the pre-scaleup development period.

A more comprehensive summary of the activities and barriers within each development stage and critical juncture of the pre-scaleup development of healthtech startups is shown in Tables 3 and 4.

Concept Stage	*Opportunity framing stage*	*Clinical Validation stage*	*Pre-Organisation stage*
• Conduct research and basic experimentation to verify the existence and prevalence of a problem, and - the feasibility of a healthtech solution in addressing this problem • Test commercial and technical feasibility of solution • Some contact with clinical stakeholders to verify clinical problem - via informal discussion, surveys etc. • Stage is either self-funded or by friends and family or by public grants • No significant allocation of resources to pursue development	• Make first measurable commitment to pursuing the opportunity - lay down resources, financial capital and time to further develop the solution • "Frame" solution within a commercial context - identify alternative markets, determine which applications of the technology to develop for those markets, and devise strategies to first reach out to potential customers and involve their preliminary feedback in the development and prototyping activities • Funding used during this stage: often bootstrapped, and government grants • Reach out to angel investors and early-stage support organisations (eg., incubators, venture builders) • Iterative development of an MVP and test prototypes in a pre-clinical setting (animal or laboratory studies) • Identify and protect the intellectual property associated with the medical technology. Conduct patent searches, file patent applications, and perhaps engage in licensing agreements to safeguard the technology's unique features and prevent unauthorised use or reproduction. • Determine needs and plan and budget for clinical validation stage	• Validation of representative prototype in clinical environment (with patients or in clinical environment) - conduct clinical trials if required • Planning and implementing quality and reporting systems to meet the regulatory requirements for the health technology under development • Connect with healthtech-specific experts and firms to support and guide the efforts to meet regulatory requirements of health technology • Gather further commitment and buy-in from clinical stakeholders by showcasing the Validation of Solution: technology has shown its effectiveness in a clinical setting and there is evidence of its value for stakeholders since it has passed the regulatory requirements and may progress to being produced, marketed and launched to customers on a large scale	• Develop specific resources or capability further, plan to acquire new resources and/or knowledge • Develop manufacturing processes and establish quality control measures to ensure the consistent production of safe and effective medical devices. This includes selecting appropriate materials, establishing production facilities, implementing quality management systems according to regulatory guidelines. • Bring in talent (grow the team) to run the organisation • Shift in focus to efficiency • Develop commercialisation plan, deploy resources for marketing campaigns • Attracting and connecting with an initial market, linking to a support network, building up and attracting new investors, and adjusting the business model to market and network requirements.

Table 3: Table of the activities in pre-scaleup development stages of healthtech startups

Problem-Solution fit juncture	*Commitment juncture*	*Credibility juncture*	*Scale-readiness juncture*
• Lack of knowledge of health industry workflows, current issues, and preferences • Lack of shared understanding of clinical problems between health professionals and technical designers or engineers • Mismatch between solution and conceptual problem. e.g. over-engineered technologies with unnecessary functions • Difficulty of access to health data and current practices due to patient privacy concerns • Lack of proof of feasibility of the solutions • Lack of verification of problem	• Lack of resources to begin prototype development and gathering pre-clinical evidence • Difficulty in gaining the commitment of the founders, initial startup team and external shareholders to provide resources • Lack of commercial and health-specific expertise within healthtech startups • Challenge in securing support of investors, reimbursement agencies and clinical stakeholders due to the communication gap between these stakeholders and the technology designers • Lack of internal commitment due to a reluctance from the founders and team to commit to actively pursuing the development of a health technology • High level of uncertainty so early in the development process	• Lack of funds to start clinical testing, implement quality management systems, or support regulatory efforts • Changes in regulatory requirements over time and in different geographies • Lack of knowledge, process capabilities, or financing to meet the regulatory requirements to continue developing and commercialising a health technology	• Lack of contact with the right stakeholders (e.g., reimbursement agencies, health professionals) in the health systems that will encourage acceptance of the health technology • Insufficient capability, resources and finance to begin manufacturing on a larger scale, implement quality management systems, and scale-up • Resistance to accept new health technology • Lack of compatibility between solution and current health system workflows and systems • Difficulty in attracting first target market, right application of technology, the best marketing approach

Table 4: Table of the barriers in pre-scaleup development junctures of healthtech startups

In addition to the development stages and critical junctures discussed, another key characteristic of the pre-scale development of healthtech startups, as with many startups, is the inherent uncertainty and the need to remain flexible to make changes within the development process. (Bosch et al., 2013). Therefore. a model to represent the pre-scale development of healthtech startups should make provisions for including flexibility.

Vohora et al. incorporated flexibility within their model in two ways. First, they allowed for two-way feedback between the stages of development; (Vohora et al., 2004) These ideas stem from some of the theory used in other models of startup development described before. The allowance of feedback between development stages is comparable to the BML loops and pivots described by Ries's Lean startup model and Blank's Customer development model. (Blank & Dorf, 2005; Ries, 2011) Mauyra's "Running Lean" (Maurya, 2012), has a similar allowance for repetition of activities within development stages until the barriers are overcome to progress the startup to the next stage of development. This same idea applied in the construction of

the model of the pre-scale development of healthtech startups in Figure 4; a continuous flow of feedback between development stages is encouraged so that the activities within the stages can be improved based on previous learnings and outcomes. Moreover, BMLloops are constructed between the development stages and critical junctures. These BML loops involved iteratively assessing the extent to which barriers in the critical junctures have been addressed, giving feedback to the stage on the progress, and incorporating this feedback into the next iteration of activities and barrier assessment. These BML loops between each stage and critical juncture create measurable feedback, validated learning and the opportunity to refine parts of the startup's business model before moving onto the next stage.

Then, the second incorporation of flexibility in Vohora et al.'s model is the non-linear fashion of the model which allows different stages to occur simultaneously, and in effect build upon one another based on two-way feedback and the accumulation of resources and capabilities as time progresses. (Vohora et al., 2004) This notion is similar to the idea of waterfall or interactive models of startup development and captures the non-linear and sometimes chaotic nature of startup development in practice since often many activities happen simultaneously and are repeated while other stages further down the line are also happening. This concept is applied in Figure 4 by showing each development stage as a build-up of itself and all the previous stages. In effect, at each stage of development, another set of activities is added to the ongoing activities within the startups development process.

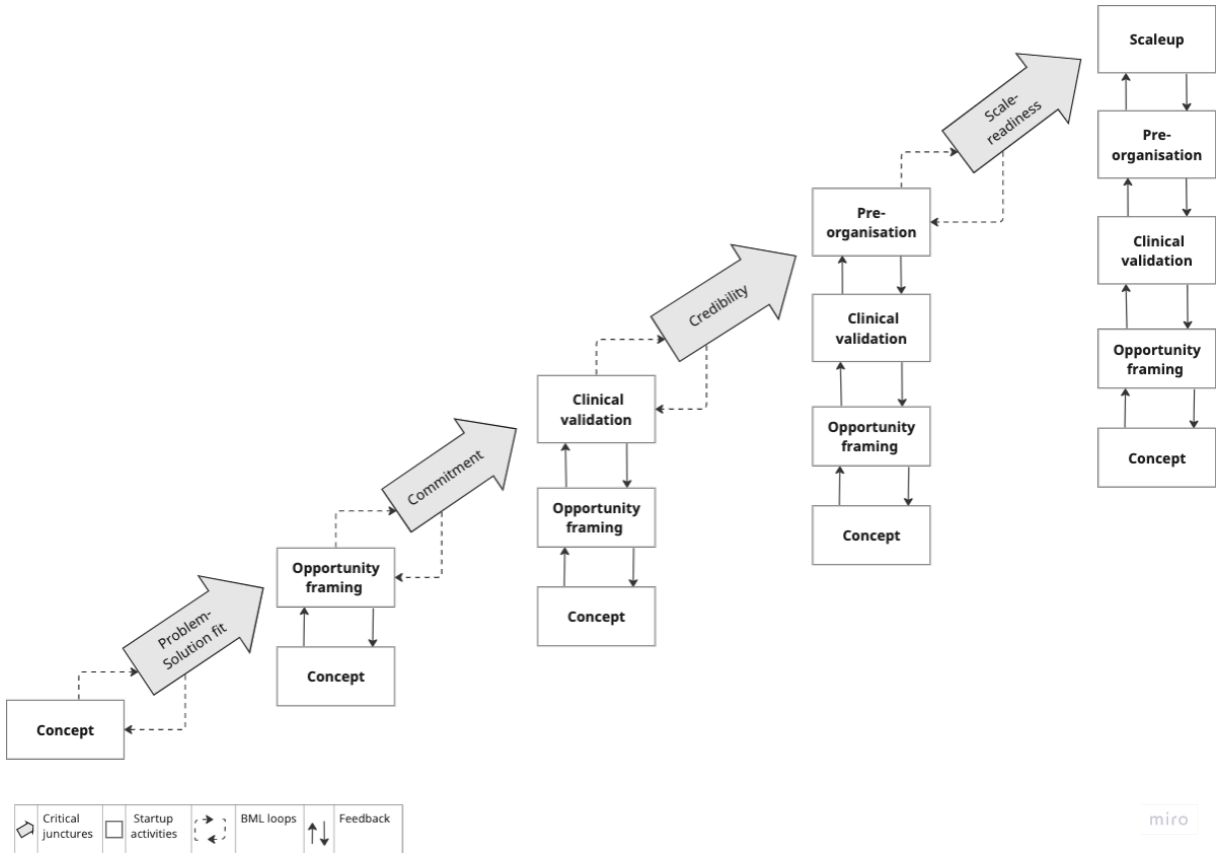

Figure 4: Theoretical model of the pre-scaleup development of healthtech startups

3.4 Chapter conclusion

Chapter 3 evaluated the current models available to represent or guide the pre-scaleup or early development of startups; and criticised their shortcomings in representing the pre-scaleup development of specifically healthtech startups. Then, Chapter 3 combined the theory of the models studied and the themes studied in Chapter 2 to characterise the uniqueness of healthtech startups; to construct a theoretical model to represent the pre-scaleup development of healthtech startups. Thereby, Chapter 3 addresses sub-research question (b): "*What implications does the uniqueness of healthtech startups have on a model to represent the pre-scaleup development of specifically healthtech startups?*". The findings in this chapter will be reflected on in Chapter 6.

4 Chapter 4: Methodology

4.1 Chapter introduction

Chapter 4 describes the methods undertaken to produce the final results in line with answering sub-research question (a), to determine the unique characteristics of the pre-scaleup development of healthtech startups. Chapter 2 already consulted literature in an attempt to address this question, but Chapter 4 builds on the results of Chapter 2 by introducing another source of data and conducting a subsequent data analysis. Chapter 4 starts with explaining the data collection methods, and then describes how the data was analysed. The results of the methods described in Chapter 4 are presented in the following Chapter 5.

4.2 Data Collection

A qualitative data collection method was conducted in the form of semi-formal interviews with various participants with experience in the pre-scaleup development of healthtech startups in the Netherlands. The methods to collect the qualitative data involved setting up interview questions, selecting and contacting participants for the interviews, and conducting the interviews.

Setting up the interview questions

Prior to the interviews, a set of guiding questions was developed, attached in Appendix B, that were used to direct the discussion between the researcher and the participant. The interview questions were structured in an open-ended manner, such that the participant had some room to steer the conversation themselves, but the questions limited the discussion from becoming irrelevant to the focus of the research. The interview questions were sequenced in way that started with broad and exploratory questions to introduce the topic of the research and get the participant's wider perspective of the research topic; and then the participant was asked narrower questions that were directed at validating specific research findings. This method of sequencing aimed to progressively steer the conversation towards the focus of the research whilst simultaneously encouraging the participant to make their own interpretations of the questions and steer the direction of the conversation themselves. This approach increased the chances of uncovering the participants' personal experiences and opinions that the research had not yet found or that the researcher had not thought of.

Participant selection

The interviews are limited to participants from within the domain of Dutch healthtech startups and their development for ease of contacting potential participants, and since the research was conducted in the Netherlands.

Prior to the interviewing process, the number of participants was unknown since it was pre-planned that interviews would be conducted until data saturation is reached. Data saturation is an iterative research approach where data is repeatedly collected and analysed until a point at which new data no longer provide new insights or reveal any novel emerging themes or categories. By employing data saturation, the researcher

could aim to ensure a thorough qualitative research method, but avoid unnecessary time spent capturing data that did not provide additional value to the research. The "Method to Assess and Report Thematic Saturation in Qualitative Research" of Guest et al. (2020) was adopted because of the method's suitability for one-on-one interviews using open-ended questions and use of inductive thematic analysis to find emergent themes in the data. (Guest, Namey, & Chen, 2020) It is important to note that this data saturation method is based on a subjective judgement and skill of the researcher identifying the number of unique themes emerging from the interview.

In terms of the selection of participants, it was beneficial to include participants with differing perspectives and roles in the pre-scaleup development of healthtech startups. The literature study on "Network" in healthtech startup pre-scaleup development from 2.3 was used to inform the selection of participants. The aim was to involve a number of different perspectives within the pre-scaleup development of Dutch healthtech startups and therefore, the participants each had slightly different roles and experiences within the network of Dutch healthtech startups. The participants that were finally included in the interview process (based on the data saturation method) are shown in Table 5, and their more detailed description follows. Only information is included that each participant gave their consent to disclose.

	Role of participant in pre-scaleup development of healthtech startups
Participant A: Healthtech startup development expert	Supporting role in the pre-scaleup development of Dutch healthtech startups. Has expertise and advice for the process to building successful healthtech ventures.
Participant B: corporate founder	Role as a founder of a now successful Dutch healthtech startup and now an advisor to other healthtech startups in the Netherlands in their development process.
Participant C: clinical expert	Represents the role of a clinical stakeholder and/or user of health technologies in the health system.
Participant D: financial expert	Has experience in the role of founding and funding multiple healthtech startups in the Netherlands
Participant E: academic founder	Represents the role of a founder of a healthtech startup in its very early phases, and has experience in developing a healthtech startup from an academic setting.

Table 5: Table of interview participants and their role in pre-scaleup development of healthtech startups

Participant A has the role of a "venture developer" at a startup support body that specialises in creating and supporting healthtech ventures and innovation. Within this role, Participant A is involved in activities typical to the pre-scaleup development process such as: sourcing interesting health technologies, performing research and due diligence, validating a number of different aspects of the technology, engaging with clinical stakeholders throughout the process, negotiating a deal and ultimately collaborating to find the CEO to run the healthtech startup. Interviewing participant A introduced a detailed perspective to inside the day to

day activities and challenges experienced in the pre-scaleup development process of healthtech startups. The type of knowledge shared will come from the participant's personal experience with the healthtech startups they have been involved with supporting. (ParticipantA, 05.06.2023)

Participant B is a founder of a high-tech health startup in the Netherlands in addition to being involved in advising other Dutch healthtech startups in their development processes. The startup is developing a digital software platform to help patients regain fine motor skills after injury or disease. Currently, the startup is in their incubation and prototyping phase, meaning that they are busy developing and testing prototypes in a user environment. Their health technology is currently operational in 8 clinics in the Netherlands. The research and development phase has been completed, and the focus now shifts towards the finalisation of the hardware for production. In relation to this research, participant B therefore can provide valuable insight into the reality of developing a healthtech startup up until before production - or in terms of the model developed in Chapter 3, scale-up. (ParticipantB, 07.06.2023)

Participant C represents a clinical stakeholder to the healthtech startup pre-scaleup development process. The participant has experience as a general health practitioner for 11 years in various countries, and has subsequently become an advisor to several healthtech startups and startup support programs due to their expert experience of the intricate workings of health systems. This participant therefore provides a unique perspective from within the health-side of the healthtech startup development systems and can provide insight into how health technologies and these startups are viewed from the perspective of health professionals, other clinical stakeholders, and the users. (ParticipantC, 09.06.2023)

Participant D is a founder or co-founder of several healthtech startups in the Netherlands, has been involved in the funding rounds of healthtech startups, and has advised many prospective healthtech entrepreneurs in the challenges of financing and developing a health technology successfully. This participant has experience with health technologies that both succeeded past their pre-scaleup phases, and that failed before. Participant D has worked in the sale of health technologies to hospitals in the Netherlands, has been involved in implementing these technologies within hospitals, and has previously strategically partnered with large health organisations. Therefore, this participant can provide valuable knowledge related to the various activities and factors to consider during pre-scaleup development of a healthtech startup - both retrospectively and as an adviser to current healthtech startups. (ParticipantD, 18.07.2023)

Participant E has the unique perspective of a healthtech startup still in the beginning stages of its pre-scaleup development in the Netherlands. This participant is the founder of a healthtech startup that originated from a university project at the Delft University of Technology, Netherlands. The participant is currently engaged in user testing of their health technology and seeking validation and support for their healthtech startup. Participant E is able to provide insight into the day-to-day challenged, considerations and experiences of a healthtech startups in its early pre-scaleup development phase. (E, 19.07.2023)

Conducting the interviews

The first step of conducting the interviews involved contacting and informing the participants of the interview process and attaining their consent to be involved in the research. The participants were contacted via the researcher's personal and professional network. The research reached out to the participants via an email including a one page summery of the research motive, background and objectives but excluding any details about outcomes or findings of the research. Therefore, the participants could familiarise themselves with the topic and objectives of the research, but were subjected to a minimal amount researcher bias related to what findings or results should come out of the research.

In accordance with the Human Research and Ethics Committee (Human Research and Ethics Committee (HREC)) (*Human Research Ethics*, NaN), the participants signed a consent form prior to partaking in the interviews; and the researcher created a data management plan, approved by the HREC) and attached in Appendix D. The data management plan described exactly what type of data is collected, and how it would be stored, manipulated, transferred, and deleted. In summary, the participants gave their consent for the audio of the interviews to be recorded and transcribed, after which the audio recordings were deleted. Moreover, personal data relating to the participant's names, gender and other personal details have been excluded from the research. Only details relevant to the purpose of the research were included.

Upon conducting the interviews, four of the participants were interviewed over virtual video calls due to availability of the participants and ease of recording. Then, one interview was conducted in person on request of the participant. The audio recordings of all the interviews were manually transcribed and the audio recordings immediately deleted.

4.3 Data analysis

Inductive coding of interviews

The interviews with these participants are transcribed but require additional work to gather meaningful insights from them. Therefore, a well-known qualitative data analysis (QDA) method is to be applied to the transcribed interviews - an inductive thematic analysis (Thematic analysis (TA)) as first described by Braun and Clark (2006) and since widely accepted in the meaningful analysis of qualitative research practices. (Braun & Clarke, 2006) Thematic analysis is a systematic method to identify, analyse and interpret qualitative data to extract meaning in the form of codes and themes that arise from the data. Codes represent the smallest analytical units that capture interesting aspects of the data that are potentially relevant to the research question. These codes serve as the foundation for constructing themes, which are larger patterns of meaning. These themes then provide a structure for organising and presenting a researcher's analytical observations. The objective of TA goes beyond merely summarising the content of the data. It aims to identify and interpret key features of the data that are relevant to the research question. (Clarke, Braun, & Hayfield, 2015)

TA as form of QDA, is specifically chosen for this research since it can produce meaningful insights in a thematic format - similar to the thematic summary that was produced by the literature study. Therefore, the results of the TA are comparable to, and can supplement and validate/challenge the research conducted thus far. Also, TA is suitable for creating valuable insights from case study research with a number of differ-

ent perspectives (Costa, 2019) - as is the case of the interview process in this chapter.

In an effort to simplify the TA method as described by Braun and Clark (Braun & Clarke, 2006), the COSTA Qualitative Data Analysis (COSTA QDA) was developed. This simpler TA framework is applied in this research to extract meaningful insights from the interviews in this chapter through a structures and rigorous research method. The COSTA QDA method consists of six steps as shown in Figure 5; (1) Data Tools, (2) Data familiarisation, (3) Initial coding stage - Coding, (4) Second coding stage - Sorting, , (5) Third coding stage - theming, and (6) Presentation of findings. (Costa, 2019)

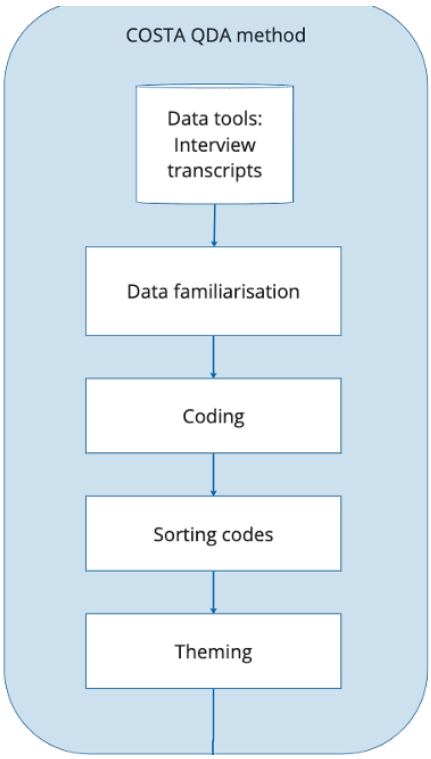

Figure 5: The COSTA Qualitative Data Analysis (COSTA QDA) method

The data tools refer to the documents or forms of data to be analysed - in this case, the interview transcripts. Next, the data familiarisation in this research involves the researcher's engagement with the data via reading the interview transcripts and re-watching the recordings of the interviews to become familiar with the emphasised points of the participant and certain personal cues that can have use in analysing the research. For example, if the participant stutters or hesitates in answering a certain line of questioning, it could indicate that they are not confident in their answer or did not fully comprehend the question - indicating that there answer may not be a true reflection practical situation being asked about. However, if the participant conveys the same behaviour throughout the interview, then it is likely that these verbal or visual cues are simply a part of their speech. The data familiarisation step ensured that the researcher took into account these cues and the perspectives of the participants (as described in 4.2) when moving to the following steps

to code the data.

First coding stage: Coding

This coding step involves deriving codes from the interview transcripts inductively. This means that codes are created from reading through the interviews line-by-line and extracting significant statements that are either repeated or emphasised by the participant, are highlighted to be important, or have already been heard several times by the researcher. (Costa, 2019) An iterative approach is adopted to the the inductive coding approach; beginning on the smallest level of analysis (words) and progressing to word combinations, and then whole statements or paraphrases to gather codes. Therefore, the first stage identifies commonly recurring words and word combinations which could point to potential codes. A list of these commonly recurring words and word combinations can be found in Appendix C, Table 10 and 11. From this word list a few codes could be identified. For example, the following words and word combinations indicated these possible inductive codes in the interviews: "problem solution", "clinical trial" "Technical Readiness Level (TRL) level", "timeline", "people", "impact", "clinical expert" etc..
Then, the next step of the inductive coding involves identifying statements in the interviews that embodied codes - both new and those already identified. The interview transcripts are read line-by-line and the important quotes are manually extracted by the researcher, and then linked to the appropriate anchor deductive code, posteriori code, or a new code if applicable. The list of transposed quotes and their linked codes is attached in Table 12 of Appendix C.

Second coding stage: Sorting codes

Some codes could be linked or grouped via manual decision-making. For example, "clinical expert", "hospital" and "patient" can be grouped under "people" or "network". Following this procedure, the sub-codes were linked and grouped under overarching codes - as shown in Figure 8.

Third coding stage: Theming

The final coding stage in the COSTA QDA method entails grouping similar codes, evaluating their frequencies and generating themes from the previous coding stages.

The outcome of this final data analysis process is a list of emerging themes and the subsequent codes, paraphrases, words and word combinations from the interview transcripts that are linked to each theme. A code tree was used to summarise the codes and sub-codes into themes and is presented in the following Results chapter in Figure 6. Also, Table 13 in Appendix Cshows which participants discussed which themes since some of the themes did no appear in every interview.

4.4 Chapter conclusion

This chapter presented the methods that were applied to collect data via interviews, and analyse the interviews to inductively gather codes and themes. The results of Chapter 4 are presented in the following chapter.

5 Chapter 5: Results

5.1 Chapter introduction

Chapter 5 presents and describes the results of the methodology outlined in Chapter 4. The chapter begins with presenting a summary of the resulting themes found from the analysis of the interviews in relation to answering sub-research question (a): "*What are the unique characteristics of the pre-scaleup development of specifically healthtech startups?*". The results described during this chapter will inform the discussion to follow in Chapter 6

5.2 Themes identified in the interviews

There were several common themes that emerged from the interviews and their subsequent analysis. The inductively derived codes were organised and grouped into themes as shown in the code tree in Figure 6. The main themes that emerged and their key codes are summarised in Table 6.

Theme	**Key codes that emerged in the interviews per theme**	**# appearances**
People	(1) experts, Key Opinion Leader (KOL), (3) users and types of adopters	74
Development process	(1) user involvement, (2) implementation, (3) time, (4) pivots	50
Solution	(1) types of health technology, (2) problem/solution fit, (3) innovation type	36
Financing	(1) types of investors, (2) risk-aversion of investors, (3) money flows within health systems	31
System context	(1) hospital workflows, (2) existing problem, (3) technological infrastructure	23
Capabilities	(1) knowledge and skills of team & founders, (2) resources, (3) flexibility	21
Evidence	(1) clinical validation, (2) Proof of Principle (PoP), (3) Proof of Concept (PoC)	16
Stakeholder Value	(1) KPIs and measures in the health system, (2) buy-in from stakeholders	16
Social aspects	(1) trust, (2) culture, (3) psychology of change	15
Regulation	(1) clinical trial pathway, (2) intellectual property, (3) documentation	13
Network	(1) health systems, (2) reimbursement agencies, (3) regulatory bodies, (4) support bodies	11
Risk	(1) clinical risk, (2) market risk, (3) business risk	11
Level of development	(1) technical readiness level, (2) value inflection points	10
Market	(1) size of market, (2) market saturation	9

Table 6: The key themes of the pre-scaleup development of healthtech startups, and related concepts

Figure 6: Code tree of the main themes broken down into their codes and sub-codes

The insights gathered from the interviews are grouped into these themes and are described as follows.

People

The interviews made a clear emphasis on the importance of specific people being involved in the pre-scaleup development of healthtech startups - the code "people" was the most common code found during the interview analysis. One participant who is an experienced employee at a company that regularly builds healthtech startups, said that "one of the biggest hurdles are ... getting the right people in our network or building out the network enough" (ParticipantA, 05.06.2023). This quote and many other references in the interviews indicated a similar notion - that merely building a network is not enough - it is in fact crucial that the network consists of the right people with specific skills, expertise, and connections. The first major insight related to this theme of "people" highlights that the significance of the people connected to a healthtech start-up's pre-scaleup development is related to these people's expertise, knowledge, and perspective. Some people or role players that the interview participants emphasised include medical, business and technical experts; doctors, nurses and other clinical professionals; patients; and advisers for the medical certification process. By connecting with these people, a healthtech startup can source specific expertise, opinions and feedback about technology-specific questions, medical speciality insights, or complex regulatory requirements. Related to this group of experts and their expertise, the participants emphasised that their opinions and feedback should be consulted from very early on in the development process of a health technology in order to best incorporate the perspectives of these stakeholders already in the early validation of the problem, technical requirements of the health technology, design iterations, prototyping, and other development activities. (ParticipantA, 05.06.2023; ParticipantB, 07.06.2023; ParticipantC, 09.06.2023; ParticipantD, 18.07.2023) It was also very clear that involving the opinions and feedback of these different perspectives is invaluable to "make sure that you're actually addressing a real problem and check that with people who should be experiencing the problem" (ParticipantB, 07.06.2023) since often technological designers or businessmen might make assumptions about circumstances or problems within health systems, but as stated by a past founder of a healthtech startup; "some of those will get dis-proven by talking to people in the field . . . [healthtech startups] should be prepared for that" (ParticipantB, 07.06.2023).

Another insight revealed in the interviews about "people", is that there can be people involved in the pre-scaleup development of a healthtech startup that possess very varied and specific roles, and that each contribute differently to the pre-scaleup development of healthtech startups. Firstly, some participants spoke of different types of adopters or groups of people used as a first entry to the health market. One participant emphasised "Key Opinion Leaders" or KOLs, who are professionals or people "who are trusted and respected in the field" and one participant highlighted the importance of getting KOL's to use a new health solution and also really engaging them in the healthtech development process". The "benefit [of the health technology] has to be acknowledged by the experts or the KOLs" as a gauge of how the solution will be accepted in the health system. (ParticipantA, 05.06.2023) Another participant with ample experience within the health system advised that healthtech startups should connect with a "person on the inside" that can act as an access point into health settings. For example, the oncology or haematology ward can push or support the iterative communication, feedback and acceptance of a new technology related to oncology or haematology from within the health system. (ParticipantC, 09.06.2023) Such a person acts as the project champion within the health system – someone who is motivated and drives the collaboration between health professionals and healthtech startups, oversees the implementation of the health technology, and pushes for the acceptance

of the solution into the health system. For example, a participant who has experience in developing and selling a new bed-pan system in the Netherlands, explained that the champions for their product where nurse managers who were really fed up with the current dirty bedpan cleaning system, and the infection control units who were very enthusiastic about a solution that could reduce infection rates. These people were motivated to be involved in the development of the new bedpan system and advocated for the solution to their colleagues and other health professionals. (ParticipantD, 18.07.2023) This is an example of a particular type of role being instrumental in boosting the acceptance and sustained use of a health technology.

Development process

The next theme of the pre-scaleup development of healthtech startups, is related to the process and activities related to this development period. Firstly, one concept related to the development process that appeared in the interviews was the involvement of clinical stakeholders and user perspectives and feedback from early on in the design and development of health technologies. A participant with experience in developing and selling health technologies in the Dutch health system, said that often "[they] would already form an expert group within the hospital before the system went live .. and then also help them on a monthly basis" and that it is advised to become [the hospital staffs'] partner ... to work with these people and make sure that they implement [the health technology] in a proper way and get their feedback" (ParticipantD, 18.07.2023). Also, a participant who works as an advisor for developing healthtech startups emphasised the importance of "bringing in that clinical perspective at the beginning and really spending time with the clinician iterating with them, involving their voice, their perspective, and looking at the workflow of a hospital" and that these "conversations with experts and people in the field pulls in a lot of the assessment perspectives" during the development process of a health technology. (ParticipantA, 05.06.2023) It is hereby clear, that the active involvement of, communication with, and feedback from multiple perspectives early on in the development of health technology is crucial.

A crucial insight from the interviews was the significance of the implementation process in the development of a healthtech startup and health technology. Although implementation most often happens after the scale-up of a healthtech startup, the implementation process needs to be pre-planned during the pre-scaleup phase, and there are some processes that can begin pre-scaleup. One participant in the interviews said that they had often set up a good relationship with clinical professionals within the hospital or health setting in which they planned on implementing a product, so that they already fostered good communication, training, and trust prior to selling or implementing the health solution. The participant also stated that "the whole implementation and change management [is critical] because that's what necessary for [eg. hospitals] to alter their way of working" and "the implementation of these [healthtech] systems is also crucial... you have to make it nurse proof... [do]a very extensive training". (ParticipantD, 18.07.2023) From these quotes, it is apparent that part of the development process of a health technology is planning for the implementation of the technology, conducting training with the users of the technology, and managing relationships with the actors in the system in which the health technology is to be implemented.

There were also a few other references to the development process of healthtech startups and their technologies. One remark from the interviews with co-founders of healthtech startups was that the process takes

a considerable amount of time, depending on what type of health technology is being developed (ParticipantB, 07.06.2023; ParticipantD, 18.07.2023); "medical technology and e-health, they're shorter processes ... typically between five and 10 years ... biotech will be 10 years plus" (ParticipantD, 18.07.2023). Moreover, "different [types of health technologies] require different types of processes, different approaches for venture building" (ParticipantB, 07.06.2023). These discrepancies in the development processes of a healthtech startup because of the nature of the technology will be discussed later in the "solution" theme.

Finally, during the interviews, it became apparent that the development process of a healthtech startup is highly uncertain and can vary or change repeatedly within the pre-scaleup period of a startup's development or growth. One participant said that often "you realise that the unmet need that [the healthtech startup] has been targeting is not a good problem solution fit. So [the startup] needs to find a different application ... need to get more people on board to keep the conversation going . . . it's a very back and forth sort of iterative process" (ParticipantA, 05.06.2023). Other participants similarly emphasised to "make sure that you have in your planning enough slack to make mistakes or to pivot" (ParticipantB, 07.06.2023) and reported having to "change [the process] twice based on opportunities that arise" (E, 19.07.2023). It is therefore evident that pivots or iterations in the development process is an inherent feature of developing a healthtech startup, and it is something that should be pre-planned and expected. The "capability" theme will expand on how a startup can be prepared to remain flexible and adaptive in their development processes.

Solution

The health technology or solution was mentioned frequently during the interviews. One concept that came up often was that it is important that a health technology has the right "problem-solution fit". Participants emphasised that health startups should try "to re-frame how [they] approach [health] technologies and ask what is really the need, what is the need statement? And is this [health] technology the best way to do it?"; because "sometimes it's hard to tell if [a health] technology is really the best solution to a problem . . . and that's often when [healthtech startups should] get into conversations with various experts that we get a lot of different perspectives" (ParticipantA, 05.06.2023). Then, a related concept that appeared in the interviews was that the adoption or acceptance of a new health technology can be dependent on the solution's interoperability with the current system (in terms of IT systems, hospital workflows and other existing infrastructure in a health system). A previous co-founder of a technology that displayed health data in operating rooms and facilitated decision making shared their experience with trying to sell their solution to Germany. The participant explained that "[The German IT systems are] very outdated - actually their electronic medical records are like 20 years behind, most of the hospitals are still writing things on paper" (ParticipantD, 18.07.2023). This made it impossible for the healthtech startup to expand to Germany since there was a lack of existing technological infrastructure on which the adoption of their technology depended.

Then, another topic related to the solution that arose during the interviews was the typology of health technologies and innovation. Firstly, several participants explained that the type of health technology being developed has major effects on the development processes, regulation requirements, timeline, and ease of adoption or implementation (ParticipantB, 07.06.2023; ParticipantD, 18.07.2023). E-health technologies which are a combination of digital technologies and data, make for a very difficult business case "because

patients don't want to pay for apps and even if [they]pay for it, ... it will be very difficult to keep your company running [on the profit made from apps]" (ParticipantD, 18.07.2023). Then, bio-technologies, focusing on developing medical drugs or compounds, have a very long development process due to very stringent clinical trial requirements, and this type of health technology is known to be the most expensive to develop (ParticipantB, 07.06.2023; ParticipantD, 18.07.2023). Related to the solution type, it is also important to consider what type of innovation the solution is. A participant made an example that if the health technology being developed is a "replacement product" meaning that it aims to replace a current product in the health system; it is easier to install since it can be implemented without drastically changing the workflow of the health system, However, completely new or disruptive health solutions need to identify and solve completely new problems, which can require more time and effort to change the current systems or convince the clinical stakeholders of the need for such solutions. (ParticipantD, 18.07.2023)

Financing

Another theme that appeared in the interviews was related to the financing of healthtech startups, especially during their pre-scaleup development. The interview participants placed emphasis on the higher capital intensity of healthtech startup and the heightened need for financing of healthtech startups. Building a healthtech startup has "longer timelines and it also means usually also higher investment amounts ... it's not only riskier, it's also a bigger scale" (ParticipantB, 07.06.2023). Additional risk stems from the uncertainty of developing startups and many have to "just accept that there's probably going to be a an error with [the budgeted] resources of both time and money" (ParticipantA, 05.06.2023). Then, another participant said that "for implementation [of a health technology] it's 12 to 18 months ... or at academic hospitals 18 to 36 months. Its long ... and very uncertain because you don't get paid for it". This participant also revealed that the Dutch health system is particularly struggling to finance new health solutions currently due to their budgets being depleted after the Covid-19 pandemic. (ParticipantD, 18.07.2023). These insights from the interviews emphasise that healthtech startups require a larger amount of financing, over a longer period, and with more risk involved.

According to the interview participants, there are strategies to tackle these unique challenges in the financing of healthtech startups. One strategy is related to choosing the type of investment to finance the development of a healthtech startup. Government grants and other forms of public funding were recommended to leverage as much as possible since this type of funding most often does not dilute the startup's share or equity of their own company. Moreover, a participant said, "undiluted funding is so important ... the more financing from grants will make it easier for when [the healthtech startups] do approach the investors . . . if you give away equity too early it's seen as like risk taking". This statement suggests that maximising the use of grants or undiluted funding, especially in the early stages of a healthtech startup's development, can increase the chances of attracting investors later in the process. (ParticipantC, 09.06.2023) This coincides with another participant's observation that for example angel investors do see healthtech as a higher risk proposition, although their suggestion was for healthtech startups partner up with a venture capitalist fund or other firms to encourage investment because "it helps if [investors] can connect to a portfolio instead of a single venture because that reduces the risk a little bit" (ParticipantB, 07.06.2023). However, another interview participant also revealed that in some healthtech startups, diluted funding is unavoidable. For example, "a

biotech company, the investment for will be like 100 million, and they often go to the stock market because they need these large amounts of money." (ParticipantD, 18.07.2023)

Another concept discussed during the interviews, was the unique financing activities and procedures found within health systems (for example in hospitals). An interview participant with extensive experience in developing and selling health technologies to hospitals in the Netherlands described a unique paradox in the financing system within the health system. The participant explained that a "hospital's purpose should be to keep the patient healthy, but instead it's to treat the patient ... you actually see that a lot of treatments they are totally unnecessary and prevention like this that is often not paid for" (ParticipantD, 18.07.2023). In other words, the business model and sustained operation of hospitals relies on the revenue generated from treating patients; therefore the more treatments they perform the better. Despite the hospital's ultimate purpose to make people healthy (i.e., reduce required treatments), this does not sustain their business model. This phenomenon makes it difficult to develop, sell and adopt health technologies within the health system; the focus of many health technologies is on "better, safer and happier patients" but "the patient is not the payer ... the hospital is paying in the end and the hospital actually benefits from more treatments". Therefore, healthtech startups need to develop technologies that also provide value in terms of cost savings or efficiency for the health system. (ParticipantD, 18.07.2023)

Finally, another topic discussed during the interviews was the reimbursement of health technologies – from reimbursement agencies or medical insurers to hospitals or health providers. All the participants in the interviews acknowledged the involvement of reimbursement agencies in the development and application of health technologies, but none had personal experience in dealing with reimbursers. However, two participants indicated that if a healthtech startup wishes to have their product reimbursed, the development process is significantly delayed – by up to 3-5 years. (ParticipantB, 07.06.2023; ParticipantD, 18.07.2023)

System context

Firstly, a common theme discussed in the interviews was the presence of a deeply ingrained workflow or existing organisation of the health system for example in hospitals or one country's public health system. A participant with experience as a healthcare professional revealed that often within the health system context, nurses and doctors have a specific way of doing things or might have found alternative methods to avoid perceived problems altogether. This is related to determining "the problem-solution fit . . . what the problem is right now, and what's the gold standard now? Where is the weakness now? Where the gap lies and this is where it can be improved [potentially by a new health solution]" (ParticipantC, 09.06.2023). Also, hospitals for example have a unique decision-making structure and it is crucial to understand the dynamics happening between role players in the health system before approaching it with a new health technology (ParticipantD, 18.07.2023). It was explained by a participant with experience in selling and implementing health technologies in hospitals, that many health systems have a decision making unit (DMU) that is responsible for allocating budgets and deciding what health solutions to implement; but the actual drive for the implementation of a health technology stems from the nurses, doctors or clinician using the new health technologies. Therefore, it can be quite unclear for healthtech startups to understand the correct approach in selling their health technologies to health systems such as hospitals. This participant advised that " [healthtech startups] have

to get all the [clinical] stakeholders in the hospital aligned. You have to start bottom up ... and also top down ... [because that's] how a hospital is organised".(ParticipantD, 18.07.2023)In other words, it is essential that healthtech startups communicate and contact both the DMUs or actors responsible for hospital budgets, and the potential users of the health technology; in order to convince both parties of their solution.

A second topic related to the theme "system context" that appeared in the interviews was the idea technological dependence and the effect of existing infrastructure on the success of a new health technology introduced into the health system. As stated by a participant with experience in founding, financing and developing healthtech startups; the success of a health technology is "dependent on the current state of the technology, and dependent on the current state of the business model ... the context can be just so different" - for example if the health system is using an outdated electronic records system, it will be near impossible to introduce a health technology using clinical data or that relies on patient data. The participant advised that countries that are very digitised are typically the Nordics, Scandinavia, the Netherlands and Switzerland - these are countries who's health systems have advance technological infrastructures and are therefore capable of adopting new technological health solutions. (ParticipantD, 18.07.2023)

Capabilities

The interviews revealed that there are several capabilities of a healthtech startup that are considered vital for their pre-scaleup development.

Foremost, every participant emphasised the ability of a healthtech startup to be flexible to changes to their development trajectory, pivot from their current pathways, or re-start from the beginning if there are changes to for example the clinical problem, regulatory landscape, or other factors. (E, 19.07.2023; ParticipantA, 05.06.2023; ParticipantB, 07.06.2023; ParticipantD, 18.07.2023) An expert in developing healthtech startups explained that sometimes "you realise that the unmet need that you've been targeting; there's not a good problem solution fit. So you need to find a different application ... You need to get more people on board to keep the conversation going . . . it's a very back and forth sort of iterative process" and its even possible "that one route is not viable, so you need to change roots ... ideally you are in the right one immediately, but sometimes you need to pivot for the best" (ParticipantA, 05.06.2023; ParticipantB, 07.06.2023). "For example, one of the companies [Participant D] invested in is UV Smart, and they have this UV device where they could disinfect medical devices.. like a patient monitor which they use in the ICU... but when they started talking to doctors, in the end ... with our disinfection tool, we didn't find a disinfection solution, we found a logistical solution" (ParticipantD, 18.07.2023). From these insights, it is evident that a healthtech startup should be capable of pivoting to address new application with their technology, and carry out many iterations of their processes.

Next, a healthtech startup's capability also lies in the expertise of its team and founder. As a founder of a academic healthtech startup explained, a startup's founder and/or team needs to "wear multiple hats at the same time" by simultaneously carrying out activities to develop and test their solution, raise funding, source new team members or expertise, and many other crucial steps in the pre-scaleup development of the startup. (E, 19.07.2023) The founder and team need a specific set of skills and tenacity to succeed through

the complex and uncertain environment of the early stages of a healthtech startup's development.

Evidence

During the interviews, there were multiple references to the concept of evidence, or creating proof of the value or feasibility of a health technology within the pre-scaleup development of a healthtech startup. An expert in the development of healthtech startups said; "[startups] need some kind of clinical validation or especially pre-clinical validation" and that it is crucial to get people to use the health technology and gather feedback and data (ParticipantA, 05.06.2023). Another participant advised that healthtech startups "need to prove that [their health technology] is actually effective in the environment that you want to apply it in" and that it is important to develop a "prototype that actually uses [the proof of principle] in a way that's helpful, then you need to prove that it's actually effective. . . to a level that you get certified" ParticipantB (07.06.2023). Finally, another participant described measuring parameters such as "efficiency" or "cost saved to the health system" to show evidence of the value of a health technology to the health system, and encourage its adoption (ParticipantD, 18.07.2023). It is clear from these quotes that a significant part of the pre-scale development of a healthtech startup involves generating sufficient evidence to prove the clinical efficacy, technical feasibility, safety and value of their health technology to clinical stakeholders, investors and regulatory bodies.

Stakeholder value

The theme " stakeholder value" appeared quite frequently during the interviews. One participant emphasised the importance of healthtech startups "understanding the value add . . . what does 'good' look like? Where do [they] add value? How can [they] measure that value? That's something again that has to be thought about very earlier on with the users" and "it's seeing where you're adding your value and then how you measure that value" (ParticipantC, 09.06.2023). The "value" referred to in this quote is the value or impact of a health technology on its stakeholders such as health professionals, patients, hospitals or clinicians. Another participant suggested to assess a healthtech startup's value to the health system to be " number of people affected ... number of people impacted, cost saved to the health system, positive clinical trial outcomes" (ParticipantA, 05.06.2023). These metrics are examples of Key Performance Indicators (KPIs) - or metrics which the health systems deems important to keep track of and assess its own performance. The interviews revealed that if a healthtech startup can aim to address these same KPIs, then they will be adding value to the health system and will perform highly in their ability to create benefit for health systems. For example, if hospitals are to be the buyer of a health technology, it is important to understand "how do they measure value? What are they monitoring? What do they get fined on? If [a healthtech startup] can align [their] value-adds to what [the hospitals'] objectives are, then [they can] show the value based on [the hospitals'] KPIs" (ParticipantC, 09.06.2023).

Social aspects

The interviews revealed a number of interesting insights into the social aspects of developing health technologies and innovating within the context of health systems. Firstly, culture has a big impact on the success of health technologies being introduced into health systems. A participant with experience in developing health technologies both in the Netherlands and the US made an example related to clinical professionals in the US being more accepting of a technology that can help them make less mistakes because of the cultural norm

in the US that mistakes are unacceptable and often result in legal battles. Whereas in the Netherlands, the same technology was not accepted because of the culture within the Dutch health system that mistakes are normal and should not be punished. (ParticipantD, 18.07.2023)

Another social concept that arose frequently during the interviews was the importance of trust. Several participants emphasised that clinical stakeholders are more likely to adopt or accept a new health technology if they trust those that are introducing the technology, and trust that their values and perspectives have been heard and taken into account (ParticipantB, 07.06.2023; ParticipantC, 09.06.2023; ParticipantD, 18.07.2023). Also, a participant currently experiencing the difficulties of building a team highlighted that trust is very important between team members or co-founders of a healthtech startup. (E, 19.07.2023) Related to this, was the concept of autonomy or the ability for people to feel in control of their own decisions. It was mentioned in several interviews that doctors and nurses do not want to feel ambushed by new technologies that might threaten their job, or do not want to accept technologies that will identify their mistakes, or rapidly change their way of working overnight (ParticipantC, 09.06.2023; ParticipantD, 18.07.2023).

Regulation

Another theme that emerged from the interviews was the importance of tackling the regulatory landscape of developing health technologies. The expert in the healthtech startup development process said that "in the regulatory spectrum, it's often quite challenging to determine what the clinical trials actually need to look like, how expensive they're going to be, who needs to be involved for those, and also in a more detailed level, what are the the almost documentation or the steps that a regulatory body or a notified body are going to want to see" (ParticipantA, 05.06.2023). This quote encapsulates the challenges brought about by the need for many health technologies to comply with strict regulatory requirements. A founder of a healthtech startup stated in their interview that "not all health tech startups realise this immediately but products do need to comply to a lot more rules and regulations than most other tech companies" ParticipantB (07.06.2023).

Moreover, another regulatory barrier raised during the interview was related to intellectual property (IP) and the complexity of filing for patents and IP right when developing new health technologies. The interview participants indicated that a large barrier in developing new health technologies is the organisation of jurisdictions (ParticipantA, 05.06.2023), and fear of sharing IP when sourcing co-founders of funding (E, 19.07.2023).

Network

The interviews revealed that in the practice, it is essential that a healthtech startup builds a strong connection to a network of relevant stakeholders, supporters, and other actors. The most common referenced network in the interview was the network attached to health systems; consisting of various clinical experts such as doctors, nurses, medical specialists, hospitals, and patients. The health systems is seemingly the most vital network for a healthtech startup to connect to and involve in the development activities; since ultimately the health system will be responsible for a large portion of the success of a health technologies acceptance, adoption and impact. For healthtech startups, connecting with various health system stakeholders "is extremely important because if people don't like [the solution], they're not gonna use it" (ParticipantA, 05.06.2023). However, three participants emphasised that achieving this connection with healthcare stake-

holders is difficult because of the bureaucracy of the health system. One participant with experience in the sales of health technologies to hospitals, described that within hospitals "it's very unclear how the money streams, how they're running, and managing the whole beast of the hospital and a big challenge is the bureaucracy". Moreover, the participant described difficulties when selling health technologies to other stakeholders in the health system such as maintenance companies, or waste management, or infection control, as "very bureaucratic people". (ParticipantD, 18.07.2023)

Another factor related to network that was mentioned multiple time during the interviews, was the importance of making contact with stakeholders from very early in a healthtech startup's development process. As emphasised by several participants; there is often a "lack of engagement of health care professionals earlier on in the design project ... but you need the buy-in and you need it early" (ParticipantC, 09.06.2023). This can be achieved by "bringing in that clinical perspective at the beginning and really spending time with the clinician iterating with them involving their voice, their perspective, looking at the workflow of a hospital" (ParticipantA, 05.06.2023). The involvement of potential users of the health technology, and other clinical stakeholders creates feedback from early on in the healthtech startup's development which can be iteratively incorporated into the successive design and development of their health technology. Also, it encourages trust and acceptance of the technology upon is launch in the health system as a health professional stated; "the other big problem is lack of engagement with whoever you're selling it to from the start to understand what they [health professionals] would want from a new product ... engaging with [nurses and doctors] early rather than coming with them to sell because they don't like the sales out of nowhere" (ParticipantC, 09.06.2023).

Another type of network connection referenced several times during the interviews was supporting bodies or firms such as innovation incubators, venture builders, regulatory advisers and other startup facilitators. Since startups require significant expertise and resources; especially healthtech startups that need specific health knowledge; it is beneficial for healthtech startups to get support from firms such as incubators or advisory bodies early into their development journey. (ParticipantB, 07.06.2023) Also, a past founder of a healthtech startup, and current employee at a healthtech startup venture builder stated that a "support structure like [a venture builder] is very helpful for . . . the timelines... and certification process . . . or if money runs out or if you read a hit a roadblock that you don't immediately know how to handle ... [a venture builder] knows how and who to go to for specific support requests" (ParticipantB, 07.06.2023). Then another example of seeking support from a network was provided by a participant who had previously experienced the need to partner their healthtech startup with a larger corporation to connect to their network, access their resources and receive other forms of support. (ParticipantD, 18.07.2023)

Risk

The notion of risk was mentioned by all the participants in the interviews. All the participants referenced to the inherent risk of developing a startup; the development process involves having to "deal with a lot of uncertainty because [as a healthtech startup, you] just simply can't answer many of the questions that are raised" (ParticipantA, 05.06.2023). However, healthtech startups have to try identify the risks as much as possible, and have to do what they can to mitigate the risks (E, 19.07.2023; ParticipantA, 05.06.2023). It is however difficult for startups to decide a "appropriate risk level" (ParticipantA, 05.06.2023).

According to one participant, a founder of a Dutch healthtech startup, there are different types of risk that can exist within the pre-scaleup development of healthtech startups. There is clinical risk which refers to the risk of a health technology's success in relation to the health system - for example the risk that the technology might cause unintended consequences within its application in the health system. Then, there is technical risk which is the risk of the technology malfunctioning or having a technical error. Finally, there is also financial risk - this refers to the risk of the health technology not generating enough funds to pay back the investors, or the risk of not sourcing enough funds during the development process to continue. (ParticipantB, 07.06.2023) Another participant made a recommendation to reduce financial risk. They suggested that healthtech startups leverage public funding or government grants as much as they can in the beginning stages of their development, since these type of investment have a much lower risk since they require very little to no return on investment in case the health technology does not succeed. Also, this type of low-risk funding, can attract other investors later on since many investors are moderately risk-adverse and would rather invest in a startup with low-risk of defaulting. (ParticipantC, 09.06.2023)

Levels of development

In the interviews, a frequently referenced assessment of progress was the level of development of the technology being developed – the "technology readiness level" (TRL). The TRLs represent the stages in a technology's development which signifies a change in the value of the solution to its stakeholders. The TRLs show what was referred to as "value inflection points". The changes to the value of a health technology is attributed to overcoming hurdles such as certification, and mitigating risk by meeting various technical, stakeholder and regulatory requirements. (ParticipantA, 05.06.2023; ParticipantB, 07.06.2023; ParticipantC, 09.06.2023) As stated during the interview with a co-founder of a healthtech startup: "the progress you can identify within a venture is tied to the steps you need to go through to get to a product that's certified and that you can sell" (ParticipantB, 07.06.2023). Therefore, the TRLs are very closely tied to the development process characteristic of healthtech startups, especially since progressing through the TRLs takes time and some can take very long and some very quick depending on the activities required before achieving the next TRL. (ParticipantB, 07.06.2023) For example, some practical metrics that can be used to assess a startup's progress in developing and selling a health solution to hospitals are ; "what you can measure is their interest; "Did we take it to the next level? Are there now multiple people involved? Do we have the whole decision making unit (Decision making unit (DMU)) involved?, Did this DMU actually apply for budget?" (ParticipantD, 18.07.2023)

Market

The next theme that emerged in the interviews was that of the market in which a health startup plans to launch their health technology into. a specific references was made during on interview to the size of the market and how this may affect a health startups development or decisions. For example, the US market is much larger than the Netherlands, allowing a healthtech startup to scaleup much quicker there than in the Netherlands. Moreover, the saturation of the market also matters - a participant explained that despite there being over 80 hospitals in the Netherlands, 20-30 of those are struggling financially and therefore have no innovation power. Therefore, the actual available market for new health startups to sell to is much smaller

than would be expected because of the financial situation of the health system. (ParticipantD, 18.07.2023)

5.3 Insights related to a theoretical model of the pre-scaleup development of healthtech startups

The interviews not only revealed thematic information about the pre-scaleup development of healthtech startups, but also produced valuable insights for the theoretical model constructed in Chapter 3.

Firstly, the interviews provided evidence of a segregation of the pre-scaleup development of healthtech startups into levels, phases or stages. One participant stated that "[the development process] is separated by the different levels for the different types of product to be developed " and that "The progress you can identify within a venture is tied to the steps you need to go through to get to a product that's certified and you can sell" (ParticipantB, 07.06.2023). Along with references made by other participants, there is a clear indication that the pre-scaleup development of healthtech startups can be divided into a number of steps, activities, or stages that can represent the progression of a healthtech startup through its growth and development journey.

Second, during the interviews, multiple references are made to "checkpoints" or particular deliverables that are expected at certain points in the development of a healthtech startup. Related to the "evidence" theme that appeared during the interview analysis; there are levels of "proof" and "technical readiness" that indicate a healthtech startup's achievement of a certain level of development. For example, interview participants mentioned a "proof of principle", and "functional prototype" and a "proof of concept" as varying types of proof or evidence of the level of development of a health technology. Moreover, there was a large emphasis placed a number of participants on "Technical Readiness levels" (TRLs) which were described in the "Levels of development" theme: the TRLs represent the stages in a technology's development which signifies a change in the value of the solution to its stakeholders. The TRLs show what was referred to as "value inflection points". The changes to the value of a health technology is attributed to overcoming hurdles such as certification, and mitigating risk by meeting various technical, stakeholder and regulatory requirements. (ParticipantA, 05.06.2023; ParticipantB, 07.06.2023; ParticipantC, 09.06.2023) These hurdles that fall into the value inflection points, indicate a natural grouping of challenges or barriers between the different stages of development.

Related to the previous observation, it was also made evident during the interviews, that there are different processes, types of evidence and development activities required for the development of different types of health technologies. Multiple participants stated that the cycle time or length of the development process varies depending on the type of health technology being developed; for example, biotechnology is known to have the lengthiest development time because of the need for very extensive clinical trials compared to other health technologies ParticipantB (07.06.2023); ParticipantD (18.07.2023). Also, pharmaceutical technologies and biotechnology are known to require higher amounts of capital which requires additional activities to source funding (ParticipantD, 18.07.2023). Moreover, different types of health technologies may require support and advice from specialised medical experts in the particular field in which the health technology is applied (ParticipantA, 05.06.2023). This leads to different activities and barriers for healthtech startups in to gain support from their stakeholders.

Finally, several participants in the interviews indicated that there is a need for flexibility and collaboration within the pre-scaleup development of healthtech startups. An expert in developing healthtech startups explained that sometimes "you realise that the unmet need that you've been targeting; there's not a good problem solution fit. So you need to find a different application ... You need to get more people on board to keep the conversation going . . . it's a very back and forth sort of iterative process" and its even possible "that one route is not viable, so you need to change roots ... ideally you are in the right one immediately, but sometimes you need to pivot for the best" (ParticipantA, 05.06.2023; ParticipantB, 07.06.2023). Evidently, any representation of the pre-scaleup development of healthtech startups should reflect the flexibility required.

The implications of the these results for a theoretical model of the pre-scaleup development of healthtech startups will be discussed in 6.3.

5.4 Chapter conclusion

Chapter 5 presented the results that aid in addressing sub-research question (a): "*What are the unique characteristics of the pre-scaleup development of specifically healthtech startups?*". The results described are the themes that emerged during interviews with experts and stakeholders from within the pre-scaleup development of healthtech startups in the Netherlands. It was apparent from the interviews, that the themes "People", "Development process", "Solution", and "Financing" were the most emphasised amongst the interview participants. The themes and any subsequent observations within this chapter are informative for determining the unique characteristics of the pre-scaleup development of specifically healthtech startups, and will be re-visited in Chapter 6. Moreover, Chapter 4 summarised any insights from the interviews that have value for developing a theoretical model of the pre-scaleup development of healthtech startups, which will be reflected on in Chapter 6.

6 Chapter 6: Discussion

6.1 Chapter introduction

Chapter 6 discussed the research conducted so far in addressing the two sub-research questions - (a): "*What are the unique characteristics of the pre-scaleup development of specifically healthtech startups?*", and (b): "*What implications does the uniqueness of healthtech startups have on a model to represent the pre-scaleup development of specifically healthtech startups?*". The chapter first consolidates the research done thus far to produce a final list of characteristics to describe the pre-scaleup development of healthtech startups, and reflect on some key observations from the interviews and literature study. Then, Chapter 6 shifts the discussion to the construction of a theoretical model of the pre-scaleup development of specifically healthtech startups that was conducted in Chapter 3, and deliberated the implication of such a model in the practice of developing healthtech startups. Finally, Chapter 6 reflects on the limitations of the research conducted in this thesis, highlights recommendations and directions for future research related to the topics covered in this thesis, and finally critically reflects on the research process and experience.

6.2 The characteristics of the pre-scaleup development of healthtech startups

There were two parts of research that aimed to address sub-research question (a): "*What are the unique characteristics of the pre-scaleup development of specifically healthtech startups?*". Chapter 2 consulted literature to gather themes that could be used to characterise the pre-scaleup development of healthtech startups; and Chapters 4 and 5 conducted interviews with experts in the development of Dutch healthtech startups to extract themes that again could be said to characterise the pre-scaleup development of healthtech startups. In order to finally answer sub-research question (a), a consolidation between the results of these two methods is required, to produce a final list of characteristics of the pre-scaleup development of healthtech startups.

6.2.1 Comparison of deductive and inductive themes

The list of themes that arose in the review of literature in Chapter 2 were expected to also arise in the interviews and are therefore called "deductive themes". The themes that actually emerged from the interviews were derived through an inductive analysis in Chapter 5 and are therefore called "inductive themes".

Upon comparison of the deductive themes and inductive themes, it was found that some themes appeared in both literature and the interviews, and some themes only arose in one or the other. The themes "people", "measures of performance", "levels of development", "stakeholder value", "risk" and "evidence" only appeared in one of the two analyses. This indicated that the prevalence of this theme was lower compared to the other themes, or perhaps these themes could be incorporated as a sub-themes with another theme that had appeared in both analyses.
The themes that appeared in both in literature and during the interviews are concluded to be more prevalent and are grouped into a set of "key characteristics of the pre-scaleup development of healthtech startups". The remaining themes are either grouped into one of these characteristics as a sub-theme or labelled as a "lesser characteristics of the pre-scaleup development of healthtech startups". This differentiation between

the key and lesser characteristics was decided based on the comparison of inductive and deductive themes, but also relied on a personal observation during both the literature study and the interviews, that certain concepts, themes or characteristics were emphasised more or less than others. However, it is vital that the differentiation between "key" and "lesser" characteristics does not equate to the lesser characteristics being less important than the key characteristics. Rather, the key characteristics are brought to attention more often in literature and the interviews which can mean that perhaps challenges or activities linked to the key characteristics arise more frequently throughout the pre-scaleup development of healthtech startup, compared to the lesser characteristics. The lesser characteristics are as important in understanding and defining the development of healthtech startups as the key characteristics, but may be brought up less often because of the specific expertise or perspectives of the interview participants, or the ability to express the characteristics using common research methods in the literature studied.

Figure 7 shows the final four key characteristics and four lesser characteristics of the pre-scaleup development of healthtech startups. These characteristic are discussed in more detail below.

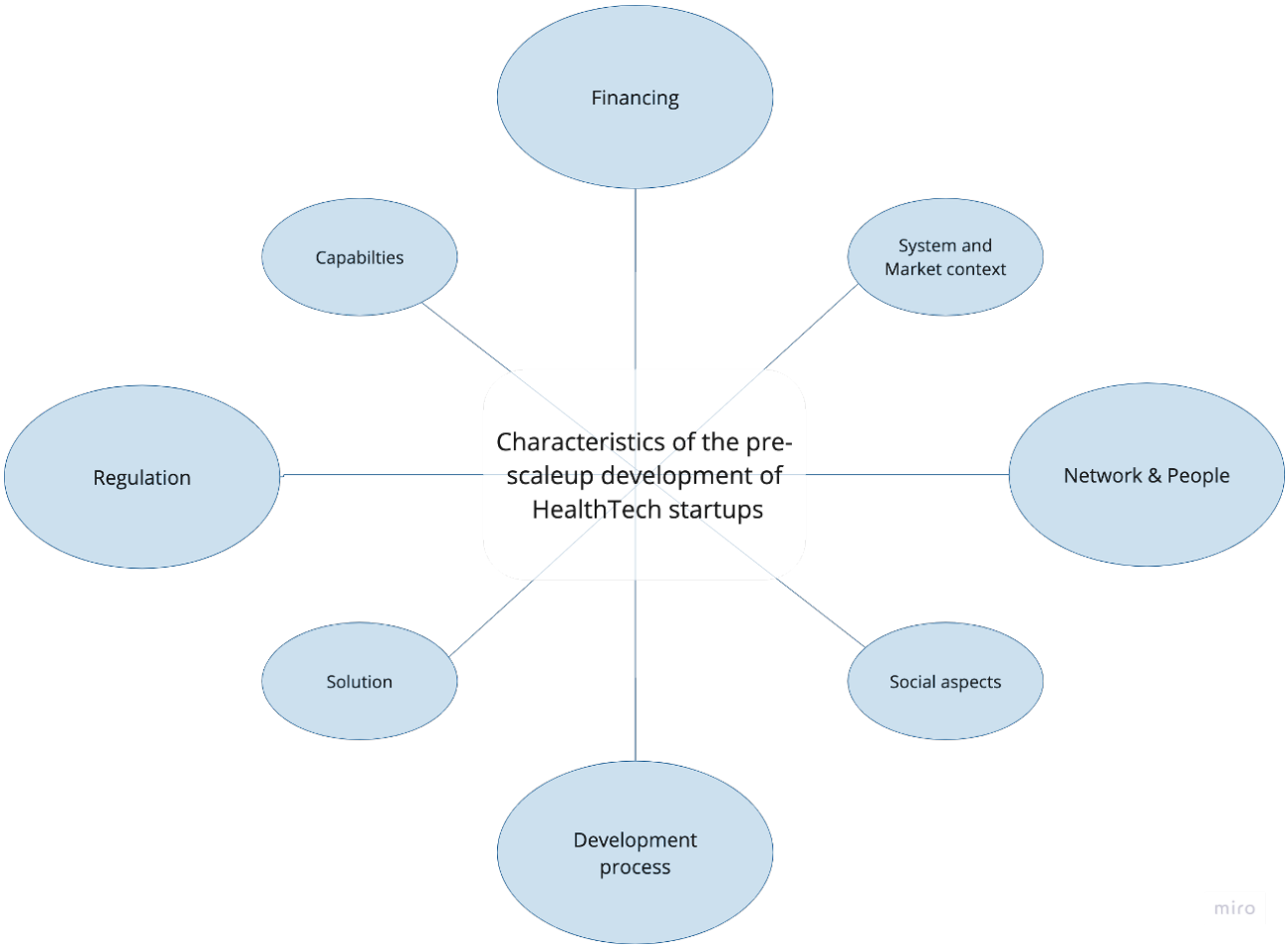

Figure 7: The characteristics of the pre-scaleup development of healthtech startups

6.2.2 Key characteristics of the pre-scaleup development of healthtech startups

Network and People

One of the most referenced themes in the interviews was related to the people and expertise involved in the development journey of a healthtech startup. Similarly, the review of literature in Chapter 2 emphasised the theme "network" as the involvement and connection with various clinical stakeholders (patients, physicians, clinicians, patient organisations), reimbursement agencies, potential users, and supporting bodies such as innovation incubators or regulatory bodies. Other highlights from the literature review included the importance of actively involving the user from early on in the design process of a health technology; communicating with reimbursement agencies to comply with the complex payment structures of many healthcare products; collaboration with other technology providers and actors that could influence the adoption of the health technology; and consultation of support services such as innovation incubators to connect with potential investors or access resources essential for the pre-scaleup development stages of healthtech startups. Moreover, both the interviews and literature advocated for the early involvement of users via for example participatory programs such as bio-design, live-in laboratories or patient-led design which involve the patients, physicians or other end users already during the design of the health technology; to facilitate the alignment between user needs and the solution design, and acceptance of the health technology.

The network and people involved in the pre-scaleup development of healthtech startups clearly has a significant effect on the development activities, on the acceptance of the health technology, and consequently the successful growth of a healthtech startup to the point it can scale-up. Therefore, based on both literature and validation from interview, network and people can be said to be a key characteristic of the pre-scaleup development of healthtech startups.

Development process

The theme "development process" arose both from the review of literature and the interviews. In relation to this characteristic, both literature and the interviews emphasised the importance of the early involvement of potential users in the design and development of a health technology via for example continuous feedback, user testing or co-design workshops. Moreover, both literature and the participants in the interviews mentioned that the development process to build a healthtech startup involves planning and executing activities in line with meeting the stringent regulatory requirements of producing health technologies. Such activities could include conducting clinical trials, implementing quality management systems, and setting up data protection measures. Finally, the interviews also introduced the concept of implementation being vital for the success of a health technology to take off in the health system. Therefore, some processes within the pre-scaleup development of healthtech startups involve setting up an implementation plan, and connecting and building up relationships with clinical stakeholder who advocate for the adoption of the new solution.

On another note, a few of the other themes found during the literature search and/or interviews, are combined under the "development process" characteristic of the pre-scaleup development of healthtech startups. Firstly, the theme "evidence" is a by-product of the processes that occur within the development of a health

technology. For example, prototypes as a form of evidence of the functionality and technical feasibility of the product are an outcome of research and development processes; and clinical validation data is an outcome of user testing or clinical trials. Secondly, the themes "measurement of performance" and "levels of development" also fall under the characteristic of development process.

Financing

Another theme that appeared in both the interviews and in literature was related to the financing of healthtech startups, especially during their pre-scaleup development. It was made clear in both literature and by experts from practice, that the financing of healthtech startups, especially in their pre-scaleup development, is particularly challenging due to the heightened capital intensity of this period compared to that of other startups, and the higher risk associated with the longer development cycle times of health technology development. Financing is a vital consideration for healthtech startups, since without sufficient funds, they are unable to continue their development.

It was emphasised by literature and the interview participants, that a crucial decision for healthtech startups need to make about financing, is related to choosing what type of investment or funds they acquire to support their development. Between government grants, venture capital, equity investment or private funding by the founder, family or friends; healthtech startups need to ultimately source funding that sufficiently supports their development, allows for a degree of flexibility in case of setback, and lowers their risk profile for future potential investors.

Finally, a concept that did not immediately appear in literature, but was emphasised by industry-experts, was the significance of the financing system and "money flow" that exists within health systems. The decision-structure, communication pathways, and bureaucratic organisation within health systems have an impact on the funding available to be spend by, for example hospitals, on new health technologies. Healthtech startups need to approach the right people within health systems, in the right manner, and at the right time to increase their chances of receiving buy-in from the health system concerning any new health technology.

Regulation

The literature reviews in Chapter 2 placed significant emphasis on the difficulty many healthtech startups face in navigating the regulatory landscape of certifying health technologies and getting them market-ready. A few of the crucial regulatory hurdles for healthtech startups to overcome is planning and executing the necessary clinical trials and other clinical validation steps, producing all the necessary documentation, setting up a quality management system and post-market surveillance system, and maintaining sufficient contact with the necessary regulatory agencies. (See 2.3 for a detailed description of the regulatory steps required of a healthtech startup)

Experts from practice did not have any detailed insight into the regulatory activities required of healthtech startups, but rather indicated some barriers they had experienced, and provided several recommendations for healthtech startups. The largest reported barrier was conducting clinical trials since often the time, cost and outcome of clinical trials is highly uncertain. Experts in practice recommended for healthtech startups to network and connect with regulatory bodies early on in their development process, or outsource regulatory advice since it is extremely domain specific and changes regularly. There is therefore a link between the regulation characteristic and the network and people characteristic - a understandable phenomenon given that the regulatory processes within a healthtech startups are driven by people and their expertise.

6.2.3 Lesser characteristics of the pre-scaleup development of healthtech startups

Apart from the four key characteristics discussed above, there are several "lesser" characteristics that can be used to describe the pre-scaleup development of healthtech startups.

Firstly, there are a number of themes that arose in both literature and from the interviews, that relate to the context in which a health technology is being developed. The themes "market", "system context", "stakeholder value" and "risk" are indicative of the state of the environment in which healthtech startups develop and operate within. These themes are grouped into a lesser characteristic called System Context, where 'system' refers to the larger context of markets, networks, processes and interacting parts that influence and are influenced by the health system as a whole. In fact, during a review of health systems and their complexity, Atun described them as open systems with many interconnected parts or components that interact with each other and the environments or contexts in which they are situated (Atun, 2012). Therefore, the first lesser characteristic of the pre-scaleup development of healthtech startups - the System Context - describes the complexity of the many actors, with dynamic roles, priorities, needs and values that create complicated and evolving conflicts and dilemmas within health systems; their presence within and relation to the socio- technical, political, or economic environment – all of which interact with and affect health systems; and the risks that are present within the significant uncertainty inherent of a large, complex system where changes have unknown types and magnitudes of consequences.

Secondly, the theme "social aspect" that appeared in both literature and the interviews is indicative of another lesser characteristic of the pre-scaleup development of healthtech startup. "Social aspects" refers to the ethical, cultural and social considerations that healthtech startup should take into account during their development or technological design. It is essential that healthtech startups consider these impacts of their health technology such as how it may strengthen existing inequalities in the health system, or exclude certain groups because of their pre-disposed social classes or positions. This characteristic will be reflected on further in 6.2.4.

Then, the third lesser characteristic is related to the Solution, or the health technology being developed. Both literature and the interviews highlighted that there are several vital aspects of a health technology to be considered during its development; the extent to which the solution addresses the problem (problem-solution fit), the interoperability of the technology with existing systems and infrastructure, the scalability and performance of the solution compared to existing solutions, and the type of technology being devel-

oped and its compliance with regulations. This characteristic helps define the pre-scaleup development of a healthtech startups, because the steps, knowledge and other resources necessary to develop a specific type of health technology, that addresses and specific problem, with a specific level of interoperability with current systems; are all factors that significantly affect the pre-scaleup development of a healthtech startups and ultimately can change the way it should occur and be defined.

Finally, the fourth lesser characteristic that can help define the pre-scaleup development of healthtech startups is Capabilities. This characteristic refers to the knowledge, skills, and expertise required within the pre-scaleup development of a healthtech startup. Understanding what type of expertise is required to develop a health technology, what learning and knowledge will encourage a better problem-solution fit and adoption, and what skills are essential for the founder and startup team; are all important elements to understand the broader picture of healthtech startups and their pre-scaleup development journey.

6.2.4 Discussion of key observations

User-centred development

One observation made during the literature review and interviews, was that a significant emphasis was placed on the active involvement of users and clinical stakeholder from early on in the design and development of a health technology. Both literature and experts from practice highlighted the effectiveness of close collaboration between healthtech startups and the system in which they plan to implement their technology. During interviews, reference was made to consulting clinical experts to guide the development of a healthtech startup, and ensure that the health technology being designed is the best solution for the problem being experienced in the health system. Literature also frequently makes reference to a user-centred approach within the development of health technologies and mentions methods such as patient participatory workshops, live-in labs and co-design workshops to facilitate the inclusion of many perspectives in the design and development of health technologies. There is am apparent trend toward such a "participatory design" approach or method in the pre-scaleup development of healthtech startups and therefore should be explored further.

The concept of participatory design (PD) is also referred to as stakeholder or multi-stakeholder engagement, methods, or design in various literature sources. The precise definition of PD may vary depending on the study or context in which it is employed. Reddy et al. present a comprehensive interpretation in their application of PD to a pharmacy system intervention. They define PD as an integral aspect of the systems approach to health innovations, encompassing the active involvement and consideration of stakeholders engaged in healthcare innovations. This encompasses their perceptions, values, demands, and interactions. In their study, a sequence of six adaptive sessions is undertaken within the PD process. These sessions range from brainstorming and converging on problems and solutions to prototyping, culminating in two evaluation phases for feedback, possibly revisiting earlier stages. (Reddy et al., 2019)
Despite differences in methodologies, the core commonality across studies applying a PD approach for health innovations lies in the active engagement of stakeholders, their perceptions, and values throughout the innovation design process. Some studies employ online patient feedback platforms (Bez, Georgescu, & Farazi, 2023; Hatzler, Kronthaler, & Beier, 2022), others utilise participatory action research (Crawford et al., 2017;

Drury et al., 2019; Pereno & Eriksson, 2020; Reddy et al., 2019), involving stakeholders directly in innovation and design activities. Qualitative interviews are conducted in certain cases to gather stakeholder feedback and attitudes (Agarwal et al., 2018; Laka, Carter, Milazzo, & Merlin, 2022; Shukla, Agarwal, & Shekhar, 2021). Additionally, a couple of studies draw from existing literature to propose future health innovation applications aligned with PD concepts. It is evident that PD, can manifest in diverse forms, all contributing positively to the successful adoption and sustainable utilisation of emerging health technologies.

The most obvious and reported reason for PD improving adoption of innovations into the health systems, is due to PD providing valuable insights for the innovation process and informing the design of health innovations. PD gathers all stakeholder perceptions, values, needs and behaviours – all of which facilitate the development of a health solution better aligned with their expectations. Consequently, the health system more readily adopts such health innovations, and the innovation is more likely to have long-term applicability in the system since the stakeholders interacting with it and their needs have been considered. (Preston & Harvey-Lloyd, 2023; Reddy et al., 2019)

Another notable contribution of PD to the development of healthtech startups lies in its ability to foster a shared comprehension of challenges within health systems, potential solutions, and the anticipated outcomes of these solutions. Agarwal et al. underscore the necessity of PD in establishing this shared understanding, revealing how customers and products possess distinct understandings of the requisites for emerging health technologies within the Indian healthcare sector (Agarwal et al., 2018). The divergence in understanding often impedes adoption and heightens the risk of conflicting interests. PD addresses this issue by convening diverse stakeholders, encouraging interaction and mutual learning, thus bridging the gap between their differing perspectives. For instance; Andersen et al. adopt a step-wise, iterative PD approach to address conflicting expectations between patients and clinicians. This involves identifying concerns, experimenting with convergence techniques through design workshops or scenarios, and evaluating the attainment of consensus or shared understanding among stakeholders. (Andersen et al., 2018)

Lastly, PD plays a crucial role in expediting the preparedness of health systems for forthcoming health innovations. For instance, Drury et al. executed a three-phase participatory action research project aimed at bolstering the self-management skills of cancer patients, enabling them to effectively utilise and adapt to emerging health solutions for improved disease management (Drury et al., 2019).

While numerous successful instances of PD application in supporting health system innovations are documented, challenges persist, and certain questions remain unanswered. One significant hurdle, as highlighted by Reddy et al., pertains to the time sensitivity and intensity of stakeholder engagement sessions, which can deter potential innovators (Reddy et al., 2019). Moreover, ambiguity prevails among various literature sources regarding the entity responsible for PD activities and management. The studies present varied perspectives, proposing hospitals, clinical laboratories, or theoretical application by authors. (Crawford et al., 2017) Additionally, the effectiveness of PD is contingent on the willingness of stakeholders to engage and the extent of their involvement. Furthermore, a key inhibitor to the success of PD applications and the subsequent adoption of health innovations pertains to the deficiency of skills, policies, standards, operational capabilities, and prevailing attitudes. (Bez et al., 2023) Multiple studies concur on the imperative need for a paradigm shift towards change, both at the health system level and on a broader scale encompassing policy

and strategic decisions. To this end, efforts must be concentrated on cultivating systematic adaptability, involving up-skilling potential users of innovative health technologies, achieving consensus on aspects such as data standards, and incentivising engagement between healthtech startups and their stakeholders throughout the development of health technologies.

There is evidently an abundance of literature and drive for user-centred development methods, such as participatory design, to be implemented on a larger scale within the pre-development of healthtech startups. Although PD in itself may not be the ideal method, there is a call for further research and investigation into this area or "user-led" development and systems thinking ideology.

Social and ethical considerations

In both the analysis of existing literature, and during the interviews with industry-professionals; the topic of culture, ethics and other social considerations arose. However, the information that appeared in both the literature and interviews was fragmented and brought forward the question of who should be responsible within the pre-scaleup development of healthtech startup, for ensuring that ethical and socially responsible practices are upheld. The ethical and socially responsible development of health technologies is a complex and multi-stakeholder endeavour that involves various actors to ensure patient safety, data privacy, and societal well-being (Bellemare et al., 2018; Felber et al., 2023; Mahlich et al., 2018). Based on a brief search of additional literature, here are some key stakeholders who are advised to take some responsibility for the ethical development of health technologies:

Startups and technology developers have the primary responsibility to ensure that their products are developed in an ethical manner, adhering to best practices, regulations, and guidelines. They should prioritise patient safety, data privacy, and transparency throughout the development process.
Regulatory bodies, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), play a significant role in ensuring the ethical development of health technologies. They establish and enforce standards that govern the safety, efficacy, and quality of medical devices and technologies (Fleming, Demets, & McShane, 2017; *Research and development | European Medicines Agency*, 27/05/2023).
Healthcare professionals, including physicians, nurses, and other practitioners, have an ethical obligation to critically evaluate and recommend health technologies that demonstrate patient safety, clinical utility, and ethical considerations. They should stay informed about the technologies they use and recommend to patients (Steerling et al., 2022).
Institutional ethics committees, review boards, and public organisations such as the World Health Organisation (WHO) or the World Medical Association (WMa) provide oversight and guidance for research involving human subjects. Their role is to ensure that research and development of health technologies adhere to ethical principles and respect the rights and well-being of participants.(Association et al., 2013; Organization et al., 2016) Industry organisations, such as the Health Information Management Systems Society (HIMSS), often establish codes of ethics and best practices for their members. They can serve as resources for startups and companies to align their practices with ethical standards. (Chamberlain, 2017)
Data protection agencies, such as the General Data Protection Regulation (GDPR) in the EU, monitor data

privacy practices and ensure compliance with data protection laws. They play a crucial role in safeguarding patients' personal health information (Martinez-Martin, Kreitmair, et al., 2018).
Patient advocacy organisations represent the interests and rights of patients. They contribute by raising awareness about ethical concerns related to health technologies, advocating for patient rights, and promoting transparency and accountability (Nelis, de Vries, & Hagendijk, 2006).
Universities and research institutions contribute to the ethical development of health technologies through research, education, and collaboration with industry partners. They can provide expertise and promote discussions on ethical considerations in technology development (Steerling et al., 2022).

It's important to note that responsibility for ethical development is shared among various stakeholders, and collaboration among these actors is essential to ensure comprehensive ethical oversight throughout the development, implementation and use of health technologies. There is a need for further research into the allocation and sharing of responsibility of the ethical and socially responsible development and lifescycle of health technologies.

6.3 Practical implications of a theoretical model for the pre-scale development of healthtech startups

Chapter 3 constructed a theoretical model to represent the pre-scaleup development of specifically healthtech startups. Such a model has very limited value unless it can be applied in theory and/or practice. In Chapters 4 and 5, interviews were conducted with experts within the industry of health technology development, startups and health systems; and these interviews revealed several insights that were valuable in the context of the theoretical model of the pre-scaleup development of healthtech startups that was constructed in Chapter 3.

Firstly, the interviews confirmed the choice made to represent the pre-scaleup development as a number of separate stages, having provided evidence of a natural grouping of development activities into levels, or stages of development. The interviews did not provide sufficient information about the detail of what activities are grouped into which stages, but only made reference to the existence of different steps, levels and stages in the pre-scaleup development of healthtech startups. Therefore, it is evident that a stage-like model is suitable to represent the pre-scaleup development of healthtech startups, but more case research should be conducted to examine the specific activities or processes that occur in the stages, and how to divide the development in a way that best reflects reality.

Secondly, the interviews reinforced the idea that the theoretical model allows for flexibility and feedback within the pre-scaleup development of healthtech startups. The interviews revealed that in the practice of healthtech startups in their pre-scaleup period of development, it is often necessary to pivot, or make changes to the development process, or repeat past development activities. It was reported that these pivots occurred most often because of feedback from various stakeholders throughout the development process, that contextual factors had changed. The multiple mentions of pivots, flexibility, and feedback are in line with the incorporation of pivots and feedback in the theoretical model constructed in 3.

Third, during the interviews, multiple references were made to particular deliverables expected at differ-

ent stages of a healthtech startup's development, as evidence of the startup overcoming a number of barriers most prevalent at each stage of development. There were references to groupings of barriers that when overcome, signify a progression of the development process to the next level of development - a very similar concept to the critical junctures that were proposed in the theoretical model in Chapter 3. Therefore, it is logical to deduce that the use of critical junctures and a stage and gate like model to represent the pre-scaleup development of healthtech startups has practical relevance.
However; a concept that the theoretical model constructed previously does not consider is the link between deliverables or levels of evidence, and the critical junctures or "value inflection points" as termed in the interviews. In the interviews, multiple participants referred to various types of evidence or proof to showcase a health technology's Technical Readiness Level (TRL) or progression through its development journey. The "Proof of Concept" for example is associated with a healthtech startup being able to demonstrate their concept to their stakeholders. Similarly, venture capitalists may assess a health technology's TRL to gauge the risk of investing in a healthtech startup (Kaminski, Hopp, & Tykvová, 2019). Therefore, a theoretical model of the pre-scaleup development of healthtech startups should assign the critical junctures or stages of development to the appropriate level of technical readiness required of that stage, of extent of evidence needed to progress to the following stage of development. Such an additional to the theoretical model makes it more applicable in practice since the TRL or state of evidence are concrete measurables - a healthtech startup could directly pinpoint their progress on the model by comparing their own state of evidence or TRL of their technology to the prescribed deliverable on the model. The model developed in Chapter 3 does not link the required state of evidence of TRL to the development stages and critical junctures. Therefore, this is a research direction that should be further explored in future.

Moreover, the interviews revealed an invaluable insight that was not taken into account during the construction of the theoretical model in Chapter 3 - that there are different processes, types of evidence and development activities required for the development of different types of health technologies. This indicates that the activities within development stages, and the barriers within the critical junctures of the theoretical model might differ depending on if a medical device, biotechnology or electronic health technology is being developed. The theoretical model in Figure 4 may still be suitable in representing the vague structure of the pre-scaleup development of different types of healthtech startups; but the detailed description of activities and barrier that were presented in Tables 3 and 4 will not apply to healthtech startups producing different types of health technologies.

In summary, it is evident from the interviews with industry experts, and the confirmation of several concepts used to construct and update the theoretical model in 4; that the model does have practical relevance, and has the potential to be applied as a tool in understanding and guiding the pre-scaleup development of healthtech startups. As a tool, it is important to keep in mind that such a model will never represent reality but can serve more a guiding framework to the "ideal" - in reality the pre-scaleup development of healthtech startups is too complex to accurately represent it using a model. However, the interviews also highlighted a number of shortcomings and other factors that had not been taken considered during the construction of the model in this research. This indicates that the model developed in this thesis may serve as a starting basis for the future work to develop a model that better represents the unique challenges and nature of the

pre-scaleup development of healthtech startups. It would be advised to first conduct extensive case study research by applying such a model in various healthtech startup contexts, and gauging the extend to which the model captures the development process. Moreover, it is suggested that many more experts involved in the pre-scaleup development of healthtech startups are involved to capture their perspectives within the model. Finally, it would be beneficial to consult experts in process and system modelling to adequately express the complexity and dynamics of the pre-scaleup development of healthtech startups in the model.

6.4 Research limitations and recommendations

The research conducted in this thesis applied multiple research methods cited by literature, followed best-practice research skills developed over the course of the researcher's masters education, and made use of external feedback and advice from a number of supervising persons. However, throughout the research, there are several limitations related to the scope of the research, the methods chosen, and contextual factors. Moreover, the research highlighted numerous areas of improvement and potential for future related research.

Foremost, there are a number of assumptions that were made throughout the thesis that may limit the accuracy of the outcomes of this research. Firstly, from the beginning, healthtech startups were assumed to be a type of technology startup and although it their unique attributions compared to technology startups was explored in Chapter 2, the search for literature and the mind frame adopted throughout the thesis stemmed from the idea that healthtech startups are at their core, technology startups. Secondly, the thesis makes a key assumption by focus specifically on the "pre-scaleup" development period of healthtech startups. Within this scope an assumption is made that the development of healthtech startups follows some type of linear journey which enables it to be split into a pre-scaleup period versus a post-scaleup period. This assumption however, undermines the inherent uncertainty or flexibility that is often experienced within the development of many startups. Moreover, these assumptions may have excluded certain perspectives and insights in literature and limited the possibility of the researcher to take on a fully exploratory approach. Future research into the domain of healthtech startups and/or their pre-scaleup development should take careful measures to explore the development of healthtech startups without making the same assumption made in this research.

Furthermore, the methodologies chosen during the course of the research introduce several limitations into the thesis.
Firstly, a very specific two-stage review process framework of Wilson et al. (2021) was selected to carry out the literature review in Chapter 2. In selecting this one framework, the scope and depth of the literature review are constrained by the limitations of the framework. Reflecting on the framework of Wilson et al. (2021), there are several points where the researcher is obliged to choose one of a few methods based on a number of guidelines in the framework. (Wilson et al., 2021) Each decision relies on the subjective interpretation of the framework and its guidelines by the researcher, and introduced subjective research bias. Moreover, during the literature review, the researcher sets a number of exclusion criteria for the literature to be included in the study - this is based on some degree of research but also depends on the academic experience and subjective judgement of the researcher. Therefore, the literature study in Chapter 2 is limited in its depth and scope by the inclusion criteria, weaknesses of the applied framework and other subjective judgements made throughout the review.

Secondly, the construction of the theoretical model in 3 also introduces a number of limitations to the thesis. The model is constructed based on the researcher's review of existing models, which were classified according to commonly used characteristics in literature. The analysis of the existing models for their suitability to represent the pre-scaleup development of healthtech startups, was based on the insights gained from literature in the previous chapter. Therefore, the researcher would have used their subjective interpretation of the results from the literature study to make deductions and analyses of the models, and subsequently construct a theoretical model in line with their individual interpretation and perspective. Although, there was an inclusion of external materials via a study of the theory relating to models of startup development; it is recommended that further effort be placed into consulting external parties and sources of information (both from literature and practice) to better inform the process of constructing a theoretical model of the pre-scaleup development of healthtech startups. Such a improvement, would increase the generalisability of the model and its applicability in practice.
Thirdly, the methodology proposed in Chapter 4 and executed to produce the results in Chapter 5 contains constraints and drawbacks that are reflected in the outcomes of this research. The interview design and execution has a few limitations. The research was restricted to participants within the domain of Dutch healthtech startups. This restriction may result in a narrower range of perspectives and insights, potentially overlooking valuable perspectives from other regions or sectors. Also, although the approach aimed to include participants with differing perspectives, the process of selecting participants could introduce bias. This bias may stem from the researcher's assumptions or preconceptions about who should be included in the study. Moreover, the researcher uses a data saturation method to determine when to stop adding more interview participants. However, data saturation, while valuable for ensuring a thorough qualitative approach, relies on the subjective judgement of the researcher to determine when no new insights emerge (Guest, Bunce, & Johnson, 2006). This subjectivity might affect the completeness of data collection and could potentially lead to the omission of relevant themes. Furthermore, although the interview questions were designed to guide discussions, their effectiveness in uncovering diverse experiences and perspectives may vary. Some participants might find it challenging to steer discussions or might not fully address the research focus. Another issue that could have arisen within the design of the interview questions is that research bias could have been introduced and may have steered the interviews according their a pre-determined direction, therefore decreasing the possibility of gathering novel insights. It would have been beneficial to organise external validation of the interview questions or the findings, which could impact the reliability and validity of the results. Finally, the COSTA QDA method and inductive thematic analysis that was used to analyse the interviews rely on the researcher's skill and interpretative ability to identify themes. There is risk that the themes were not identified were not completely inductively derived since the theme identification relied on the researcher's subjective judgement which could be influenced by pre-conceived ideas and knowledge of which themes should appear.

A related factor that may have limited the accuracy and applicability of the research outcomes, is the natural constraint on the skill level, capabilities and perspective of the researcher. Being the sole responsible researcher for this thesis, the quality of the research methods carried out and their outcomes is dependent on the capability, skill and pre-existing knowledge of the researcher. During the thesis, insight and advice from external parties such as supervisors, fellow researchers, and industry experts was consulted to guide

and broaden the set of knowledge and perspectives included within the thesis. However, the final outcome of the research is still constrained by the ability of the researcher to source and process information, conduct research methods, communicate findings, and draw academic deductions throughout the thesis.

Then, due to this research occurring in the context of a masters thesis, and a constraint on the time to conduct the research, several concepts were not further explored despite having significant relevance to the research.

First, it was evident from the literature review and interviews that the regulatory landscape that healthtech startups face is complex and difficult to navigate. The literature addressing this topic is currently very scattered or focuses on particular contexts or case studies. Therefore, there is a need for research to consolidate the information available related to the regulatory requirements and actions required for health technologies.

Second, throughout the study of the pre-scaleup development of healthtech startups, and the construction of the theoretical model; there are a significant number of references made to various stakeholders, actors, influencing parties, and their subsequent perspectives, values and needs. This observation highlights a need for a deeper look into particularly which people or groups are involved in the pre-scaleup development of healthtech startups, how they are involved or influenced, and what type of relationships or network dynamics are at play and how this complex web of connections affects healthtech startups and their development. It is advised that tools such as stakeholder mapping, network maps, stakeholder value mapping or value process mapping may be useful in gaining a better understanding about who is involved in the realm of healthtech startups and how these people and their actions may have wider consequences than expected.

Third, there was a frequent mention of supporting bodies such as venture capital firms, accelerator programs, incubators and venture builders, throughout literature and the interviews. Many bodies of literature suggest that such startup support bodies are vital to the success of healthtech to aid them in for example their regulatory challenges, early-stage funding, development support, or connection to a network of health system key stakeholders (Ngongoni, 2021). However, there appears no literature considering the role of these startup support bodies particularly in advancing healthtech startup success and innovation. Therefore, there is a call for research to consider the role that startup might play in aiding the success of healthtech startups, how this might be achieved and look like, and what impact this may have on the future of healthtech startups and their pre-scaleup development.

Fourth, as explained in 6.3, the theoretical model developed in Chapter 3 lacks external validation of its theoretical and practical applicability. It was advised that extensive case study research be conducted, and external expertise in model development be consulted to improve the relevance of the model in theory and practice.

These points of discussion and identified limitations underscore numerous areas of potential investigation for future research in the realm of pre-scaleup development within the healthtech startup sector. They also shed light on avenues through which research methodologies can be enhanced to mitigate the shortcomings observed in this thesis, ensuring a more robust approach in similar investigations.

7 Chapter 7: Reflections and conclusions

7.1 Critical reflections

The research process and the researchers experience through it, brought up several opportunities for learning and self-improvement. In the beginning of the thesis, the following three objectives were set:
I. To contribute to creating a better understanding of the pre-scaleup development of specifically healthtech startups
II. To develop novel theoretical insights related to developing a model to represent and/or guide the pre-scaleup development of healthtech startups in practice
III. To propose recommendation for future research into understanding, modelling, and guiding the pre-scaleup development of healthtech startups
Throughout the thesis, these objectives acted as a guide, and can be used to reflect on the research conducted thus far.
Considering Objective *I*, the thesis focused on creating a better understanding of the pre-scaleup development of healthtech startups by studying relevant literature, and conducting interviews with experts involved in this period of development in Dutch healthtech startups. In particular, this research produced a list of characteristics or elements that may be used to better define and describe the pre-scaleup development of healthtech startups. Within the proposed characteristics, there is an abundance of related information that is essential to obtain a full grasp of the pre-scaleup development of startups. Yet, the thesis only provides a summary of this information in order to conceptualise each characteristic, providing a fairly shallow exploration of the element it prescribes to characterise healthtech startups and their pre-scaleup development.
Next, in reflection of Objective *II*, the thesis conducted a review of existing models used to represent or guide the development of startups, and gathered several core concepts to be used to newly construct a theoretical model better aligned with the unique nature of healthtech startup development. However, the research lacked in demonstrate the application of this model in practice, and thereby recommended for this direction be taken up in future.
Finally, in line with Objective *III*, the thesis carried out an extensive discussion of the limitations experienced within the research and made several recommendations for future research directions.

Moreover, this research set out to produce learnings with both theoretical and practical relevance. In a theoretical sense, in the list of characteristics and theoretical model proposed to better understand, define and represent the pre-scaleup development of healthtech startups, there are many novel theoretical insights that have relevance to further research into healthtech startups and their development. Then, the research showed some evidence of having practical relevance, by conducting interviews with industry-experts and validating that several concepts that were summarised from literature, also appear in practice. However, further exploration is required via case studies or other methods of practical application of both the proposed characteristics and theoretical model to validate and assess the applicability of the research outcomes in practice.

Finally, in terms of the researcher's reflection on the journey throughout this research process, there were several learning points and key insights gained throughout the study. Foremost, the reflecting upon the past months of rigorous research, data analysis, and countless hours spent poring over scholarly articles, the

dynamic nature of the research process became evident. What began as a set of well-defined research questions evolved into a journey marked by unexpected twists, intriguing revelations, and, at times, even a few stumbling blocks. Furthermore, being reminded of the time required to conduct this research derived a sense of satisfaction at the level of dedication and perseverance displayed. However, remaining conscious of the limitations inherent in any research endeavour; despite the meticulous planning there are aspects that would be approach differently if given the chance to rewind time. Acknowledging these limitations is a reminder that knowledge is a dynamic, ever-evolving entity, and there will always be more to explore. This thesis marks not just an academic achievement, but a personal milestone as well. It signifies an ability to embrace challenges, adapt to new methodologies, and delve into the unknown. In summary, from the inception of the research idea to the completion of this written document, has been a voyage of both intellectual discovery and personal growth.

7.2 Conclusions

Throughout the thesis, it is evident that addressing the problem of the under-explored pre-scaleup phase of development in the context of healthtech startups presents a crucial opportunity to enhance our understanding of this critical period. The existing literature extensively covers various aspects of healthtech startup development, including the study of specific startups, health technologies, phases of growth, barriers, success factors, challenges, and strategies. However, the specific pre-scaleup phase has been largely overlooked, despite its pivotal role as the stage where many healthtech startups falter due to heightened uncertainties and complexities. This gap underscores the necessity for a comprehensive exploration of the pre-scaleup phase, driven by an exploratory approach that avoids overly narrowing the analysis to particular cases or technologies. Furthermore, a key aim within this thesis was to recognise the unique nature of the pre-scaleup development of healthtech startups. While there is a plethora of literature and practical wisdom that outlines challenges and activities crucial to this developmental phase, it's important to acknowledge that a one-size-fits-all approach, especially those used for general tech startups, might not be apt for healthtech startups. This differentiation is grounded in the distinctive attributes of healthtech startups, necessitating a tailored approach that takes into account their unique challenges and opportunities.

In sight of addressing this gap; a study of literature pertaining to technology and health technology startup development was conducted in Chapter 2 to explore the state of knowledge relating to the pre-scaleup development of healthtech startups. This study found a natural tendency within literature to describe this period of startup development according to a number of key themes. This finding guided the subsequent characterisation of information available in literature to define the pre-scaleup development of healthtech startups by nine themes; regulation, network, development processes, financing, capabilities, measures of performance, solution, system and market context, and social aspects. The literature study highlighted the unique nature of healthtech startups and their pre-scaleup development, and brought to attention the need to investigate how this differentiation of healthtech startup development can be represented. Consequently, the thesis undertook an evaluation of existing models designed to guide or depict this early development of startups, critically assessing their limitations in effectively capturing the distinctive aspects of pre-scaleup development within the healthtech sector. Chapter 3 proceeded to synthesise the insights gathered from the examined models and the themes found in Chapter 2. This aimed to characterise the unique features

inherent to healthtech startups, culminating in the formulation of a theoretical model tailored to represent the pre-scaleup progression of healthtech startups.

Next, the thesis proposed and executed a method to consult additional data to furthermore inform and contribute to the understanding of healthtech startups and their pre-scaleup development. A series of interviews were conducted with participants with expertise and experience within the pre-scaleup development of healthtech startups in the Netherlands. The interviews and their subsequent analysis revealed a number of insights that were grouped into themes to characterise the pre-scaleup development of healthtech startups. Furthermore, the interviews uncovered information relevant to the previously constructed theoretical model.

Given the appearance of themes from both literature and the interviews, a subsequent comparison of these two research approaches was completed. The outcome of this comparison was a final list of four key and four lesser characteristics of the pre-scaleup development of healthtech startups that can be used to characterise, define and understand this period of development better. Moreover, the insights gained from the interviews related to the theoretical model resulted in several suggestions for future research to investigate the practical applicability of a model similar to the theoretical model developed in this thesis, and noted a number of limitations of the method followed to construct the model.

Finally, a few other key observations arose throughout the research process. One significant concept that was emphasised by both literature and the interviews, was the benefit of user-centred design of health technologies, or encouraging the participation of stakeholders such as doctors, nurses and patients from early in the development of a health technology. It was suggested that this concept be explored further in future research. Also, another issue that was highlighted throughout the analysis of existing literature and industry-professional interviews was the fragmented nature of information regarding responsibility for ensuring ethical and socially responsible practices in the pre-scaleup development of healthtech startups. The ethical and socially responsible development of health technologies involves multiple stakeholders, and collaboration among these stakeholders is crucial to ensure comprehensive ethical oversight throughout the life cycle of health technologies. Further research is needed to delve into the allocation and sharing of responsibilities for ethical development in this context.

In essence, the proposed characteristics and theoretical model in this thesis recognise that the pre-scaleup development of healthtech startups is a multifaceted endeavour that can be characterised by specific defining characteristics. By identifying the defining characteristics of this phase, a clearer and more applicable knowledge base can be established, allowing the insights gained to be effectively translated into practical strategies and actions. Moreover, this thesis offered a stepping stone towards the creation of a theoretical model that encapsulates the intricacies of this developmental phase. By bridging the gap in the literature and industry knowledge, this solution sets the stage for a more comprehensive understanding of the pre-scaleup phase and its role in the successful growth of healthtech startups. Ultimately, this research contributes to refining strategies and approaches that align with the specific needs of healthtech startups, propelling them toward sustainable and impactful growth within the dynamic healthcare technology landscape.

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A Appendix: Literature Search Results

A.1 Scoping review results

Source	Year	Keywords	Common themes
Google Scholar			
(Okanović, Jevtić, & Stefanović, 2020)	2021	Organisational, development process	Capabilities, process
(Prasetio, Yuana, & Anggarini, 2020)	2020	grant-effectiveness	Finance
(Hashai & Zahra, 2022)	2022	team, experience	Capabilities
(Rannikko, Buffart, Isaksson, Löfsten, & Tornikoski, 2022)	2022	finance, legitimacy	Finance, network
(Chammassian & Sabatier, 2020)	2020	costs, business model design	Finance, process
(H. J. Kim, Kim, & Sohn, 2020)	2020	cooperation	Network
(Tritoasmoro, Ciptomulyono, Dhewanto, & Taufik, 2022)	2022	incubation, metrics, viability	Performance, network
(Pavlenko, Kubatko, & Ziabina, 2020)	2020	economic, social, technological success factors	Market, solution characteristics, social
(Jeong, Kim, Son, & Nam, 2020)	2020	venture capital, investment, absorbative capacity, reputation	Network, finance, capabilities
(Harms & Schwery, 2020)	2020	operationalising, capabilities, performance	Capabilities, process, performance
(Khodaei et al., 2022)	2022	facilitators, junctures	Network
(Eliakis, Kotsopoulos, Karagiannaki, & Pramatari, 2020)	2020	growth, entrepreneurship	process

Source	Year	Keywords	Common themes
(Rizvanović, Zutshi, Grilo, & Nodehi, 2023)	2023	marketing, growth drivers	Market, capability, network
(Moro & Moro Visconti, 2020)	2020	valuation	Performance
(De Cock, Bruneel, & Bobelyn, 2020)	2020	start-up method, market knowledge	Market, process
(Kurpjuweit & Wagner, 2020)	2020	supplier programs, corporate-startup partnership	Network
(Choi, Sung, & Park, 2020)	2020	innovation performance, employment change	Performance, capabilities
(Berg, Birkeland, Nguyen-Duc, Pappas, & Jaccheri, 2020)	2020	agility, quality, product development	Capabilities, process
(Dellermann, Lipusch, Ebel, Popp, & Leimeister, 2021)	2021	predicting success	Performance
(Rok & Kulik, 2021)	2021	circular startup development	Process
(Sullivan, Marvel, & Wolfe, 2021)	2021	learning activities, network ties, performance, incubators	Capabilities, network, performance
(Dehghani, Abubakar, & Pashna, 2022)	2022	market-driven	Market
(Kalyanasundaram, Ramachandrula, & Mungila Hillemane, 2021)	2021	startup attributes, failure	Capabilities, performance
(Cico, Souza, Jaccheri, Nguyen Duc, & Machado, 2021)	2021	transitioning, technical debt	Finance, process
(Baek, Kim, Lim, & Xiong, 2023)	2023	quality evaluation	Performance

Source	Year	Keywords	Common themes
(Baltrunaite & Sekliuckiene, 2020)	2020	organisational learning	Capabilities
DOAJ			
(Pond et al., 2023)	2023	inter agency collaboration	Network
(Sari, Dewanti, Fajar, Priantinah, & Pranesti, 2022)	2022	evaluation model, angel investor	Performance, finance
(Sudiana, Sule, Soemaryani, & Yunizar, 2020)	2020	support needed	Network
(Ashtari Mehrjerdi, 2020)	2020	social ecology of startups	Social
(Matsuoka, Uchiyama, Woraitthinan, & Kohsaka, 2023)	2023	cultural acceptance	Social
Science Direct			
(Andries et al., 2021)	2021	External actors	Network, market
(Barry & Alfaro, 2022)	2022	Economic, investment	Finance
(Binz, Harris-Lovett, Kiparsky, Sedlak, & Truffer, 2016)	2016	Legitimisation, institution	Regulation, network
(Burkhardt & Nazemi, 2019)	2019	Legal, law-conflicts	Regulation
(Calado et al., 2019)	2019	Multi-use technology, value	Solution
(Cedano & Hernández-Granados, 2021)	2021	Strategies, market assessment, technology assessment	Process, Market, Measure of performance
(Colecchi & Tancredi, 2016)	2016		Finance
(de Villemeur, Scannell, & Versaevel, 2022)	2022	Outsourcing	Capabilities

Source	Year	Keywords	Common themes
(Deligianni, Voudouris, Spanos, & Lioukas, 2019)	2019	Technological competence, resources	Capabilities
(di Biase, Kowalski, Devlin, & Oleszkiewicz, 2019)	2019		Process
(Dijkstra, van Beukering, & Brouwer, 2022)	2020	Business model, entrepreneurship	Process, capability
(Evers & Andersson, 2021)	2019	Exploration, exploitation	Capabilities
(Fearis & Petrie, 2017)	2021		Process
(Gupta, Venkatesh, Ray, & Srivastava, 2014)	2014	IP issue, funding	Financing, regulation
(Gbadegeshin et al., 2022)	2022	Model	Process
(Alvi & Ulrich, 2023)	2022	Innovation finance, incubators, accelerators	Finance, network
(Hällerstrand, Reim, & Malmström, 2023)	2023		Capabilities
(Helgesen & Gjernes, 2016)	2016		Solution
(Hoenen, Kolympiris, Schoenmakers, & Kalaitzandonakes, 2014)	2014	Signaling value, venture capital	Finance, measure of performance
(Islam, Fremeth, & Marcus, 2018)	2018	Research grants, venture capital	Finance
(Kaminski et al., 2019)	2019	Technology assessment, venture capital	Finance, measure of performance
(M. Z. Khan, Khan, Hameed, & Zada, 2021)	2021	Venture capital	Finance
(W. Kim, 2015)	2015	Education	Capabilities

Source	Year	Keywords	Common themes
(P. H. Kim et al., 2019)	2019	Evaluation, resources	Measures of performance, capabilities
(Konietzko, Baldassarre, Brown, Bocken, & Hultink, 2020)	2020		Process
(Lam & Law, 2018)	2018	Stakeholders	Finance, network
(Laplume, Pathak, & Xavier-Oliveira, 2014)	2014	Intellectual propert	Regulation
(Leete, Xu, & Wheeler, 2013)	2018	Investment, venture capital	Finance
(Lehrer & Almor, 2022)	2021	Internationalising, business model	Network, process
(Lermen, de Moura, Bertoni, Graciano, & Tortorella, 2023)	2022	Agile methods, design thinking	Process
(Maiti, 2022)	2022	Venture capital investments, green growth	Finance, process
(Matsuoka et al., 2023)	2023	Cultural contexts	Social aspects
(Meijer, Huijben, van Boxstael, & Romme, 2019)	2023	transitioning, drivers, barries	Process
(Mueller, 2023)	2023	Stage, startup support program	Process, Network
(Nian, 2017)	2017	Global, international cooperation	Network
(Polzin, Sanders, & Serebriakova, 2021)	2021		Finance
(Pradhan, Arvin, Nair, Bennett, & Bahmani, 2019)	2019	Venture capital, economic growth	Finance, network, market
(Reid, de Brentani, & Kleinschmidt, 2014)	2014	Competence, radical innovation	Capabilities, solution

Source	Year	Keywords	Common themes
(Renko, Yli-Renko, & Denoo, 2022)	2022	Product-market fit	Market, solution
(Rubin, Aas, & Stead, 2015)	2015	Knowledge, incubators	Capabilities, network
(Schultz & Querques, 2014)	2014	Commercialisation pathway	Process
(Sharma, Gent, Burke, & Stelfox, 2014)	2014		Process
(Soeder, 2018)	2018	Resources	Process, capabilities
(Temmes, Heiskanen, Matschoss, & Lovio, 2021)	2021		Finance
(Townsend & Busenitz, 2015)	2021	Entrepreneurial teams	Capabilities
(Tuan et al., 2019)	2019		Capabilities, process
(Eenennaam & Werth, 2021)	2021	learning	Capabilities
(Visintin & Pittino, 2014)	2021	Founding team, growth	Capabilities, network, performance
(Wallnöfer & Hacklin, 2013)	2013	Business angel, communicative interaction	Finance, network
(Wang, Qureshi, Deeds, & Ren, 2019)	2019	quality evaluation	Measures of performance
(Warhuus & Basaiawmoit, 2014)	2014	Education	Capabilities
(Young, 2022)	2022		Process, solution
(Yu & Fleming, 2022)	2021	Crowdfunding	Finance, measure of performance
(Zaheer, Breyer, Dumay, & Enjeti, 2019)	2017	Founders	Finance, process
(Zhu, Liang, Mirza, & Umar, 2023)	2023	Gearing, blue economy startups	Finance
(Zinner et al., 2021)	2021		Process, solution

Source	Year	Keywords	Common themes

Table 7: Appendix table of the included records of the scoping review

A.2 Rapid review results

Source	**Year**	**Keywords**	**Theme**
(Agarwal et al., 2018)	2018	shared understanding, product requirements, markets	Network, market
(Andersen et al., 2018)	2018	aligning concerns, patient-centred e-health	Network
(Atun, 2012)	2021	health systems, system thinking, health policy	Network
(Augustin et al., 2020)	2020	biodesign innovation program, teaching opportunities, value-driven	Network, process
(Barros et al., 2015)	2015	Competition, health economics	market
(Bellemare et al., 2018)	2018	Ethics, health technology assessment	Social
(Bianchini & Mayer, 2022)	2022	Medical device regulation	Regulation
(Chakraborty et al., 2022)	2021	healthcare service delivery	Regulation, Network, Capabilities, Solution, market
(Colloud et al., 2023)	2023	Regulation, digital health technology, medicinal product development	Regulation
(den Exter, n.d.)		ehealth EU law	Regulation
(Dhainaut et al., 2020)	2020	Research	Network, Capabilities
(Dixon et al., 2013)	2013	Health information security and privacy	Network
(Europe, 2022)	2022	European medical technology industry	market
EU IVD regulatory (Council of European Union, 2014a)		IVD EU regulation	Regulation
EU regulation (Council of European Union, 2017)		medical device EU regulation	Regulation
(Fearis & Petrie, 2017)	2017	Medical device development, quality management system	Solution
(Felber et al., 2023)	2023	Ethical issues	Social

Source	Year	Keywords	Theme
(Fernández-Alemán et al., 2013)	2013	Security, privacy, electronic health records	process, Capabilities
(Ienca et al., 2018)	2018	Ethics review, big data, health research	process, Capabilities
(*ISO - ISO 13485 — Medical devices*, NaN)		Medical Devices	Regulation, process
(Kang, 2018)	2018	R&D stages, financing sources, biotechnology industry	Financing
(Koskinen & Ihamäki, 2018)	2018	Design thinking, health innovation	process
(Levaggi et al., 2014)	2014	Reimbursement, investment, health technologies	Financing
(Madan, 2022)	2022	Medtech companies in EU	market
(Mahlich et al., 2018)	2018	Cultural beliefs, utility values, health technology assessment	Social
(Mantas et al., 2012)	2012	Ehealth indicators	Performance
(Marques et al., 2019)	2019		Solution
(Nyikos et al., 2019)	2019	Design thinking research	Financing
(Ostrovsky & Barnett, 2014)	2014	Healthcare delivery, academic medical centres	Network
(Plattner et al., 2020)	2020	Design thinking research	process
(Reddy et al., 2019)	2019	Participatory design	Network, process, Solution
European medicines agency (*Europe's regulatory process for medical devices MDRC*, 2023)	2023	Research and development	Regulation
(Ross et al., 2016)	2016	Influencing factors, implementation of e-health	market
(Semler et al., 2015)	2016	Clinical informatics, clinical trials	Performance, Solution
(H. P. Silva et al., 2022)	2022	Incubators	Network
(Sorenson et al., 2013)	2013	Med tech relationship with health expenditure	process, Capabilities
(Stafinski et al., 2011)	2011	healthtech funding	Financing
(Stange et al., 2014)	2014	metrics, assessing improvements, primary health care	Performance
(Tuan et al., 2019)	2019	business model, strategy	Network

Source	Year	Keywords	Theme
(Vasanth & Sbert, 2014)	2014		Performance
(Vedlūga & Mikulskienė, 2017)	2017	stakeholder-driven, ehealth performance	Performance
(Young, 2022)	2022	special challenges	Network, Capabilities, Solution

Table 8: Appendix table of records from rapid search and resulting themes

Theme	Sub-themes	Relevant articles	#
Regulation	Privacy laws, technology regulations , policies, property rights	(Binz et al., 2016; Burkhardt & Nazemi, 2019; Laplume et al., 2014)	3
Network	External actors , network ties, cooperation, industry dynamics, finance ecosystems , incubators, intermediaries, programs	(Alvi & Ulrich, 2023; Andries et al., 2021; H. J. Kim et al., 2020; Nian, 2017; Sullivan et al., 2021; Wallnöfer & Hacklin, 2013; Zinner et al., 2021) (Alvi & Ulrich, 2023; Mueller, 2023; Rubin et al., 2015; Sullivan et al., 2021; Warhuus & Basaiawmoit, 2014)	12
Development process	Stages of development, strategies, methods, growth pathways, best practices	(Alvi & Ulrich, 2023; Cedano & Hernández-Granados, 2021; Fearis & Petrie, 2017; Gbadegeshin et al., 2022; Hällerstrand et al., 2023; Konietzko et al., 2020; Mueller, 2023; Polzin et al., 2021; Reid et al., 2014; Schultz & Querques, 2014; Sharma et al., 2014; Soeder, 2018; Tuan et al., 2019; Yu & Fleming, 2022; Zaheer et al., 2019)	15
Financing	Venture capital, angel investors, governmental investment	(Alvi & Ulrich, 2023; Colecchi & Tancredi, 2016; Eenennaam & Werth, 2021; Hoenen et al., 2014; Islam et al., 2018; Kaminski et al., 2019; M. Z. Khan et al., 2021; Lam & Law, 2018; Leete et al., 2013; Maiti, 2022; Polzin et al., 2021; Pradhan et al., 2019; Temmes et al., 2021; Wallnöfer & Hacklin, 2013)	13
Capabilities	Resources, knowledge management, learning , ambidexterity , entrepreneurial skills, team, education	(Deligianni et al., 2019; de Villemeur et al., 2022; Eenennaam & Werth, 2021; Evers & Andersson, 2021; Hällerstrand et al., 2023; P. H. Kim et al., 2019; Reid et al., 2014; Rubin et al., 2015; Soeder, 2018; Sullivan et al., 2021; Townsend & Busenitz, 2015) (Deligianni et al., 2019; Townsend & Busenitz, 2015; Visintin & Pittino, 2014; Warhuus & Basaiawmoit, 2014; Zaheer et al., 2019)	11
Measures of performance	Financial ratios, quality , signalling values	(Hoenen et al., 2014; Islam et al., 2018; Kaminski et al., 2019; P. H. Kim et al., 2019; Visintin & Pittino, 2014; Wallnöfer & Hacklin, 2013; Wang et al., 2019; Zhu et al., 2023)	8
Solution characteristics	Use, quality , requirements, compliance, current developments	(Calado et al., 2019; de Villemeur et al., 2022; di Biase et al., 2019; Helgesen & Gjernes, 2016; Renko et al., 2022)	5
Market influences	Market orientation, globalisation, digital disruption, industries, economic paradigm, time to market	(Barry & Alfaro, 2022; de Villemeur et al., 2022; W. Kim, 2015; Lehrer & Almor, 2022; Nian, 2017; Pradhan et al., 2019; Renko et al., 2022)	7
Social aspects	Cultural acceptance, technology literacy	(Deligianni et al., 2019; Matsuoka et al., 2023)	2

B Appendix: Interview questions template

First introduce background: For the purpose of this interview, we are interested in looking into the challenges and activities that occur in the development or growth of a healthtech startup before they launch their technology into the market in a large scale. I would like to hear about your personal experience in the development of health ventures, and if you have advice or recommendations for how these ventures can navigate their development journey.

Questions:

Broad:

1. What in your opinion are some of the biggest challenges in the development process of a health tech startup before they launch?
   (a) What makes these things particularly challenging? E.g., Is it related to other factors such lacking knowledge or financing?
   (b) How have you taken action to tackle these challenges?
2. Are there any points in the development process of a health technology venture that you would consider pivotal turning points? Ie. Can mean the success or failure of the venture?

Narrowing down:

1. Especially in the early stages of a venture, it is known that the risk of failure or change is quite high. Have you experienced this, and how do you suggest that ventures can remain flexible, especially in the realm of health technologies? Have you experienced having to pivot or abandon current trajectories to repeat past development activities? What was or is often the cause for this and how can you recommend incorporating these pivots in a venture's development?

Narrow:

1. It has been found before that other health technology ventures often struggle to navigate the regulatory landscape of developing a technology for use in a health setting. Have you experienced this to be a major barrier? And how have you or would you suggest overcoming it?
2. Another difficulty that ventures have experiences is gaining the approval of clinical stakeholders such as physicians, reimbursement agencies and other health professionals. What has been your experience with this?
   (a) How can this be overcome?
3. Another struggle that has been experienced is related to funding health ventures due to their longer development cycles and regulatory barriers. Do you have any advice for how to approach this barrier?
4. How do you suggest that health technology ventures measure or assess their growth and performance in the early stages of their development? eg. Measuring their problem/solution fit? Measuring product/market fit? KPIs?

C Appendix: Interview analysis

C.1 Word frequency analysis

Word	Frequency	Rank	Appearance in interviews %
technology	55	1	100.00
venture	51	2	100.00
people	49	3	100.00
process	48	4	100.00
health	44	5	100.00
time	34	6	100.00
problem	32	7	100.00
tech	32	7	100.00
challenge	31	9	100.00
early	29	10	100.00
level	27	11	100.00
team	26	12	33.33
change	25	13	100.00
solution	22	14	100.00
value	21	15	100.00
build	20	16	100.00
clinical	19	17	100.00
product	19	17	100.00
expert	18	19	66.67
lead	18	19	66.67
startups	17	21	66.67
money	16	22	100.00
perspective	16	22	100.00
stage	16	22	66.67
hospital	15	25	100.00
interest	15	25	100.00
pivot	14	27	100.00
fund	13	28	100.00
market	13	28	100.00
measure	13	28	100.00
diligence	12	31	100.00
ceo	11	32	66.67
development	11	32	100.00
evidence	11	32	66.67
information	11	32	66.67
patient	11	32	100.00

Word	Frequency	Rank	Appearance in interviews %
progress	11	32	66.67
quality	11	32	66.67
startup	11	32	100.00
impact	10	40	100.00
flexible	9	41	66.67
investment	9	41	66.67
trial	9	41	100.00
deal	8	44	66.67
nlc	8	44	100.00
portfolio	8	44	66.67
prove	8	44	66.67
technical	8	44	66.67
timeline	8	44	66.67
user	8	44	33.33

Table 10: Appendix table of the 50 most frequent words from the interviews

Word combination	Frequency	Rank	Appearance in Interviews %
health tech	21	1	100.00
problem solution	9	2	100.00
health tech startups	7	3	66.67
tech startups	7	3	66.67
venture capital	7	3	66.67
clinical trial	6	6	66.67
trl level	6	6	33.33
venture developer	6	6	33.33
early stage	5	9	66.67
health tech venture	5	9	66.67
tech venture	5	9	66.67
health technology	4	12	66.67
time frame	4	12	66.67

Table 11: Appendix table of the most frequently occurring word combinations in the interviews

C.2 Quote analysis

Key Quotes	Codes	Sub-codes
Participant A		

Key Quotes	Codes	Sub-codes
"we validate a number of, of different aspects of the proposition. So, of course, what is the clinical reality? And what are the unmet needs? Is there an unmet need in this space? Would this technology address that need? How big is the market? What is does the financial case look like? What are the steps that would be required to get there? Both resources and and otherwise funding? And yeah, do we think that we've identified the risks enough that this technology can be brought forward through the vehicle of a, of a startup?"	Evidence, problem, solution, financing, risk, process, market	Unmet needs, clinical context,
"So speaking with the clinicians or technical experts or business experts to get opinions and feedback and ultimately help us make a decision."	Network, expertise	Clinical stakeholders, technical experts, business experts, feedback, expert opinion
"biggest hurdles are.. getting to the right people in our network or building out the network enough."	Network, people	
"we try to validate from a few different perspectives . . . and sometimes it's challenging also to find the person who really has the specific perspective that you're looking for."	People, process, validation	Perspective
"In terms of the biggest hurdles. . . we tend to encounter in what seems like it will be hard for the venture is often the regulatory and clinical trial pathway"	Regulation, process	Clinical trials
"In the regulatory spectrum, but it's often quite challenging to determine what the clinical trials actually need to look like, how expensive they're going to be, who needs to be involved for those,and also in a more detailed level, what are the the almost documentation or the steps that a regulatory body or a notified body are going to want to see"	Regulation, network, process	
"we just accept that there's probably gonna be a an error with with resources of both time and and money."	Process, financing	Reseources, time
"I think some of the the other challenges in that process . . . is also the problem solution fit . . .	Problem, solution, process	problem-solution fit
"sometimes it's hard to tell if this technology is really the best solution to that problem . . . that's often when we start to get into conversations with various experts that we get a lot of different perspectives"	Solution, problem, people	Expertise, problem-solution fit
"reimbursement: I think we lack a lot of knowledge internally... it's hard to find on what technologies can be reimbursed, why and for how much."	Financing, people	Expertise
"a big sticking point is the jurisdiction	Process	Intellectual property
"another go, no go – the level of development is always one"	Process, measurement of performance	

Key Quotes	Codes	Sub-codes
“we need some kind of clinical validation or especially preclinical validation, but it’s always hard to say upfront what that actually looks like. . . . it changes per technology”	Process, evidence, solution	
“seeing which have the most risk, what is the potential benefit - to the health care system, to the patient or to NLC financially, ideally all of the above. Then evaluating which risks are we most comfortable taking for each technology"	Risk, value, people, solution	
“we don’t have a lot of checkpoints, we can move a little bit faster”	Process	Time
“we do still try to build in some structure structure to our process”	Process, organisation	
“stages also involve getting feedback from other internals - either peers or experts. And the idea is that it’s that we incorporate that feedback”	Process, people, expertise	
“process does work so long as everybody is involved and also trusts that all of the teams have other teams best interests in mind”	Process, team, organisation, social aspect	Trust
“deal with a lot of the uncertainty because we just simply can’t answer many of the questions that are raised - so it’s whether or not the risk is worth taking anyway”	Risk	
“you realize that the unmet need that we’ve been targeting, there’s not a good problem solution fit. So we need to find a different application ... You need to get more people on board to keep the conversation going . . . it’s a very back and forth sort of iterative process.”	Process, solution, problem, people	
“it can mean a lack of experts, a lack of capacity, challenges in getting you a deal with the team, information”	People, expertise, team, capability	
“a number of people affected can be a KPI a number of people impacted, cost saved to the health system, positive clinical trial outcomes”	People, measurement of performance, value, evidence	
“the impact assessment becomes really important in portfolio as a quality indicator.”	Measurement of performance	
“Does this seem like a solution to the need? Really trying to structure the way that we do due diligence not to encourage that tunnel vision.”	Solution, evidence, organisation	
“trying to reframe how we approach these technologies as what is really the need, what is the need statement? And is this technology the best way to do it?”	Problem, solution	
“conversations with experts and people in the field and a lot of internal conversations pulling in a lot of the assessment perspective”	People, expertise	Perspective
“ it is extremely important because if people don’t like it, they’re not gonna use it”	Value, people	

Key Quotes	Codes	Sub-codes
"get really good data" and "get a couple of important people to try it"	Evidence, people	Key opinion leaders
"gauge sort of how acceptable will this technology be by talking to different experts and KOLs [key opinion leaders] and also looking at things you have to look at financially as well, is their reimbursement? Will it make the life of a hospital easier, or cheaper?"	Solution, financing	Expertise, Key opinion leaders, reimburesement
"benefit has to be acknowledged by the experts or the KOLs"	Value, people	Key opinion leaders
"finding a couple of people who are trusted and respected in the field and getting them to use it and then also really engaging them in the process."	People, value, process, social aspect	Key opinion leaders, trust
"but bringing in that clinical perspective at the beginning and really spending time with the clinician iterating with them involving their voice, their perspective, looking at the workflow of a hospital."	People, process, context	Hospital workflows, perspective
"The experts you can involve in the, in the iterative process, but the KOLs are ultimately the one whose opinions you need"	People, expertise, process	Key opinion leaders, perspective
Participant B		
"So [for healthtech startups] you do need a very long period to bring a product to market. And that means you need to raise more funds. That means that you need to have stamina so you cannot have people leaving half halfway through"	Financing, people, capability	Time, team
"not all health tech startups realize this immediately but products do need to comply to a lot more rules and regulations than most other tech companies"	Regulation	
"make sure that you have in your planning enough slack to make mistakes or to pivot"	Capability	Structure, pivot
"SymBio therapy was a pivot from educational technology"	Capability	
"So the evidence that you need to get certified within the health tech space	Evidence, regultion	
" [sometimes you'll be in] a position that you really need to start from the beginning."	Capability	Pivot
"getting from a proof of principle where you know that the technology does a certain thing that might be helpful, You also need to prove that it's actually effective in the environment that you want to apply it in"	Evidence, context, solution	
"getting to a functional prototype can be a challenge"	Process, evidence, solution	
"you need to have a prototype that actually uses [the proof of principle] in a way that's helpful, then you need to prove that it's actually effective. . . to a level that you get certified"	Solution, evidence, regulation	
"very big difference whether you are developing a compound that is therapeutic or whether you're developing a device that you apply or an implant"	Solution	Type of healthtech

Key Quotes	Codes	Sub-codes
"[the process] is separated by the different levels for the different types of product to be developed."	Process, measurement of performance, solution	
"If it's software, [the process] typic ally already relatively flexible ... but when it comes to biotech, there's not much flexibility actually; either a compound works or it doesn't work"	Solution, capability	Flexibility, type of healthtech
"different domains require different types of processes, different approaches for venture building."	Solution, process	Type of healthtech
"talk to the doctors whether they need what you are making - that you should do very, very early"	People, problem, evidence	Clinical experts, unmet need
"make sure that you're actually addressing a real problem and check that with people who should be experiencing the problem"	Problem, people	Expertise
"usually start with a lot of assumptions and so some of those will get disproven by you talking to the people in the field . . . you should be prepared for that"	People, capability	Expertise, flexibility
"its also important to be critical of the feedback that you get ... sometimes it's a device or a development that will prevent certain mistakes or errors - and then the arrogant doctor says, well, I don't make mistakes so it is not necessary and then still people are dying because mistakes are made."	People, evidence	Perspective
"when you go into certification, you get into different type of expertise that you want to include"	Regulation, people	Expertise
"startups . . . . they may outsource that support and expertise . . . because of their scale - the amount of time they spent on a specific subject is usually not enough to warrant a full time employee doing that"	Process, capability, network	Support, expertise, time
"support structure like NLC is very helpful for . . . the timelines . . . or if money runs out or if you read a hit a roadblock that you don't immediately know how to handle ... [NLC] knows how and who to go to for specific support requests"	Network, financing, process	Support, expertise, time
"angel investors do see healthtech as a higher risk proposition ... it helps if they can connect to a portfolio instead of a single venture because that reduces the risk a little bit"	Financing, risk, people	Angel investors
"[healthtech has] longer timelines and it also means usually also higher investment amounts also means that it's not only riskier, it's also a bigger scale."	Financing, process, risk	Time
"the TRL levels, which is a proxy for the stage of a venture ... each of those represent a technical or a clinical risk being mitigated."	Measurement of performance, risk	Technology readiness level

Key Quotes	Codes	Sub-codes
"But the TR levels show the end points and each of those represent what we've called a value inflection point - as soon as you have the next hurdle conquered your value increases because you have mitigated a certain risk and lower risk means higher value."	Measurement of performance, value, risk	
"The progress you can identify within a venture is tied to the steps you need to go through to get to a product that's certified and you can sell"	Measurement of performance, process	
"the timescales are not linear between the TRL levels. Sometimes the next step is very close and then it takes a very long time to get through, through the clinical trials"	Measurement of performance, process, regulation	Time, clinical trials
"at any point you may drop a few TRL levels. . . that's a bit jarring because it does look like your progress goes in reverse but its actually not true . . . you have just proven that one route is not viable, so you need to change roots ... ideally you are in the right one immediately, but sometimes you need to pivot for the best	Measurement of performance, capability	Pivot
Participant C		
"there is often a lack of understanding of the clinical problem to a real granular level . . . often, clarifying those assumptions realises that actually this problem isn't an actual problem for the workers in health care . . . sometimes we'll know it might be a problem but actually we've already solved it by using a different pathway"	Problem, evidence, people, context	Hospital workflows
"the other big problem is lack of engagement with whoever you're selling it to from the start to understand what they would want from a new product . . . engaging with [nurses and doctors] early rather than coming with them to sell because they don't like the sales out of nowhere"	People, process, solution, social aspect	Expertise, autonomy
"lack of engagement of health care professionals earlier on in the design project . . . you need the buy-in and you need it early"	People, process, evidence	Buy-in
"the language difference between the health people and the business people. . . if it becomes too commercial, too sales to these people, they don't want to know . . . you need to explain [the busienss plan] to them [health stakeholder] without actually overwhelming them with jargon"	Social aspect	Language and jargon
"the psychology of the cycle of change ... if you start questioning how people do a process then that will set a seed for the user challenging the status quo"	People, social aspect	Psychology of change, user
"a lot of the time we [health workers] do things on complete and utter autopilot because that's just the way we have to do it."	People, context	Perspective

Key Quotes	Codes	Sub-codes
"asking someone to shift, that's not something that's going to happen overnight. They have to understand what's your drivers, what's your values for getting involved in this space, how are you going about doing it in a safe manner that they can be confident to use it? What is the value added or the impact?"	People, value	Psychology of change, trust
"[unintentional applications of healthtech] might happen less nowadays because there's so much regulation around its licensed uses"	Regulation	
"understanding the value add . . . what does good look like? And where do you add value? And then how can you measure that value? And that's something again that has to be thought about very earlier on with the users"	Measurement	Value
"quite difficult when you don't have a lot of data, it's very hard to then work out your QALY, which is the quality of adjusted living years and obviously you need a longer time frame of data."	Measurement	Value
"it's seeing where you're adding your value and then how you measure that value . . . needs to be something around reduction"	Measurement	Value
"the budget is already allocated [in hospitals] . . . so saving money isn't as good as a reduction from a new pathway that will reduce certain things. The other thing as well with value, it's always good to see how hospitals or whoever is your potential buy sees value."	Measurement, people, context	Hospital workflows, value
"the buyer . . . let's say it's hospitals, how do they measure value? What are they monitoring? What do they get fined on? If you can align your value-adds to what their objectives are, well, then you're doing the work for them . . . think about who your buyer is and then try and show the value based on their KPIs"	Measurement, people, context, prganistion	Hospital workflows, value
" I think you'll need somebody on your side [to help in acceptance] . . . if you have an advocate for you in, [for example] the hematology ward or the Oncology Ward, who's kind of pushing from the inside"	People, social aspect	Trust, clinical stakeholders
"it's a lot more common that there is clear access points into primary care or hospitals to trial things . . . But it's a lot easier if you have somebody on the inside who can push on both sides so you're not just nobody, it's the network"	Network, people, social aspect, evidence	Trust, clinical stakeholders, clincal validation
"you need a lot of public funding government grants and you have to maximize that out to the very end . . . that kind of undiluted funding is so important . . . the more financing from grants will make it easier for when they do approach the investors . . . if you give away equity too early it's seen as like risk taking"	Financing, risk, social aspect	Government grants, image, risk-adverseness
"I think early on it's about getting your grant funding in or putting in your own funding as well, but not diluting or giving away equity . . . because it shows a lack of understanding of the financial modeling"	Financing	Expertise

Key Quotes	Codes	Sub-codes
"The problem-solution fit . . . what the problem is right now, and what's the gold standard now? Where is the weakness now? Where the gap lies and this is where it can be improved."	Problem, solution, context	Problem-solution fit
"The problem needs to be clearer. I think people underestimate that . . . they don't have the network or the users involved soon enough to really be confident that that is the issue."	Problem, people, network	Expertise, users
Participant D		
"you have to follow the money in the hospitals. If you want to sell something, you have to follow the money."	Funding, context	Organisation
"You have to make sure that there's a valid business case, which means your product has to earn money for the hospital."	Solution , value	Value
"That's the whole kind of contradiction. Although you want to keep patients healthy.. but that's not where A hospital is paid for, a hospital is paid for the number of procedures."	Value	
"hospital's purpose should be to keep the patient healthy, but instead it's to treat the patient. So you actually see that a lot of treatments they are totally unnecessary and prevention like this that is often not paid for."	Value, Financing	Value
This was my other business - a bed pan system. So it started with the business case check - this is a good business case. Then it starts with having, other benefits for infection control. And nurses were very happy with it because a pan washer takes about an hour, now, I think it was 15 minutes. And the maintenance was better, the nurses like the system, the money, infection control.	Value, people	Value
"So if you have that combination of benefits and a replacement product. . . . they could easily install this system. . . But if it's a totally new product, you have to probably find a new problem."	Measurement, solution, problem	Value
"However, we had to convince infection control of the Netherlands, we had to convince the waste water companies . . . these are very bureaucratic people. "	People,	Value
"the implementation of these systems is also crucial. . . you have to make it nurse proof. . . [do]a very extensive training"	Process, people	
"in healthcare systems you have the decision making unit (DMU). . . have users.., typically the nurses,.., the champion for our products could be like a nurse manager who was really fed up with these dirty back pans. . . or infection control who were very enthusiastic. . . or also the maintenance staff, like facility management. . . you could also have like detractors - people who suddenly said no."	People, value, context	User, decision making structure, adoptors, champion
"And you had to get all these stakeholders in the hospital aligned. You have to start bottom up.. and also top down,. . . [because that's] how a hospital is organized."	Network	organisation

Key Quotes	Codes	Sub-codes
"[the CEOS] are not that powerful leaders, they have the doctors - they're more decisive most of the times than the CEO."	People	
"you have to understand the dynamics of how a hospital works as well and how you experience that"	Context	Organisation, network dynamics
" a surgeon isn't a project manager"	People	
"for implementation it's 12 to 18 months and it could also be at academic hospitals 18 to 36 months. Its long ... and very uncertain because you don't get paid for it."	Process, financing	
"So these are actually the difficulties with hospitals - it's very unclear how the money streams, how they're running, managing like the whole beast of hospital and a big challenge is the bureaucracy."	Financing, people, context	Organisation
"if you go to reimbursement, it's even a lengthier process. If you want ... a product which is then reimbursed - for example, a patient product which is reimbursed by the insurance company - that can be like a four or five year process."	Financing, people, solution	
"it's hardly possible nowadays to start up a medical technology company without funding because you have that very long startup cycle, you have these very lengthy change cycles."	Process, financing	Time
"I think it even got more difficult because we actually now the innovation funds in hospitals there after COVID - they're fully dried up"	Financing	
"these hospitals ...what they buy is an outcome".	People, value	
"the whole implementation and change management because that's what necessary they have to alter their way of working, that is crucial in the hospital."	Process, context, social aspect	Organisation, Psychology of change
"we would already form an expert group within the hospital before the system went live .. and then also help them on a monthly basis"	People, process	
"it's a constant change management process ... you become [the hospital staffs'] partner ... you have to work with these people and make sure that they implement it in a proper way, get their feedback."	Process, people, social aspect	Organisation, Psychology of change
"And if you don't understand like one aspect of it, the how to navigate through hospital, how to follow the money, how to actually make sure that you implement the product correctly and that people are love to work with it, then these are the pivotal points"	Financing, process, people	
"you have some measuring moments .. how many sales qualified leads"	Measurement of performance	
"what you can measure is their interest; did we take it to the next level?, are there now multiple people involved?, do we have the whole DMU involved?, and did this DMU actually apply for budget?"	Measurement of performance, people	

Key Quotes	Codes	Sub-codes
"For example, one of the companies we invested in is UV Smart, and they have this UV device where they could disinfect medical devices.. like a patient monitor which they use in the ICU... but we started talking to doctors and in the end ... with our disinfection tool, we didn't find a disinfection solution, we found a logistical solution."	People, solution, process, pivot	
"obviously sometimes you don't know at all [the parameters] but then you make assumptions or you get an expert opinion .. and just work through this model with the customer."	Measurement of performance, people, process	
"And we started selling first to nursery homes because this was an easier sell because the DMU is easier, more compact... and only later we started to sell to hospitals.	People, process, financing	
"the Dutch market is pretty saturated because in the Netherlands, there are 80 hospitals, I think 20 to 30 are almost bankrupt. So they don't have any money or innovation power"	People, financing, context	Market
"be aware that other countries can be a totally different market."	Context	Market
"For example; we tried to import this product - a gauze counter which was a huge success in the US, ... but when we tried to sell it in the Netherlands, and we failed. In the US is that the whole process is less efficient and less well organized - so actually the problem here in the Netherlands is much lower."	Solution, organisation, context	
"money streams and this business model can even vary per country."	Financing, context	
So just going to another country, for example Germany, there are totally different markets from an IT perspective. [The German IT systems are] very outdated - actually their EMRS, their electronic medical records, they are like 20 years behind, most of the hospitals are still doing writing things on paper."	Context, solution	Market
"it's dependent on the current state of the technology, and dependent on the current state of the business model ... the context can be just so different."	Solution, context, value	Market
" with very lengthy sell cycles, it was still a very a tough product to sell ... so we partnered with Stryker in the US ... now we have 100s of sales people that are running with this product ... and have access to 2000 hospitals [in the US] that are suitable for this product. That's a lot larger market than the Netherlands."	Process, solution, people, context	Market
"E-health is very difficult because patients don't want to pay for apps and, even if you have them pay for it, ... it will be very difficult to keep your company running [on the profit you make from apps]"	Solution, people, financing	

Key Quotes	Codes	Sub-codes
"Germany is the largest market with 80 million people, but they are so outdated, so they're so far behind. The countries that are very digitized are typically the Nordics, Scandinavia and the Netherlands and maybe Switzerland and these are quite advanced countries. The UK is totally down the NHS - It's terrible."	context, people, solution	Market
"So the large markets and they're such huge systems between the UK and Germany, for example - so that just makes it very hard to scale up."	context, process	Market
" I would say get your proof of concept here in the Netherlands and then go to the US as soon as possible because it's a huge and highly digitized market."	Value, context, process	
"biotech and Pharma; these are even lengthier processes because you have to do your clinical trials and you have to be successful."	Solution, process, regulation	
"So typically a biotech company, I think the investment for these companies will be like 100 million, and they often go to the stock market because they need these large amounts of money."	Solution, financing	
"I think medical technology and e-health, they're shorter processes ... typically between five and 10 years but, and biotech will be like 10 years plus."	Solution, process	
"it was hardly possible to actually prove that [better hygiene] was caused by [our product] and not some other parameters"	Process, measurement of performance	
"we actually rejected 90 percent of [the healthtech ideas] because of they were only focused on a better, safer and happier patient .. but you have to earn money to have a sustainable business and you don't earn money with happy safer patients"	People, value, financing	
"its also challenging that the patient is not the payer ... the hospital is paying in the end and the hospital actually benefits from more treatments."	Financing, people	
Participant E		
"My [original] team did not see a startup for themselves, so ever since my team dissolved... I've been the only one moving forward ... I have been wearing multiple hats at the same time|	People, capability	Team
"But I'm trying to recruit co-founders and team members... i do not think that you can go by yourself alone."	People, process, capability	Team
"It's the chicken of the egg ... I had a one big challenge of funding issue, but then they really were ready to invest and then fund in my startup and the idea etcetera. But then the other problem was that the team ... I was the sole founder, so that's a risk for investors."	Financing, people	

Key Quotes	Codes	Sub-codes
"I need to get the team so then I can have the funding; but then for the team ... since I didn't have funding, so that means they cannot get salaries ... I was for one year stuck in this cycle."	People, financing	Team
"I would get a really nice cofounder candidate, but then they were not comfortable because there's no funding coming in place for salary. And then the other aspect was that people who wanted to invest in you [were dissuades because] a sole founder. So this was a major challenge for me - where I was stuck in the cycle."	People, financing	Team
"the startup with the very first two years it was funded by myself in the sense that I was bootstrapping from my own income. And then later, I also raised funds by myself as well through a small preceded round."	Financing	
"I was then applying for this one particular funding which I got in the end ... that was for me the the pivotal"	Financing	
"There was also managing everything ... I couldn't move forward with the development of the product itself, because the business was what I was focusing on, but luckily now with this funding, at least the product has continuing to be developed."	Capability, process	
"I've been trying to develop a market ready product that can be used for a large scale user testing. The idea is to get as much feedback from this large scale user testing of this product and then hopefully actually launch the product next year ... the user testing and the feedback gives us a feeling of how the market gauges or feels about [the product]."	Process, evidence, solution, people	User
"some of the challenges or the risks that come with [trying to find co-founders] is that of course you're exposing your technology"	Regulation, people, social aspect	Intellectual property, trust
"people who come in with that mindset are mostly in the mindset of the glitz and glamour that the startup comes up with, but the glitz and glamour is like 1% of it and 99% of it you are really struggling through the modern, the toil and etcetera. Not many people understand that seriousness of it."	People, capability	Perspective
"the other risk of [sourcing co-founders] is that some certain candidates already come with this mindset of a really high equity share ... bit its a risk on my part to just give you that equity share without seeing how [they] work or function.	Risk, people, financing	
"But this is usually the gamble that you have when you're doing this cofounder recruitment either you get candidates who kind of know how the startup game works, or you get candidates who are just like in for the idea, etcetera and don't really know how the startup game works and that takes them a lot of time to really understand."	People	Expertise
"I am quite flexible because I this is still a learning process in the sense you still take the feedback that you get as much as you can"	Capability, process	Flexibility

Key Quotes	Codes	Sub-codes
"But of course, I think like any, any other founders or maybe any other entrepreneurs, you must have also heard of it. There are certain things you do not agree upon because for the fact that this person just saw you for the first time and they cannot really judge the whole process. You yourself, I know how the process goes. "	People, capability, social aspects	Team, expertise, trust
"So sometimes I think what what a founder needs to do is then really try to see which feedback is actually relevant and which is not relevant because the person giving the feedback is coming from a place of not full knowledge"	People	Expertise, perspective
"when co-founders come into play, they of course want to implement changes and that is what you want as a founder ... But what I disagree with is if [a co-founder] wants to shift the core focus of the product"	People, process, solution, social aspect	Autonomy
"[if] you resonate with my startup's core focus, .. and the purpose ... and then you want to improve [it], then this is the startup for you."	People, social aspect	Trust
"I haven't had the chance to pivot yet .. but there are strategies in place that, if that doesn't work, then we have to pivot."	Capability	Pivot
"for me, pivot is in terms of processes. Because I'm doing multiple hats at the same time [my priorities] have to be always moving around."	Capability	Pivot
"So far I have changed [the process] twice- and that's based on opportunities. I got the funding – now funding is done. So then I had to runaway to focus really on the product and then simultaneously in focusing on the team. "	Capability, process, financing, solution	Pivot
"I'm just moving around within my own business like in the sense of what comes first or comes second etcetera. it's really based on strategy and opportunities and timing of it."	Process, capability	
"I haven't had the chance to be really on a serious level of regulatory barriers, but there was a moment that we were supposed to be pilot testing at a hospital and that gave us a glimpse of how the paperwork works ... and the bureaucracy of it."	Regulation, network, context	Organisation, network dynamics
"The product and the paperwork that's associated with it ... risk analysis ... designing something safe ... that's the first regulatory step. But then when going seriously into the into a hospital setting, that's a very different approach and then you really need to be specific, you really need to go into the details ... so that sort of made it a bit of a challenge"	Regulation, risk	
"The whole bureaucracy [of the medical certification process] was taking quite a bit of time that nearly costing me again like 6 to 8 months almost ...And that I decided I'm not going through this sort of trajectory"	Regulation	Organisation, network dynamics, time

Key Quotes	Codes	Sub-codes
"I haven't gone through that strict regulatory process but like at least from the the components of the subsystems that we were using we're making sure it's C marked etcetera and a minimal level of quality assurance in place"	Regulation, solution	
"I actually thought it would be a challenge to convince stakeholders, but ... it really depends from topic to topic and product to product."	Solution, people	
"it was easily accepted ... the idea itself, because the doctor saw the relevance of the problem that the parents face."	People, evidence	Adopters
"It was good to know that I have that assurance from medical experts and medical stakeholders that they see [my solution] as something that can really help parents ... and that this problem still exists. This problem still needs to be addressed and there needs to be a good solution, so that's why it seems very nicely accepted by medical experts.	People, solution, problem	Expertise
"we took part in plenty of awards and competitions the first two years when we were a startup. Somebody gave our contact to this group of medical experts that work with babies. And then they decided to reach out to us."	Network	Support
" I don't think I would have been a company ... the very beginning it was a project that we were showcasing ... but then when you go [to the awards and competitions] and get validation ... then we saw that there seems to be potential coming out of this ... the jury panel to get the feedback from experts and all of it kind of made it a bit more tangible"	Network	Support, expertise, time

Table 12: Appendix table of the key-quotes from the interviews, their codes, and sub-codes

C.3 Theme analysis

Figure 8: Tree of codes and their sub-codes from first and second stage of coding

Theme	Participant A: Health startup expert	Participant B: corporate founder	Participant C: clinical expert	Participant D: financial expert	Participant E: academic founder	**Total number appearances**
People	✓	✓	✓	✓	✓	74
Development process	✓	✓	✓	✓	✓	50
Solution	✓	✓	✓	✓	✓	36
Financing	✓	✓	✓	✓	✓	31
System context	✓	✗	✓	✓	✓	23
Capabilities	✓	✓	✗	✓	✓	21
Evidence	✓	✓	✓	✓	✓	16
Stakeholder value	✓	✓	✓	✓	✗	16
Social aspects	✓	✓	✓	✓	✓	15
Regulation	✓	✓	✓	✓	✓	13
Network	✓	✓	✓	✓	✓	11
Risk	✓	✓	✓	✓	✓	11
Levels of development	✓	✓	✗	✓	✓	10
Market	✓	✗	✗	✓	✓	9

Table 13: The themes that inductively emerged from the interviews with each participant in Chapter 4

D Appendix : Data Management Plan

Saskia's Data Management Plan

0. Administrative questions

1. Name of data management support staff consulted during the preparation of this plan.

N/A

2. Date of consultation with support staff.

2023-06-15

I. Data description and collection or re-use of existing data

3. Provide a general description of the type of data you will be working with, including any re-used data:

Type of data	File format(s)	How will data be collected (for re-used data: source and terms of use)?	Purpose of processing	Storage location	Who will have access to the data
Non-anonymised expert opinions and feedback to a standard set of questions	Transcribed interviews in appendix of thesis	Video interview	To get insights on the development process of healthtech startups and its challenges	Personal computer, thesis submission portal and storage	Thesis supervisors and TU Delft
Job function, experience	Description of participants in thesis		To define the perspective of the participant on the development process	Personal computer, thesis submission portal and storage	Thesis supervisors and TU Delft

4. How much data storage will you require during the project lifetime?

- < 250 GB

II. Documentation and data quality

5. What documentation will accompany data?

- Methodology of data collection

III. Storage and backup during research process

6. Where will the data (and code, if applicable) be stored and backed-up during the project lifetime?

- OneDrive

IV. Legal and ethical requirements, codes of conduct

7. Does your research involve human subjects or 3rd party datasets collected from human participants?

- Yes

8A. Will you work with personal data? (information about an identified or identifiable natural person)

If you are not sure which option to select, first ask your Faculty Data Steward for advice. You can also check with the privacy website . If you would like to contact the privacy team: privacy-tud@tudelft.nl, please bring your DMP.

- Yes

Name and job function will be available only to the researcher but when the thesis is submitted, this will be anonymous.

8B. Will you work with any other types of confidential or classified data or code as listed below? (tick all that apply)

If you are not sure which option to select, ask your Faculty Data Steward for advice.

- No, I will not work with any confidential or classified data/code

9. How will ownership of the data and intellectual property rights to the data be managed?

For projects involving commercially-sensitive research or research involving third parties, seek advice of your Faculty Contract Manager when answering this question. If this is not the case, you can use the example below.

The researcher (me) will keep ownership over non-anonymised data. All shared versions of the interviews are anonymised.

10. Which personal data will you process? Tick all that apply

- Signed consent forms
- Names and addresses

11. Please list the categories of data subjects

Employees

12. Will you be sharing personal data with individuals/organisations outside of the EEA (European Economic Area)?

- No

15. What is the legal ground for personal data processing?

- Informed consent

16. Please describe the informed consent procedure you will follow:

Prior to the interviews, I shared a summary if the objective of the research alongside a consent form which asked for permission to record, transcribe and use quotes from the interviews in the research.

17. Where will you store the signed consent forms?

- Same storage solutions as explained in question 6

18. Does the processing of the personal data result in a high risk to the data subjects?

If the processing of the personal data results in a high risk to the data subjects, it is required to perform a Data Protection Impact Assessment (DPIA). In order to determine if there is a high risk for the data subjects, please check if any of the options below that are applicable to the processing of the personal data during your research (check all that apply).
If two or more of the options listed below apply, you will have to complete the DPIA. Please get in touch with the privacy team: privacy-tud@tudelft.nl to receive support with DPIA.
If only one of the options listed below applies, your project might need a DPIA. Please get in touch with the privacy team: privacy-tud@tudelft.nl to get advice as to whether DPIA is necessary.
If you have any additional comments, please add them in the box below.

- None of the above applies

22. What will happen with personal research data after the end of the research project?

- Anonymised or aggregated data will be shared with others

The data will only be shared in the form of anonymous transcripts and quotes within the thesis document. Any personal data eg., video recordings are deleted immediatly after transcribing the interviews

25. Will your study participants be asked for their consent for data sharing?

- Yes, in consent form - please explain below what you will do with data from participants who did not consent to data sharing

I will blank out/hide the data if the participant did not provide consent for it to be shared. In these cases, I will only include my own deduction from that data but none of the transcripts or details about the participant.

V. Data sharing and long-term preservation

27. Apart from personal data mentioned in question 22, will any other data be publicly shared?

- I do not work with any data other than personal data

29. How will you share research data (and code), including the one mentioned in question 22?

- My data will be shared in a different way - please explain below

- I will upload the data to another data repository (please provide details below)

I will not share any data to a data repository with public access. Only the submission portal to submit my final research to my own research supervisers and other employees of TU Delft.

30. How much of your data will be shared in a research data repository?

- < 100 GB

31. When will the data (or code) be shared?

- Other - please explain
- At the end of the research project

The data will only be shared in the form of anonymous transcripts and quotes within the thesis document. Any other personal data collected (eg. video recordings) are deleted immediately after transcription.

32. Under what licence will be the data/code released?

- Other - Please explain

I don't require a license for interviews

VI. Data management responsibilities and resources

33. Is TU Delft the lead institution for this project?

- Yes, the only institution involved

34. If you leave TU Delft (or are unavailable), who is going to be responsible for the data resulting from this project?

My supervisor: Pieter vandekerckhove:
p.b.m.vandekerckhove@tudelft.nl

35. What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?

No resources required