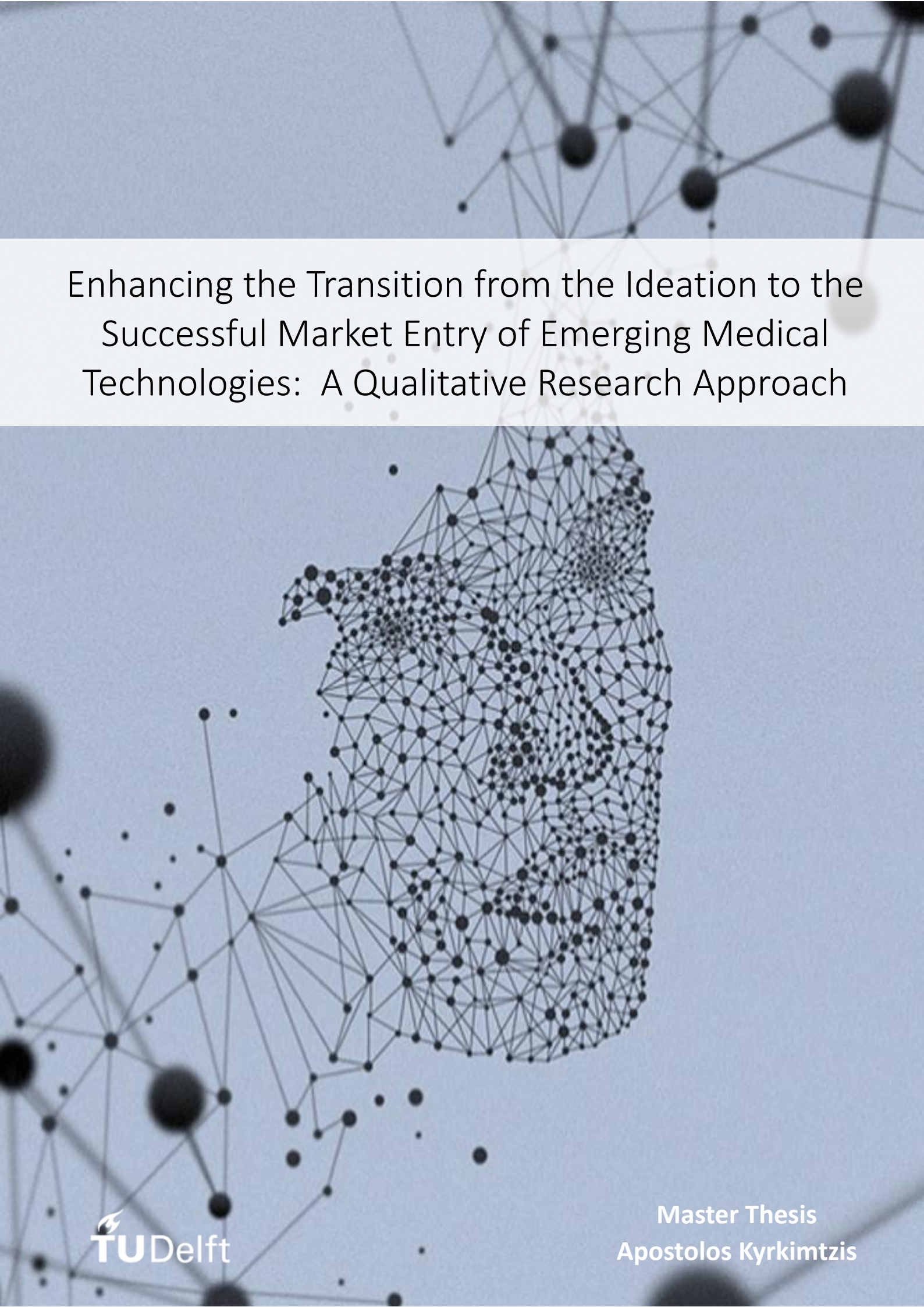
Enhancing the Transition from the Ideation to the Successful Market Entry of Emerging Medical Technologies: A Qualitative Research Approach



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Master Thesis
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Enhancing the Transition from the Ideation to the Successful Market Entry of Emerging Medical Technologies: A Qualitative Research Approach

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

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”Without change there is no innovation, creativity, or incentive for improvement. Those who initiate change will have a better opportunity to manage the change that is inevitable.”

- William G. Pollard

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Executive Summary

Background: In recent years, healthcare has witnessed rapid advancements, driven by innovative technologies and breakthrough discoveries. The post-pandemic era, coupled with the integration of emerging medical technologies such as virtual reality, artificial intelligence, blockchain, Internet of Things (IoT), and Big data, has significantly contributed to the exponential growth of the MedTech industry. Medical technologies play a pivotal role in transforming the current healthcare landscape by addressing the inherent problems that impact the sustainability of the health system. However, navigating the MedTech commercialization pathway poses significant challenges. Despite the increasing efforts and R&D investments, a large amount of emerging medical technologies fail to enter the market successfully. Scientific researchers have pointed out the methods and enablers to navigate the MedTech commercialization pathway, but these methods come with inherent limitations which can hinder innovators to go through a seamless process. Currently, there is a lack of understanding of the dynamics which can influence and enhance the transition from a good idea to the successful market entry of emerging medical technologies. A holistic strategic roadmap to guide innovators through this transition is missing.

Purpose: This study aims to enhance the current understanding of the MedTech commercialization process and make a valuable contribution to the existing knowledge base. It seeks to explore and analyze the dynamics involved in transitioning from the ideation phase to the successful market entrance of emerging medical technologies. Ultimately, the scientific research objective of this study is to develop a strategic roadmap that captures these dynamics and provides a better understanding and guidance toward crossing this multifaceted commercialization pathway for innovators.

Methods: To achieve the objectives of this thesis, a qualitative research approach was employed, utilizing semi-structured interviews as the primary method for data collection. 8 interviews were conducted, with participants representing different stakeholders along the value chain of the MedTech ecosystem. This methodological choice allowed for an in-depth exploration of the experiences, and insights from multidisciplinary and, in a way, complementary angles. The sample was selected utilizing the convenience sampling method. The research validity was enriched through the saturation method, by asking already discussed questions in a different manner to identify potential inconsistencies between their initial answers and reach a point where new knowledge and insights are not generated. Thematic analysis was employed as the primary method for data analysis. This involved a systematic process of coding and categorizing the data to identify relevant themes, and sub-themes within the dataset. The themes and sub-themes emerged employing a mixed approach, both utilizing deductive and inductive reasoning.

Results: 6 dimensions have been identified to capture the dynamics in transitioning the MedTech commercialization process. There have been identified 6 dimensions that entrepreneurs should elaborate on to assess, develop and deliver their products successfully, or respectively abort their idea early before high investments are done. The organizational strategy of the company plays a critical role in transitioning from the idea toward market entry. A strong startup team consisting of business leaders, medical experts, and developers can efficiently materialize the innovation into a problem-solving product while enhancing its credibility towards investors, care providers, and strategic partners. The design strategy of the startup needs to be carefully determined since it can shape the long-run trajectory of the medical technology. Next to involving patients and physicians to define technical characteristics and adjust the medical technology to their needs and workflows, entrepreneurs need to strategically decide upon the development trajectory. In-house development can enhance control, safety, and IP establishment, while an open innovation approach and strategic partnerships with companies who have the technical know-how can accelerate development, reduce the risk and cost, lead to knowledge spillovers, and finally, depending on the credibility (e.g., reputation, network, partners, legitimacy, track record, etc.) of that partner, facilitate market entry. Another critical dimension is the business strategy of the startups where a thorough understanding of the value chain of the health ecosystem is crucial and demon-

strating the cost-effectiveness of the technology early. Through early stakeholder engagement, entrepreneurs can align their value propositions and pricing strategy to the financial and societal incentives of these enabling players. Engagement with insurance companies and reimbursement bodies can provide valuable insights about the market startups should pursue considering the risk aversion of customers and care providers. Intellectual property (IP) should be strategically established to enable additional revenue streams in the long run. In terms of commercial strategy, startups need to decide upon the pathway they want to follow; either pursue the regular mass market or strive for the professional care pathway. These two trajectories are not mutually exclusive, but potentially complementary. Besides having a good product, entrepreneurs should invest efforts in reaching the necessary customer channels and develop a thorough marketing strategy to make an impact with their medical innovation. Finally, early consideration of the post-commercialization strategy of the company and especially adopting a flexible business orientation for future opportunities is a key success factor toward long-term success.

Conclusion: The dynamics in transitioning from the ideation phase to the successful market entry of emerging medical technologies lie in the ability of entrepreneurs to build the business foundation proactively, considering six dimensions: organizational, design, business, commercial, marketing, and post-commercialization. Successful MedTech commercialization demands a robust organizational strategy, uniting experts to forge a credible, investor-attracting team and product. Thoughtful design strategies, shaped by patient and physician input, dictate technology's trajectory—choosing between in-house control and partnered acceleration. Understanding the health ecosystem's value chain and demonstrating the cost-effectiveness through early HTA can build a dynamic business strategy, aligned with stakeholders' financial and long-term incentives. Intellectual property safeguards pave the way for sustained revenue streams. Commercial success lies upon a dual trajectory approach- mass market and professional care pathway-, backed by potent marketing. Beyond launch, flexibility and proper surveillance cement long-term success. A strategic roadmap has been developed, which can more effectively describe these dynamics in transitioning from the ideation phase to the successful market entrance of emerging medical technologies. This roadmap is meant to facilitate and lead the way on how this transition should be approached, rather than accelerate it. This study contributes to the overall understanding of the dynamics of the MedTech commercialization pathway and highlights the key steps and decisions that entrepreneurs need to overtake to successfully materialize and bring their medical innovations into the market.

Abbreviations

Abbreviation	Definition
AI	Artificial Intelligence
AR	Augmented Reality
AYA	Adolescents and Young Adults
BMC	Business Model Canvas
CE	Conformité Européene
EPM	Entrepreneurial Process Model
GDPR	General Data Protection Regulation
GP	General Practitioners
GUI	Graphical User Interface
HI-NL	Health Innovation Netherlands
HTA	Health Technology Assessment
IoT	Internet of Things
IP	Intellectual Property
MedTech	Medical Technology
ML	Machine Learning
MoT	Management of Technology
PESTLE	Political, Economic, Sociological, Technological, Legal, and Environmental
PICO	Patient Population, Intervention, Comparator, and Outcomes
QMS	Quality Management System
QoL	Quality of Life
R&D	Research and Development
RQ	Research Question
RTL	Readiness Level of Technology
SMEs	Small and Medium-sized Enterprises
TTO	Technology Transfer Office
VR	Virtual Reality
3D	Three Dimensional

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1 Introduction

1.1. Background

The healthcare industry, characterized by its complex nature and stringent regulatory framework, necessitates significant investments and efforts in R&D to deliver impactful, cost-effective, and scalable care solutions (Jiu et al., 2022). The healthcare industry is facing several challenges that threaten its sustainability, including the aging population, personnel shortages, and the increasing costs of care delivery (Kulkov et al., 2023, Janssen and Moors, 2013). With the increasing size of R&D expenditure (Yeganeh, 2019), the health system is under increasing pressure to justify the investments in and adoption of new health technologies (IJzerman et al., 2017). The Iron Triangle of Healthcare represents the interdependence among quality, cost, and healthcare access, which are critical components that influence the overall sustainability of the healthcare industry (Collins et al., 2016, Immerwahr et al., 2008). The healthcare industry requires innovative technological solutions to overcome its sustainability challenges (Friebe, 2020, Janssen and Moors, 2013). Medical technologies play a pivotal role in driving the constant progress of healthcare by introducing innovative solutions that challenge conventional approaches and reshape the delivery of treatments (Haleem et al., 2022). The definition of a medical device according to the Global Harmonization Task Forces is "*an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means*" (Asanuma, 2012).

Over the past few decades, the MedTech industry has witnessed remarkable advancements driven by rapid technological progress (Statista, 2021, Durrani, 2016). The COVID-19 pandemic has caused significant shifts in societal dynamics and has redefined the potential avenues for global healthcare entrepreneurial scope (Mishra and Pandey, 2023). The pandemic has not only accelerated the adoption of digital technologies but has also emphasized the need for innovative solutions addressing public health crises and promoting resilience in healthcare systems, paving the way for a new era of healthcare entrepreneurship (Umair et al., 2021). Scholars are referring to the integration of emerging medical technologies (e.g., Virtual Reality, Artificial Intelligence, Blockchain, Sensors, Big Data, etc.) as enablers toward the Next Generation of Healthcare systems (Friebe, 2020). In such a new healthcare landscape, novel interventions will be more patient-centered and will create new opportunities for prevention, early detection, monitoring, and pro-active treatment, leading to substantial transformations in the way we encounter, perceive, and provide healthcare (Wehde, 2019, Friebe, 2020). Technology entrepreneurship in healthcare involves the creation, growth, and scaling of businesses that utilize innovative technologies to develop valuable products, services, and business models, benefiting patients, healthcare providers, and other stakeholders (Kulkov et al., 2023).

Despite the strong motivation of entrepreneurs to create and deliver novel medical solutions, commercializing new medical technologies into the healthcare industry is a challenging endeavor (Sebastianski et al., 2015),

which entails navigating a complex and multifaceted landscape. In this landscape, startups need to be able to go through different phases. IJzerman and Steuten (2011)) describe how the product is being developed associated with three key stages of health technology assessment (HTA) (see Figure 1.1). The medical technology lifecycle initiates with basic research on the main principles of the technology (IJzerman and Steuten, 2011). Entrepreneurs at that stage adopt a human-centered approach to identify existing healthcare problems and needs, and develop problem-solving ideas that could efficiently satisfy these needs (Boni and Abremski, 2022). This stage is described as very early HTA, and is characterized by huge uncertainty about the market size, the effectiveness of the technology, the health impact as well as the steps and prospects for market entry. During the translational research entrepreneurs aim to develop a proof of principle of their technology and develop their working prototype. This stage falls within the early HTA scope where certain technological and business decisions about the technology have been made despite the lasting uncertainty, and the innovators should be in a position to make rational assumptions about the trajectory of the technology. After this prototype is developed, clinical research and trials are undergone to ensure that the technology is effective and safe. After the clinical trials are successfully completed, entrepreneurs apply for regulatory approval and receive the necessary Conformité Européene (CE) mark. Finally, entrepreneurs develop their business model to enter the market and scale up their innovative technologies (IJzerman and Steuten, 2011). This process is characterized as the mainstream HTA where a proven concept is being developed, the early cost-effectiveness assumptions can be validated or rejected with evidence and the value proposition of the technology can be adjusted upon the interests of stakeholders along the value chain.

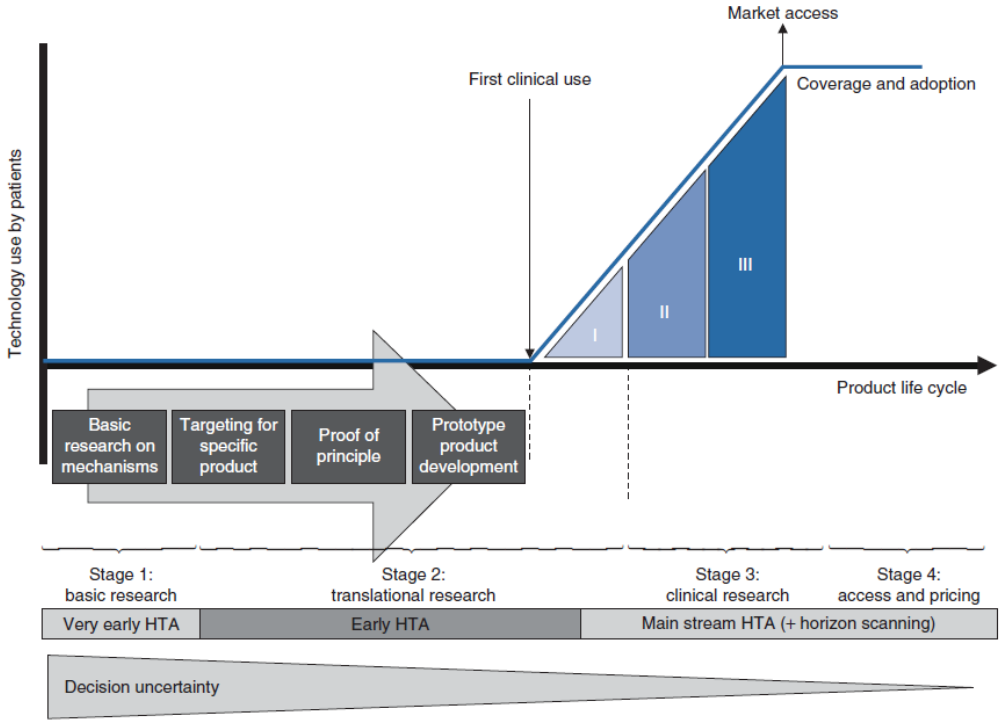


Figure 1.1: MedTech Commercialization Pathway (IJzerman and Steuten, 2011)

Healthcare entrepreneurs and innovators strive to commercialize health-related technological innovations that enhance general health and societal outcomes, while proving to be cost-effective within the healthcare ecosystem (Peiffer et al., 2019). However, the capital and effort invested are disproportionate to the number of technologies that finally reach market entry according to Chaudoir et al. (2013) and Beaulieu and Lehoux (2018). A similar disparity is found in the cumulative improvement in health care quality delivered (Peiffer et al., 2019) and the level of accessibility to the end-users (Scarbrough and Kyratsis, 2022). Consequently, emerging medical technologies either fail to reach the market or if market entry is partially achieved, they cannot be sustained and tend to be abandoned and inaccessible for end-users (Scarbrough and Kyratsis, 2022). Unsuccessful endeavors not only lead to a lack of economic returns for entrepreneurs and startups but also impose additional societal costs without yielding substantial improvements in healthcare (Lim et al., 2009 and

Vallejo-Torres et al., 2008). The commercialization of medical technologies plays a crucial role in bridging the gap between scientific discoveries and their practical application in healthcare settings. As the field of medical technology continues to rapidly advance, understanding and optimizing the process of commercializing these innovations becomes paramount (Lehoux, Miller, et al., 2017).

1.2. Research Gaps

By reviewing the state-of-the-art in the current literature, it was possible to identify key knowledge gaps that still need to be filled regarding the MedTech commercialization pathway and its challenges.

1) ***There is a lack of understanding regarding the dynamics which can enhance the transition from the ideation to MedTech commercialization.***

Numerous researchers have delved into the multifaceted aspects of MedTech commercialization, considering its significance in the scientific research, as well as the practical and societal implications. Scholars, by investigating multiple cases, have identified numerous obstacles and facilitators throughout the innovation to commercialization pathway that influence the translation of innovative medical technologies into solutions that have proven value for end-users and the health system (Thijssen et al., 2023, Warty et al., 2021, MacNeil et al., 2019, Chaudoir et al., 2013). As depicted in figure 1.1 there is an increasing need to perform health technology assessment during the early stage of development (IJzerman and Steuten, 2011). However, currently, HTA is used mainly to demonstrate the cost-effectiveness of the technology. HTA recognizes more attributes, but there seems to be a lack of understanding of how to incorporate them in the early assessment. Delving into this area could help scientifically and practically to understand how to close the gap between the ideation phase and the successful commercialization of emerging medical technologies, as it was described in the previous section. Thijssen et al. (2023) highlight the need for a more qualitative research approach to better understand the influence of the barriers and the enablers in crossing the MedTech commercialization pathway. Tummers et al. (2020) and Whitelaw et al. (2021) encourage interviewing diverse stakeholders involved in the MedTech ecosystem to gain an understanding of the dynamics that can hinder and enhance the innovation ideation-to-commercialization process.

2) ***A holistic strategic roadmap to guide entrepreneurs in navigating the transition from the ideation phase to the commercialization of their medical technologies is missing.***

In a rapidly advancing MedTech landscape, efficiently navigating the commercialization pathway is critical to cross the chasm between innovation ideation and market entry and ensure that the health care delivery is enhanced and stakeholders' needs and problems are satisfied (Silva et al., 2020). Various methods and frameworks were identified in the literature which can guide entrepreneurs, including the Design-Thinking, the Business Model Canvas, the Lean Startup, and other secondary frameworks, which however come with limitations which may deviate entrepreneurs from capturing the necessary knowledge to commercialize their medical technologies. Scholars have, also, explored the role of the universities and Technology Transfer Offices (TTOs) in enabling the translation of medical research into valuable marketed medical solutions (Brantnell and Baraldi, 2022, Collins et al., 2016). However, as emerging technologies such as VR, AI, Big Data, Edge Cloud, etc. become more widely adopted, medical innovations can be explored outside the university and research setting; healthcare entrepreneurship can become more decentralized. Consequently, the research scope needs to be broad, so that more elements are explored and valuable knowledge is created especially for new healthcare innovators. Considering the long, uncertain, capital-intensive R&D cycle and the accompanying strict regulatory framework, the ability of entrepreneurs to properly manage commercialization risks is critical to materialize innovations and build a successful business case for emerging medical technologies (Lehoux, Miller, et al., 2017). A rigorous and disciplined commercialization roadmap could ensure informed and guided decision-making toward the development and delivery of valuable health interventions which correspond to the health systems' needs (Silva et al., 2020).

1.3. Research Objective

Considering the pragmatic problem and the research gaps in the scientific setting, this study aims to examine, analyze and identify the potential barriers and common pitfalls that hinder the commercialization process, as well as investigate the enablers and facilitators that contribute to the successful market entry of emerging medical technologies. I seek to contribute to the existing knowledge base by enhancing the understanding of the MedTech commercialization pathway. The scientific research objective of this study is to develop a holistic strategic roadmap that effectively captures the dynamics involved in transitioning from the ideation phase to the successful market entrance of emerging medical technologies. Such a roadmap can enrich the understanding and navigation of the multifaceted commercialization pathway, while at the same time can support innovators in maximizing the potential for successfully bringing their medical technologies into the market.

1.4. Research Questions

Along with the research question, a group of sub-questions is presented with the aim of structuring the research and meeting the research objective.

1.4.1. Main Research Question

The main research question which aims to better correspond to the research objective is the following:

> ***What are the dynamics in transitioning from the ideation phase to the successful market entrance of emerging medical technologies and how can they be captured?***

1.4.2. Sub-Questions

To better answer the main research question, a set of sub-questions is identified.

SQ1*: What are the potential barriers and common pitfalls toward successful commercialization of emerging medical technologies?*

SQ2*: What are the potential enablers and facilitators toward successful commercialization of emerging medical technologies?*

SQ3*: What are the key considerations and strategies to efficiently transition from the idea to the successful commercialization of emerging medical technologies?*

1.5. Relevance to Management of Technology

This research holds significant relevance to the pillars of the Management of Technology (MOT) curriculum. Firstly, the study centers on a scientific investigation conducted within a technological context, exploring areas such as medical technology commercialization, strategy design, knowledge management, decision-making, and healthcare entrepreneurship. This aligns with the first pillar, as it demonstrates a comprehensive understanding of the diverse applications of technology within corporate healthcare environments. Secondly, the work emphasizes the recognition of technology as a corporate resource. This highlights the second pillar, which underscores the importance of perceiving technology as a strategic asset and explores its evolution, commercialization, and utilization within organizational settings. Lastly, the research employs scientific methods and techniques to analyze a specific problem, effectively integrating the third pillar of the curriculum, which emphasizes the application of rigorous scientific methodologies to address complex challenges. Extensive lit-

erature review and qualitative research with semi-structured interviews were employed to satisfy the research objective. By addressing these three pillars, this study complies with the requirements of the MoT program, equipping students with the knowledge and skills necessary to navigate the complex landscape of technology management in the corporate realm as well as the scientific domain.

2

Literature Review

The following chapter aims to explore and identify the current state-of-the-art in the commercialization of emerging medical technologies. The first section highlights the key methodologies and models that entrepreneurs follow to assess, develop and commercialize their products and reflects on the benefits, limitations, and challenges they carry. Next, HTA is discussed as well as the way it can complement the aforementioned methods in order to bridge the gap between ideation and commercialization. Also, potential healthcare commercialization barriers and accelerating factors have been highlighted. Finally, reflections on the current state-of-the-art are included, highlighting howthe key elements that could enhance the MedTech commercialization process and the existing research gaps. The following chapter aims to explore and identify the current state-of-the-art in the commercialization of emerging medical technologies. The first section highlights the key methodologies and models that entrepreneurs follow to assess, develop and commercialize their products and reflects on the benefits, limitations, and challenges they carry. Next, HTA is discussed and how it can help to bridge the gap between ideation and commercialization. Finally, analyzing the potential healthcare commercialization barriers and accelerating factors in the MedTech commercialization process the key elements that could enhance the transition from the ideation to commercialization, as well as the ways that HTA complements the aforementioned methods are elaborated.

2.1. Search Method

To conduct the literature review, the methodological approach of Darlow and Wen (2016) was used. It is a structured narrative method, suitable for a broad research scope, where the focus is primarily on qualitative interpretations of prior knowledge and there are no particular exclusion criteria except for the relevance (Paré and Kitsiou, n.d.). The research was conducted using Scopus, PubMed, National Library of Medicine, Web of Science, and Google Scholar, with no restrictions on publication date or country. Multiple terms and free text words were used in a suitable combination to collect a substantial volume of articles within a specific subject area and synthesize it. The key terms used were (commercialization, healthcare innovation, entrepreneurship, diffusion, barriers, facilitators, frameworks, roadmap, strategy, HTA AND medical technologies OR MedTech). Relevant articles were also found through the snowballing approach, by reviewing the references included in the found articles. Finally, healthcare-oriented grey literature was also an object of research throughout the review.

2.2. Navigating the MedTech Commercialization Pathway

To navigate through the innovation ideation-to-commercialization pathway, entrepreneurs employ various frameworks, methods, and methodologies which aim to enhance the potential for the successful market entrance of medical technologies.

2.2.1. Design Thinking Methodology

The most common method that entrepreneurs employ to strengthen the business case of their innovative medical technologies is the Design Thinking methodology (Council, 2004, Boni and Abremski, 2022). It is an empathize-driven method which adopts a human-centered approach. It aims to identify existing healthcare problems and needs and develop scenarios to better serve these needs (Oliveira et al., 2021). The methodology encourages creativity and willingness to explore unconventional and innovative solutions (Bender-Salazar, 2023). It highlights the identification of problem-solving ideas that could efficiently satisfy these needs. These solutions are then carefully designed to ensure that end users' preferences are incorporated as well as high quality, efficiency, and safety criteria are met. Such considerations facilitate the clinical trials and regulatory approval, while at the same time guide entrepreneurs on the commercialization strategy which could help them bring their innovative products into the market (Council, 2004, Tschimmel, 2012). Some authors have used design thinking to adopt a value-based healthcare approach, underlining the added value for the patients, and the adjustment of the medical practice around their medical conditions and care cycles (Nilsson et al., 2017).

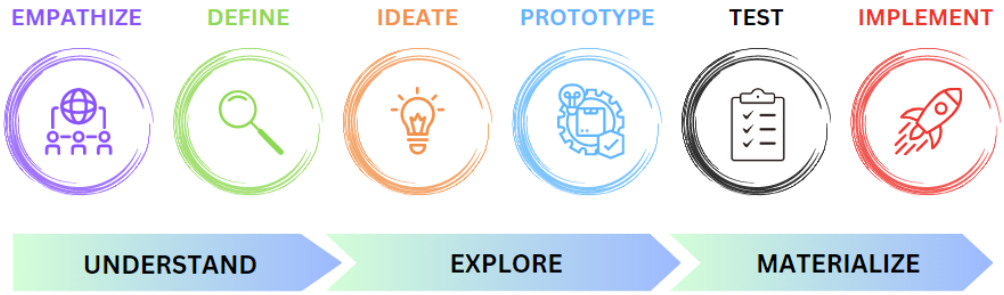


Figure 2.1: Design Thinking Methodology

Limitations

The design thinking methodology has gained traction in healthcare considering its streamlined process and the attention toward a patient-centered problem-solving solution. However, it has certain limitations. Initially, it tends to ignore the external environment (e.g., competitors, politics, economy) which is the key to an efficient market entry (Keown et al., 2017). Following the fast pace of technological advancement, it is critical that entrepreneurs determine healthcare needs and assess relevant health environments in advance so that they bring valuable products into the market (Triberti et al., 2019). Also, it does not incorporate early economic evaluation and assessment of the commercial viability of emerging health technologies (Ministerie van Volksgezondheid, 2022b). Incumbent companies have the resources to proceed with high investments and absorb the risk of failure, but new ventures cannot afford such an outcome (Schilling, 2016). The motto of "fail fast, fail cheap" is crucial for startups that aim to innovate in the capital-intensive healthcare industry (IJzerman et al., 2017). Also, the design thinking methodology lacks a comprehensive analysis of the ecosystem where the technology is intended to be integrated. It adopts a human-centered approach and tends to miss that the pursuit of a higher profit margin from stakeholders is not always in line with the welfare and desires of patients and the public (Porter and Lee, 2015). Not aligning the benefits of novel medical interventions with the needs and priorities of the entities which enable healthcare delivery (hospitals, care providers, insurers, etc.) can significantly affect the decisions towards procurement, reimbursement, and eventually market entry (MacNeil et al., 2019).

2.2.2. Business Model Canvas

To contextualize the commercial viability of their emerging medical technologies, entrepreneurs aim to develop an effective business model. Business model development is a critical process for small and medium-sized enterprises (SMEs) to strengthen the business case of their innovative ideas (Khodaei and Ortt, 2019). Scholars highlight the development of a business model that strategically defines the value proposition, value creation and delivery, and value capture within the healthcare ecosystem (Teece, 2010, Porter and Lee, 2015). The business model canvas (BMC) is being widely adopted as a proof of principle to develop successful business

models during the early stages of technology development, facilitating and accelerating the commercialization (Sibalija et al., 2021). The BMC can help healthcare entrepreneurs find responses to the initial high risk and uncertainty during the early stage of medical technology development. The BMC incorporates various elements including key partners and resources for R&D and relevant activities, strategic distribution channels, value proposition development along with customer segmentation, cost-structuring and revenue streams, and customer relationships (Osterwalder and Pigneur, 2010). The utilization of the business model canvas enables more comprehensive and practical planning of healthcare services (Teece, 2010). It helps entrepreneurs and startups design their business models, manage product and service portfolios, and identify and engage key stakeholders such as healthcare providers, payers, and patients (Sibalija et al., 2021).

Challenges

However, the BMC has certain limitations. It lacks the identification of the competitive landscape and the influence that these players have on the business model and commercialization strategy development (Khodaei and Ortt, 2019). In such a fragmented market it is important to be aware of the competition not only to forsee potential overtake but also how to leverage those players to enable strategic market entry. Also, external factors that could disrupt the commercialization outlook of a medical technology are not considered (Sibalija et al., 2021). The technology development trajectory in MedTech is uncertain, and fluid, with multiple changes and unexpected events. Khodaei and Ortt (2019) call SMEs to enhance flexibility and innovation during the development of their business model in order to respond to the dynamic changes in the healthcare landscape. They call on entrepreneurs to properly identify the key variables that can influence the trajectory of the technology and understand their interconnection, formulate their business model to adapt their value propositions, and capture economic returns. Scholars highlight, also, the PESTLE analysis (Political, Economic, Sociological, Technological, Legal, and Environmental) as a means to comprehend the external environment and strategically drive entrepreneurs' decision-making toward pivoting, abandoning, or persevering on the business plan (Perera, 2017).

2.2.3. Lean Startup Methodology

Another method that can drive the commercialization process is the lean startup methodology which best aligns health technologies' scope with patients' actual desires and needs. The lean methodology incorporates learning and feedback streams which enable entrepreneurs to identify the possibility of failure fast, before additional efforts and resources are invested in a non-viable venture (B. Eppley et al., 2021). It focuses on the business validity of the product not only evaluating the short-term implications but also the long-run sustainability (B. Eppley et al., 2021). It, initially, identifies the key assumptions underlying the technology, including assumptions about customer needs, preferences, and willingness to pay. After having successfully integrated the customer within the feedback and design loop to test these hypotheses, a decision to pivot or persevere with the existing venture is made (Aulet, 2013). The lean startup methodology is mainly used to inform entrepreneurs about the expected return of their innovation, while developing a product that fits patients' needs. Attention is given to customer engagement and early prototyping and experimentation while minimizing unnecessary expenses (B. Eppley et al., 2021). In case of a decision to proceed with further development, lean startup incorporates the agile methodology to increase production scale while ensuring high quality and efficiency.

Challenges

When following the lean startup methodology, it gets complicated for entrepreneurs to decide on what objectives they should insist on and what outcomes to pursue (Senna et al., 2016). Entrepreneurs often have a multitude of objectives they want to achieve, ranging from financial growth and market share to social impact. Entrepreneurs must align their goals with the core values of their business and their resource constraints while also considering the expectations of stakeholders, investors, and customers. It remains unclear how the lean method can be used and what conclusions and knowledge are meant to be generated to inform the commercialization strategies. Also, little insights are generated regarding the technology assessment from the perspective of stakeholders and decision-makers. Although patients determine the potential value generated from a technology, healthcare providers and stakeholders are the ones who are able to deliver it (Sibalija et al., 2021). No

compliance and addressing of both aspects' needs and requirements can jeopardize the time to market as well as the viability, commercialization, and diffusion of the technology (MacNeil et al., 2019).

2.2.4. Entrepreneurial Process Model

The literature highlights, also, the adoption of the Entrepreneurial Process Model (EPM) to enhance innovation and reshape the commercialization outlook of emerging health technologies (Boni and Abremski, 2022). As depicted in Figure 2.2, the model starts with the recognition, validation, and development of a new opportunity; evolves with the acquisition and deployment of the necessary resources for the new venture; and is completed with the management and building of the Team (Srivastava et al., 2019). Healthcare entrepreneurship urges innovators to engage with stakeholders and identify unmet needs, functional limitations, or cost-ineffective practices in order to validate their value propositions and proceed with the appropriate commercialization strategy and business model to penetrate the market (Aulet, 2013). According to Boni and Abremski (2022) proper assessment of the technology and fruitful engagement with the relevant stakeholders can not only secure operational, regulatory, and investment reassurance but also can minimize financial exposure and failure risk. Collaborative business models are especially important for small technological firms and startups which require agility and flexibility to secure their commercial position within a fast-paced dynamic environment (Pellikka and Malinen, 2014).

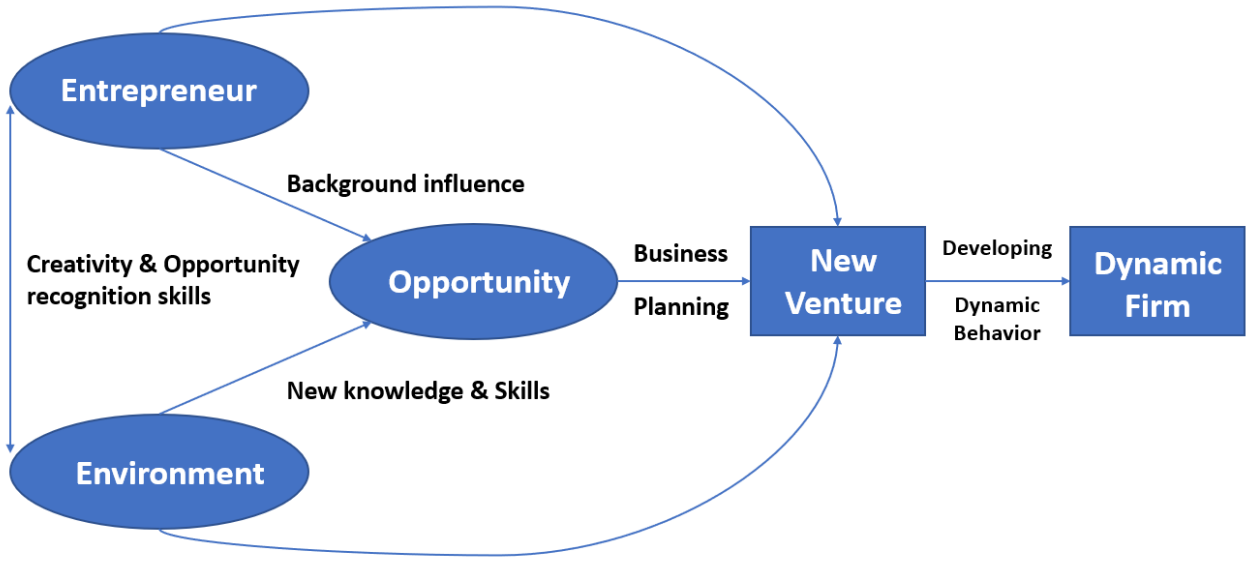


Figure 2.2: Entrepreneurial Process Model (Srivastava et al., 2019)

Challenges

To navigate efficiently the commercialization process, entrepreneurs need to be cautious about the strategies and information they reveal about their technology. Stakeholder engagement and partnership need to be properly assessed, not only by defining the objectives and accompanying risks but also by critically selecting the proper stage along the commercialization process to be involved (Pellikka and Malinen, 2014).). In this way they can receive the appropriate feedback and recommendations while they can maintain a protection wall for their intellectual property and ideas. Also, entrepreneurs may find it difficult to navigate complex regulatory frameworks, ensure data privacy and security and develop evidence-based clinical validation and the cost-effectiveness of emerging technologies (MacNeil et al., 2019), especially when they lack the required expertise in healthcare delivery (Boni and Abremski, 2022).

2.2.5. Other frameworks

In the existing literature, there have been identified two frameworks that create new insights and bring new perspectives into the healthcare commercialization outlook. The following frameworks, developed by Buisman et al. (2016) and Bakker et al. (2021) respectively are mainly focused on predicting the trajectory and justifying the worthiness of the emerging health technology during the early stages of development. Both frameworks embrace early health economic modeling.

Buisman et al. (2016), initiate the framework determining what the application would serve, utilizing the Patient Population, Intervention, Comparator, and Outcomes (PICO) method. The PICO method helps to identify the target population, determine the outlook and features of the intervention, identify and compare existing practices and finally define variables that could measure the expected outcomes and benefits in the healthcare system. The framework seeks new experts' input in order to proceed in the next phase and build a conceptual model to estimate the added value of the new technology for the healthcare ecosystem. Lastly, an early cost-effectiveness analysis is performed which leads to the final go/no-go decision regarding the further development of the technology.

Bakker et al. (2021), provide a more generic framework. They start by identifying a problem where an emerging technology would be useful. Then, with the aim of understanding whether the technology is worthwhile, existing data and evidence are integrated into the assessment model. After a positive outcome is measured, the authors proceed with the PICO method to determine the scope of the technology. What they include in this go/no-go phase is the identification of the possible barriers which could hinder the successful commercialization of the technology. If optimistic results are found, the last step is the economic evaluation which determines whether the developers of the technology should proceed with further investment and efforts to bring the technology to the market.

Limitations

The framework proposed by Buisman et al. (2016) prioritizes the economic evaluation of the technology. As a result, the decision-making process focuses on extracting knowledge that could better capture the expected monetary aspects of the technology. However, not a lot of attention is given to the practical aspects of the technology, the way that it could better correspond to the needs of relevant stakeholders, and the position of the technology in the healthcare system in such a way as to achieve higher economic returns. Also, the model utilizes solely cost-effective analysis. Considering the health technology assessment guidelines, constructing the early health economic modeling is not always clear and alternative methods, such as the real options, could be proved more effective.

On the other hand, the framework proposed by Bakker et al. (2021) is more concrete. It integrates into the assessment loop not only quantitative economic methods but also the pragmatic perspective of the assessed technology. However, this framework assumes the existence of available data to be analyzed in order for the technology to be better positioned in the PICO method. This can be the case when similar interventions have already been marketed, or evidence through research has been published. On the contrary, when no available data can be fed into the assessment loop, the first two steps of the framework can be problematic. Another point to mention is that the framework prioritizes the identification of potential barriers that could hinder technology growth. However, through proper stakeholder engagement, certain factors that can support the implementation of medical technologies need to be identified as well, so that potential risks are mitigated.

2.3. Health Technology Assessment

Entrepreneurs and policy-makers employ health technology assessment (HTA) methods in order to determine the cost-effectiveness of medical technologies, demonstrate their commercial viability (INAHTA, 2023) and predict market uptake, based on the benefits that the technology could bring into the healthcare ecosystem (IJzerman and Steuten, 2011). Traditionally, HTA has been applied in the form of health economic modeling, as a policy tool to inform reimbursement decisions, during the last two phases of the medical technology development, once clinical evidence is generated and regulatory requirements have been sufficiently satisfied (Grutters et al., 2019). HTA incorporates various elements which can drive the commercialization of medical

technologies (see Fig. 2.3) and employs various qualitative and quantitative methods to capture those elements that can be found in the Appendix A.

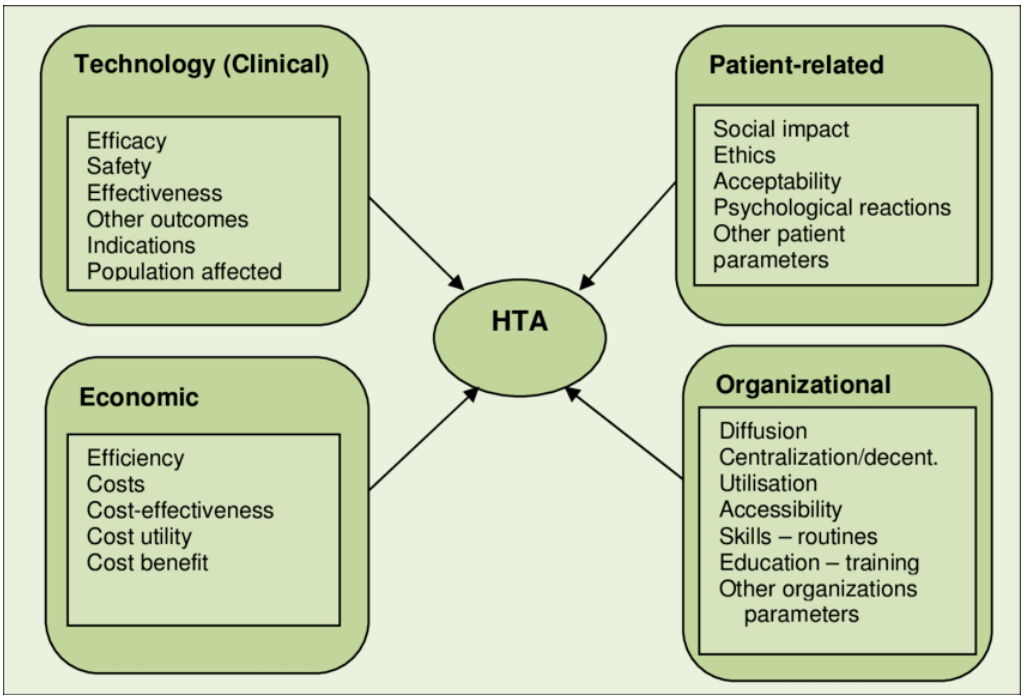


Figure 2.3: Health Technology Assessment Attributes (Draborg et al., 2005)

However, performing HTA at that late stage of development can be financially risky for startups (MacNeil et al., 2019). If the HTA body does not give a favorable recommendation, the new venture may not be able to recover the significant costs incurred in developing and launching the product (Sebastianski et al., 2015). Potential failure to demonstrate the relationship between healthcare economics and expected outcomes during the HTA can hinder the successful commercialization of emerging technologies, considering the time, flexibility, and budget constraints for market entry (Peiffer et al., 2019 and Markiewicz et al., 2014). In a rapidly evolving healthcare setting with rising investment costs of health and R&D initiatives (De Pinho Campos et al., 2011), relevant stakeholders are expecting developers and entrepreneurs to demonstrate the value and cost-effectiveness of emerging technologies during the early development stages, before clinical evidence is generated (Grutters et al., 2022, Ministerie van Volksgezondheid, 2022a, Grutters et al., 2019). IJzerman et al. (2017) introduces Early HTA, as a concept to demonstrate to the industry and relevant stakeholders the expected value of new medical technologies during the translational stage (see Figure 1.1), while quantifying and managing uncertainty.

Early HTA aims to minimize the technology development failure risk and, if evidence foresees an unfavorable business opportunity, eliminate efforts at the earlier stages with low capital investment (Bakker et al., 2021). Early HTA incorporates efficient R&D processes, proper resource allocation, and stage-gate with go/no-go decision-making methods to evaluate and determine the trajectory of the emerging technologies (Markiewicz et al., 2014). It embraces stakeholder involvement and engagement in the early development stages to reduce uncertainty (Grutters et al., 2022), and promotes risk-sharing through knowledge diffusion, agreements, and formation of common standards, policies, and values (IJzerman and Steuten, 2011 and Markiewicz et al., 2014). However, currently, a lot of attention in performing early HTA refers to the economic and commercial viability of the technology. The methods highlighted in the Appendix A can be utilized in the early stage of development, prioritizing sensitivity analyses due to the higher uncertainty level, and provide valuable insights on the commercial worthiness of the technology. However, the cost-effectiveness alone cannot be sufficient to capture the commercial viability in the long run. Kristensen et al. (2019) urges the health system and stakeholders to apply HTA further than just a standard policy tool to inform stakeholders about the efficient entrance and use of emerging technologies. During the early stage, there is uncertainty which can

jeopardize the market uptake and economic returns, especially considering the fluid and unpredictable external environment. Early HTA requires a more structured approach to capture the wider range of MedTech commercialization. The idea of early HTA which promotes the proactive assessment of the technology, is important to decide whether or not additional investments and efforts towards further development are needed.

2.4. Barriers

Numerous obstacles often impede the successful translation of healthcare innovations from research and development to market entry, thereby affecting the commercialization of these technologies.

Lack of market and healthcare needs understanding is identified as one of the main barriers that hinder the commercialization success of health technologies (Grutters et al., 2019, Keown et al., 2017, MacNeil et al., 2019). Entrepreneurs, startups, and small & medium-sized enterprises (SMEs) fail to fully understand the needs and preferences of healthcare providers and patients (Keown et al., 2017, MacNeil et al., 2019). They develop weak value propositions (B. Eppley et al., 2021) that do not address real problems or do not align with the needs of potential users (Grutters et al., 2019). As competition increases with an overwhelming number of novel interventions it is more likely that the technology is outpaced (B. Eppley et al., 2021).

Policy-makers are expecting entrepreneurs to demonstrate technology's cost-effectiveness and key outcomes that justify the positive reimbursement decision (Grutters et al., 2022, Ministerie van Volksgezondheid, 2022a, Grutters et al., 2019). Demonstrating the value of the technology alone for the patient relative to current care, without elaborating on the expected return for stakeholders, can lead to failure of adoption and diffusion of the technology (Schuetze et al., 2023). Also, considering that hospitals and care providers sometimes lack a cost breakdown of their services and treatments, it gets difficult for entrepreneurs to measure the expected cost effects of their technology and eventually demonstrate the cost-effectiveness (MacNeil et al., 2019). Lacking insight into the actual expenses of treating patient conditions and their interconnection to the expected outcomes can lead to uninformed decisions on embracing new technologies and embracing new care processes (MacNeil et al., 2019).

Also, the resistance to change in the fragmented healthcare system is identified as a critical factor that affects the adoption and diffusion of emerging technologies (Schuetze et al., 2023, MacNeil et al., 2019). The key reasons behind that could be the low level of readiness of the health system to adopt the technology (Schuetze et al., 2023), lack of incentives to incorporate in daily operations due to increasing workload (Chindalo et al., 2016), potential conflicts with practitioners' positions and practices (Chindalo et al., 2016), or insufficient empowerment, training and support to the end-users (Schuetze et al., 2023). In the same direction is the fragmented reimbursement system (MacNeil et al., 2019). Healthcare reimbursement systems can be complex and startups may struggle to navigate these systems and secure reimbursement agreements for their products (Lehoux, Miller, et al., 2017). Especially when emerging technologies do not reach cost-effectiveness, or do not comply with the cost-attainment and sustainability goals of healthcare institutions, procurement cannot be justified, and eventually, the technology loses its commercial momentum (MacNeil et al., 2019).

Lack of the necessary resources, capital and human, can significantly affect the trajectory of the technology toward market entry (MacNeil et al., 2019). Startups may struggle to secure the necessary funding while investors may also be hesitant to invest in health technologies due to the high level of risk and uncertainty involved (Grutters et al., 2019). In parallel, entrepreneurs either to secure their intellectual property or due to limited experience and flexibility, do not proceed with partnerships to navigate R&D and boost commercialization efforts (MacNeil et al., 2019). Lack of partnerships and experience can also has an impact on scalability. Difficulty in scaling the new venture can be a critical barrier in the adoption and diffusion of a healthcare technology (Grutters et al., 2019).

Furthermore, entrepreneurs may fail to meet healthcare providers' expectations regarding the performance and technical requirements of the technology (Schuetze et al., 2023). The health industry is heavily regulated, and startups may struggle to navigate complex regulatory frameworks (Grutters et al., 2019). Obtaining regulatory approval for health technologies can be a long and costly process, and failure to comply with regulations can result in hefty fines or even legal action (Lehoux, Miller, et al., 2017). Finally, ethical considerations with

data privacy and security concerns can increase the risk of failure (MacNeil et al., 2019).

2.5. Facilitators

The literature identifies numerous factors that can assist in promoting the successful commercialization of medical innovations, aiding their transition from the ideation phase to market entry.

Among the most important, researchers highlight the development and promotion of patient-centered innovations, that empower patients and put pressure on stakeholders to move forward with procurement (Grutters et al., 2019). Early patient involvement in the development process can ensure quality, safety, utility, and ease of adoption and diffusion to accelerate the commercialization of the technology (MacNeil et al., 2019). A strong value proposition should be developed along with optimal market segmentation and a clear value map that depicts and interconnects each stakeholder's needs (Grutters et al., 2019). There is an increasing interest in the empowerment of patients and physicians, providing wider solutions that unlock new opportunities and promote new more convenient ways of operation and treatment (Keown et al., 2017). Modularity has been a critical factor during development, considering the future transformation capabilities that could be generated both for the developers and the healthcare providers (Keown et al., 2017).

To accelerate regulatory processes as well as procurement and reimbursement decisions, an early evidence-based strategy should be employed to demonstrate the cost and utility effectiveness of the emerging health technology (Lehoux, Miller, et al., 2017). Early health technology assessment and early health economic evaluation can justify reimbursement decisions and accelerate commercialization efforts (IJzerman et al., 2017, MacNeil et al., 2019). Implementing quality management systems (QMS) during the early stage of health technology development can help entrepreneurs to better navigate regulatory processes (Fearis and Petrie, 2017). It prioritizes the maximization of expected outcomes, assurance of high-quality aspects, and minimization of safety risks and go-to-market time. As technology development evolves, the remaining requirements can be systematically reviewed and fulfilled (FDA, 2023, Fearis and Petrie, 2017), until full compliance is reached at the final stages of development. Early policy orchestration and economic evaluation can also help the company assess its commercial pathway and identify the necessary strategies to properly allocate scarce resources (MacNeil et al., 2019).

Last but not least, entrepreneurs, startups, and SMEs should adopt a more flexible business strategy; they should embrace open innovation, seek partnerships, spread awareness, and engage strategic stakeholders during the early stages of development (MacNeil et al., 2019). The knowledge spillovers can facilitate the commercialization process and guide them around regulatory, design, and commercial strategies to materialize their innovative applications (Lehoux, Miller, et al., 2017, Shakeel et al., 2020). Scholars have examined strategies to enhance the translation of medical research into successful medical products, highlighting the critical role of Technology Transfer offices (TTOs) in Intellectual Property management and the role of the Universities in bridging the gap between the researchers and the industry and investors (Collins et al., 2016, Brantnell and Baraldi, 2022).

2.6. Discussion

Adopting commercialization practices from various industries, new opportunities, processes, tools, and elements have emerged that can guide entrepreneurs toward a successful business case for their innovative medical interventions (Boni and Abremski, 2022). However, there are still certain challenges that can easily distract entrepreneurs from capturing the pragmatic value of the technology and deviate them from developing and marketing successful products in the healthcare ecosystem (Keown et al., 2017). The announcements, efforts, and investments in new innovative medical technologies do not correspond to the number of new interventions that manage to enter the market successfully and be adopted and make an impact within the healthcare system (Beaulieu and Lehoux, 2018, Thijssen et al., 2023). Past efforts for implementation have identified that many medical devices miss their scope, and are not used as supposed to (Ministerie van Volksgezondheid, 2022b).

As healthcare technology continues to evolve and become more complex, traditional commercialization practices may no longer be effective in bringing these innovations into the fragmented healthcare industry (MacNeil et al., 2019). Considering the post-pandemic era, e-Health for example, has gained traction and has already reshaped certain dimensions of the healthcare industry (Cooper-Jones et al., 2022). Emerging technologies require new healthcare commercialization, assessment and delivery approaches that account for their unique characteristics and challenges (Wehde, 2019). The potential benefits that technologies can bring to the healthcare systems are influenced not only by the target users (such as physicians, nurses, or patients) but also by the potential buyers, such as hospitals, insurers, or national health systems, which are the ones which would deliver novel health technologies so that entrepreneurs reap economic returns (Lehoux, Miller, et al., 2017). Conducting an early evaluation of an emerging technology offers valuable information for the developer and other stakeholders, aiding in the determination of subsequent actions and eventual implementation and expansion in healthcare (Ministerie van Volksgezondheid, 2022b). Although there are certain methods to perform early HTA, it is not yet fully understood in the scientific setting how early HTA should be performed in order to manage uncertainty and extract valuable insights and make informed decisions. Early HTA should aim to explore, enhance innovation and identify valuable pathways rather than provide solely judgment about the worthiness of the technology mainly considering the monetary aspects (Kristensen et al., 2019). A more holistic approach needs to be incorporated to capture the overall dynamics of the MedTech commercialization, which could lead to sufficiently informed decisions regarding the strategies to enter and penetrate the market. These dynamics however are not yet fully understood (Thijssen et al., 2023).

Entrepreneurs need to identify key stakeholders that can drive their innovations. Stakeholder engagement in terms of co-design strategies and collaborative business models can be increasingly important for new ventures (Pellikka and Malinen, 2014). However, currently used methodologies do not capture such an approach. Entrepreneurs need to identify the critical elements along the value chain and proceed with knowledge extraction in order to optimize their commercialization efforts (Grutters et al., 2019, MacNeil et al., 2019). Defining and testing their product's value proposition is necessary during the early development stage to avoid investments in initiatives that cannot generate actual value for the industry and stakeholders (Pellikka and Malinen, 2014). Thijssen et al. (2023) emphasizes the necessity to gain deeper insights into the factors influencing the progression of MedTech innovations along the commercialization pathway. Tummers et al. (2020) and Whitelaw et al. (2021) advocate for diving into the MedTech ecosystem with the aim to comprehend the intricate dynamics that can impede or facilitate the journey from ideation to commercialization in the context of innovation.

2.7. Conclusion

Taking all the aforementioned points into consideration, it becomes obvious that there is a growing need to reconsider the MedTech commercialization outlook enhancing the ideation to commercialization pathway for emerging medical technologies to better correspond to the priorities of the health system. Although considerable efforts and investments are being done in the MedTech setting, the number of medical technologies which finally reach market entry is disproportionate. While various frameworks and methods exist to capture different elements along the commercialization pathway, they often possess inherent limitations. These models tend to be used alone, but they rather hold promising expected results if they are applied in a complementary way. The previous sections provided valuable directions on the MedTech commercialization pathway, highlighting the need to enhance the early validation and development of the business plan of the new venture. The Figure 2.4 depicts a conceptual framework which incorporates the elements that were identified throughout the literature review constituting a new approach on how to navigate the pathway from ideation to market entry.

PICO Method

In the early ideation phase, entrepreneurs have already envisioned the technology and are keen on evaluating how it would fit in the market to better serve the healthcare community. The literature highlights the need to develop a clear scope and vision of the expected outcomes that stakeholder engagement should generate. To determine the commercial trajectory of health technologies, entrepreneurs can utilize the Patient Population, Intervention, Comparator, and Outcomes (PICO) method. The PICO method can help entrepreneurs identify

the most suitable way that the technology can fit into the healthcare system based on the existing evidence, stimuli, stakeholder priorities, and personal input and insights, incorporating elements both from a health and societal perspective. The entrepreneur needs to understand the current care practices, along with accompanying problems and associated costs. This includes understanding the ways to measure the potential benefits and barriers of implementing the technology and its potential impact on healthcare outcomes and costs, and its level of maturity. Engaging all pertinent stakeholders from the outset can provide transparency regarding an innovation's potential value in healthcare, the implementation process in healthcare, and the necessary steps for successful commercialization. Consequently, by engaging the appropriate stakeholders entrepreneurs should be in the position to develop three key strategies that would help with the assessment of the commercial viability of their health technologies and the definition of the proper commercialization trajectory. These strategies are as follows:

1. **Design Strategy**: The entrepreneur should be in a position to determine the characteristics, features, performance, and elements that the technology should incorporate in order to maximize its potential value. In that way, the achievement of a successful entrance of the technology within the health system can be secured, or in case the technology does not correspond to the health system's needs, an early decision to pivot or abandon the idea can minimize the failure risk and save entrepreneurs from investing additional resources which would not lead to the expected economic returns.

2. **Business Strategy**: The entrepreneur, having determined the aspects of the PICO method should be in a position to identify the key variables that could impact the health, economic, and societal outcomes of implementing the technology into the healthcare system. The available data at this point will be used in defining a business strategy that promotes fairness and sustainability both for the entrepreneurs and relevant healthcare stakeholders. The entrepreneur at this point should be able to position the technology within the healthcare system, estimate the cost-effectiveness of the technology, and demonstrate the commercial viability of the product.
3. **Commercialization Strategy**: This step involves identifying factors and actors that could accelerate the implementation of the technology, as well as risks and barriers that could hinder this process. This includes identifying potential enablers such as supportive policies, infrastructure, and resources that could facilitate the successful adoption and implementation of the technology. Finally, a risk mitigation plan can be developed to address the identified risks and barriers before proceeding with further efforts.

Afterward, entrepreneurs proceed with the development of the minimum viable product (MVP) or prototype to proceed with the clinical trials. These prototypes can be physical, digital, or conceptual, and allow developers to test and refine their ideas. As the prototype is being developed, close stakeholder engagement and proper policy-making could ensure the successful meeting of the health system's needs and priorities, while minimizing the failure rate. Safety, quality, utility, effectiveness, and ease of adoption can be ensured through co-development with end-users and the involvement of policy-makers, while QMS can help with the surveillance of the overall process.

Such a process follows the HTA principles, in a way that in case the overall validation of the technology concludes that the technology does not hold the expected potential, it should be unplugged from further efforts or a transition toward re-scoping should be embraced.

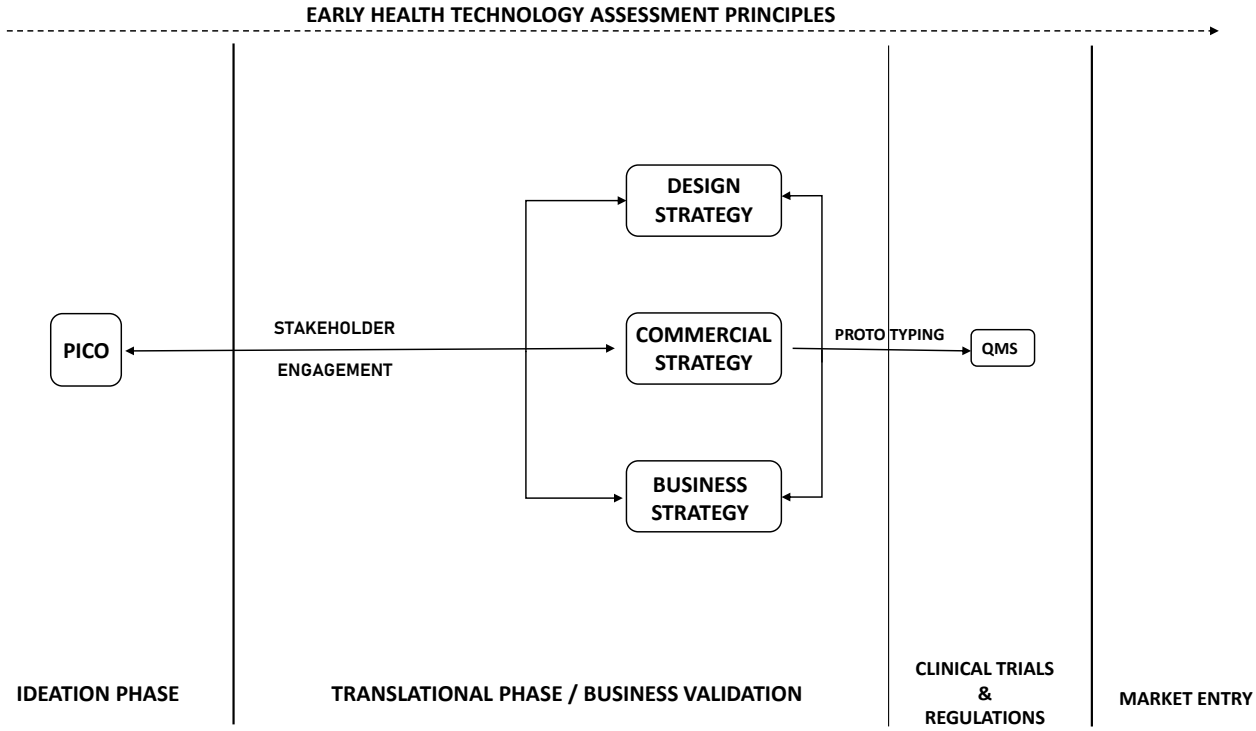


Figure 2.4: Proposed Conceptual Framework

Although the above framework can capture certain dynamics in transitioning from ideation to market entry, there is a need to further research and comprehend the barriers, enablers, and essential steps required to cross the chasm between the ideation phase and successful market entry. A greater understanding of the specific outcomes and knowledge that should be extracted during the validation phase is necessary to be achieved. It is critical to capture the perspectives and needs of the key players along the MedTech value chain to dive deeper and expand the current knowledge base. Ultimately, a strategic roadmap that better captures the dynamics of the transition from the ideation phase to the successful market entry needs to be developed.

3

Research Methodology

This section aims to provide a clear overview of the research methodology that was followed in the thesis research so that all research questions are thoroughly answered and the research objective is satisfied by employing academic research methods for qualitative studies. This section initiates with the general research strategy of the current study. Then, the data collection and data analysis methods are explained. To better help with reporting the key elements of the research methodology, and the reader to have a transparent overview of it, the principles of the research work of Tong et al. (2007) were adopted. They developed a thorough checklist that helps to report various elements of the qualitative data collection and analysis. I proceeded with a thorough reflection on the mitigation plan to enhance the research validity along with potential threats. Finally, the ethical aspect of the research is included.

3.1. Research Strategy

The purpose of this master's thesis is to develop a comprehensive strategic roadmap that captures the dynamics involved in transitioning from ideation to market entrance for emerging medical technologies. This roadmap holds the potential to enhance the understanding of the commercialization pathway and empower innovators to adjust their approach when striving to market their emerging medical technologies. Through the literature review (Chapter 2) I identified certain barriers and factors that could facilitate entrepreneurs in navigating the complex MedTech commercialization pathway. A conceptual roadmap has emerged. Here the aim was to validate the elements included and identify additional ones which could secure a more effective transition toward MedTech commercialization. Consequently, to further enhance the current scientific knowledge, and achieve the research objective of this thesis research, a qualitative research method was deemed appropriate (S. Bell, 2009, Braun and Clarke, 2013). It helped to understand and proceed with an in-depth interpretation of meanings that were not identified in the literature or were not fully clear. Qualitative research allows for the analysis of qualitative data which can generate knowledge that facilitates broader insights and theory generation (Braun and Clarke, 2013). This study employed both deductive and inductive analysis. Valuable knowledge was extracted from the literature review (deductive) and was enhanced with qualitative research to expand the data and knowledge base and develop a new theory (inductive). Ultimately, the strategic roadmap which better captures the dynamics of the transition from the ideation phase to the successful market entry of emerging medical technologies has been developed.

3.2. Data Collection

Semi-structured interviews were used as the data collection method with participants from diverse roles, experience, and expertise along the value chain of the MedTech ecosystem. Questions which aim to capture the common pitfalls and barriers along the commercialization process, as well as the elements to enhance the transition from the ideation to the market entry have been determined and provided in advance to the participants. The research study and data collected are restricted to the Dutch setting, considering the identity and area of operation of the participants.

Table 3.1: Qualitative research checklist *Part (i) Research team and reflexivity*

Personal Characteristics	
Interviewer/facilitator	The author of this work conducted the interviews
Credentials	The author is a Management of Technology Master's student in Delft University of Technology
Occupation	Master's student
Gender	Male
Experience and training	Semi-structured interviews have been performed in the past for academic purposes
Relationship with participants	
Relationship established	The relationship with the participants started after the commencement of the research study
Participant knowledge of the interviewer	The participants were informed about the interviewer's position and his research objective
Interviewer characteristics	The characteristics that were reported to the interviewees about the interviewer include his interest and motive about the research topic and the MedTech industry

Table 3.2: Qualitative research checklist *Part (ii) Study design*

Participant selection	
Sampling	The participants were selected based on their expertise and position. They need to have diverse backgrounds and an active role along the value chain of the MedTech ecosystem. They had to have knowledge and experience in MedTech development, policy-making, and commercialization in either a position related to strategy, care delivery, or technical expertise in the Dutch health care setting. The sample for the semi-structured interviews was selected employing the convenience sampling strategy considering the accessibility and the flexibility of key stakeholders. Snowballing or friendship pyramiding was also employed to access a higher network more efficiently.

Method of approach	The participants were approached through e-mail or LinkedIn. The participation informed consent was sent prior to the interviews along with the pre-determined questions so that they prepare themselves.
Sample size	8 participants: • **(1) Healthcare Business Developer**, with expertise in innovation strategies in the healthcare and MedTech setting. • **(1) Policy-Maker in the Dutch Health System** with expertise in accelerating the introduction of new medical technologies into the health system. • **(1) Hospital Manage**r, with expertise in innovation management in the health care setting and facilitating emerging medical technologies implementation within the hospital setting. • **(1) Patent Advisor**, with expertise in guiding startups to establish ownership, IP rights, and explore commercialization and business opportunities. • **(1) Healthcare Organizations Analyst**, with expertise in health policy, procurement, hospital finance as well as insurance requirements, planning, and payment. • **(1) Expert in the Business of Healthcare (Chief Commercial Officer)**, with expertise in taking the idea and bringing it to market and building out the sales and marketing to make it grow and upscale. • **(1) Medical Technology Developer**, with expertise in medical research, design, development, and regulations. • **(1) Nurse** working as a breast clinic coordinator in a Dutch regional hospital
Non-participation	No participant dropped out of the research.
Setting	
Setting of data collection	The data was collected through online video calls in MS Teams (TU Delft approved) software.
Presence of non-participants	No one else was present during the interviews.
Description of sample	There was no important characteristic of the sample aside from their technical knowledge or position and expertise in the Dutch Healthcare system.
Data collection	
Interview guide	A set of pre-determined questions was sent in advance so that the participants have time to prepare themselves.
Repeat interviews	No repetition of any interview was necessary.
Audio/visual recording	The interviews were recorded and transcribed using the MS Teams (TU Delft approved) software.

Field notes	Very few notes were taken during the interviews because the participants were providing constantly new information and I needed to follow a track in order to better approach the semi-structured interview with new questions or comments wherever it was determined critical to enhancing the knowledge, understanding and insights. The interview was recorded and during the data analysis everything would be properly assessed and highlighted.
Duration	Each interview lasted approximately 1 hour.
Data saturation	I employed the interview saturation method. I asked questions (which were answered before) in a different way to see if the participants deviated from their initial answers and if potential inconsistencies are identified. In that way, the reliability of the results was enhanced. Also, this method helped to reach a point where new information or insights are not generated, indicating that the data collected is adequate and satisfying, and further interviews may not yield significant additional information.
Transcripts returned	The transcripts were only used for processing the data and were not shared back with the participants. However, during the interview, I was trying to summarize the key knowledge provided by the experts in order to verify understanding and consistency.

3.2.1. Interview Structure

The interviews were conducted in a semi-structured principle with open-ended questions to acquire knowledge about various elements concerning the MedTech commercialization pathway. Initially, the reasons behind the fact that although huge investments are being made, the majority of medical technologies do not make it to the market, were explored. Discussion topics were also the common pitfalls and barriers along the commercialization process, as well as the key enablers, tactics, and steps that should be incorporated to enhance the transition from the ideation to the successful market entry of medical technologies. The participants are considered key stakeholders in the MedTech industry who have evidence-based knowledge of the processes to foster innovation. Consequently, to further enhance the findings and capture this evidence, I posed additional questions (carefully adjusted to the expertise of the participants) about a reference case (AYA Smart - medical technology).

Reference Case - AYA Smart

To capture more precise answers to certain questions, I used as a reference case the development of a medical technology, called AYA Smart to make participants dive deeper into their experience and provide more accurate knowledge and insights. The AYA Smart, is an innovative emerging medical technology that aims to improve the quality of life (QoL) and the management of uncertainty of adolescents and young adults (AYA) who suffer from breast cancer. The reason why this particular technology was selected as a reference case is because the AYA Smart is currently in the ideation phase and a prototype has not been yet developed. The developers have envisioned a new interactive paradigm that aims to revolutionize the current services and medical practices in alleviating the uncertainty and other emotions experienced by adolescents and young adults who get diagnosed with breast cancer. The intervention refers to a physical-digital technology compatible with Virtual Reality headsets. On top of the pre-determined questions, I included certain specific questions to

get insights on the strategies which could facilitate the pathway from the current stage of ideation toward the successful commercialization of the AYA Smart. Such an approach led me to acquire valuable results which can be generalized to a broader setting as well as data that imply practical implications referred solely to the case and cannot be generalized to the general setting for other medical technologies.

3.3. Data Analysis

For the data collected, thematic data analysis was used based on the framework developed by Braun and Clarke (Braun and Clarke, 2006). I utilized a mixed approach for themes development. Initially, in a deductive way, a list of overarching themes was determined based on the literature review. Then, inductively, during the interviews new themes were identified. The initial and second ones were triangulated and final themes were selected which formed the final coding tree. The data generated from the interviews were not analyzed separately, but rather cross-checking and comparison of the different perspectives provided by the participants was necessary to make the understanding of the context stronger.

Table 3.3: Qualitative research checklist *Part (iii) Data analysis and reporting*

Data Analysis	
Description of the coding tree	The coding tree is constituted by the 6 themes related to the transition from the ideation to the commercialization of medical technologies and the 12 sub-themes refer to the dimensions and elements of these strategies that can enhance this transition.
Derivation of themes	Certain themes were derived deductively from the literature review and certain inductively through the interviews.
Software	The data analysis took place in Excel.
Participant checking	Considering the time constraint of the participants, no results were returned back to the participants for comment. However, during the interview, I was trying to summarize the key knowledge provided by the experts in order to verify the future findings in advance.

Through extensive data analysis, 6 overarching themes were identified along with 12 sub-themes that best represent the qualitative data acquired. The following table (3.4) provides a description of the overarching themes and whether they emerged inductively or deductively. The literature review led to the identification of 3 overarching themes. The qualitative research helped me gain a deeper understanding of these themes while inductively led to the identification of three additional themes.

Table 3.4: Themes Description

Code	***Description***	***Reasoning***
Organizational Strategy	Team orientation to align organizational goals and decision-making	Inductive (from Expert Interviews)
Design Strategy	Principles and actions toward a successful product development	Deductive (from Literature Review)

Business Strategy	Business model development to capture and deliver value, ensure growth, and achieve long-term prosperity	Deductive (from Literature Review)
Commercial Strategy	Actions and decisions toward the market entry trajectory, distribution, and selling of a product	Deductive (from Literature Review)
Marketing Strategy	Actions to reach target markets and boost sales	Inductive (from Expert Interviews)
Post-Commercialization Strategy	On-going actions and decisions after market entry is achieved	Inductive (from Expert Interviews)

3.4. Research Validity

To ensure a certain quality level, the validity of the research performed should be thoroughly considered. The interview saturation method was employed which refers to an approach where I asked questions on pre-discussed topics but from other angles so that he/she observes if new themes are coming into light or no additional information is generated (Braun and Clarke, 2013). When participants were starting their responses with expressions such as ”As I told before..” and ”..that leads me to what I mentioned earlier in question X..”. The interview reached saturation and, as a result, I can be confident about the high rigor, quality, and validity of the research and the findings. During the data analysis, when I was comparing the knowledge and insights generated by the participants, theme saturation was also achieved. I saw that participants were repeating the same information in various cases, making the findings and arguments stronger. The saturation method was used to increase the research rigor and add a sense of confidence in the findings to be presented understanding whether the participants remain consistent with their responses and knowledge provided and do not deviate from them. By recognizing and actively confronting its inherent limitations, this approach has the potential to generate comprehensive and socially conscious insights into present-day challenges.

3.5. Ethics Approval

Ethics approval was obtained from the Human Research Ethics Committee of the Delft University of Technology (26/05/2023). Written or verbal informed consent was obtained from all the participants.

4

Results

This section provides an overview of the findings as derived from the expert interviews. The qualitative data were analyzed by positioning the discussion takeaways in themes and sub-themes as described in the research methodology section. To keep a coherent structure, the data will be presented as summaries of the quotes that emerged from the expert interview transcripts, after cross-comparison is performed. A more extensive analysis of the expert interviews can be found in the Appendix B, where the detailed data thematic analysis is performed. The first section introduces the overarching themes of the thematic analysis, along with a short description of what they represent as well as the theoretical reasoning behind them. The second section depicts the main results of the qualitative research. Finally, the practical implications that emerged about the AYA Smart, the reference case, are presented..

4.1. Themes & Viewpoints Emphasized by the Participants

This section presents the key viewpoints that the interview participants highlighted based on their expertise. Initially, a short briefing of the key elements discussed by each participant is provided and then based on the type of the overarching theme (inductive/deductive) the 2 tables below summarize where each one of them contributed to throughout this research.

Interview #1 - Healthcare Business Developer
The interviewee emphasized the need for innovators to quantify the market size accordingly adjust their business strategy to better capture economic returns or respectively change their vision and scope. Properly analyzing the health ecosystem, receiving feedback from key stakeholders and aligning the value proposition with everyone's priorities were highlighted. Early engagement with insurance companies was strongly underlined for entrepreneurs to decode the insurance packages, select the proper market segment to pursue and finally adjust the intervention to be in line with the requirements of insurers to integrate the technology into their reimbursement plans. The need for business model flexibility and constant exploration and validation of the idea was pointed out to ensure that the technology fits the health system's needs and does not lose its scope in the pre-market phase and in the long run. Based on the participant' expertise in business development, there was an urge for innovators to be open-minded, understand the context and potential of the technology and strategically decide on whether to pursue the professional care pathway or the regular mass market. In the same context, the decision to operate locally or adopt a more ambidextrous organizational strategy with different R&D and market entrance locations was emphasized. The participant also highlighted the need for startups to consider elements to enhance their post-commercialization strategy. Finally, the organizational strategy of startups and especially the team formation was thoroughly elaborated.

Interview #2 - Healthcare Organizations Analyst
The participant highlighted the need of an interdisciplinary team which can capture stakeholders' needs into the final solution while the business strategy development for new ventures extensively elaborated as well. More specifically, a lot of attention was given on the ability of entrepreneurs to capture the market size and the necessity to understand the extend that the technology corresponds to the needs of the health system and solves a critical problem; otherwise, the scope should be changed, or the idea should be left on the shelf. Early stakeholder engagement to feed the decision-making and build consensus among the entities of the value chain. Similar to the first interview, early engagement with insurance companies was strongly underlined because it can help startups identify and monetize their market segments while at the same time can guide them towards reimbursement agreements. In terms of the health ecosystem analysis, competition and innovation reluctance was elaborated with emphasis in exploration of more promising markets for startups to prosper even outside the national borders. Early HTA and mainly the ability to demonstrate cost-effectiveness and MVPs during the early stage is a key step toward the transition from an idea to a commercially viable product. Finally, marketing strategies have been highlighted by the participant, with the reasoning tha a good functional product alone cannot alone lead to long-term sustainability.

Interview #3 - Expert in the Business of Healthcare (CCO)
The participant elaborated on the necessity of entrepreneurs to comprehend whether their medical innovation is actually solving a critical problem in the health system. The need to properly analyze the health ecosystem and its limitations (e.g., hospitals' lack of staff/time, reluctance) was also highlighted in terms of building a strong business case that can be implemented smoothly in the health system. For example, as with the previous interviews, this participant urges entrepreneurs to understand where their value propositions lie and critically consider whether these are in conflict with stakeholders' priorities and financial incentives. Early engagement with stakeholders was extensively elaborated. Partnerships with hospitals and care providers are necessary to capture their needs and ways the technology can support their daily routines while also can facilitate clinical trials. Early dialogue with insurance companies to understand their financial incentives and their requirements for the integration of the technology into their reimbursement schemes is paramount. Early HTA and mainly the ability to demonstrate cost-effectiveness and safety during the early stage was mentioned as a key step toward the transition from the ideation phase to a commercially viable medical solution. Effectively navigating the competition among care institutions and early exploration of R&D and funding programs were items which were also underlined. Finally, regarding the commercial success of the technology, the marketing strategy of startups was another discussion point, particularly about customer segmentation and how to reach these channels.

Interview #4 - Policy-Maker in the Dutch Health System
The participant highlighted the need for entrepreneurs to build a strong business strategy which aligns the technology's value proposition with stakeholders' needs and financial requirements. The economic buyer, either the patient, the hospital, or the insurance company needs to be identified and be involved in the decision-making process in terms of the design strategy and the business model development. The policy-maker strongly underlined the constant validation of the technology in the pre-market phase to avoid the occurrence of one more technology which does not add significant value to the health system. Early HTA to demonstrate the efficacy of the technology and its added value in the value chain was also elaborated. The recommendation to explore and chart the post-commercialization strategy of the startup during the early stage of development was emphasized. Methods to enhance post-market surveillance as well as flexibility toward future re-scoping of the technology to the market flow and obtaining additional funding were pointed out. Finally, in terms of the commercial trajectory of startups, considering that the health system is scattered with few big players, the participant expects startups to embrace open innovation and seek partnerships with these players who have the know-how to drive new medical technologies into the market.

Interview #5 – Hospital Manager
The participant emphasized the need for entrepreneurs to explore and engage with hospitals during the early

stage and understand the added value of their technology. Hospitals have their own initiatives and innovation funding schemes that entrepreneurs should pursue; early exploration and aim for compliance with their requirements can facilitate market entrance. On the other hand, as long as there is a proven concept as an MVP or through early HTA or clinical evidence, hospitals are willing to find common ground with startups on how to implement new technologies independently of their budget schemes. The participant highlighted the staff shortages as a major barrier for nurses and managers to understand new technologies and invest time to learn and deploy them in their daily workflow. Finally, the post-market phase is critical for hospitals considering that as the technology evolves over time it is important to have the flexibility and capacity to improve it through the additional data.

Interview #6 – Patent Advisor
The participant brought an interesting side to the research topic, emphasizing especially leveraging IP rights as additional commercial paths and revenue streams. The advisor urges entrepreneurs to initiate the exploration of the current patents and to identify competitors, enrich their design characteristics, and finally identify the key players in the area which could be leveraged as business or co-development, or licensing partners. By taking care of their IP, startups show commitment and rigor which could help them establish themselves in the market and prevent other players from copying their innovations, while at the same time acts as a positive sign for future investments.

Interview #7 - Medical Technology Developer
The participant emphasized the importance of a strong design strategy which captures elements not only during the early stage but also in the long run. A user-friendly and safe solution needs to be developed not only for the final launch but also considering the potential implication during the clinical trials. Attention was given to the technical characteristics of the technology, and especially the modularity to achieve future flexibility and customizability as well as the mitigation of technical risks. Early stakeholder engagement can guide the startup to understand the current needs and where the technology should be integrated into the current system to satisfy these needs. The participant emphasized the regulatory requirements which need to be explored and processed during the very early stage. Given that new technological breakthroughs arise, the participant strongly underlined the need to enhance the research regulations on how to demonstrate the efficacy of novel medical technologies. To navigate the current blur landscape of clinical evidence with novel technologies the developed discussed the need to have an interdisciplinary team highlighting the existence of a member with medical expertise which retains the scientific rigor and guidelines while at the same time increases the credibility toward investors.

Interview #8 – Nurse
The participant highlighted the need for entrepreneurs to understand the current limitations and staff shortages in the hospitals, and adjust their approach to their time, expertise, and knowledge in order to receive the necessary input for their innovations. The participant expects innovators to develop user-friendly, safe and efficient technologies which correspond to and improve patients' health outcomes and at the same time simplify the nursing staff's daily workflow. Early HTA is important for hospitals to justify the investment in the technology, with the decision-making flow being double-folded. Nurses expect to see the effectiveness of technology while the executives expect to see the economic benefits and the long-term impact.

4.1.1. Table Representation

The following tables summarized the knowledge presented in the previous section. The table 4.1 depicts the level that the interviewees elaborated on the deductive themes which were identified throughout the literature review, providing additional insights and extending the current knowledge base. The table 4.2 presents the inductive themes that emerged throughout the qualitative research and marks the individuals who elaborated on each one of them.

Table 4.1: Descriptive Themes Elaborated in Interviews

Theme	Interviewee							
	# 1	**# 2**	**# 3**	**# 4**	**# 5**	**# 6**	**# 7**	**# 8**
Design Strategy	+	+	-	+	-	++	++	++
Business Strategy	++	++	++	++	++	+	-	+
Commercial Strategy	++	+	++	++	++	++	-	++

Legend:
++, Extensive Elaboration
+ , Moderate Elaboration
- , No Elaboration

Table 4.2: Inductive Themes Emphasized in Interviews

Theme	Interviewee							
	# 1	**# 2**	**# 3**	**# 4**	**# 5**	**# 6**	**# 7**	**# 8**
Organizational Strategy	X	X				X	X	
Marketing Strategy		X	X					
Post-Commercialization Strategy	X			X	X	X	X	X

4.2. Key Findings

The following paragraphs introduce the key takeaways from the interviews as summaries of participants' viewpoints and responses. They are categorized under the overarching themes which were developed during the data analysis. The sub-themes are highlighted in bold.

Overarching Theme #1 - Organizational Strategy

Team formation is a critical success factor in medical technology development and commercialization. Not optimally formed teams, mainly in terms of expertise and vision, can hinder the business case of innovative medical technologies. An interdisciplinary team constituted by members with a business orientation, medical background, and people who can realize and develop the technology, has strong formation which enhances productivity. The team itself plays a critical role in securing funding from potential investors, especially during the early stage when prototypes and scientific evidence are missing. Members' expertise, long-term vision, and ambition are key consideration and selection points for venture arms to decide upon which new startups they should incorporate under their funding and support schemes.

Inside the team shared values and vision are important in fostering innovation. Members' **empowerment** is another factor that contributes to the successful business case development for emerging medical technologies. A startup environment that promotes ideas sharing and "..motivates members to do so..", meaning incorporating their different perspectives into the decision-making process can more effectively transition from the ideation phase towards the successful development and successful market entry of medical technologies.

Overarching Theme #2 - Design Strategy

The development of an effective design strategy requires a thorough **market analysis**. The identification of current problems along the current care pathway is important to validate the need for a new medical technology. Innovators need to invest time and effort during the early stage of ideation and through engaging with potential stakeholders capture patients' and care providers' flavors and preferences. Having understood the current pathway they should prioritize the design of a solution which better corresponds and adds value to their daily work routines.

Innovators should proceed with **strategic partnerships** with hospitals and care providers to understand the current care pathway and proceed with the development of a solution that better corresponds and adds value to their daily work routines. Closely collaborating with these entities can provide valuable insights on how the final outlook of the technology should be. It is important to consider that nurses and physicians do not always have knowledge about the use of emerging technologies. This "technology illiteracy" may not allow hospitals to understand the potential benefit of the new technology while at the same time, it makes it difficult for them to feed innovators with the proper feedback and recommendations about the implementation of the technology. Considering the time constraints of the nursing staff, teams should adjust their "language" to make the solution clear and identify the key personnel and decision-makers within the hospital to move the design of the technology forward. Early training and support to patients and clinicians can act as an enabler toward the future implementation of the technology. Similarly, establishing early stable partnerships can facilitate evidence development and clinical trials preparation. Except for collaborating with hospitals in a co-design method, startups should decide upon the development of the technology. More specifically, a decision to proceed with open innovation and outsource the development of the technology should be made considering the risk and cost sharing as well as the time constraints and the technical know-how. Alternatively, financing partners which could support the R&D processes should be identified and enhanced during the very early stage of the MedTech lifecycle. Entrepreneurs can take advantage of early innovation and transformation programs either provided by hospitals and insurance companies or seek external partners such as governmental funds or venture arms from big pharma companies.

In terms of the design strategy, startups should carefully consider the **technical characteristics** of their medical technology to ensure functionality and long-term survival. First of all, developers should ensure that the technology is safe and user-friendly both for the end-user and the nursing staff and incorporate all the necessary features that better solve the current care problems. In case the technology requires additional effort from users, then hospital implementation is hindered. Entrepreneurs should understand the general context of the technology and especially the complementary goods that are required so that the technology is accessed by the end-user (e.g., smart device, smartphone, VR headset, etc.) or the compatibility options that could protect the innovation and enable its scaling-up. Developers should in advance embrace the modularity of the technology incorporating customization options which enhance flexibility and promote technology diffusion to a larger number of end-users in the long run. Finally, the potential **technical risks** of the technology should be identified in advance and an efficient mitigation plan should be developed. Security and privacy risks when dealing with private health data are of great importance. Startups can incorporate measures such as data encryption, GDPR compliance, data anonymization, and cybersecurity penetration tests. Education and training of the end-users as well as embracing offline software updates could minimize potential security threats.

Startups should consider during the early stage the **regulatory landscape** of their medical innovations. Safety measures regarding future clinical trials should be designed in advance while the technology is still in the development phase. To ensure a smooth transition towards obtaining the CE mark and authorization of the technology, early engagement with regulatory bodies is paramount to understand and comply with the requirements should be prioritized. The Dutch health system highlights the rigorous clinical investigation as well as post-market surveillance to secure the CE mark.

Overarching Theme #3 - Business Strategy

The ability of entrepreneurs to properly **analyze the health ecosystem** where their medical technology is intended to be integrated is a critical success factor for developing an effective business strategy which could help them transition from the idea to a viable commercial product. Initially, entrepreneurs need to invest time and effort to determine the economic buyer and the end-user of their medical technology. In that way, and by analyzing market intelligence data and market trends they will be able to quantify the market size and accordingly adjust their value propositions to potential stakeholders. Currently, not a lot of attention is given to the market forecast, although it is a factor which provides hints about the trajectory of the medical innovation itself as well as the evolution of the MedTech industry. The Dutch healthcare ecosystem is not ideal for startups to prosper. It was quoted that "..the Dutch healthcare ecosystem is not ideal for startups to prosper, it is scattered, with very few big players, and the rest aim for scale-up.." There is a brain drain from the Netherlands abroad, e.g., the US which is more innovation-driven and has a bigger market. However, there is an effort in the last few years to enhance the discussion towards innovation pulling, facilitation of emerging medical technologies commercialization and early elimination of technologies that do not have significant added value to the health system. What was particularly underlined as a common pitfall in MedTech commercialization is that the technology may be fully functional, but it does not solve a critical problem for healthcare providers or does not align with the health system's priorities, leading to market entry failure. These cases of past failures have made hospitals and insurance companies more reluctant in embracing new medical technologies.

Early stakeholder engagement is critical for entrepreneurs to move their innovations forward while collecting feedback and valuable recommendations from different players along the value chain which are then fed into their decision-making. Such knowledge gives startups the necessary arguments to reject options and the directions to pursue the most efficient pathway toward market entry. Health Innovation Netherlands (HI-NL) is an initiative that enables early dialogue between startups and the relevant stakeholders along the MedTech value chain. Early dialogue helps startups understand where their value propositions lie and progressively quantify them. In many cases, a new technology aims to replace one service and save additional costs for the hospital, but since this service belongs under the fee-for-service payment scheme, adoption is hindered because hospital revenue margins are decreased. It is important that entrepreneurs understand the current procurement and investment policy of hospitals and respectively adjust their business case. Similarly, they need to engage with insurance companies during the early stage to understand their financial incentives. Demonstrating how

the technology aligns with insurers' requirements and reimbursement policies as well as how the technology achieves the long-term expectations of the treatment timeline is critical to the transition from a good idea to a successful market adoption. The latter was strongly underlined because the health system has a huge technology push where interventions aim to improve certain aspects along the treatment process. However, insurance companies seek more radical solutions which do not just simply save some money but lead to an end in the treatment process. Practically, they are not in favor of constant reimbursement of an intervention that simply cuts certain costs, but they expect to see how this intervention can lead to the actual cure of patients.

In terms of the pricing strategy, entrepreneurs need to carefully determine the revenue model and pricing point allowing profit margins and sustainability in the long run not only for their venture but also for the stakeholders which enable healthcare delivery. Although these stakeholders have conflicting interests, to enable the market entry and scale up of the technology, a consensus on the price needs to be made so that everyone is satisfied by the agreement regarding either the money they earn as profit or the money they save and the added health value and customer satisfaction they achieve. Properly quantifying their medical technology's value propositions and demonstrating its cost-effectiveness during the early stage of development should be prioritized. Early HTA in terms of early economic modeling has become paramount in the Dutch health system to justify additional efforts and future investments. Despite the national data on common diseases and treatment processes, the cost breakdown of health providers can sometimes be difficult to be accurately retrieved in the Dutch setting. As a result, in case a startup aims for cost reduction, it can either observe the existing health system if data are available or compare other countries' payment systems which may provide relevant cost breakdown and guide innovators towards their economic modeling. Last but not least, strategically navigating reimbursement agreements with insurance companies can facilitate market entrance. It would be wise to engage with entry-level insurers and understand their authority in enabling the integration of new technologies in the insurance and premium packages. Such employees are working in junior positions and can approve certain technologies to be included in the insurance packages up to a specific amount without the authorization of upper-layer employees. Startups should try to align their business model with the thresholds of these persons who have the freedom to approve reimbursement up to a particular monetary value without requiring additional approval along the corporate climb. Flexibility is key in business development to navigate the complex and fragmented healthcare ecosystem as well as the potential landscape changes.

Finally, **strategic partnerships** play a crucial role in guiding the business strategy of the startup. Pharma companies have venture arms that support startups with R&D and can guide startups in developing their business strategy and pursuing the most suitable market. In the same direction, early engagement with hospitals, care providers, and insurance companies can lead entrepreneurs to identify and leverage innovation funding components or schemes which mainly focus on healthcare transformation. Lastly, entrepreneurs need in advance to navigate strategically competition among hospitals and care providers. Such competition has the potential to accelerate technology upscaling since these entities aim to remain innovative in the market and aim for higher quality care.

Overarching Theme #4 - Commercial Strategy

Depending on the nature of their medical innovation, entrepreneurs have to proceed with a thorough **market analysis** to decide upon the commercial pathway they should pursue. On the one hand, the regulated care market is stricter but the steps and processes are more straightforward while on the other hand, the regular mass market tends to be bigger but more uncertain. In the professional care market, hospitals and care providers are the ones who enable care delivery, but it requires time and effort for them to understand and use the new technology. On top of that, the fact that these entities are usually understaffed, in nursing staff and project managers, should be a key consideration in how to approach market entry. Dutch hospitals are currently focusing on privatization which hinders technology diffusion and upscaling since they aim to keep new technologies in-house. However, in the last few years, there is a willingness for more open collaboration among these institutions which could drive the improvement of new technologies and could achieve faster proof of concept leading eventually to market diffusion acceleration. The regular market holds more potential considering its less fragmented product lifecycle. Entrepreneurs need to capture the market needs and proceed

with the identification of the early adopters. Such individuals or institutions are willing to experience new innovative medical technologies despite the lack of scientific evidence about the technology. They are innovation and curiosity-driven and can help the startup test its product and build its final proof of concept to reach higher market segments. Finally, early engagement with insurance companies and exploration of the premium packages relevant to the intervention context can guide entrepreneurs to quantify the market and respectively decide how to enter the market and what segment to go for.

Strategic partnerships are critical for entrepreneurs to develop their commercial strategy. Startups should seek and exploit the initiatives and programs provided by the Dutch government, insurance companies, or hospitals, which aim for the transformation of care delivery. In case a technology does not fall within the existing budget capacity of the hospital, Dutch hospitals give the opportunity to implement a technology in their funding programs delivered by friend foundations built on private contributions of ex-patients or organizations. In terms of market entrance enablement, except for funding resources, partnerships with a hospital or a group of care providers who share startups' vision accelerate clinical data and efficiency demonstration, decrease cost and risk, and facilitate market entry.

The **operational trajectory** of the startup can unlock new opportunities for startups. More specifically, they can have their R&D in one nation and proceed with commercialization in another country leveraging more beneficial conditions and fewer barriers towards the market entrance.

Finally, **venture ownership and IP rights** have been highlighted as key components of startups' commercial strategy. Firstly, ownership, Tradename, and Trademarks should be prioritized during the early stage of development to signal marketplace establishment for emerging startups. They show commitment, rigor, and insurance toward potential funding and commercialization. Early exploration of the registered patents and design can prevent startups from accidentally falling within competitors' inventions which could lead to future conflicts. Also, it helps entrepreneurs find major players in the field which could unlock new partnerships or outsourcing opportunities for startups that can take advantage of the technical know-how and achieve market entry with less cost and risk. Finally, the technical know-how that startups acquire during clinical trials can be registered as trade secrets that in the future may have significant value for startups.

Overarching Theme #5 - Marketing Strategy

As mentioned before, a good functional efficient product is not enough to reach the market and prosper in the long run. Marketing has been identified as a critical component of the MedTech commercialization pathway. Entrepreneurs need to determine in advance their strategies to reach **customer channels** and enable the diffusion of their innovations. Efficient marketing and sales strategies can alleviate customers' reluctance to adopt a new technology. Involving middle entities in care provision (General Practitioners, private doctors, etc.) with referrals, could be an effective marketing approach. It is important to understand how customers could have access to the medical technology. Implicit marketing in social media, patient groups, support groups, and word-of-mouth can increase awareness. A pull strategy to enhance hospitals' and care providers' competitive advantage by increasing their customer base while improving their care delivery quality can be an efficient decision.

Overarching Theme #6 - Post-Commercialization Strategy

Another part of early HTA is the consideration of the post-commercial phase of emerging medical technologies. Such decisions can help startups foresee the expected trajectory of their technologies and in advance adopt a flexible business model and a **long-term strategy** which could enable a faster and more efficient transition. As the technology evolves a large amount of data is generated which could help the team improve its product. In case the startup decides initially to enter the regular mass market, these early data could be sufficient to proceed with extensive clinical trials and seek the professional care pathway. Except for its strategic decisions, a thorough observation of the potential long-term effects of the technology should be carefully undertaken. For example, potential over-reliance on novel medical technologies should be considered. New interventions

should not replace current methods because not all patients will respond positively. Also, transforming or enabling more digitalized care can threaten the interpersonal contact between physicians and patients, and should be carefully examined. Post-market surveillance is an aspect that is highly underlined by policymakers in the health system.

Last but not least, in terms of the post-commercialization strategy of the startup, **strategic partnerships** should also be explored during the early stage. A flexible technology core could allow startups to change directions in the long run and seek new partners and funding. Without continual financing after market entry, it would be difficult for startups to sustain and innovate to scale up. The Dutch government provides funding for post-market entry phases for scale-up, where the readiness level of the technology (RTL) is a key factor.

4.3. Practical Implications - AYA Smart

Having the AYA Smart medical technology as a reference case to deepen and enhance the findings and understanding throughout the semi-structured interviews there were certain results that cannot be generalized to the broader setting of medical technologies and need to be distinguished as practical implications. More specifically, exploring elements that could enhance the transition from ideation to market entry of medical technologies, there were certain specific recommendations and directions provided by the participants based on their expertise and experience along the value chain of medical technologies commercialization. Although these findings are considered non-generalizable to the general research setting, they can act as an evidence-based strategic roadmap for future entrepreneurial endeavors, especially for medical technologies which aim to be compatible with VR environments.

Overarching Theme #1 - Design Strategy

Features of Intervention

Important features to include are customization options, a wide variety of scenarios and stimuli to cover diverse needs, and comprehensive analytics to track progress. Outcomes like reduced symptoms, improved quality of life, better cognitive function, emotional functioning or improved social skills can be expected. Especially for social functioning, social interaction can be done with a 3D Avatar of real people (breast cancer survivors, clinicians, friends, teachers, etc.) that interact through their phones with the VR application that the patient is logged in to. We can measure these outcomes using validated and objective scales and questionnaires, supplemented with data from the VR application itself such as the heartbeat when the patient is exposed to stimuli. It's crucial to ensure that the technology is user-friendly for both patients and medical staff and is able to provide meaningful insights. Some insights may be more beneficial to be retrieved through built-in analytics, while others may require the supervision of clinicians. For cognitive functioning, or tracking of patients' emotional responses to different stimuli VR-exported data should help to measure improvements. However, particularly in early stages where there is uncertainty or severe mental disorders, VR interventions might be best carried out under the supervision of a clinician. The clinician can monitor the patient's reactions, provide real-time guidance and support, and adjust the intervention as necessary. Also, a decision toward the VR headset itself should be made. Developing the technology on existing VR glasses can leverage existing infrastructure and reduce costs. However, a closed device may offer more control over the user experience and ensure compatibility. The final decision will depend on the use case and the available resources. The aforementioned features are highlighted not only because of the nature of the intervention in the mental health but also because according to the interviewees there is an increasing research interest around VR technologies in mental health. Also, it is important to recall the feedback of the nurse about the proof of concept not only from the intervention itself but also the acceptability around existing technologies or clinical evidence. Taking these 2 points into consideration, the developers strategically can embrace those features and be alert about scientific evidence that can emerge from other scientists (for free) to demonstrate the potential effectiveness of their technology to relevant stakeholders.

Benefits

There is a growing acceptance of VR technologies in medical care. Currently, the readiness level varies. There are applications with a high level of maturity, like PTSD and pain management, but also fields where we are still in the research stage. Quality, stimuli, and environment included in VR applications need to be tailored to the individual needs of patients, and analytics should offer comprehensive insights to allow the personalization of care. VR technologies can provide safe and controlled environments where patients can confront and cope with various situations, which ultimately lead to mental health improvement. In terms of social functioning these technologies can enhance social cognition in individuals with social anxiety and through virtual social interactions individuals can practice and hone their social skills and have better real-world social functioning. In terms of cognitive functioning, patients can experience VR environments with virtual tasks and challenges that eventually stimulate cognitive functions like memory, attention, and problem-solving. In terms of emotional functioning, VR has been particularly useful in exposure therapy for conditions like post-traumatic stress disorder (PTSD) and various phobias. By gradually exposing patients to their fears in a controlled, virtual environment, anxiety levels can be reduced over time. Finally, physical functioning is another aspect that VR technologies can improve through personalized VR-based exercises and activities. It is important that in the reference hospital, AYA are familiar with new technologies and are willing to adopt this new technology and help the developers and nursing staff to identify potential hurdles and bottlenecks.

Technical Risks

In terms of user safety, VR environments can cause symptoms like nausea, dizziness, or even seizures in some individuals. It's important to design the VR experience to minimize these risks, and to warn users of the risks beforehand. When demonstrating the technology it is critical to analyze what type of simulation is that, whether it is going to be a passive experience that you just sit on a chair and see a video or is it something interactive that you have to walk around which are very different interventions. Security and privacy risks need to be identified and mitigated since the AYA Smart technology may involve collecting sensitive patient data. To mitigate these risks implement:

- *Data Encryption*: All data, whether at rest or in transit, should be encrypted.
- *Access Controls*: Implement strong user authentication measures and limit data access to those who need it.
- *Anonymization*: When storing or processing data, make sure to anonymize it, meaning that it cannot be traced back to the individual patient it came from.
- *Offline Production*: Whenever it's possible, when conducting a research trial with VR, if it can be used in an offline mode makes it safer. Offline usage reduces the exposure to potential vulnerabilities associated with online communications. Additionally, it can offer greater control and privacy to the user, as the data doesn't leave their physical device.
- *Regular Audits*: Regular security audits and penetration testing can help identify vulnerabilities before they can be exploited.
- *Compliance*: Make sure to comply with all relevant regulations, such as the General Data Protection Regulation (GDPR).
- *Education*: It's important to educate both users and staff on the importance of security and best practices, such as not sharing passwords, recognizing phishing attempts, and ensuring secure connections.

Overarching Theme #2 - Business Strategy

Health Ecosystem Analysis

The hospitals do not see this technology implemented in the breast cancer clinic but they recognize benefits in the whole oncology clinic section. Knowledge can be faster gained and shared among nurses and end-users

and clinical evidence would be stronger. It is important to have customization options not only among the different types of cancer but also among the patients of the same one. For example in the AYA segment, there are patients who struggle to follow their school obligations (stimuli should be adjusted to this need), while other patients are suffering from anxiety about their future professional career (the intervention should try to mitigate this aspect of their daily life).

AYA are less lost, they know who to contact, and what questions they need to ask, and they can get more personalized care by approaching the proper person. The nursing staff know when to send AYA in another specialist, social worker or psychologist.

To quantify their value propositions and perform early HTA except for the benefits included in the design strategy subsection, it is important for developers to be aware of the key cost drivers in developing the AYA Smart. Such amount includes hardware and software development, regulatory compliance, content creation, and user interface design. Ongoing costs like software updates, user support, and data management should also be considered.

Overarching Theme #3 - Commercial Strategy

To accelerate implementation, it would be helpful to engage stakeholders early on, build strong evidence for efficacy, and provide thorough training and support for the end users. Also, you need to identify current problems and identify paths to ensure that the technology can be implemented efficiently into existing daily operations, systems, and workflows. The hospital where the co-design session was employed has transformed its approach towards interviewing the AYA to capture their needs. This new information aims to be digitalized while also these interviews aim to be done from home at the convenience of the patients. The developers behind AYA Smart should try to align their technology with these new modifications along the care pathway.

Strategic Partnerships

Although in Europe VR technologies have clear regulatory requirements, there is a need for stronger guidelines for the research being done with VR in healthcare in order to build the evidence which could enable the adoption by the health system.

The AYA Smart technology could leverage the Impact Explorer which can secure €30,000 for 12 months for early high-risk and high-uncertainty research and guides startups for their prototyping. It is an NWO grant and somebody registered in the university can apply for this particular fund. Also, the AYA Smart medical technology could take advantage of the IZA Coöperatie VGZ agreement for transformational funds provided to hospitals under the support of the government and the supervision of insurance companies. The technology could justify its worthiness by contributing with three criteria:

1. Prevention including value-driven care
2. Relocation including capacity improvement and digitization
3. Replacement including professionalism

Ownership & IP

In terms of intellectual property rights, the AYA Smart Technology should initiate Trade Name and Trademark registration, at the Netherlands Chamber of Commerce and the Benelux Office for Intellectual Property (BOIP) respectively. Also, the development team should consider during the early stage to apply for design rights in the GUI of the VR environment. Then, early clinical trial data can be utilized as trade secrets of technical know-how; such information may not be valuable in the beginning but in the long run, they may have a strategic advantage. Finally, the company should ensure that the medical technology has ownership in terms of copyright IP rights as a creator with global and long-lasting validity. Even the GUI could have accompanied copyright as a software creation that is close-sourced. Finally, Blockchain has been identified as a way to register your idea and certain content creation so that you have evidence that you had this idea; it could be an argument with legal validity that you had it on blockchain and somebody had access illegally on

that block.

Overarching Theme #4 - Post-Commercialization Strategy

Long-Term Risk Considerations

There are certain long-term risks that need to be considered:

- *Over-reliance*: While VR offers exciting possibilities, it shouldn't replace traditional care methods entirely, but rather augment them. Over-reliance on VR could risk alienating patients who don't respond well to it or prefer traditional methods.
- *Effects of VR after treatment*: Patients may experience physical or psychological symptoms when they stop using VR after a prolonged period of time. If a patient has become highly accustomed to a certain VR therapy or environment, they might experience distress, discomfort, or disorientation upon discontinuing its use. If it´s abruptly stopped, patients may experience a resurgence of symptoms or a decrease in the therapeutic gains made during treatment. This is similar to what can happen when any form of therapy is abruptly discontinued. This problem should be considered in all research or CT using VR, especially with more vulnerable patients such as children or anyone with a mental health condition.

4.3.1. Summary of Practical Implications

The table below summarizes the key elements that are relevant to the strategic directions of the AYA Smart development, categorized by the main themes that can build the MedTech commercialization roadmap.

Strategic Theme	Directions to Consider	Examples
Design Strategy	Social interaction	Use real people as Avatar
	Complementary goods	Either for safety go for built-in device or consider adoption, time-to-market, and compatibility with existing VR headsets
	Use as medical intervenetion	Use heartbeat outcomes & Built-in analytics
Business Strategy	Leverage existing research as proof of concept/clinical evidence to accelerate the effectiveness demonstration	4 types of functioning are currently under research for VR environments
Commercial Strategy	IP	GUI rights & Trademark
	Leveraging Programs	1. Impact Explorer (30,000 euros) 2. IZA Cooperatie VGZ 3. Zorgtransformatiemodel
Post-Commercialization Strategy	Long-Term Risks	Over-reliance / effects of VR after treatment / effects from less patient-nurse interaction

Table 4.3: Key Consideration Points in AYA Smart Development

5 Discussion

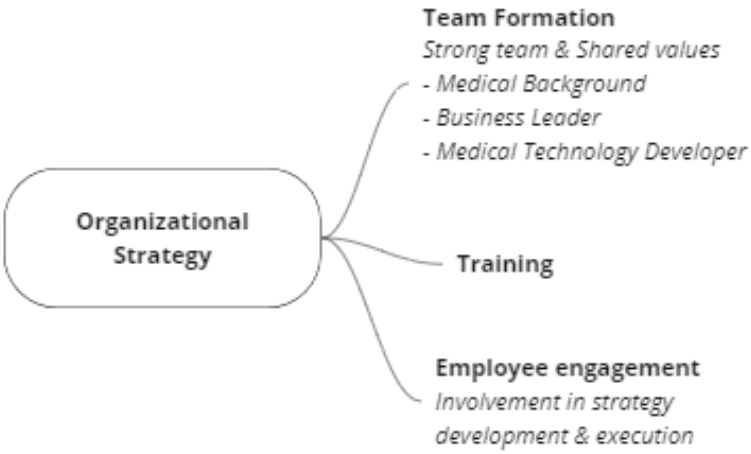
This chapter aims to combine and critically reflect the insights and viewpoints that emerged both from the literature and the expert interviews. In the last section I expand refine and complete the conceptual framework that emerged through the literature (Fog. 2.4), introducing a novel strategic roadmap for innovators to navigate the MedTech commercialization journey.

5.1. Reflection on Study Findings

5.1.1. Organizational Strategy

The formation of an effective startup team holds significant importance in the successful commercialization of Medical Technology (MedTech) innovations. A strong and cohesive team with a shared vision is crucial for navigating the complex landscape of MedTech commercialization (Srivastava et al., 2019). The multidisciplinary nature of MedTech necessitates an interdisciplinary team comprising individuals with complementary expertise in areas such as development, healthcare, business, and regulatory affairs. Collaboration among team members with different skill sets and empowerment to incorporate their perspectives into the decision-making fosters innovation, problem-solving, and a holistic approach to product development and market entry. The qualitative research highlighted that team members with an entrepreneurial mindset can materialize the innovative idea into an effective product which can solve real problems and develop a business case that can achieve economic returns. Additionally, having in the team people with medical background is a key success factor. It emerged from the results that members' deep understanding of the medical field and clinical context can be valuable in guiding the design and implementation of the system. These medical experts can offer unique insights into the specific needs of patients and healthcare providers, the clinical relevance of various features, and the potential impact of the technology on patient care. They can also help ensure that the technology complies with healthcare regulations and standards and that it can be seamlessly integrated into existing healthcare workflows. Moreover, having a medical professional on board can enhance the dynamics of product development, facilitating partnerships with healthcare organizations, and bolstering confidence among potential users. Their ongoing involvement ensures that the system remains clinically relevant and user-friendly, as they are uniquely positioned to bridge the gap between technology and healthcare. Lastly, people who are analytical and have development and design skills to realize the technology can lead the technical side. Overall having an organization with a well-balanced strong team can enhance the credibility of the startup in the eyes of investors, regulators, and potential partners, thereby increasing the chances of securing funding and pursuing critical collaborations. By pooling together diverse talents, experiences, and knowledge, a robust startup team in MedTech can effectively address the complexities of the commercialization process and pave the way for successfully introducing impactful medical technologies into the market. On top of that, it is critical to empower these talents creating the opportunity and the environment for enabling the exchange of information, knowledge and ideas, the involvement in strategy development, as well as the blossom of individuals (Srivas-

tava et al., 2019). To conclude, in terms of the organizational strategy of new ventures, the key elements that need to be prioritized toward effective MedTech commercialization can be depicted in the figure below.



5.1.2. Design Strategy

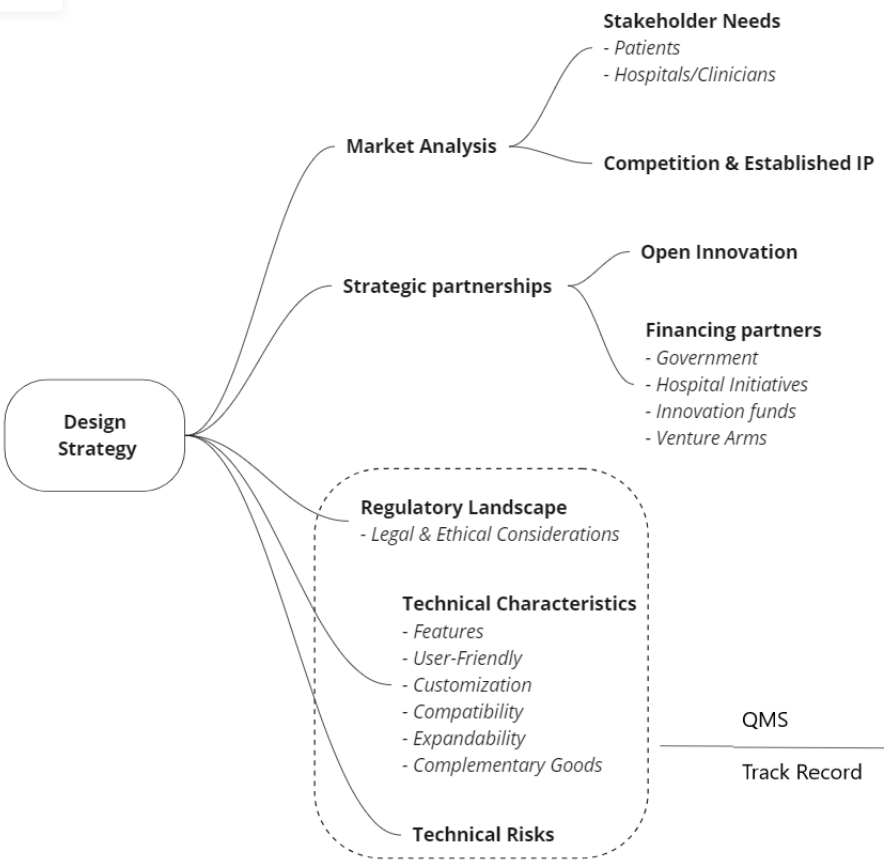
Developing a comprehensive design strategy is critical to facilitate the successful transition from the ideation phase to the market entry of medical technologies. In-depth market analysis is imperative to identify the prevailing problems along the care pathway and align the intervention with existing work routines. By embracing early patient and stakeholder engagement and understanding the needs and preferences of patients and care providers, startups can develop solutions that address the most radical challenges and increase acceptance and adoption rates (MacNeil et al., 2019). Establishing strategic partnerships, particularly with hospitals, holds great potential for startups, as they can leverage these collaborations to gather evidence, validate their technology, and facilitate implementation. In line with the literature, it was found that the co-design of the technology with the hospital, early training, and support provided to both patients and clinicians play a crucial role in ensuring the successful uptake and effective utilization of the medical technology (Pellikka and Malinen, 2014). Such an experience can guide startups for future collaborations to achieve clinical evidence and later on, scale up. Considering the technical characteristics of the medical technology, startups need to carefully identify the general context in which their innovation operates. Factors such as compatibility with existing systems and the requirements for customers to access the technology should be evaluated. It is important to be aware of the complementary goods to deliver their products, what patients and end-users need to possess to access the technology, and what value these goods bring to the overall experience of the user (Keown et al., 2017). It was validated through the qualitative research that the user-friendliness of the technology for both patients and clinicians is vital, as it enhances acceptance and satisfaction (Bakker et al., 2021, MacNeil et al., 2019). Incorporating flexibility and customization options in the design can further facilitate the diffusion of the technology to a larger user base, catering to individual needs and preferences.

The expert interviews highlighted dynamics in the commercialization pathway, regarding the exploration of their Intellectual Property (IP). It will help them define their freedom to develop and operate their technologies while it may provide valuable insights into enhancing current unsolved technical obstacles by developing high-end solutions. Observing what is in the market they can either find a market gap and create a better solution or take existing IPs as inspiration to other similar or not technologies. Also, they are able to define their establishment rights in the marketplace (e.g., design rights), avoiding the pitfall to develop antagonistic products of already established products. Ultimately, startups can make informed decisions incorporating marketing intelligence and technical information.

Finally, in line with the existing literature, early engagement with regulatory bodies, understanding their requirements, and proactively seeking appropriate certifications, such as the CE mark, can accelerate the approval process (Fearis and Petrie, 2017). The interviews went deeper on the surveillance and the post-market phase consideration, elaborating that startups must consider user safety during clinical trials, addressing potential risks and adverse human effects which can jeopardize the well-being and health condition of the trial

participants. Potential harm or adverse effects on the individuals involved in the study should be in advance considered, since it can also compromise the integrity and reliability of the trial results, potentially hindering the development of safe and effective medical interventions. Moreover, the potential long-term human impact of the technology should be carefully evaluated, taking into account factors such as durability, sustainability, and overall benefit to patient well-being. Rigorous clinical investigations, track records, and implementation of quality management systems (QMS), pre-market assessments, and post-market surveillance, are essential to meet the stringent regulatory requirements and ensure the safety and effectiveness of the medical technology throughout its lifecycle (Fearis and Petrie, 2017).

Taking all these points in mind a graphical representation of the elements that need to be addressed in terms of the design strategy of the medical technology can be found below.



5.1.3. Business Strategy

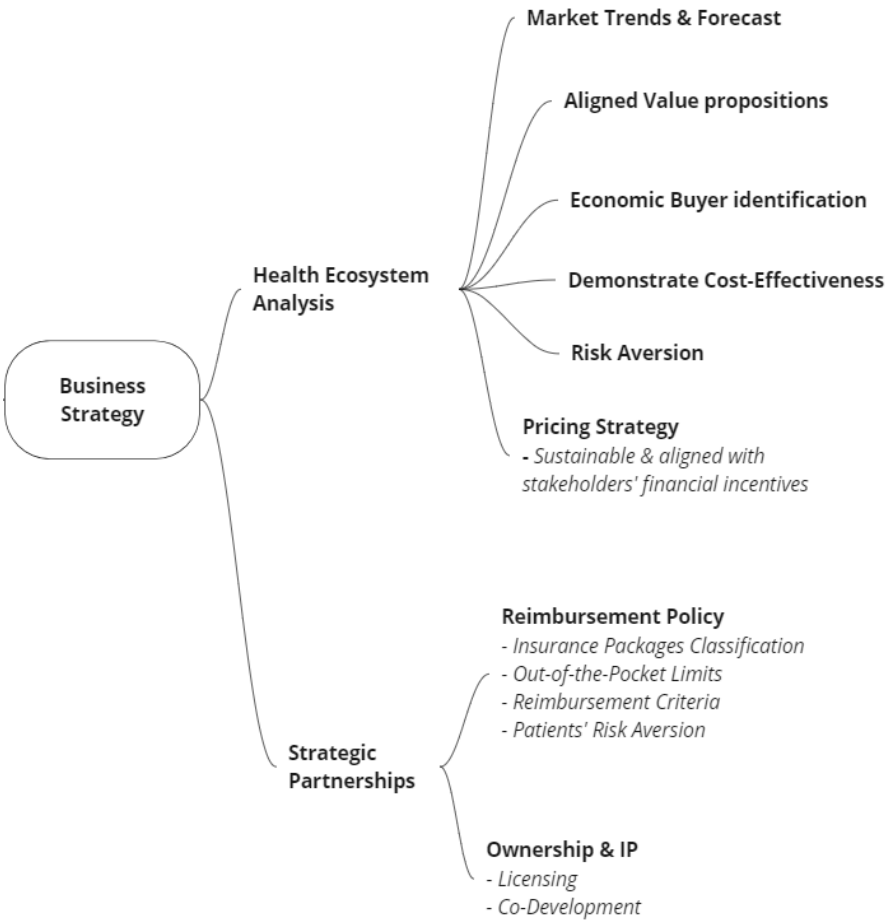
The results agree with the literature review validating that the development of an effective business strategy for the startup is key to the successful transition from the ideation phase to the effective market entry of medical technologies. The MedTech industry is fragmented and efficiently navigating along the value chain can create opportunities for novel technologies to enter the market and prosper (Schuetze et al., 2023). Correctly identifying the economic buyer and end user of the medical technology is paramount. It enables startups to tailor their value propositions effectively, aligning their offerings with the needs, demands, and priorities of the target market. Early stakeholder engagement plays a fundamental role for startups venturing into MedTech commercialization (Pellikka and Malinen, 2014). By actively involving stakeholders, such as healthcare providers, patients, and regulatory bodies, entrepreneurs can gather valuable data and feedback necessary for informed decision-making. This engagement fosters a collaborative approach, allowing startups to address potential concerns and refine their strategies based on real-world insights. Furthermore, involving stakeholders early on provides a solid foundation for building relationships and securing support, which can be instrumental in overcoming barriers to entry and facilitating market adoption (Schuetze et al., 2023, MacNeil et al., 2019).

Hospitals and insurance companies tend to be reluctant in adopting new technologies. Past failures and

the cautious nature of these institutions create a challenging environment for startups. By demonstrating how the technology can be integrated seamlessly into the existing system and addresses specific needs, startups can enhance the likelihood of adoption and procurement (Bakker et al., 2021). Although early stakeholder engagement can build trust and credibility and guide startups toward positive agreements, extensive clinical trials that validate the effectiveness and safety of the technology are the milestone that materializes these outcomes. The expert interviews underlined the importance for entrepreneurs to understand the current procurement criteria, reimbursement policy landscape, and the financial and innovation-driven incentives of care providers and insurance companies to properly align their business model to their requirements. For example, it is very common for startups to achieve better care with fewer services. In case these services are reimbursed with a fee-for-service model, these technologies decrease the profit margins of care providers and adoption is hindered. Developing an efficient pricing strategy is also critical for startups to prosper. On the one hand, they need to secure profitability, but at the same time find the pricing point which balances affordability and sustainability in the long run for the key enablers along the health system value chain. Insurance companies act as gatekeepers in the care pathway. A valuable hint that emerged through the expert interviews is that innovators that aim efficiently navigate through the professional care path could align their pricing points on the bundle thresholds of entry-level assessors to accelerate agreement, without requiring verification and additional assessment from employees at higher corporate positions. Additionally, it was found that delving into insurance companies' insurance package classification to identify customers' preferences, out-of-pocket limits, and risk aversion enables startups to define their business and commercial trajectory more effectively.

Finally, proactively exploring Intellectual Property options can assist startups to explore and identify new business models. Finding the key players in the market can unlock new opportunities such as co-development where risk and cost are shared, or licensing which allows for additional revenue streams (Lehoux, Miller, et al., 2017). It is important for startups to embrace flexible business models, remain agile, seize emerging opportunities, pivot when necessary, and stay ahead of the curve in the evolving healthcare ecosystem (Khodaei and Ortt, 2019).

The figure below summarizes the elements that constitute the business strategy dynamics as emerged from the literature review and were enhanced from the expert interviews.



5.1.4. Commercial Strategy

Another dimension that needs to be considered in the decision-making funnel for new ventures which aim to transition from the ideation phase to the succesful market entry of their medical innovations is the commercial strategy. It was emphasized in the interviews the importance to adopt a data-driven approach so that entrepreneurs quantify the market size to enhance the accuracy of their medical technologies' market positioning. More specifically, observing market intelligence data and market forecast enables startups to capitalize on emerging opportunities and, eventually, adjust their commercial strategy. Based on such insights, startups will need to carefully decide on the commercial pathway they should pursue to better respond to the market needs and enjoy the return on their investments (Buisman et al., 2016). Depending on their design and business strategy they can follow either the traditional regulated professional care pathway or aim for introducing their medical technologies into the regular mass market. The first one increases credibility and sustainability in the long run, with a proven concept. Startups could take advantage of the innovation schemes that hospitals and insurance companies or governments promote, in order to venture their medical products. Depending on the cost of the technology development, either a partnership with one hospital or a consortium of care providers dedicated to enhancing care transformation, can enable market entry while accelerating clinical evidence and reducing risk and costs. The Zorgtransformatiemodel is an example of an initiative which can enable actions, discussions, and funding that promote and facilitate the transformation of healthcare delivery. On the other hand, the regular market unlocks opportunities for a larger market adoption and flexible scale-up. Early adopters are willing to embrace and experience new innovative technologies without scientific evidence, leading eventually startups to gain momentum and diffuse their products to bigger market segments after providing their feedback and validation (Ortt and Schoormans, 2004, Dedehayir et al., 2017). The possibility for startups to pursue initially the regular market to have access to clinical evidence in a faster way, and then proceed with the analysis of these data in order to make a more efficient, less risky, and less capital-intensive transition to-

ward the professional care pathway, was identified as a strategic move to cross the chasm between ideation and implementation while managing uncertainty and capital shortages. In this way, they ensure revenue streams and knowledge acquisition while innovating.

From a commercial perspective, another pool of options that startups have come from the selection of their operational trajectory. It is common for MedTech startups to operate their R&D in one country and market their product in another one, operating as contractors. This approach unlocks additional opportunities for startups to reach bigger markets, establish themselves in broader health systems and enjoy higher economic returns.

Lastly, to establish a stronger commercial presence in the market, medical startups should thoroughly consider their Intellectual Property and ownership. Having IPs such as tradename, trademark, copyrights, design rights, or patents increase credibility toward potential investors and partners. In parallel, observing competitors can guide startups to avoid conflicts and provide insights on how to pursue new markets. Finally, during the early stage potential clinical evidence may not be of great importance but in the long run such data could act as trade secrets that could protect the commercial viability of the product or even create new sources of revenues in case the startup decides to seek further partnerships or licenses.

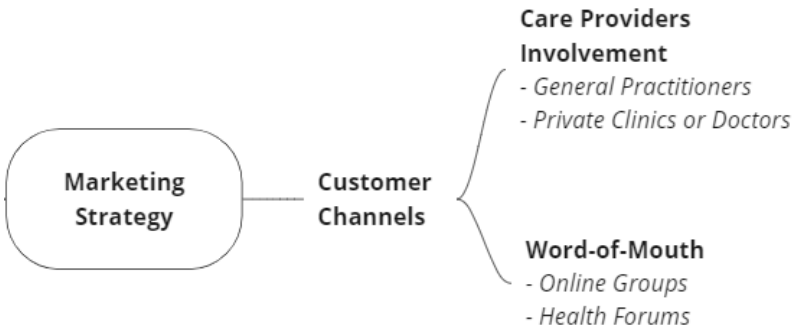
Taking all these points into consideration, a graphical depiction of the key decisions and possible directions of entrepreneurs when developing their commercial strategy during the early stage of development can be found below.

5.1.5. Marketing Strategy

The results validated the literature's point that a good and efficient technology, along with a well-balanced business model is not enough to ensure a successful market entry (Grutters et al., 2019). What was emphasized in the interviews is that medical startups should seriously consider their marketing strategies to better capture value. In the dynamic and competitive healthcare industry, it is crucial for startups to effectively communicate the value, benefits, and differentiating factors of their technologies to key stakeholders. A well-executed marketing strategy helps startups create brand awareness, establish credibility, and generate interest among healthcare providers, investors, and potential customers. By strategically targeting and reaching the right audience through tailored messaging and channels, startups can build relationships, foster collaborations, and drive the adoption of their technologies. Furthermore, an effective marketing strategy allows startups to showcase the clinical efficacy, safety, and economic advantages of their medical technologies, addressing any concerns or skepticism within the healthcare community. Entrepreneurs need to identify the proper customer channels to reach their audience. Early engagement with insurance companies to be informed about their customer

base in terms of the insurance package classifications can create valuable knowledge about the marketplace that the intervention should intend to be implemented. It was also found that approaching middle care entities such as general practitioners or private care providers to embrace and reference startup's medical products can lead to faster diffusion. Also, directly reaching customer segments through care-related platforms can be more efficient to spread awareness and increase curiosity and adoption. Finally, another recommendation from the experts for startups was to decipher the competition among care providers, especially hospitals, and accordingly decide strategically where to market their products and how. More specifically, hospitals aim to remain competitive and would more easily adopt new technologies with proven concepts to other hospitals. Decisions such as pull marketing strategies should be considered during the early stage to identify and establish partnerships with key players in the market.

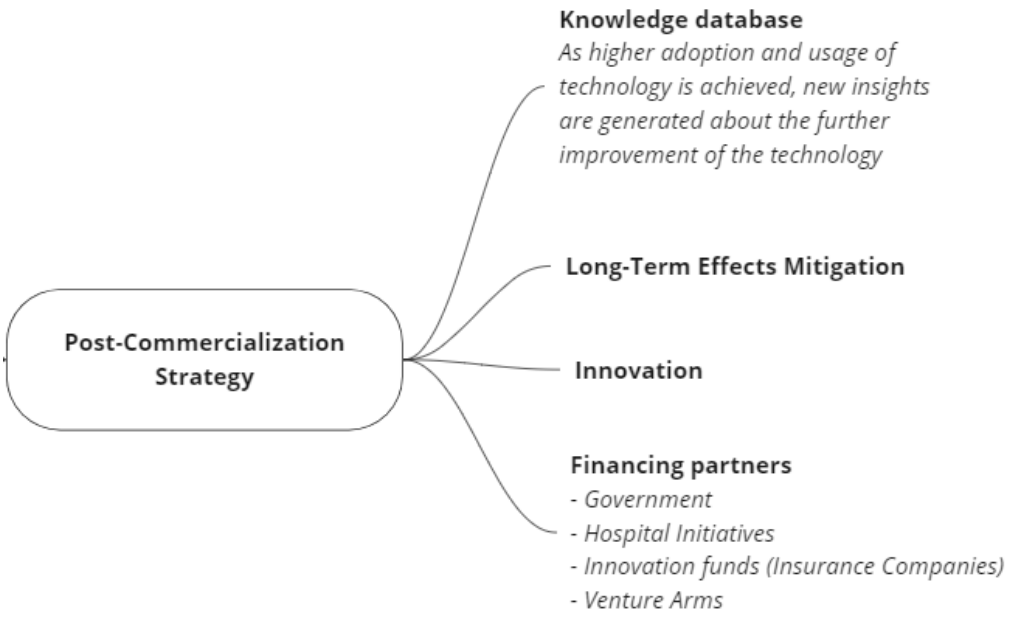
The aforementioned elements can be better summarized and graphically depicted in the following figure.



5.1.6. Post-Commercialization Strategy

The qualitative research pointed out that although much emphasis is often placed on the pre-commercialization phases, it is equally important to proactively plan for the post-market phase to ensure long-term success. By envisioning the trajectory of the technology beyond the initial launch, startups can strategically align their resources and efforts to address challenges that may arise in the post-commercialization phase. This includes anticipating potential regulatory requirements, monitoring and managing potential risks, and establishing a framework for continuous improvement and innovation. Moreover, a well-defined post-commercialization strategy allows startups to proactively gather real-world data, assess the technology's performance in diverse settings, and refine their value proposition based on user feedback (Gbadegeshin et al., 2022). Also, early identification and mitigation of the long-term implications to patients and care providers enhance credibility and trust. By actively engaging with stakeholders, including healthcare providers, patients, and regulatory bodies, startups can adapt and optimize their technology to meet evolving market demands and ensure its sustained adoption and market competitiveness Scarbrough and Kyratsis, 2022). Flexibility in terms of business model development allows startups to adapt to potential changes along the value chain of medical care (Khodaei and Ortt, 2019). Strategically designing the potential future trajectories would keep startups alert for future opportunities as well as additional funding, which is imperative for their needs to achieve scale-up. Therefore, by investing in a comprehensive post-commercialization strategy early on, startups can effectively navigate the complexities of the post-market phase, drive ongoing innovation, and maximize the long-term success and impact of their medical technologies.

The elements that constitute the post-commercialization strategy for new ventures can be found in the figure below.



5.2. Enhanced Strategic Roadmap

Taking all the aforementioned points into consideration, it can be understood that the main dynamics of the transition from the innovation ideation phase towards the successful market entry of emerging medical technologies lie upon the organizational, design, business, commercial, marketing, and post-commercialization strategy. Entrepreneurs should incorporate these dimensions into their early decision-making process to assess, develop and deliver their products successfully, or respectively abort their idea early before high investments are done. To better capture and depict those dynamics along with the key actions to accomplish this transition, a novel strategic roadmap is deemed necessary. The enhanced strategic roadmap in Fig. 5.1 incorporates elements that better correspond to the value chain of the MedTech industry and has the potential to facilitate and increase market entry establishments for emerging medical technologies. To cross the chasm between ideation and market entry, there is an increasing need to proactively consider and assess the future outlook of medical technologies, aligning the current process with the early HTA principles, during the early stage of development, before clinical trials. After entrepreneurs have identified the problem in the healthcare setting and have envisioned a technology that could potentially solve this problem an intensive period of business validation is being initiated where several strategic decisions need to be made. These strategies can pave the way toward clinical trials and, eventually, market entry or help entrepreneurs identify the lack of potential for the new venture and either maneuver or abandon the idea. The MedTech industry is quite fragmented, complex and risk avert in adopting new technologies; it is difficult to accelerate the market introduction since it is highly related to the development and clinical trials. As a result, the following strategic roadmap aims to facilitate the transition towards market entry, rather than accelerate this process. It is important to understand that the steps of the strategic roadmap are iterative, meaning that the presented strategies are interconnected and should be adjusted to potential internal and external changes.

Ideation Phase

- **Organizational Strategy**

  Organizational strategy is crucial for startups to establish a strong foundation, define their mission and vision, and chart the commercialization pathway. It involves building a skilled and multidisciplinary team, fostering a culture of innovation, and embracing a robust, collaborative, and empowering environment. Startups with individuals coming from diverse backgrounds and expertise can improve the

ideation stage. The team is critical for future partnerships, funding, and managing uncertainty and clinical risks. A person that can lead the business side, a person with medical background to lead the clinical and health side, and technology developers to materialize the ideas are key players and need to be carefully selected.

- **Design Strategy**

The startup should be in a position to determine the characteristics, features, performance, and elements that the technology should incorporate in order to maximize its potential value. A thorough examination of the market and early engagement with patients and clinicians should be prioritized to align the final solution with their needs, and the existing work routines, capturing their preferences to increase the likelihood of successful adoption. In parallel, early exploration of strategic partnerships for technology development needs to be initiated. Either embracing an open innovation model, in terms of outsourcing the development, or leveraging national schemes or corporate venture arms for in-house development, are decisions that the startups should make early based on the current healthcare ecosystem. Finally, proactively evaluating the regulatory requirements and the technical risks of the technology along with key enablers for future up-scaling such as compatibility and complementary goods are critical components that need to be taken into account. The development of a comprehensive design strategy can facilitate the successful entrance of medical technologies within the health system, or in case the technology does not correspond to the health system's needs, an early decision to pivot or abandon the idea can minimize the failure risk and prevent entrepreneurs from investing additional resources which would not lead to the expected economic returns.

Translational / Business Validation Phase

- **Business Strategy**

A strong business strategy plays a crucial role in the successful commercialization of medical technologies in the dynamic field of MedTech. It encompasses a thorough understanding of the value chain in the MedTech ecosystem. Startups need to clearly articulate their unique value propositions and differentiating factors of their technology compared to existing solutions. The identification of the economic buyer and end-user and accordingly the early demonstration of the cost-effectiveness utilizing early HTA methods with variables that can measure patient and societal impact as well as the economic benefits are key steps towards an efficient business strategy. Startups can leverage partnerships with hospitals and care enabling institutions to validate their technology's value propositions. Early engagement with stakeholders, including clinicians, regulatory bodies, and payers, can provide valuable insights and support for navigating regulatory requirements, reimbursement policies, and market access challenges. Strategic establishment and proper management of the IP can create new opportunities for startups to navigate the MedTech commercialization and identify additional revenue streams.

- **Commercial Strategy**

The entrepreneur at this point should be able to position the technology within the healthcare system and determine the commercial viability of the product and eventually determine the proper commercialization strategy to penetrate the market. Entrepreneurs can either seek the professional regulated care pathway or adjust the intervention to reach the regular mass market. Each scenario involves identifying factors and actors that could accelerate the implementation of the technology, as well as risks and barriers that could hinder this process. Partnerships with hospitals can facilitate clinical evidence, foster innovation on the go, and enable diffusion channels. A strategic decision on the area of operation and market establishment based on the market size needs to be made. Also, startups should carefully

consider their IP not only to establish themselves in the market but also to take advantage of strategic collaborations to drive their innovations in the market or seek to license their IP rights and deviate their focus for other ventures while enjoying economic returns.

- **Marketing Strategy**

  Marketing strategy is vital for creating awareness, building brand equity, and driving adoption. It involves targeted messaging, leveraging appropriate customers and sale channels to reach the target audience, and establishing credibility through leadership and evidence-based communication. A good product alone is not adequate to enhance market entry and return on investment. Entrepreneurs need to capture the market dynamics and insights and make informed decisions regarding the effective marketing of their products. Continuous support and customer relations should be prioritized to enhance satisfaction and trust and eventually boost technology adoption and diffusion.

- **Post-Commercialization Strategy**

  During the early stage, entrepreneurs should evaluate and mitigate potential long-term implications of their medical technology. As the technology gets diffused, clinical evidence is generated that needs to be further exploited. Developing a comprehensive knowledge database can guide startups towards further innovation and improvement of their products. The potential future trajectories should be considered early on so that the company survives in the rapidly evolving healthcare industry. Also, alertness and operational flexibility are vital for securing additional funding and expanding market access.

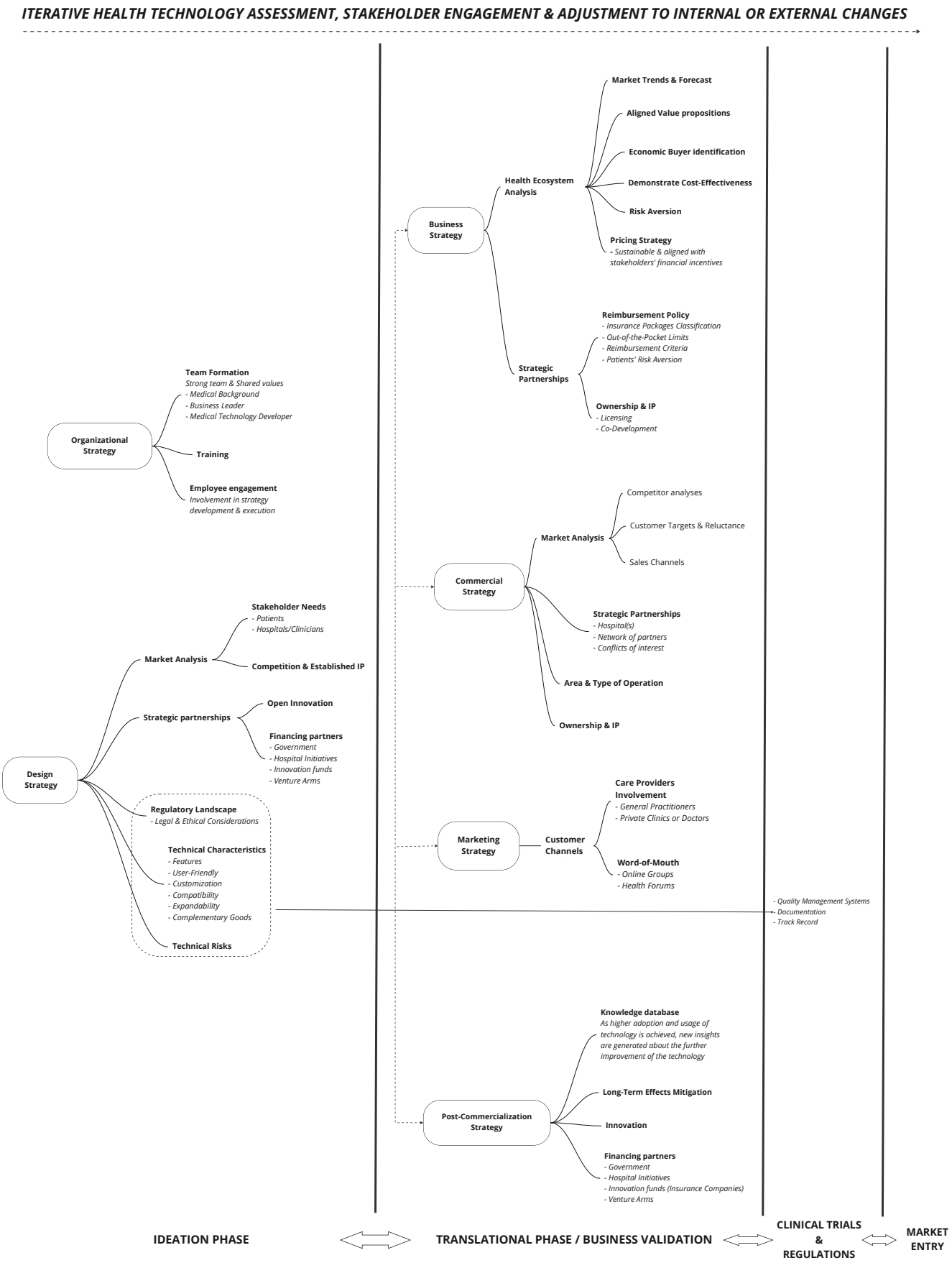


Figure 5.1: Strategic Roadmap from Ideation to MedTech Commercialization

6

Conclusion

6.1. Research objective and Main Research question

The main purpose of this research was to create a greater understanding of the dynamics of the transition from the ideation phase to the successful market entry of emerging medical technologies, and ultimately develop a strategic roadmap which captures those dynamics. Through the literature review, various methods and frameworks were identified which aim to help innovators navigate the MedTech commercialization pathway, but each one had its inherent limitations. There is a need to perform early health technology assessment to predict the commercial viability of the technology, but currently, it focuses solely on measuring the cost-effectiveness during the early stage of development. Scholars highlight the need for a more comprehensive evaluation of the general landscape which could eventually enable a successful market entry. Critical barriers and potential facilitators were identified mainly focusing on the design strategy and the technical efficacy of the technology, the business strategy and the alignment of the startups' value proposition with stakeholders' values, and finally, the commercialization strategy where the focus was mainly on the policy-making, regulatory approval, safety and the reimbursement decisions to help the technology be diffused. However, a deeper understanding of the strategies to overcome potential barriers and develop a more comprehensive commercialization pathway is essential. Overall, delving into the scientific evidence, it became obvious that there was a need to enhance the current knowledge base about the dynamics to navigate the MedTech commercialization pathway. In this respect, I performed qualitative research with 8 semi-structured expert interviews with diverse stakeholders along the value chain of the MedTech industry. Such an approach helped to gain insights from diverse perspectives and enhance the understanding of the dynamics in the commercialization process of emerging medical technologies. Through this qualitative research, various additional dynamics and strategies were identified.

More specifically, the importance of a strong team, with an interdisciplinary background to foster innovation, was highlighted. The ability of individuals to drive the business side of the startup is paramount, while a lot of attention was given to the existence of team member(s) with medical expertise. The latter can guide technology development while providing unique insights into patient and provider needs, ensuring medical compliance and seamless integration. They, also, enhance startup credibility toward care providers, partners, and investors since they instill confidence, and maintain clinical relevance. Developers to materialize the idea into a safe, efficient, and user-friendly solution are also a critical component of the team.

The design strategy holds a dynamic role in the ability of medical technologies to enter the market and sustain in the long run. Except for the technical characteristics in terms of user-friendliness, safety, and efficiency, participants highlighted the importance of the early involvement of patients and physicians to better understand their needs. On the one hand, in-house development can lead to higher control over the development and the IP, and leads to higher know-how and ability to achieve safety and efficiency. On the other hand, in case the startup decides upon a more open-innovation strategy, financing, and development partners should be identified during the early stage in such a way minimize risk and cost, accelerate development, enable

knowledge spillovers, and, depending on their power and credibility, enable smoother market entry. Finally, early consideration and track recording of the clinical evidence and regulatory requirements are paramount to enable a smooth transition toward commercialization.

In terms of the business strategy of the startup, the need to comprehend the health ecosystem value chain was prioritized. Entrepreneurs need to quantify the market size and identify the economic buyer and end-user of the technology. Understanding the financial and health incentives of the relevant stakeholders, entrepreneurs should proceed with the definition of key variables to measure and demonstrate the cost-effectiveness of the technology. It is important to build the story focusing on aligning their value propositions to their expectations to build consensus and a fair and sustainable revenue model which enables everyone to prosper and benefit. Interestingly, early engagement with insurance companies holds great importance in transitioning from the ideation phase to business validation and eventually market entry. To have a coherent business strategy, market analysis is critical and insurers can provide valuable insights into the insurance packages, the risk aversion and out-of-pocket limits of the patients, as well as the reimbursement criteria of insurers. In that way, entrepreneurs can adjust their business model to fit into these dynamics. Finally, ownership and Intellectual Property were key considerations toward a successful product, not only preventing competitors but also because early exploration of existing competitors and copyrighted products/designs could unlock new opportunities for partnerships or strategic movements to obtain additional revenues through licensing for example.

The commercialization strategy of the startup refers mainly to the decision to follow the professional care pathway or targeting of the mass regular market. Observing the market size, as well as the sales and distribution channels entrepreneurs should adjust their strategy to better capture and deliver value. Also, another dimension of the commercial pathway is the decision about the area of market entrance and operation. Strategic partnerships with hospitals can enable clinical evidence and build trust in the medical industry. The option to implement the technology in the regular market and obtain the necessary clinical evidence while innovating and having financial returns was identified as another strategic decision that enables the transition toward the professional care domain later on.

While the literature focused mainly on the business and commercial strategy of the startup, the qualitative research highlighted the need for a strong market strategy which complements and monetizes the aforementioned strategies. Entrepreneurs need to successfully identify and leverage customer channels. Depending on the commercialization trajectory they decide to follow, entrepreneurs can either reach the target market explicitly through word-of-mouth and other marketing techniques, or they could leverage intermediate entities such as general practitioners, who after having a proven concept, can enhance care delivery and foster innovation by referring new medical technologies. Competition among care providers should also be considered another dimension which holds a dynamic position in the commercialization process and technology diffusion. Practically, a proven concept in a hospital can be more easily adopted by other institutions with the aim to improve their care practices and maintain their customer base.

Finally, early considerations on the post-commercialization strategy of the medical technology hold substantial importance. The milestone of market launching itself does not guarantee long-term success. As the technology is adopted new clinical evidence is generated. It is critical that the startup has developed a comprehensive knowledge database which would enable further innovation to improve the products or strategically deviate to more promising directions. Being alert and having a flexible business model can help the startup obtain additional funding to scale its product. Carefully obtaining financing partners is critical in the post-market phase and early evaluation of them along with the potential trajectories to reach them should be proactively prioritized. Lastly, in terms of the technical characteristics, the team should consider the potential long-term implications of the technology and prepare a thorough mitigation and awareness plan to ensure societal well-being and customers' safety.

Main Research Question

What are the dynamics in transitioning from the ideation phase to the successful market entrance of emerging medical technologies and how can they be captured?

Answer: The dynamics can be captured in a strategic roadmap which includes six strategies to move from the ideation to the successful market entrance. More specifically, the development of a cohesive organizational strategy and a thorough design strategy are positioned in the early ideation phase to enable the team to efficiently envision the medical technology outlook which better responds to health systems' and patients' problems. After the intervention is determined, during the business validation phase the key strategies which capture the dynamics in transitioning to market entry are the business strategy, the commercial strategy, the marketing strategy, and the post-commercialization strategy. Such strategies are complementary, which means that throughout the iterative health technology assessment process, many informed decisions are made which could influence the other strategies as well. Continuous stakeholder engagement and vigilance for potential internal and external changes are necessary to better capture and understand the key enablers toward commercialization are necessary so that go/no-go decisions are made in relation to the uncertainty, risk, and investments. The strategic roadmap which can more effectively capture the dynamics in transitioning from the ideation phase to the successful market entrance of emerging medical technologies consists of 6 strategies allocated in the early ideation phase and the translational/business validation phase. Such a strategic roadmap incorporates the key dynamics that can enhance the understanding of how to approach and navigate the MedTech commercialization pathway. It rather focuses on facilitating the transition from the ideation toward market entry, rather than accelerating that.

6.2. Research Contribution

Overall, the commercialization process in the healthcare setting holds significant scientific interest. The research leans towards healthcare and mainly drug development and commercialization. Considering the fast pace of technology improvement and the introduction of emerging technologies (e.g., Industry 4.0, IoT, Edge Cloud, etc.) in the MedTech sector, it becomes essential to be aware of the emerging and newly formed landscape. Initially, this research contributes to the research field by critically reviewing the existing literature and especially the key methodologies which are used in helping entrepreneurs to navigate the commercialization pathway. It identifies certain limitations which should be considered. However, the greater contribution comes with the qualitative research approach and the in-depth expert interviews which were undergone. This research aims to enhance and enrich the understanding of the dynamics of transitioning from the ideation phase toward the market entry of emerging medical technologies. Developing the strategic roadmap can better depict those dynamics and their interconnections and, ultimately, help innovators navigate the MedTech commercialization. I consider the involvement and participation of multidisciplinary stakeholders from the MedTech industry quite a unique opportunity to capture and deliver valuable insights which have evidence-based validity considering their expertise and previous endeavors.

6.3. Limitations

Every research project may encounter certain limitations that should be acknowledged. My personal biases, experiences, and perspectives can unconsciously affect different aspects of the research process, such as gathering data, analyzing it, and interpreting the results. Although I strived to increase self-awareness and minimize bias by reflecting critically on my views, it is crucial to recognize the potential influence of my subjectivity on the outcomes of the study. The sampling method may encounter certain limitations. There is the potential for sampling bias since I aimed to recruit participants who represent diverse stakeholders along the value chain of the MedTech commercialization pathway. Such an approach may have led to a focus on specific domains and restricted others which could be equally important for the generalizability of the findings to a broader

setting. Also, the participants had experience in the MedTech industry not only in the Netherlands but also in other countries. However, restricting the research interest in the Netherlands, it loses generalizability to other countries, European mainly, which could agree with the results; but such a case is not examined in the current study. Finally, the fact that the strategic roadmap that was developed was not returned to the participants for further validation and feedback, should be another point of consideration, because the opportunity to get a collective ”criticizing” on the elements written by me as well as the opportunity for them to add to their views and dive deeper into additional valuable knowledge were lost.

6.4. Future Research

It would be interesting to assess the long-term impact of implementing the strategic roadmap on the commercialization process in the MedTech industry. This could involve evaluating the success of companies that have adopted the roadmap and measuring their growth, market penetration, and overall success in bringing innovative medical technologies to market. Also, it would be interesting to have this roadmap discussed and validated in national programs where diverse stakeholders in MedTech come into discussion, such as the HI-NL. As a round table session, they could enhance the current research and the current roadmap by providing their perspectives while achieving common ground and a consensus with the other members who have diverse or even conflicting interests. However, since they all expect to have low risk and the strategic entrance of medical technologies which add value to the health system their input and effort are expected to be productive and effective. Integrating metrics to measure the level of maturity in strategy development based on the outcomes and actions initiated by the innovators could be another valuable intervention. For example, technology readiness level is one variable which can give a glance at the transition toward market entry. Similar metrics could be explored and incorporated into the strategic roadmap to enhance its understanding and its efficiency. Also, the strategic roadmap is restricted mainly to the actions and decisions that need to be made during the early stage of development. For example, clinical trials and regulatory approval are processes that could hinder the commercialization journey. It would be interesting to explore how the next phase, after the validation phases can be enhanced. The qualitative research pointed out that there is a need for research standardization around emerging technologies that aim to be implemented in the medical field. Such a remark makes me wonder how the clinical trials and CE mark process outlook would be in a healthcare ecosystem that fosters innovation and transformation, and a general consensus is made to accelerate these processes. What room for innovation and different angles of view can be achieved in the clinical evidence and bureaucracy behind the rapidly evolving MedTech field?

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A

Health Technology Assessment Methods

A.0.1. Qualitative Methods of HTA

HTA can be performed through various qualitative and quantitative methods. Desk research with basic market analysis, stakeholder analysis, SWOT and trade-off analyses, as well as, PEST analysis to measure the political, technological, societal and economic impact, are some of the key qualitative methods that technology developers and decision-makers can adopt to realize the potential value of a business opportunity (Markiewicz et al., 2014).

Horizon scanning is a method that integrates wider strategic considerations. It aims to discover and prioritize emerging health technologies and evaluate their potential impact on the healthcare system, enabling a constant feedback loop from the end-users and stakeholders along a long time horizon (Oortwijn et al., 2018). It adopts a policy formation perspective considering patients' expectations as well as legal, ethical, and political concerns considerations rather than providing quantified cost-effectiveness results. Oortwijn et al. (2018) point out certain limitations of the horizon scanning method in the technology assessment, including the lack of clear scope and the inability to identify all stakeholders in the early stages along with their actual needs.

Multi-criteria decision-making analysis is one key method to interconnect various variables during the evaluation of an emerging medical technology. In a qualitative manner it can be used to depict the possible preferences of the stakeholders and through certain criteria highly connected to the cost of production, the performance, the health system acceptance and technical feasibility, it could lead to the selection of the most efficient prototype (Angelis et al., 2020).

A.0.2. Quantitative Methods of HTA

Various quantitative methods and metrics are used to extract valuable insights regarding the economic, medical and societal impact it generates (Grutters et al., 2022). They are distinguished as probabilistic and non-probabilistic, based on the uncertainty level they integrate into their models. Probabilistic models have the ability to identify uncertainty factors and implement their effect in the model, leading to higher validity results.

Non-Probabilistic Methods

Considering the pressure to justify the economic return of emerging health technologies, the main method that is adopted is the cost-effectiveness analysis (CEA). In the healthcare setting, such analyses are performed with reference cases in order to capture not only the societal impact but also the pragmatism of the health system (Neumann and Sanders, 2017). CEA provides valuable insights regarding internal management, resource allocation and the decision to develop further the technology based on its expected performance and price ranges, and accordingly informs about the proper strategy preparation for market entry and reimbursement policy (Buisman et al., 2016). The analyses' outcome can be presented through the incremental cost-effectiveness ratio (ICER), which is expressed as the difference in costs compared to previous medical practices divided

by the difference in benefits that the emerging technology generates (Bakker et al., 2021). This benefit is measured in quality-adjusted life years (QALYs). Such metric calculates the additional life expectancy or the improvement of the quality-of-life that a medical technology creates for patients and converts that into labor productivity and monetary value (Lakdawalla et al., 2018). The future monetary costs and benefits are discounted to estimate the present valuation of the technology, and estimate the capital required and justify the return on the investment (Girling et al., 2015).

CEA is usually performed in combination with the Headroom method. After having determined the health and social care costs and benefits or utility gains of a medical intervention, decision-makers can estimate the potential reimbursable price of the technology (Girling et al., 2015). Except for providing insights on the pricing strategy and policy outlook, Headroom analysis gives a realistic hint regarding the viability of the technology and the necessary readjustments to ensure market success.

Finally, clinical trial simulation to evaluate the potential spectrum and drivers of technology's performance (Pietzsch and Paté-Cornell, 2008), or discrete-choice experiments and decision trees designed under stakeholders' engagement and preferences, generate valuable information.

Probabilistic Methods

The main limitation when applying the health technology assessment methods is the way to deal with uncertainty, especially when the emerging technology lacks previous evidence. The main uncertainties that manufacturers and decision-makers need to consider are identified during the development and the post-market decisions (Girling et al., 2010). The former refers to the recognition of the benefits and costs of the technology development considering the uncertainty on the potential performance and stakeholders' preferences as well as the access and proper allocation of the necessary resources. The latter concerns the commercial potential of the technology where decisions mainly about the production volume, pricing and supply as well as the negotiation on reimbursement and coverage arrangements need to be taken.

A common way to decrease uncertainty and progressively statistical error during the technology assessment is by integrating probabilistic sensitivity analysis (IJzerman et al., 2017). It helps to quantify the confidence rate of the measurements considering the data gathered and the population which the experiments or assessments have examined and qualify further decisions (Baumann et al., 2020). Usually, there is a graphic depiction regarding the acceptance of the final results through a cost-effectiveness acceptability curve. However, the urgent need when dealing with uncertainty is the way to quantify it and integrate its impact on the assessment methods applied.

The iterative probabilistic Bayesian method has gained traction in technology evaluation, considering its ability to combine past evidence with new findings and statistically allow for better accuracy in the interpretation of the results (Grutters et al., 2022). It reveals a long-term evaluation of the variables measured, based on certain parameters that can eliminate uncertainty within the model. The Bayesian method can be applied in early HTA during the translational phase, in a way to measure cost-effectiveness, eliminate non-promising technologies, determine the optimal prototypes, and identify key parameters that could affect the potential return on investment (Vallejo-Torres et al., 2008).

Markov models development is another efficient way to apply probabilistic measurements of the cost-effectiveness of a medical technology (IJzerman et al., 2017). Initially, it identifies the various conditions that the patient can go through during his life, considering his/her disease or illness, or mental state. Then, it integrates probability-measured interconnections between those conditions based on the application of the medical intervention. The expected result is the measurement in QALYs of the potential benefit of the technology (Baumann et al., 2020).

Finally, real options analysis is another efficient method to integrate during HTA with the aim to tackle uncertainty on the potential future value of a technology. Considering the technology as a financial call option this method gives the opportunity to the holder to assess the technology at the bigger image rather than just the medical and financial benefits it generates (Gorupec et al., 2022). As time passes the method considers new circumstances which induce a call to action regarding further investments or project abandonment. Such methods give greater flexibility in unexpected exogenous and endogenous factors and variables (Gorupec et

al., 2022).

B

Thematic Analysis

In this section, the thematic analysis of the interviews performed is presented. In the following tables, the relevant overarching themes along with the accompanied sub-themes of the discussion as performed per case are analyzed, supplemented with the quotes from the transcripts.

Interview #1 - Healthcare Business Developer		
Overarching Theme	**Sub - Theme**	**Interview Key Quotes**
Business Strategy	Health Ecosystem Analysis	Entrepreneurs need to determine the economic buyer or payer and the end-user of the medical technology.
Business Strategy	Health Ecosystem Analysis	Entrepreneurs need to identify the market size, through a thorough market analysis which includes both stakeholder engagement and access to market intelligence data from databases which elaborate on the market forecast . If the market is big they could pursue a share of it. If it is small they need to consider that the scope is narrowed and aim to readjust and expand the vision, without basing this strategy to the scientific perspective but rather to the entrepreneurial endeavor.
Business Strategy	Strategic Partnerships	Early engagement with insurance companies can help startups identify whether the medical technology fits their criteria and requirements.
Business Strategy	Strategic Partnerships	Early engagement with insurance companies can help startups recognise the available packages (basic or premium) and identify which market they should pursue and how.
Commercial Strategy	Market Analysis	Startups could go for the regular commercial market and attracting early customers. Although there is no scientific proof, people are prone to experimentation and adopt new technologies anyway.
Post-Commercialization Strategy	Long – Term Strategy	Startups obtaining data from the regular market could then proceed in analyzing strategies on implemented their medical technology in the professional care market and proving their efficacy.
Business Strategy	Strategic Partnerships	Startups during the exploration phase regarding their product should be alert for the venture root. There are venture arms or high-risk programs initiated from Dutch healthcare companies, mainly pharmaceuticals, which can help early startups not only proceed with their R&D but also test waters about the future commercialization pathway for their medical innovation. These venture arms can give the startup an international outlook to expand their vision and reach bigger markets. Also, these strong players can open doors more easily. Criteria for venture arms: the most important is the team itself, then is the idea potential and finally, whether this venture fits their mission.
Commercial Strategy	Strategic Partnerships	Hospitals in the Netherlands endorse initiatives and announce programs to enhance innovative technologies which could transform current care. These programs enhance sustainability for the long run.
		Startups should identify the key stakeholders involved in their medical technology ecosystem and engage with them during the early stage, before prototyping, to capture their needs and preferences. HI-NL is an initiative which enables round tables with stakeholders but since these stakeholders have different needs the startups should be able to change their story to

Business Strategy	Health Ecosystem Analysis	attract each one of them. Also, conferences are ideal to informally approach and receive relevant information. First there is the idea and then there is an exploration phase where startups should collect as much data as possible, talk to as many people and entities as possible identified along the technology value chain, receive feedback on their innovations, and then they can prioritize actions based on what they feel they can do, what their strengths is, their team's strengths, and finally make the most effective decisions according to where they identify where the product would fit and what would be the maximum benefit.
Business Strategy	Health Ecosystem Analysis	You start from the idea, you proceed with the exploration phase which then should direct you to the business strategy development based on the key elements and factors identified along that phase. The exploration phase is critical because it will provide you with reasons and arguments to reject or abandon certain actions, directions, pathways and strategies, or even the whole idea. The decision-making process in terms of validating the product takes many years based on the changes identified in the relevant setting or environment.
Business Strategy	Health Ecosystem Analysis	Startups to decide on their pricing strategies should observe how past similar products have been marketed in the health system or in the commercial market. Also, the novelty and the number of investments required can drive the identification of the proper pricing point. Also, the location of production plays critical role in the cost moderation.
Design Strategy	Technical Characteristics	It is important for the startup to identify the general context of its medical technology. For example, for VR technologies, Apple has released its Vision Pro headset. If your medical technology falls within this domain you should explore the available options to deliver your product (application compatible with the Apple VR headset or a fully-owned product developed by your startup).
Business Strategy	Health Ecosystem Analysis	The Dutch healthcare ecosystem is not ideal for startups to prosper. The Dutch healthcare ecosystem is scattered. There are very few big players, and the rest are startups or scale-ups. Even if they originate in the Netherlands, they tend to do their clinical trials in the US, they have their first IPO in US and so on. There is a brain drain from Europe towards the US. Startups operate as contract research organizations or enablers for solution making and not solution makers per se. The US has a bigger market, a more innovation driven health system which embraces novel interventions.
Organizational Strategy	Team Formation	Wrong teams can hinder the business case of medical technologies. New ventures in the MedTech industry are mainly constituted by scientists or biotechnology-oriented people without business mindset and who are not motivated to do so.
Business Strategy	Health Ecosystem Analysis	Lacking an MVP because either the development team cannot realize the medical technology or there is lack of resources. Consequently, entrepreneurs cannot demonstrate the value of the technology.

Business Strategy	Health Ecosystem Analysis	Startups fail to demonstrate their vision. The business case of their medical technology is either too focused or too broad.
Business Strategy	Health Ecosystem Analysis	Startups usually proceed with business analysis (market analysis, business model canvas, etc.) but they do not use tracking numbers to quantify and validate these business models and value propositions.

Interview #2 - Healthcare Organizations Analyst		
Overarching Theme	**Sub - Theme**	**Interview Key Quotes**
Design Strategy	Market Analysis	Medical technologies are usually developed from engineers who are not healthcare experts and have no medical background, who do not capture end-user's preferences and deliver a product which is not simple in use and does not correspond to their daily needs.
Business Strategy	Health Ecosystem Analysis	The healthcare industry is very complex. Having a good technology alone is not enough because even if the product is efficacious and easy to use, if it doesn't fit the business models of the healthcare stakeholders, or is antagonistic to their revenue model, it will not be adopted. If the value proposition of startups is not clear on what the care providers receive in return for paying for a medical technology it does not matter if the technology is good.
Business Strategy	Health Ecosystem Analysis	Medical technologies may achieve reduction of the use of some of the hospital resources, and create more financial margin for them based on the insurance bundles they receive. But if there are certain utilization which are fee for service and the medical technology achieves reduction of that utility then it will never be adopted by the hospital because it takes money from them, even though it is good for patients.
Business Strategy	Health Ecosystem Analysis	The Dutch healthcare system prioritizes cost-effectiveness when adopting new technologies. Maybe a technology is very innovative and has potential but if it is not saving money or improves healthcare at similar cost is will not be adopted. In the US for example there is curiosity by healthcare providers in adopting the latest technologies to experiment with.
Business Strategy	Health Ecosystem Analysis	Emerging medical innovations which aim to transform current care (e.g., Home Care, Virtual Care), create a concern on insurance companies. They expect new technologies not only to demonstrate that they are saving money, but also that the technology can reach treatment success in a faster or more efficient way.
Business Strategy	Health Ecosystem Analysis	Entrepreneurs should ensure that their value propositions are in alignment with the business models and financial incentives of the payer and the provider.
Business Strategy	Health Ecosystem Analysis	Entrepreneurs need to make hypotheses about their medical technologies, invest time and effort in capturing the change in volume of utilization of different services provided by the hospitals and eventually by the insurers. Then, to quantify and demonstrate these numbers you need to retrieve data either from Dutch databases (e.g., CBS) or in case there is no cost breakdown on services because these are privately negotiated among care providers, insurance companies and the government, you can observe other countries' payment system and average charge cost ratios to have an educated estimate for your medical technology benefits.

Marketing Strategy	Customer Channels	You can proceed with a pull strategy which typically refers to agreements with hospitals to include new medical technologies to be more competitive in the market and increase their customer base. It is important to understand how the patients can reach your technology, if they have the freedom to decide which hospital or clinic to visit or whether the network they can access is defined by their insurance package. Or even if the pull strategy works and patients decide to visit these hospitals which provide your medical technology, it will be very costly in terms of marketing. Social media patient groups can spread awareness is a more soft and cheap way. Convincing the GPs in referencing patients to certain hospitals with higher quality of care could be another efficient way to realize the pull strategy which could increase returns both for the startup and the hospitals which will provide higher service volumes. Such strategy creates pressure to hospitals in becoming competitive and winning patients.
Business Strategy	Health Ecosystem Analysis	Competition can be an enabler for medical technologies procurement in terms that one more technology as a fee for service can increase their margins and make them more attractive for patients in terms of quality of care providing.
Business Strategy	Strategic Partnerships	Insurance companies or care providers may have a component of payment/fund for innovation. Startups should engage with hospitals and insurance companies to see how they could leverage these financial incentives to commercialize and bring their medical technologies into the hospital and health system.
Business Strategy	Strategic Partnerships	You need to find the potential customer segments that are the most promising for the business case of the startup. You can extract this information through engaging with insurance companies and analyzing their customers' and hospitals' financial arrangements.
Business Strategy	Health Ecosystem Analysis	You need to quantify the numbers of your value proposition and monetize it.
Business Strategy	Strategic Partnerships	You need to identify governmental and health providers' or companies' funding and research programs. To leverage those programs you need to demonstrate an MVP as a early indication of efficacy and the benefits and how the medical technology can reach or progress toward the goals of care providers, the health system and the society.
Business Strategy	Health Ecosystem Analysis	Technology push is dependent on a strong business strategy which fits stakeholders' models and marketing strategies to make patients, physicians and hospitals want it. Such case puts pressure on insurance companies to reimburse it.
Business Strategy	Strategic Partnerships	In terms of procurement, you need to identify who is at the entry level, the supervisor or economic buyer. You need to understand their authority and how they proceed with their decision making and what is their freedom (in terms of price or technicalities) in purchasing new technologies without climbing the ladder for approvals. It could facilitate the procurement process for the technology if you could align your pricing strategy with their thresholds and requirements.

Business Strategy	Health Ecosystem Analysis	Data to demonstrate efficiency could be patient reported outcome measures (Proms), patient reported experience measures (Prems) as well as an actual clinical measure.
Business Strategy	Health Ecosystem Analysis	Startups need to identify the market size, the out-of-the-pocket market size which would be willing to pay extra for the technology.

Interview #3 - Expert in the Business of Healthcare (CCO)		
Overarching Theme	**Sub - Theme**	**Interview Key Quotes**
Business Strategy	Health Ecosystem Analysis	Startups focus on the solution to be functional without validating whether they are actually solving a critical problem or whether there is a problem that was critical to be solved in the first place. It may be good solution, but it's not the perfect time because priority and focus are on another context right now.
Business Strategy	Health Ecosystem Analysis	You may have a good solution which solves a problem but you lack the proper marketing and sales strategy to diffuse your technology.
Business Strategy	Health Ecosystem Analysis	Health systems is understaffed, meaning that, uh, they don't have the bodies to explore and implement ideas and in general health systems are poor at bringing new ideas into their day-to-day work. Usually, the biggest problem arrives when in deploying a new technology requires the change along the management and operations involved.
Business Strategy	Health Ecosystem Analysis	Because of failures in the past, health system executives are extremely conservative and their decision making, they're not going to buy something or try a new idea unless they either can go look at another entity in the health system and prove that the idea got the result they wanted or they understand the problems so well that they recognize immediately that this technology is the solution they are looking for (which is rare).
Business Strategy	Health Ecosystem Analysis	If the hospital is reimbursed for providing a service and your technology decreases the volume of this service (as a benefit) then you decrease their revenues and the technology will not be adopted.
Commercial Strategy	Market Analysis	Competition among hospitals and care providers who operate in the same market may hinder the scale up of the technology. If you decide to partner with a specific hospital to demonstrate the value of the technology, then there may be conflicts of interest seeking sales to other hospitals and care providers.
Commercial Strategy	Strategic Partnerships	After ideation, the number one thing to do is to have a partner, a hospital or other entity of the health system and get the product built and deployed. And then understand what the benefits and costs are, and constantly trade all your energy on doing that, because if you can prove that you've solved the problem in one place and you've gone through all the trials and tribulations, all the problems that you have to solve to get there, that is by far the best, the best use of resources. Then you having the evidence you can spend resources on sales and marketing.

Commercial Strategy	Strategic Partnerships	In case the technology is expensive to build and there is high-risk you should create a group of customers as champions (hospitals, care providers) who share in the belief that this is the right technology that they want and so they want to nurture an organization to build that technology.
Business Strategy	Health Ecosystem Analysis	You need to engage with hospitals and care providers to see where your intervention should be located and after you identify that you need to understand how these entities make money through their current operations at that area and what are their costs.
Business Strategy	• Health Ecosystem Analysis • Customer Channels	You need to define your economic buyer. If it is the hospital it is a large organization with experience but you need to prove safety, efficiency, and cost effectiveness. If you follow the regular market pathway then you need to consider the size and return of that market and you also need to consider that customers may be reluctant and want to purchase a product or service that somebody else has told them which requires an efficient marketing strategy.
Business Strategy	Strategic Partnerships	You need to engage with insurers to understand their financial incentives, their financial requirements and what programs they initiate in collaboration with hospitals, and the government. You can leverage these programs to accelerate and facilitate the commercialization and adoption of the technology.
Business Strategy	Health Ecosystem Analysis	To reach an agreement for reimbursement with insurance companies you need to have a business and pricing strategy which aligns all stakeholders interests and financial incentives. You need to reassure that there is enough “monetary room” for all including the startup to succeed. You need to calculate your running and operational costs and then define a pricing point that is fair and sustainable.

Interview #4 - Policy-Maker in the Dutch Health System		
Overarching Theme	**Sub - Theme**	**Interview Key Quotes**
Design Strategy	Market Analysis	Not capturing end-users preferences can become a backlash for them or there may be some distrust or some unawareness and lack of understanding and all kind of practical issues that resulting in the product not being successfully launched and scaled up at the end of the day.
Business Strategy	Health Ecosystem Analysis	The Dutch healthcare system is hesitant in adopting new medical technologies which have the potential to transform practices. For example till Covid-19 teleconsultations were not acceptable and after the pandemic there was a technology push which finally lead to societal and health impact and benefit.
Post-Commercialization Strategy	Strategic Partnerships	There is lack of continual financing after commercialization that no matter how good the initial idea is and how well it has been processed to enter the market, it's difficult to actually sustain and secure structural financing for innovation in order to allow for scale up.
Business Strategy	Health Ecosystem Analysis	The priorities of the health system during the early stage of development are safety of the medical technology, its clinical effectiveness, its cost effectiveness and societal impact.
Post-Commercialization Strategy	Long-Term Strategy	You need to consider during the early development stage the post commercialization strategy of the startup. Inevitably they are important during the development and design phase and can drive the successful diffusion of the technology. For example you need to explore except for the technical features the potential relevance of the technology in the future considering the fast pace of MedTech and digital tech progress. Also, to achieve additional finance for further innovation, it is critical for the startup to have flexible design and business model which can enable iterations in the commercial context, the directions, even the whole solution.
Design Strategy	Market Analysis	Embrace patients' engagement and involvement in the design and development phase to test and incorporate their preferences.
Business Strategy	Health Ecosystem Analysis	It is important to identify and engage with the economic buyer (either payers/patients, or hospitals or insurance companies who reimburse for the technology).
Business Strategy	Health Ecosystem Analysis	Embrace a more iterative on-going validation and update of the solution from the ideation phase till the commercialization, and post-market entry phase. Startups should not focus on the technical specifications but the whole business model of the solution. At the end of the day you will be able to demonstrate the added value of the technology to the relevant stakeholders.
Commercial Strategy	Strategic Partnerships	Partnerships with bigger companies can enhance the market entry and post-market sustainability because these companies have the know how based on their early-stage innovations and technologies.

Business Strategy	Health Ecosystem Analysis	Stakeholder engagement is critical for the on-going validation of the solution, and the ability to exchange knowledge and adjust the business model based on feedback they receive. In the Netherlands also and in a more well widely recognized infrastructure called HI-NL whose task is to help startups be engaged with the appropriate stakeholders.
Business Strategy	Strategic Partnerships	The National Healthcare Institutes in the Netherlands have just published among the network of startups about possible financial routes based on the type of technology, based on the requirement of these financial schemes and a little bit also based on the where the technology is in terms of the TRL (technology readiness level) or the regulatory needs. But these programs are mainly for the post-market phase, for scaling up. The Dutch Research council provides funding programs for early research up until commercialization.
Business Strategy	Health Ecosystem Analysis	You need to analyze the market in terms of the target market size, the direct and indirect competitors.

Interview #5 – Hospital Manager		
Overarching Theme	**Sub - Theme**	**Interview Key Quotes**
Commercial Strategy	Market Analysis	The Dutch healthcare system has focused in the past two decades on more privatization which hinders the adoption and diffusion of medical technologies.
Commercial Strategy	Market Analysis	It would require time for clinicians to understand the technology and implement it in their current practices, especially considering the staff shortages.
Commercial Strategy	Strategic Partnerships	There is a movement in the last few years from the Dutch government and hospitals to announce initiatives and funding programs that enhance collaboration and innovation in terms of care delivery. The hospitals are the ones who apply for these funds, and it is critical for startups to sell their story effectively to convince the hospitals to pursue these funds in order to implement such technology in their daily operations.
Post-Commercialization Strategy	Long-Term Strategy	As patients base increase the performance of the technology would be improved with more data.
Commercial Strategy	Strategic Partnerships	A lot of initiatives which are quality of care/life improving, but do not fall within the requirements of the Dutch governmental or insurers' funds can be subsidized by the friend foundation built on private contributions of ex-patients or organisations.
Business Strategy	Health Ecosystem Analysis	Startups have to prove that their innovation leads to less costs and more quality of care or more quality for the same amount of money

Interview #6 – Patent Advisor		
Overarching Theme	**Sub - Theme**	**Interview Key Quotes**
Commercial Strategy	Ownership & IP	Startups focus on the development and demonstration of the technology and do not proceed with processes to determine their ownership. Such incident does not show commitment, rigor and insurance toward further funding, risking commercialization efforts.
Commercial Strategy	Ownership & IP	Not looking in the registered patents in a national or broader setting to find similar products or designs can be a barrier, because there may be some establishments of designs or apparatus which fall within the scope of your medical technology, and practically prevent you from following this path. Not identifying such an occasion during the early stage can risk the financial capacity of the startup or even its whole venture.
Business Strategy	Health Ecosystem Analysis	Startups need to have a proven track record, to demonstrate their technologies' effectiveness, readiness level (TRL), to test investors' and stakeholders' readiness level in adopting or paying for these technologies. When you need more funding for research or when you need external investors, these investors will definitely ask you for what your intellectual property is and what is your ownership, especially the closer you come to the market.
Commercial Strategy	Ownership & IP	The startup name should be registered as a Trade Name in the Netherlands Chamber of Commerce during the very early stage to make the company known in the marketplace. Also, the Trademark registration at Benelux Office for Intellectual Property (BOIP) is important as you come closer to the market and aim to start with marketing or additional funding. These actions are independent of the technology itself and should be prioritized to have an establishment in the marketplace and be able to proceed with potential partnerships with medical centers to further develop your product. A special attorney should be employed to guide the startup along the process toward IP rights applications in the land of interest.
Commercial Strategy	Ownership & IP	Observing the registered patents or design rights can help the startup explore its commercialization strategy options. You can identify who are the competitors who have already manufactured similar medical devices or medical technologies that look very similar and maybe you can work together with them and see if we can have another angle or more technical know-how and see whether we can bring it Dutch market or license it, or we could partner with these players to co-develop this technology.
Commercial Strategy	Ownership & IP	The technical know-how that the startup acquires during the concept validation, as well as the design and development phase can become a trade secret.

Interview #7 - Medical Technology Developer		
Overarching Theme	**Sub - Theme**	**Interview Key Quotes**
Design Strategy	Technical Characteristics	Not user-friendly design and technology for patients and clinicians can influence the technology's commercialization
Design Strategy	Regulatory Landscape	Startups need to consider user safety during clinical trials
Post-Commercialization Strategy	Long-Term Strategy	Consider potential over-reliance on the new technologies (current methods should not be eliminated because not all patients may respond to the novel treatments), ethical considerations mainly on data management and impact on human behavior, as well as the long-term effect of using the technology.
Design Strategy	Strategic Partnerships	To accelerate implementation, it would be helpful to engage stakeholders early on, build strong evidence for efficacy, and provide thorough training and support for the end users.
Design Strategy	Market Analysis	Identify current problems and identify paths to ensure that the technology can be implemented efficiently into existing daily operations, systems, and workflows.
Design Strategy	Regulatory Landscape	Mitigating security and privacy risks is a critical aspect of any healthcare technology, especially when through medical technologies personal sensitive data are collected. Risk mitigation actions involve: data encryption, anonymization, regular security audits and penetration tests to find vulnerabilities, compliance with GDPR, education of end-users and supervisors
Design Strategy	Regulatory Landscape	Securing CE marking can be a complex and costly process. Several factors can contribute to these costs, and given the complexity, it's important to plan the CE marking strategy carefully since the very start when aiming to develop a new medical device. Accelerating CE marking would involve early engagement with the relevant regulatory bodies, careful planning and documentation, and possibly using the services of a consultancy with experience in the process. It's important to keep up with updates in regulations and standards. Requirements for CE marking of medical devices include more rigorous clinical investigation and post-market surveillance requirements, which need to be prioritized.
Organizational Strategy	Team Formation	It is highly recommended to include a medical professional in the team from the project's inception to guide development, regulatory actions and ensure safety and efficiency of the technology.
Design Strategy	Technical Characteristics	In terms of design, it should be wise to have some flexibility in the features of the technology, some customization options to better correspond to a higher number of potential customers / patients / clinicians.

Interview #8 - Nurse		
Overarching Theme	**Sub - Theme**	**Interview Key Quotes**
Design Strategy	• Market Analysis • Technical Characteristics	We are not all really good with technology and there are a lot of things we do not understand about new technologies. This makes it difficult to know how the technology would help and how the hospital can help the entrepreneurs.
Design Strategy	• Market Analysis • Technical Characteristics	The technology needs to be users friendly and do not add additional time to the user to perform a process, because otherwise it will not be used.
Business Strategy	Health Ecosystem Analysis	The reason new technologies are not implemented in the hospital is money because it needs to pay for the services and with everything that is on the market, they cannot pay everything.
Business Strategy	Health Ecosystem Analysis	Entrepreneurs need a lot of input and effort from the nurses and supervisors, and if they fail to demonstrate that the technology will help them in their daily process, they are not willing to invest time on it.
Business Strategy	Health Ecosystem Analysis	Either the nurses and hospital should be benefited or the patients or ideally both.
Business Strategy	Health Ecosystem Analysis	The decision making in the hospital goes both ways. The top layer decides whether there is the budget to allocate on the new technology and the floor decides if there is the need for this technology.
Business Strategy	Health Ecosystem Analysis	Technology implementation needs time, and it is important that there is support from the startup so that end-users can ask questions and in case of struggles resolve them right away.
Business Strategy	Health Ecosystem Analysis	To demonstrate efficiency could be patient reported outcome measures (Proms) but the technology should also consider the differences among the patients in terms of disease, age, prognosis, etc. Overall, it is difficult to benchmark in reality.
Business Strategy	Health Ecosystem Analysis	The technology has to fit in with the care that you want to provide.
Business Strategy	Health Ecosystem Analysis	Patients' needs, nurses' needs, and hospital's financial incentives have to be aligned with startup's value proposition.
Business Strategy	Health Ecosystem Analysis	If patients like the technology, then nurses will use the technology despite potential struggles or additional effort.
Commercial Strategy	Market Analysis	Project managers within the hospital can contribute to the implementation of new technologies but currently hospitals have many projects running and few project managers.
Commercial Strategy	Strategic Partnerships	Hospitals embrace trial and error to validate that a promising technology can reach its potential in the daily workflow.

Post-Commercialization Strategy	Long-Term Strategy	Entrepreneurs need to be aware of the effects of the technology in terms of what are the missing parts implementing the technology compared with the current care. For example, a technology which aims to transform current care and eliminate consultation hours with the nurses may influence the relationship between the nurses and the patients. You cannot put everything in technology because hospital care is human-centered and human contact is important. It needs to be complementary to current care.