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# EMPOWERING MEDTECH STARTUPS: UNVEILING THE PATH TO COMMERCIAL TRIUMPH WITHIN THE EUROPEAN UNION

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**ABSTRACT**

**Purpose:** This research delves into the realm of Medtech startup ventures within the European Union (EU) context. It tries to shed the light focusing on their business strategies and challenges. A significant focal point is the imperative of a meticulously crafted marketing strategy, a strategy that addresses the market regulatory and prerequisites in addition to financial accessibility. The study will attempt to unearth profound insights into personal encounters and outlooks concerning startups in the Medtech sector.

**Theoretical Framework:** This research investigates existing literature and introduces a set of research hypotheses aimed at scrutinizing the triumphant trajectory of Medtech startups. Based on the Literature theoretical investigations, several proposition were derived. Proposition 1 advocates for the prominence of market leaders as a means to optimize returns and evade the peril of the "Valley of Death." Proposition 2 accentuates the role of academic engagements in aligning with genuine market requirements whereas Proposition 3 attempt to investigate the deleterious repercussions stemming from the intricate EU regulatory landscape on the commercial performance of Medtech startups. Finally Proposition 4 underscores the pivotal nature of timing across diverse startup phases, spanning from patent acquisition to market entry.

**Design/Methodology/Approach:** The research methodology uses a qualitative aspects, it encompasses interviews with founders, investors, and industry experts. Additionally, the research integrates case studies addressing both successful and unsuccessful Medtech startups within the European Union. The primary aim is to bridge the existing gaps in the literature surrounding the adept management of successful Medtech startup journeys and the intricate interplay between startups and flourishing business models.

**Findings:** Based on the investigations and tests, this study bequeaths valuable insights, serving as a cornerstone for evaluating and refining strategies, fostering successful outcomes, and nurturing the symbiotic relationship between startups and prosperous business frameworks.

**Conclusion:** This paper not only fills existing voids in the literature but also lays the foundation for prospective exploration. It offers an avenue for further expansion by potentially encompassing a broader spectrum of Medtech startups, thereby deepening our understanding of management strategies, marketing dynamics, and the intricate dynamics underpinning triumphant business models in the Medtech sphere.

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## CAPACITAÇÃO DE START-UPS DA MEDTECH: REVELANDO O CAMINHO PARA O TRIUNFO COMERCIAL NA UNIÃO EUROPEIA

**RESUMO**

**Objetivo:** Esta pesquisa aprofunda-se no âmbito das empresas start-up da Medtech dentro do contexto da União Europeia (UE). Ela tenta lançar a luz focando em suas estratégias e desafios de negócios. Um ponto focal significativo é o imperativo de uma estratégia de marketing meticulosamente trabalhada, uma estratégia que atende aos pré-requisitos e regulatórios do mercado, além de acessibilidade financeira. O estudo tentará desenterrar conhecimentos profundos sobre encontros pessoais e perspectivas sobre start-ups no setor de Medtech.

**Estrutura Teórica:** Esta pesquisa investiga a literatura existente e introduz um conjunto de hipóteses de pesquisa destinadas a esmiuçar a trajetória triunfante das start-ups da Medtech. Com base nas investigações teóricas da Literatura, várias proposições foram derivadas. A Proposição 1 defende a proeminência dos líderes de mercado como um meio de otimizar os retornos e evitar o perigo do "Vale da Morte". A proposta 2 acentua o papel dos compromissos acadêmicos no alinhamento com os requisitos genuínos do mercado, enquanto a proposta 3 tenta investigar as repercussões prejudiciais decorrentes do intrincado panorama regulamentar da UE sobre o desempenho comercial das start-ups da Medtech. Finalmente, a proposta 4 sublinha a natureza fundamental do timing em diversas fases de arranque, abrangendo desde a aquisição de patentes até à entrada no mercado.

**Design/Metodologia/Abordagem:** A metodologia de pesquisa utiliza aspectos qualitativos, englobando entrevistas com fundadores, investidores e especialistas do setor. Além disso, a pesquisa integra estudos de caso que abordam start-ups de Medtech bem-sucedidas e mal-sucedidas na União Europeia. O principal objetivo é colmatar as lacunas existentes na literatura em torno da gestão hábil das viagens bem-sucedidas de start-ups da Medtech e a intrincada interação entre start-ups e modelos de negócios florescentes.

**Constatações:** Com base nas investigações e testes, este estudo lega insights valiosos, servindo como base para avaliar e refinar estratégias, promover resultados bem-sucedidos e fomentar a relação simbiótica entre start-ups e estruturas de negócios prósperas.

**Conclusão:** Este artigo não apenas preenche os vazios existentes na literatura, mas também estabelece as bases para a exploração prospetiva. Ele oferece um caminho para uma maior expansão, englobando potencialmente um espectro mais amplo de start-ups da Medtech, aprofundando assim nossa compreensão de estratégias de gerenciamento, dinâmicas de marketing e a intrincada dinâmica subjacente a modelos de negócios triunfantes na esfera da Medtech.

**Palavras-chave:** Start-Ups MedTech, Estratégias de Comercialização, Europa, Fatores de Sucesso MedTech.

## EMPODERAR A LAS STARTUPS DE MEDTECH: DESVELANDO EL CAMINO HACIA EL TRIUNFO COMERCIAL DENTRO DE LA UNIÓN EUROPEA

**RESUMEN**

**Objetivo:** Esta investigación profundiza en el ámbito de las empresas emergentes de Medtech en el contexto de la Unión Europea (UE). Trata de arrojar luz centrándose en sus estrategias de negocio y desafíos. Un punto focal importante es el imperativo de una estrategia de marketing meticulosamente diseñada, una estrategia que se ocupa de la regulación del mercado y los requisitos previos, además de la accesibilidad financiera. El estudio tratará de desenterrar profundos conocimientos sobre encuentros personales y perspectivas relativas a las startups en el sector Medtech.

**Marco Teórico:** Esta investigación investiga la literatura existente e introduce un conjunto de hipótesis de investigación dirigidas a escrutar la trayectoria triunfante de las startups de Medtech. Con base en las investigaciones teóricas de la literatura se derivaron varias proposiciones. La propuesta 1 aboga por la prominencia de los líderes del mercado como un medio para optimizar los retornos y evadir el peligro del "Valle de la Muerte". La propuesta 2 acentúa el papel de los compromisos académicos en la alineación con los requisitos genuinos del mercado, mientras que la propuesta 3 intenta investigar las repercusiones perjudiciales derivadas del intrincado panorama regulatorio de la UE en el desempeño comercial de las empresas emergentes de Medtech. Por último, la propuesta 4 subraya la naturaleza fundamental del momento en las diversas fases iniciales, que abarcan desde la adquisición de patentes hasta la entrada en el mercado.

**Diseño/Metodología/Enfoque:** La metodología de investigación utiliza aspectos cualitativos, engloba entrevistas con fundadores, inversores y expertos de la industria. Además, la investigación integra estudios de casos que abordan startups de Medtech exitosas y fracasadas dentro de la Unión Europea. El objetivo principal es cerrar las brechas existentes en la literatura en torno a la gestión experta de viajes exitosos de emprendimientos de Medtech y la intrincada interacción entre emprendimientos y modelos de negocios florecientes.

**Hallazgos:** Basado en las investigaciones y pruebas, este estudio lega valiosos conocimientos, sirviendo como una piedra angular para evaluar y refinar estrategias, fomentar resultados exitosos y nutrir la relación simbiótica entre las empresas emergentes y los marcos de negocios prósperos.
**Conclusión:** Este trabajo no solo llena los vacíos existentes en la literatura, sino que también sienta las bases para la exploración prospectiva. Ofrece una vía para una mayor expansión al abarcar potencialmente un espectro más amplio de startups de Medtech, profundizando así nuestra comprensión de las estrategias de gestión, la dinámica de marketing y la intrincada dinámica que sustenta los modelos de negocio triunfantes en la esfera de Medtech.

**Palabras clave:** Startups MedTech, Estrategias de Comercialización, Europa, Factores de Éxito MedTech.

## INTRODUCTION

The history of medical technology dates back centuries, with notable inventions such as the magnifying glass for medical purposes by Roger Bacon in the 1200s and Benjamin Franklin's flexible catheter for bladder stone patients. The stethoscope was also invented in France during this time. However, it wasn't until 1947 that most MedTech innovation involved creating new technologies rather than repurposing existing ones (Bhhatarai et al, 2019). In this highly competitive industry, startups must have a clearly defined commercialization strategy to navigate the complex market and regulatory environment. The commercialization strategy includes various aspects, including identifying the target customers, building sales channels, developing a sustainable business model and complying with regulatory requirements.

A clear commercialization strategy is necessary to identify the target customers and their needs accurately. By understanding the customers' needs, startups can develop products that satisfy the market demands, thus generating revenue. Roper and Cheney (2015) argue that a clear commercialization strategy helps startups identify and target the right customer segments, ultimately leading to increased revenue generation. Moreover, investors are more likely to fund startups with a strong commercialization strategy as it demonstrates a clear understanding of the market and a viable plan for revenue generation. Tarabishy (2015) confirms the presence of a direct link between the likelihood of investment and a clear understanding of the market. Buyers and investors need to see a detailed plan for commercialization, which includes market studies, marketing and sales strategies, and revenue projections. Consequently, startups that have a sturdy commercialization method are much more likely to draw traders and secure investment, which is crucial for their increase and success.

For MedTech startups, necessities occurs in the commercialization strategy and is even more critical as they ought to observe regulatory requirements to bring their merchandise to market. Those necessities may be complicated and time-ingesting, making it difficult for startups to navigate the approval system. Thus, a well-finished commercialization method can

help MedTech startups navigate the regulatory environment and comfy regulatory approval for their merchandise mitigating the risk of these necessities. In this context, Wiltz and DiStefano (2016) argue that a robust commercialization method can help startups overcome regulatory hurdles and boost up their product improvement and commercialization procedure.

Furthermore, MedTech startups must set up relationships with healthcare providers, payers, and other stakeholders inside the healthcare enterprise to reap commercial achievement. Those relationships are essential for MedTech startups to recognize the market dynamics, inclusive of reimbursement structures and other elements that influence marketplace adoption. The commercialization strategy must, consequently, incorporate a plan for growing and maintaining those relationships to attain lengthy-term success. Landry et al. (2006) argue that a successful commercialization method can assist startups set up a foothold within the marketplace, construct a devoted patron base, and achieve profitability, which lays the muse for lengthy-term growth and fulfillment.

The commercialization of products and services developed by MedTech startups is a critical aspect of the healthcare industry. Such products and services would affect positively the communication within hospitals for instance. In this context, communication was considered by Prabadevi and Subramanian (2023) as a crucial factor in employee's contentment, it facilitates the introduction of new medical technologies to the market, thereby improving patient outcomes and the overall efficiency of the healthcare system. The unique challenges that MedTech startups face, such as navigating the complex regulatory environment and gaining access to key stakeholders, make it important to understand their commercialization strategies (Kwak, 2002). Moreover, understanding the economic and financial considerations involved in bringing a new medical technology to market is crucial for the success of these companies, as they often require significant investments of time and money (Deloitte Touche Tohmatsu Limited, 2017).

This study aims to investigate the different commercialization strategies available for MedTech startups and identify best practices and key success factors. Additionally, the study will explore the common challenges and obstacles faced by MedTech startups when commercializing their products and services. The study will analyze the advantages and limitations of MedTech startups' commercialization strategies, and provide insights for policymakers, regulators, and investors on how to support the growth and development of MedTech startups. The study can also serve as a benchmark for startups to compare their strategies with industry standards and identify areas for improvement. Furthermore, the study

will examine how MedTech startups can use different commercialization strategies to secure funding, and explore the implications of commercialization strategies on their exits.

It is equally important to stress that Mrdtech startup operates within a turbulent context amidst this landscape of transformative healthcare technology. In this context, applying the accurate commercialization of MedTech products and services is of great importance and stands as a linchpin for propelling advancements to patients and healthcare systems alike. Thus, inlight of this backdrop, this research aims to expound upon the spectrum of commercialization strategies accessible to MedTech startups, delineating optimal practices and crucial drivers for success, while also unearthing the common obstacles and hindrances they encounter during their commercialization endeavors.

The main objective of this research is to dissect the nuances of MedTech startups' commercialization strategies, shedding the light on their advantages and limitations as well. This study extends beyond the startups themselves to encompass stakeholders, policymakers, regulators, and investors also. By delving into these strategies, the research aims to provide actionable insights that foster the growth and advancement of MedTech startups while concurrently setting benchmarks for the industry at large. And as the world grapples with recessions, pandemics and turbulence many startups have emerged as indispensable tools for navigating these unprecedented hurdles and ameliorating patient outcomes. Thus, addressing the following research question “How do different commercialization strategies impact the success and growth of MedTech startups, and how can policymakers, regulators, and investor’s best support these strategies for optimal outcomes within many unforeseen challenges?” Became a necessity to be addresses

Noting that the COVID-19 pandemic has significantly impacted the different industries raising the unemployment rate drastically (Parinding et al,. 2023) where healthcare industry including the MedTech startup sector are no exception. The pandemic has highlighted the need for innovative medical technologies, including those developed by startups, to address the challenges of the pandemic (Lakdawalla, 2021). Therefore, it is essential to study commercialization strategies for MedTech startups during and after the COVID-19 pandemic to understand how these companies can contribute to the response to the pandemic and improve patient outcomes. Additionally, the pandemic has also had a significant impact on the investment landscape for MedTech startups, with some investors becoming more risk-averse and cautious (Kaplan, 2020). Therefore, understanding the best commercialization strategies

for MedTech startups during and after the pandemic can help these companies secure funding and navigate the changing investment landscape.

## THEORETICAL FRAMEWORK

Today, Medical Technology encompasses a wide range of products aimed at diagnosing and treating various diseases, and there is no unified definition. MedTech Europe defines Medical Technologies as "the products, services or solutions used to save and improve people's lives". Medical Devices are categorized as medical devices (MDs), in vitro diagnostics (IVDs), and digital health and care (Europe MedTech, 2019).

In 2017, the MedTech industry was estimated to be worth €115 billion, making it the second-largest medical technology market after the United States. Over the past decade, the European medical device market has grown at an average of 4.3% per year, although demand fell in 2009 due to the economic crisis (Europe MedTech, 2019). Accurate statistics on the industry's performance in its respective markets are essential for MedTech startups, as growth in the industry correlates positively with demand and innovation rates. However, different MedTech technologies have different growth dynamics, with some moving faster or slower than others, and the size of their respective businesses also changes. Therefore, long-term planning for academia in life science and bioengineering must consider this factor.

The COVID-19 pandemic has also brought the importance of MedTech to the forefront, with the urgent need for medical devices such as ventilators, personal protective equipment, and diagnostic tests. This crisis has highlighted the critical role that MedTech startups play in addressing healthcare challenges and has underscored the importance of investing in research and development in this field (Vlckova and Thakur-Weigold, 2019). Moreover, it has revealed the need for agile regulatory frameworks that can quickly adapt to new innovations while maintaining safety standards this need has been demonstrated within the healthcare industry also where Silva and his colleagues investigated the regulatory compliance program in a large philanthropical hospital institution (Silva et al., 2023). Their findings stressed that a regulatory compliance must constantly evolve and adapt with the changes that occurs. Such findings is also applicable to MedTech startup that faces many challenges where Covid 19 was the recent one. Hence this pandemic serves as a reminder of the importance of having strong MedTech and its potential to improve healthcare outcomes.

**MedTech Competitive Advantage and Startups Valuation**

According to Yock et al. (2015), the basis of competition for MedTech companies is determined by features, benefits, prices, and brand positioning. Thus, to establish and deliver a compelling value proposition, MedTech companies must identify and reinforce their competitive advantage. For instance, a cost advantage can be achieved by streamlining production processes or reducing manufacturing costs through economies of scale. Alternatively, differentiation can be achieved by offering unique features, providing superior customer service, or leveraging a strong brand reputation. Commercializing a MedTech product requires a comprehensive understanding of the competitive landscape in which it operates. Adopting any of the commercialization strategies mentioned above entails identifying and capitalizing on the MedTech's competitive advantage. This advantage can be achieved through cost or differentiation strategies, as well as the effective utilization of corporate resources and financial capabilities.

Figure 1: The Different Commercialization Strategies


Source: Authors own work

The identification and utilization of a competitive advantage are crucial for the success of any commercialization strategy. By identifying the unique selling proposition and operationalizing it effectively, MedTech companies can better differentiate themselves in the market, and secure a larger share of customers. For example, by focusing on the benefits of their products, MedTech companies can create strong customer loyalty, and reduce the likelihood of competitors copying their offerings. This is particularly important in the MedTech industry, where new technologies are often quickly imitated by competitors, and where differentiation can mean the difference between success and failure. Therefore, identifying and reinforcing a competitive advantage is crucial for the long-term success of MedTech companies. By leveraging their strengths and differentiating themselves from competitors, MedTech companies can establish themselves as leaders in the market and improve their chances of commercialization success. In this context, Valuation is a crucial factor in the

success of MedTech startups, as it can directly impact their ability to attract investment and secure funding for growth and development.

As Yock et al. (2015) suggest, valuation represents the worth assigned to a business, and it is a key consideration for investors, both in the public and private markets. However, for younger MedTech startups, arriving at an accurate valuation can be a significant challenge due to the lack of historical data, forecasted cash flows, and growth rates (Ceulemans, 2016; Carey, 1993). Moreover, the internal structure of a MedTech startup and the quality of its management team can also significantly impact its valuation. A well-structured company with a competent management team is likely to be viewed as more valuable by investors. Additionally, the expected return on investment for different types of startups is another essential factor in determining a MedTech startup's valuation. Startups that carry higher risk also offer higher potential returns for investors, and this is an important consideration for anyone looking to invest in a MedTech startup. Therefore, startups need to demonstrate their competitive advantage, management competence, and potential to deliver higher returns to secure funding and achieve commercial success.

**Technology Readiness through Research and Development**

Research and development (R&D) plays a crucial role in the commercialization strategy of MedTech startups, as it is often the commercial stakeholders and consumers who determine the final commercial applications of these technologies. However, this can result in a disconnection between the research source and its commercial stakeholders, leading to unwanted side effects (Ceulemans, 2016). To avoid these issues, MedTech startups can establish a clear R&D plan, which allows them to understand the high-level issues related to engineering personnel, resources, and timelines, necessary to achieve specific milestones leading to successful commercialization. The main R&D milestones that a MedTech startup can optimize are shown in the following table (Yock et al., 2015).

Another factor that complicates MedTech startups is their Technology Readiness Level. The Center for Integration of Medicine and Innovative Technology (CIMIT) established the "Healthcare Innovation Cycle" in 1998 to help startups locate themselves within development stages and identify their strengths and weaknesses. The cycle examines clinical needs, the widespread use of technology, clinical requirements, market in its business context, regulatory environment, and technical opportunities and limitations. Startups must also examine their growth in terms of milestones, where different steps mature at different stages (Collins &

Dempsey, 2019). Supplier management is another significant challenge for MedTech startups, as there is often limited coordination between R&D and purchasing departments (Melander, 2014). Moreover, R&D presents a major challenge in the MedTech industry. Digital Healthcare, which includes mobile phone sensors, smartwatches, fitness trackers, apps, and artificial intelligence, delivers tangible outcomes in shorter periods, making it more attractive to venture capitalists and governmental entities (MTPConnect, 2020).

**MedTech Startups Business Development and Characteristics**

Laage-Hellman et al. (2017a) conducted a study on the commercialization of research-based inventions through startups and emphasized the importance of a well-crafted business development plan that focuses on how the founders will develop the business rather than solely securing funding (Yock et al., 2015). The plan must consider several factors, including the regulatory environment, management team's track record, market opportunity, competitive advantage, infrastructure, technology, sales plans, and growth potential (Laage-Hellman et al., 2017a). The success of a MedTech startup heavily relies on the business development plan, which affects the commercialization and exit plan of the company as a whole and its portfolio. To ensure successful product development, the plan must involve continuous customer involvement, feedback, and commercial traction (Sennett et al., 2021; La Rocca et al., 2013).

Figure 2: Summary of The Commercialization Strategy


Source: Authors own work

The MedTech industry has specific characteristics, including a complex regulatory framework, high research and development costs, and a tight relationship with the public sector's research, funding, and infrastructure. Regulatory planning is a crucial aspect of the MedTech Go-To Market strategy, as it is a prerequisite for commercializing the technology in

any country. While every MedTech startup has specific milestones, it faces both risks and opportunities, including the "valley of death" risk model in the life cycle of a MedTech startup (Marten, 2019).

The regulatory environment for MedTech startups is complex, with each geopolitical region having its definition of a medical device. The regulatory requirements in the EU are particularly stringent, requiring every medical device sold in Europe to bear a CE mark, which corresponds to the product. Notified bodies conduct pre- and post-market assessments to ensure the product conforms to EU directives (Eucomed, 2011). However, the regulatory system changed in May 2017, from Medical Device Directive 93/42/EEC (MDD) to Medical Device Regulation 2017/745 (MDR), which added complexity and increased financial and managerial costs for MedTech startups (O'Brian, 2017). Moreover, the transition from MDD to MDR presents challenges due to the increased pressure on scientific and technical clinical data, which affects academic research activity and financial resources (Letourneur et al., 2020). MedTech startups must prioritize their work by studying each factor alone and deciding which region to explore first, allocating the corresponding regulatory spending budget, and expecting a break-even or a profitable return post-commercialization. Constant governmental policy changes such as Brexit make commercialization planning even more complex, requiring quick adaptation to new regulations (O'Brian, 2017).

## METHODOLOGY

This paper investigate commercialization in MedTech startups in the EU by using a qualitative approach to explore and analyze people's reactions to specific situations, events, or triggers. The researchers recognizes that qualitative studies offer a unique perspective on social phenomena, providing a deeper understanding of the experiences, behaviors, and attitudes of individuals or groups. Through this approach, the researchers intends to identify the commercialization strategies and elements that MedTech startups adopt to become successful, and to assess the impact of different factors on their success.

To achieve these objectives, this paper proposes a set of research propositions based on the identified limitations in the literature. The first proposition suggests that successful commercialization in MedTech startups requires a well-defined commercialization strategy that considers various factors such as market demand, regulatory requirements, and funding sources. The second proposition proposes that the commercialization strategies adopted by MedTech startups are influenced by the startup's characteristics, such as the founder's experience, team

composition, and funding sources whereas the third proposition suggests that the adoption of innovative technologies and intellectual property protection strategies plays a significant role in the commercialization success of MedTech startups.

As mentioned earlier, this research will focus on conducting a qualitative investigation to explore and test propositions considered crucial for the success of MedTech in this turbulent environment. This investigation will involve interviews with MedTech startup founders, investors, and other industry experts to gain insights into the commercialization strategies and elements that contribute to their success. The study will also analyze case studies of successful and failed MedTech startups in the EU to identify common patterns and factors that influence their commercialization success. Thus to summarize the main gaps derived from literature in the European Union context, the researchers identifies the following points:

Table 1 Main Gaps to be addressed

| |
|---|
| *The scarcity of studies associated with MedTech startups' success and failure paths specifically during and after the pandemic,* |
| *The absence of data linking MedTech startups with commercialization strategies,* |
| *The absence of proven association between MedTech startups and successful commercialization strategies.* |

Source: Authors own work

As for the research proposition and based on Gehman et al. (2018), our are the main statement derived from gaps in literature based on through investigations leads us to test and investigate the following propositions as follows

**Proposition 1**

A MedTech startup can adopt one or several strategies to succeed. In this context, there are a few preset exit models where companies can either take full responsibility for bringing their product to market or use other market leaders' resources. In the latter case, high-risk tolerating companies who invest high amounts will indeed have expectations of a high return (Boni, 2013). Additionally, startups are to plan an entire development process that can avoid them falling into the "valley of death" before their product reaches its final milestone and objective, which is launching the technology in the market (Marten, 2019).

- Proposition 1 – Acquisition by a market leader is the strategy of choice to ensure high returns and avoiding the valley of death of MedTech's startup.

**Proposition 2**

It is worth mentioning that it is common for MedTech startups to spinoff from biomedical academia. As a matter of fact, "academic institutions are shifting towards collaborative models that incorporate local small-medium enterprises (SMEs) and multinational medical device and pharmaceutical companies (MNCs) to develop innovative, clinically-relevant solutions" (Letourneur et al., 2020, p. 2). In Sweden, for instance, like in many other countries, entrepreneurship stemming from academia has during the last two decades become a popular phenomenon and it is actively supported in different ways by governments and public entities. (Laage-Hellman et al., 2017a). In this context, the challenge at hand is maintaining the connection between the creation and development of the technology and meeting the medical market's needs and trends (Coviello & Joseph, 2012).

- **Proposition 2 - Startups that are university spinoffs tend to answer real market needs.**

**Proposition 3**

Throughout the product development and before commercialization, MedTech startups face a lengthy regulatory process that is country and region-dependent. In addition, the new EU regulatory system MDR adds more time and cost challenges to startups (Letourneur et al., 2020). In most instances, the MedTech startups must establish direct contacts with regulatory authorities, as it would be a necessary element in their product development. Additionally, for the purpose of carrying out clinical trials the companies may also need to interact with local and regional authorities (Laage-Hellman et al., 2017b). A survey carried out by O'Brian (2017) identified that one main challenge identified by Regulatory Affairs professionals is how different regulatory frameworks exist in different regions i.e. the lack of regulatory harmonization across neighboring geographies. O'Brian indicates that there is no quick fix solution to this challenge however a Regulatory Affairs professional can define and follow a robust regulatory strategy. Accordingly, this regulatory landscape can be mapped out and communicated to the startup's business team, which requires further coordination so that it matches the company's business goals.

- Proposition 3 - The EU regulatory environment negatively affects the commercialization performance of MedTech startups.

**Proposition 4**

The time factor is crucial for MedTech startups because, even though the time from design to commercialization is long enough, it is about being in the right place at the right time. Additionally, it is also about being open to new ideas and catching new opportunities right when they arise (Yock et al., 2015). As a consequence, timing is crucial at so many stages of MedTech's startup's development: It is important for the cofounders to decide when to patent their technology, when to start prototyping, when to enter the market and when to go into external partnerships in order to commercialize their product for good. For instance, while there is not a "right" time to start prototyping, innovators who begin this process as early as possible learn from it and apply that learning to further design and development processes (Yock et al., 2015). On the other hand, and specifically when it comes to intellectual property processes, "a timing strategy employed by some innovators and companies is colloquially called "evergreening" – a process of introducing modifications to existing inventions and then applying for new patents to protect the invention beyond its original 20-year patent term" (Yock et al., 2015, p. 399). Additionally, by planning scientific milestones early on, innovators can also use R&D to their strategic advantage by sequencing and timing these types of milestones to correspond with other important events in the company's evolution like financing or commercialization (Yock et al., 2015).

- **Proposition 4 – MedTech startups control the choice and timing of their commercialization strategies in order to achieve success in the market.**

Table 2: Propositions to be tested

| | |
|---|---|
| Proposition 1 | Acquisition by a market leader is the strategy of choice to ensure high returns and avoiding the valley of death of MedTech's startup. |
| Proposition 2 | Startups that are university spinoffs tend to answer real market needs. |
| Proposition 3 | The EU regulatory environment negatively affects the commercialization performance of MedTech startups. |
| Proposition 4 | MedTech startups control the choice and timing of their commercialization strategies in order to achieve success in the market. |

Source: Authors own work

It is crucial to stress that in order to test the above propositions, the data collection technique is in-depth interviews using a questionnaire containing a series of open-ended questions. In addition, the target population of this study is founders and co-founders of Biotech and MedTech startups based in Europe. Furthermore, they can also be senior managers in top leadership positions. The sample size is 13 different companies developing unrelated types of products. Before starting the interviews, a pilot study was performed with one startup. During

the interview with the company's CEO, the researchers discussed the interview questions and then readjusted some small nuances to make the interview process more intuitive and unbiased. After conducting the interviews, the researchers isolated the results, and performed a thorough data analysis, shifting inductive and deductive reasoning.

## RESULTS AND DISCUSSION

It is worth noting that all managers and founders from the 12 companies and the pilot company completed the interview as they all agreed to either a personal meeting or a video call. Therefore, no respondents were discarded from this interview. The aim was to gain interview responses from more than 10 MedTech companies in the EU to ensure reduced response variability.

### Findings and Assessment of Proposition 1

Assessing the results of the respondents through Ninvo reveals the following findings. When answering the questions that targets the first proposition, the respondents discussed several opportunities and limitations to different commercialization strategies that suit their respective companies. The answers of the respondents go in line with the literature review, as the most common commercialization strategies were licensing the technology, partial or total acquisition, and achieving high sales. All the respondents preferred a relatively short to medium-term commercialization plan rather than a long-term IPO. In contrast, none of the respondents addressed the possibility that their company could reach a revenue greater than $100 million per year, making it typically backable by a venture capital firm, leading to an IPO. As found in the literature review of this study, specifically in the book Biodesign by (Yock et al., 2015), MedTech startups often face unique challenges in commercializing their products and services, as the healthcare sector is heavily regulated and requires a significant amount of investment.

The status of a MedTech startup, including the stage of product development, the size of the company, and the level of funding, can significantly impact the commercialization strategy it adopts, which explains the respondent's different answers and their view of their startups' success strategy. Additionally, in this study's literature review, the study by Marten (2019) also confirms that early-stage startups tend to focus on developing partnerships with established companies or securing funding through grants and venture capital. As the company grows, it may shift its focus to building a sales and marketing infrastructure to directly reach

customers. In some cases, startups may choose to license their technology to larger companies in exchange for upfront payments and ongoing royalties. This strategy can provide the startup with valuable financial resources to support its continued growth while allowing the larger company to benefit from the startup's innovative technology (Yock et al., 2015).

Another factor that can impact a MedTech startup's commercialization strategy is the level of regulatory approval required for its product. Startups developing products that require heavy CE or FDA clearance may need to secure significant funding to support the clinical trials and regulatory submissions required for approval (Cologne, 2008).

**Findings and Assessment of Proposition 2**

On the other hand, addressing the second proposition reveals that the highest regarded strategies seen by the respondents were acquisitions by a top industry leader (67%) and a hybrid structure (50%) where they maintain a particular direct contact with the market and their products' users. As seen in the literature review in the study by (Pienta, 2010), there are several advantages to adopt this strategy, in terms of cash flow and for the sake of the company's general survival. This was confirmed by the respondents during the interviews, and some of them had that plan clear from the day they created their company. However, they also expressed concern over the future of their technologies and their scope once commercialized by a third party whose market scope does not align completely with their company's vision. MedTech startups often face numerous challenges in commercializing their products and services, including regulatory hurdles and a need for significant investment as seen in the study (Letourneur et al., 2020) in the literature review. So, for many of the interviewed startups, being acquired by a market leader can provide a fast-track to success by leveraging the resources and expertise of the acquiring company.

In fact, the research by (Jones, 2013) in this study's literature review has shown that MedTech startups view acquisition by a market leader as a preferred option for success. This is because market leaders typically have established sales and marketing channels, regulatory approval processes, and access to funding. The acquisition can provide the startup with immediate access to these resources, allowing them to rapidly scale their product offerings and reach a wider customer base. Additionally, Marten (2019) confirms that acquisition can provide financial benefits to the startup, such as upfront payments and ongoing royalties, which can support its continued growth. The above confirms partially the first research proposition that this study aims to explore, which states that acquisition by a market leader is the strategy of

choice to ensure high returns and avoiding the valley of death of MedTech's startup. In this context the choice of the commercialization strategy depends on the market need the startups is seeking to answer, therefore, another important question that the literature review has explored the different ways to uncover uncovered needs. This was specifically examined by (Tarabishy, 2015) in this study's literature review. Accordingly, the researchers believes additional research is needed to support the second proposition, which states that university spinoffs tend to answer real market needs, compared with startups that do not originate from academia.

**Findings and Assessment of Proposition 3**

Moreover, the researchers analyzed the answers that addresses the third proposition and the findings shows that some respondents used acquisition by an industry leader as a way to continue financing the development of their technologies. Hence, they shifted from applying to public funds, launching private investment rounds, and applying for bank loans, to getting internal innovation loans from their acquiring company. In addition, other respondents used their salesforce to sell their products and use the incoming cash flow in reinvestments or additional product development and regulatory maintenance operations. As confirmed by the literature review of this study, MedTech startups often face significant challenges in securing funding for their products and services, including the need for significant investment in research and development, regulatory approval, and commercialization (Pienta, 2010). The commercialization strategy of a MedTech startup can be used as a funding strategy to secure the necessary financial resources to support its growth and success (Ali et al., 2017; Landry, Amara & Siggelkow, 2006; Marten, 2019).

Additionally, studies have shown that the commercialization strategy of a MedTech startup can be used to attract investment from venture capital firms and angel investors (Ali et al., 2017; Porumboiu, 2020; Yock et al., 2015). For example, a startup that has a well-defined commercialization strategy, including a clear target market, a differentiated product offering, and a plan for regulatory approval, is more likely to secure funding from investors. This has been discussed by the respondents, and it has also been explored in the study by mentioned earlier in the literature review (Landry, Amara & Siggelkow, 2006). In this context, the research proposition number three, which states that the EU regulatory environment negatively affects the commercialization performance of MedTech startups proves only partially true, as a small part of the respondents mentioned that they believe the regulatory restrictions can have a

positive impact on the commercialization of their products, as it will naturally eliminate unfit competitors. This has shown to be a question for further investigation as studies in the literature review (Hirsch, 2013; Letourneur et al., 2020) have shown that the EU has a complex and demanding regulatory environment for medical devices, which requires extensive documentation and clinical trials, adding significant time and cost to the product development and commercialization process.

According to another research by (Gassmann et al., 2016), the EU regulatory environment can lead to delays in the time-to-market for MedTech startups, as they must navigate complex regulations, including product registration, certification, and approval processes. This can result in reduced competitiveness and a smaller target market for the startup. In addition, the high costs associated with regulatory compliance can strain the financial resources of MedTech startups, making it difficult for them to secure funding and scale their operations (European Commission, 2017). This can result in lower commercialization performance and reduced profitability for the startup. Moreover, the EU regulatory environment can also limit the ability of MedTech startups to innovate and bring new products to market. The regulations can be restrictive and slow to adapt to new technologies and innovations, reducing the ability of MedTech startups to bring innovative products to market.

**Findings and Assessment of Proposition 4**

Finally testing the fourth proposition shows that the respondents all agreed that to overcome the challenges of regulatory costs, product development pathways, and overall company charges, choosing a commercial strategy that overlaps with their long-term vision is imperative. Some respondents had to take a step back after they realized the commercialization strategy that they had picked was not one that would optimize their exit. On the other hand, the overall concern of the respondents (42%) stressed the importance of finding a balance between financial survival and the timing of picking and implementing a commercial strategy. The above mentioned findings link back to the view of Yock et al. (2015) in the literature review of this study. Concretely, the book Biodesign explains how a MedTech startup's commercial strategy can significantly impact its exit, which refers to the process of selling the company or its assets to another company or investors. The commercialization strategy of a MedTech startup can influence the type of exit, the timing of the exit, and the financial return received by the founders and employees of the startup. On the other hand, this insight investigates the fourth proposition of this study, which looks into the time factor in the MedTech industry.

As previously discussed, this proposition states that MedTech startups control the choice and timing of their commercialization strategies to achieve success in the market. It is unclear whether this proposition is supported, as several factors affect the timing and decision-making in this context. Other studies in the literature review have shown that the commercial strategy of a MedTech startup can impact the type of exit it experiences (Pienta, 2010). For example, a startup that has a well-defined commercialization strategy and a clear target market is more likely to experience an acquisition by a larger company, while a startup that has a limited commercialization strategy is more likely to experience a merger or joint venture with another company. Additionally, the commercial strategy can impact the timing of the exit, as startups with a well-defined commercialization strategy are more likely to experience an exit at an earlier stage in their development, while startups with limited commercialization strategies are more likely to experience an exit at a later stage in their development. Accordingly, this statement has been confirmed by the literature review and discussed by one of the respondents of the interviews.

**Summary of the Findings**

Based on the above analysis the below tables summarizes the study proposition findings. The findings of the first propositions shows the following.

Figure 3: Different commercialization strategies they can implement to survive and thrive

| | |
|---|---|
| In line with the Literature Review | The most common commercialization strategies are **licensing the technology, partial or total acquisition, and achieving high sales.** |
| | MedTech startups often face unique **challenges** in commercializing their products and services, as the healthcare sector is **heavily regulated** and requires a **significant amount of investment** ***(Yock et al., 2015)*** |
| | The status of a MedTech startup, including the **stage of product development**, the **size of the company**, and the level of **funding**, can significantly impact the commercialization strategy it adopts, which explains the respondent's different answers and their view of their startups' success strategy. |
| | **Early-stage startups** tend to **focus on developing partnerships with established companies or securing funding through grants and venture capital** ***(Marten, 2019)*** |
| | As the company grows, it may **shift its focus to building a sales and marketing infrastructure to directly reach customers**. In some cases, startups may choose to license their technology to larger companies in exchange for upfront payments and ongoing royalties. This strategy can provide the startup with **valuable financial resources to support its continued growth** while **allowing the larger company to benefit from the startup's innovative technology** ***(Yock et al., 2015)*** |
| | Another factor that can impact a MedTech startup's commercialization strategy is the level of regulatory approval required for its product. **Startups developing products that require heavy CE or FDA clearance may need to secure significant funding to support the clinical trials and regulatory submissions** required for approval ***(Cologne, 2008)*** |
| Observations | All the respondents **preferred a relatively short to medium-term commercialization plan rather than a long-term IPO**. |
| | None of the respondents addressed the possibility that their company could reach a **revenue greater than $100 million per year**, making it typically backable by a venture capital firm**, leading to an IPO**. |

Source: Authors own work

As for the investigation of the second proposition the summary of the researchers findings were as follows:

Figure 4: the advantages and limitations of the commercialization strategies identified

| | |
|---|---|
| **In line with the Literature Review** | The highest regarded strategies seen by the respondents were **acquisitions** by a top industry leader (67%) and a **hybrid structure** (50%) where they maintain a particular direct contact with the market and their products' users, there are several advantages to adopt this strategy, in terms of cash flow and for the sake of the company's general survival. Some respondents had that plan clear from the day they created their company *(Pienta, 2010)* |
| | MedTech startups often face numerous challenges in commercializing their products and services, including **regulatory hurdles and a need for significant investment** as seen in the study in the literature review. So, for many of the interviewed startups, **being acquired by a market leader can provide a fast-track to success by leveraging the resources and expertise** of the acquiring company. *(Letourneur et al., 2020)* |
| | MedTech startups view **acquisition** by a market leader as a preferred option for success. This is because market leaders typically have established **sales and marketing channels, regulatory approval processes, and access to funding. It all leads to a faster scale up.** *(Jones, 2013)* |
| | **Acquisition** can provide financial benefits to the startup, such as **upfront payments and ongoing royalties, which can support its continued growth**. The above confirms partially the first research proposition that this study aims to explore, which states that acquisition by a market leader is the strategy of choice to ensure high returns and **avoiding the valley of death of MedTech's startup**. *(Marten, 2019)* |
| **Observations** | The respondents expressed **concern over the future of their technologies and their scope once commercialized** by a third party whose market scope does not align completely with their company's vision. |
| | The choice of the commercialization strategy depends on the market need the startups is seeking to answer, therefore, another important question that the literature review has explored the different ways to uncover uncovered needs. Accordingly, the researcher believes **additional research is needed to support the second proposition**, which states that university spinoffs tend to answer real market needs, compared with startups that do not originate from academia. *(Tarabishy, 2015)* |

Source: Authors own work

The summary of the third proposition findings were as follows:

Figure 5: How can MedTech startups use the Commercial Strategy as a funding strategy

| | |
|---|---|
| **In line with the Literature Review** | Some respondents used **acquisition by an industry leader to continue financing the development of their technologies.** Hence, they **shifted from applying to public funds, launching private investment rounds, and applying for bank loans**, to getting internal innovation loans from their acquiring company. In addition, **other respondents used their salesforce** to sell their products and use the incoming cash flow in reinvestments or additional product development and regulatory maintenance operations<br>*(Pienta, 2010; Ali et al., 2017; Landry, R., Amara, N., & Siggelkow, 2006; Marten, 2019)* |
| | The commercialization strategy of a MedTech startup can be **used to attract investment** from venture capital firms and angel investors<br>*(Ali et al., 2017; Porumboiu, 2020; Yock et al., 2015; Landry, R., Amara, N., & Siggelkow, 2006)* |
| **Observations** | The **research proposition number three,** which states that the EU regulatory environment negatively affects the commercialization performance of MedTech startups **proves only partially true, as a small part of the respondents mentioned that they believe the regulatory restrictions can have a positive impact on the commercialization of their products**, as it will naturally eliminate unfit competitors. This has shown to be a question for further investigation as studies in the literature review (Hirsch, 2013; Letourneur et al., 2020) have shown that the EU has a complex and demanding regulatory environment for medical devices, which requires extensive documentation and clinical trials, adding significant time and cost to the product development and commercialization process. |

Source: Authors own work

As for the investigation of the fourth proposition the summary of the researchers findings were as follows:

Figure 6: What are the implications of the commercial strategy on the exits of MedTech startups

| | |
|---|---|
| In line with the Literature Review | **Choosing a commercial strategy** that overlaps with their long-term vision is imperative to overcome the challenges of regulatory costs, product development pathways, and overall company charges |
| | The overall concern of the respondents (42%) stressed the importance of **finding a balance between financial survival and the timing of picking and implementing a commercial strategy** *(Yock et al., 2015)* |
| | The commercialization strategy **can impact the timing of the exit**, as startups with a well-defined commercialization strategy are more likely to experience an exit at an earlier stage in their development, while **startups with limited commercialization strategies are more likely to experience an exit at a later stage in their development.** |
| Observations | The commercialization strategy of a MedTech startup can **influence the type of exit, the timing of the exit, and the financial return** received by the founders and employees of the startup. On the other hand, this insight investigates the fourth proposition of this study, which investigates the time factor in the MedTech industry. This proposition states that MedTech startups control the choice and timing of their commercialization strategies to achieve success in the market. **It is unclear whether this proposition is supported, as several factors affect the timing and decision-making in this context**. *(Pienta, 2010)* |

Source: Authors own work

## IMPLICATIONS

Conducting a qualitative study of commercialization strategies of MedTech startups in Europe can have important theoretical and managerial implications. From a theoretical perspective, this study can contribute to the understanding of the factors that influence the success of MedTech startups in Europe. These companies often face unique challenges when it comes to commercializing their products, such as navigating complex regulatory environments, securing funding, and competing with established players in the industry, in case the startups choose to commercialize their products by themselves. And if they don't, they still need to establish strong relationships with these industry leaders. By studying the strategies that MedTech startups use to overcome these challenges, the researchers can identify key factors that contribute to success and inform future research on commercialization in the MedTech industry. Additionally, the study can provide insights into the role of government policies and regulations in the commercialization of MedTech products and the impact of these policies on the success of the relevant startups.

Moreover, one of the key theoretical implications of the study is that it can provide a deeper understanding of the commercialization process of MedTech startups in Europe,

including the different stages of the commercialization process, such as product development, market validation, regulatory compliance, funding, and scaling-up, and the specific challenges that MedTech startups face at each of these stages. This can help researchers and policy-makers to identify the bottlenecks in the commercialization process and to develop policies and interventions to support the commercialization of the products and services provided by MedTech startups in Europe.

From a managerial perspective, the study can provide valuable insights for MedTech startups and investors. The study can identify best practices for commercializing MedTech products and help startups develop effective commercialization strategies. Additionally, the study can provide investors with insights into the commercialization challenges faced by the startups and help them make more informed investment decisions. Overall, this research can provide valuable information that can be used to support the growth and success of MedTech startups in Europe.

The first managerial implication of this study is that it can provide a rich understanding of the complex interplay between different actors in the commercialization process of MedTech startups in Europe, such as startups, investors, regulators, and customers. This understanding can help managers and entrepreneurs of startups to identify opportunities and challenges in the commercialization process, and to develop more effective strategies to navigate the complex environment. Second, this study can provide a better understanding of the specific needs and preferences of patients, which can be used to develop more effective marketing strategies and to create products that better meet the needs of the customers. Accordingly, this can help MedTech startups to differentiate themselves from their competitors and to increase their chances of success.

## CONCLUSION

Based on this research paper, the researchers can recommend, first, to focus on understanding the regulatory environment and compliance requirements in the countries where the startup plans to operate. This can help to ensure that the startup is able to navigate the legal and regulatory landscape and bring its products and services to market in a timely and efficient manner. Another recommendation may be to focus on building partnerships and collaborations with key stakeholders in the European market, such as hospitals, clinics, Key Opinion Leaders and other healthcare providers. This can help to establish a strong market presence and increase the chances of success for the startup.

In addition, the study can also contribute to the understanding of the role of entrepreneurship in the MedTech industry and the specific characteristics of entrepreneurs in the European medium. This can inform policy-makers and researchers about the importance of supporting entrepreneurship in the industry and the specific needs of entrepreneurs in the MedTech startups in Europe. It is worth noting that qualitative studies, by nature, are not intended to provide generalizable results, but instead, they provide rich and in-depth understanding of a specific phenomenon. The results of the study would be more useful for patients, managers and entrepreneurs of MedTech startups in Europe and for researchers in the field, rather than being just a generalization.

Moreover, the researchers may recommend startups to explore different funding options available in the European market, such as venture capital, grants, and crowdfunding, and to understand the pros and cons of each option. Moreover, another recommendation for startups can be to focus on building a strong online presence and digital marketing strategy. This can help startups to reach out to a broader customer base, increase brand awareness and generate leads. Finally, the researchers may recommend startups to continuously keep an eye on the market trends, competitor's strategies, and customer needs. This can help startups to stay innovative, relevant, and adapt to the changing market conditions. Moreover, market research should be an ongoing process and involve collecting data, analyzing trends, and gathering feedback from key stakeholders, including healthcare providers, patients, and regulatory bodies. Ultimately, taking a customer-centric approach, driven by thorough market research and early stakeholder engagement, will position MedTech startups for success and help them bring innovative solutions to the market.

On the other hand, the researchers recommends that MedTech startups consider the benefits of globalization. By expanding their operations and reach beyond their domestic markets, startups can tap into new customers, technologies, and resources, which can help them grow their business and achieve their goals. Globalization also provides opportunities to leverage best practices and innovative solutions from around the world, which can improve their products and services and provide a competitive advantage. In addition, by expanding their reach, startups can also access new sources of funding, such as foreign investors, and benefit from trade agreements that promote cross-border commerce. To realize the benefits of globalization, startups should develop a strategic plan that considers the cultural, regulatory, and economic differences in the markets they want to enter. This can include partnering with local companies and organizations, establishing a presence in key markets, and building

relationships with regulatory agencies. By leveraging the opportunities offered by globalization, MedTech startups can position themselves for long-term success and contribute to the growth and development of the global healthcare industry.

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