

# **How can the application of the Business Model Canvas and the Lean Start-up Method facilitate the successful introduction of medical products into the Portuguese healthcare market.**

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## **ABSTRACT**

This thesis delves into the specific challenges that are faced by integrating medical products in the Portuguese healthcare market. Furthermore, it will explore opportunities that arise through the implementation of the Business Model Canvas and the Lean Start-up Method. A key focus will be addressed; the existing research gap by analysing the limitations and shortcomings of the BMC and Lean Start-up Method in the context of medical product developments.

Another goal is to explore the potential of these methods in improving the success of introductions of medical products in the Portuguese healthcare market. This will be done through conducting comprehensive analysis of the Portuguese healthcare landscape and its regulatory framework. After this we can identify the specific challenges and following opportunities that are faced within the market, and new entrants. While also considering the ethical side that is associated with introducing a new medical product into the healthcare market.

The thesis will finalize with a discussion section of potential areas for further research to see what impact the BMC and the Lean Start-up Method has on the broad Portuguese healthcare market. The aim is to provide valuable information and show new insights that will contribute to the knowledge of development of the Portuguese healthcare market and to showcase the successful integration of medical products.

This research contributes to the existing body of knowledge by offering a nuanced understanding of how these frameworks can be used effectively to support the integration of innovative medical products, thereby providing valuable information for practitioners and researchers in this specific field.

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## 1. INTRODUCTION AND LITERATURE

The landscape of the healthcare market is in global transition, due to advancements in technology in the medical world and constant changing patient needs (Meskó, 2017). In such a dynamic environment the introduction of new medical products may seem like a challenge. The research which will be conducted in this study will hereby try to explore the evolution of the Portuguese health market by looking at the different variables determining the different changes, such as cultural differences, regulations, and other implications for entering the healthcare market in Portugal and gather information for possible future research. The goal is to help companies understand how to proceed in the Portuguese healthcare market when introducing a new medical product. Theories such as the Business Model Canvas and the Lean start-up method and using other examples and successful strategies will try to guide companies on how to enter the Portuguese healthcare market successfully which is the main goal of this paper. In these circumstances, the Portuguese healthcare market has gone through a lot of changes with improving their craft and they tried solving a lot of problems in turbulent times. The system faces challenges mainly from demographic changes, evolving morbidity rates where the part of the population is suffering from a disease or medical condition. Another point is the constant rising expectations and demands during these times. In 2005, a major shift took place which included several addressing of several concerns, improving efficiency and effectiveness (Magalhaes & Faria, 2015). Despite advancements in the Portuguese healthcare system the challenges are still currently present (Dixon, 2000).

The main challenge here is to look at the challenges and opportunities that are associated with introducing a medical product into the Portuguese healthcare market. Identifying factors that contribute to its success and/or failure. This is where Portugal has a well-defined regulatory framework or medical products with INFARMED. It is a way of overseeing the safety and efficacy during the products release (Herdeiro, 2016) Cultural differences, price issues, and regulatory issues are things the companies in the health sector must bypass. All things considered, it is also important that the company in question still stays profitable, usually firms enter new products in markets driven by profit expectations and competitive pressure (Kim, 2015). This may be challenging due to the competition of already settled products which is why a crucial factor in product integration success is capitalizing on a first-mover advantage (Marinov, 2020). Budgets that are limiting due to the early stages and newness of the product and other rules that must be complied with for a successful market entry (Kim, 2015). The usual level of structure in pricing and reimbursements processes usually varies across different European countries, with some requiring regional or hospital-to-hospital approach (Gonzalez, 2019). Additionally, factors such as shared borders or languages between the innovating firm and target country can significantly increase the likelihood of product launches (Kyle, 2006).

In general, we can clearly state that the landscape in which we work is highly volatile. This means that stating the theoretical framework transparently is important for our research. That is why the chosen frameworks that will conduct our research in this thesis are the Business Model Canvas and the Lean start-up method. Both frameworks fit combined with up-to-date literature. Consequently, the literature and the theoretical approaches will show that the different variables and concepts are related to the used literature. Both framework tools are normally used to develop and clarify their business strategies

(Mahendra,2022). It is also important before conducting this research that the Portuguese healthcare market is explored. This will help develop a good understanding of the main topic and will give us a transparent look at the various research possibilities. Starting with the Business Model Canvas, it consists of nine components: value propositions, key partners, key activities, key resources, customer relationships, channels, customer segments, cost structure and revenue streams (Osterwalder, 2010). (See Figure 1) These components give you a clear understanding and help the company understand how to create and deliver value. This framework can visualize and analyze the key components of the model so that the user can improve their own business models. When planning to introduce a medical product, aligning the product and the needs of customers becomes a central task while also optimizing your used resources so that you create the maximum value possible (Markou, 2022). By addressing these components in a transparent way and conducting fierce analysis to maximize your output. From defining what unique value you can offer with the medical product to the customer, and how you can maintain these relationships. The Business Model Canvas covers all. While understanding what the situation is also depends on how you fill in the Business Model Canvas due to situational differences. While also having its implications it also comes with a lot of simplicity, because the Business Model Canvas offers a variety of sectors. Helping you with organizational planning, portfolio management and assisting stakeholders' needs. (Sibalija, 2021). All things considered, it helps you with making important decisions that conclude the company, when used correctly (Sibalija, 2021). This will come of use in the healthcare setting because here it becomes evidently true that this is a setting of highly volatile changes in the environment, that is why the Business Model Canvas is relevant due to its ability to manage these projects. This will certainly help you respond to these highly volatile changes in the environment if all the necessary steps are taken.

With the Business Model Canvas putting the focus more on extensively approaching and planning the product development before the official market launch (Sibalija, 2021), the Lean start-up method focuses more on a systematic approach, focusing on rapid experimentation and shortening product development cycles and immediately looking at whether the product in question is feasible or not, to prevent continue wasting time and resources on and instead looking for a better alternative (Ries, 2022) This principle is mostly based on several core components.

-Build-measure-learn.

-The MVP (minimum viable product)

-Pivoting

Core components such as these allow the company to approach a growing business and focus on experimenting rapidly while also looking at validated learning and having customer-centricity Applying these components organizations most likely will increase the chances of success with developing new products that are well-aligned with the current and future market needs (Ghorashi, 2015). By applying this it ultimately will give you the most chance of achieving the sustainable growth that the organization is looking for. Creating a 'early prototype' is meant by the MVP (minimum viable product). This can be seen by having the core needs in check to further pursue the Portuguese healthcare market. A version of the product with the most minimal features that still allows the customer to give feedback for further development in the future. This will give the organization an edge because it significantly cuts back on the time and resources consumed by making this simplified version

that could still indicate the value proposition (Dennehy, 2019). So not having a lot of time consumed and resources wasted gives the organization the chance to identify potential risks much earlier in the product lifecycle than when the product is already at its peak state. This approach has put a large emphasis on the fast-learning aspect of it. Putting the most focus on improving the product and its value proposition (York, 2018). This way the organization can get the most out of it and increase their chances for a successful product in the high-risk healthcare market.

While having used scientific platforms such as Google Scholar and Scopus I came across several sources that could be of use during my research. Scientific literature with a lot of citations is something that I found important. Another important thing to point out is that the author should not hold a biased view towards the subject. To prevent from creating one-sided biases looking for unbiased literature became one of my priorities. The actual date of publication is crucial in determining whether a source is viable or not because of the changes the healthcare market went through in Portugal, political and economic wise. Because of the intercultural barrier, it should be important that the literature on this matter is somewhat reliable and admired by a lot of people with a better understanding of the Portuguese health system.

Looking at the theories I found several sources using the following keywords: Portuguese healthcare market, I used this to gather general information and found several good sources that could indicate more about this. Keywords such as Business Model Canvas and Lean start-up method were used to integrate these theories into the research about its general use and how it could help an introducing medical product in the Portuguese healthcare market. The studies of Osterwalder and Ries about the Business Model Canvas and the Lean start-up respectively there have been a lot of studies conducted about the success, the challenges, and other uncertainties. A lot of scientific papers have been written about these matters so that will be used in this research. These models will eventually complement each other if used correctly by sticking to the norms within the spectrum realizing the strengths and weaknesses of the models.

## 2. METHODOLOGY

A systematic literature review will serve as a key component of my research methodology, offering a structured and methodical approach to integrate existing research. This technique is commonly recognized for its ability to provide a comprehensive overview of current findings, helping to map out the landscape of the topic under study. By systematically searching through literature, I will ensure that the research process is transparent and replicable, which is crucial for generating reliable insights (Garcia-Penalvo, 2022).

In addition to the systematic literature review, I will analyze a wide range of scientific sources and other relevant publications. These sources will provide a better understanding of the subject, allowing me to establish a clear perspective on the relationship between the Lean Start-up Method and the Business Model Canvas. Through this analysis, I aim to uncover patterns and potential areas of synergy between the two frameworks, enabling me to bridge any existing theoretical or practical gaps.

Moreover, the systematic literature review will allow me to critically examine key studies, identifying gaps in the literature and uncertainties within existing research. This will not only guide the formulation of new hypotheses but also help in addressing unresolved questions within the field. The combination of methodical literature review and detailed analysis of academic and professional sources will equip me with the

insights needed to propose solutions and develop a coherent framework that integrates these methodologies effectively.

The insights from the literature will be carefully synthesized with the theories mentioned in the introduction and the literature review sections of my research. By integrating these theoretical perspectives, I will create a foundation that supports the development of a nuanced understanding of how the Lean Start-up Method can be effectively aligned with the Business Model Canvas. This will ultimately contribute to more refined strategic models that entrepreneurs and startups can adopt to enhance their business planning and execution.

The main aim of a systematic literature review is to identify knowledge gaps for future research, summarize current and existing literature (Garcia-Penalvo, 2022). It is mostly considered highly, offering a broader and more accurate understanding of a certain research topic than normal literature reviews (Howie, 2019; Pati & Lorusso, 2018). Additionally, it's also important to note that it gives reliable information about the researched topic at hand without showing signs of biases which is a point I mentioned in finding sources (CRD, 2009). I will also clearly state the ethical implications that would be addressed throughout this research. Implications such as privacy and other rights shouldn't be misused. Which I will further touch on later. These segments are what I intend to use as the methodology for my thesis.

In order to gather all the information to answer my research question I used several key words that I imagined being useful to find helpful literature, that could help me in my analysis. Websites such as SCOPUS, Google Scholar. Most literature were in the English language, but I found several that were Portuguese so I had to extract those from my searching engine to ensure validity and having reliable sources where I could understand where I am getting my information from. Another thing that I was thinking off while gathering information and literature was the number of times cited and the usage count and also figured it would be best to get the literature that was somewhat recent to link them to recent studies that were done on the Portuguese Healthcare market. With big changes in the recent years in their healthcare market, the gathered information had to be accurate.

The usage of keywords were the common words that are repeatedly mentioned in the thesis are; *the Business Model Canvas, the Lean start-up, medical product, integration (of a medical product), Portuguese Healthcare market*. When searching up these keywords the overall count of these papers was a lot. After that I decided to narrow down the search results to find better suitable literature. While removing key words narrowed the articles down, the articles also became more general. So, I decided to use other methods to find more sources about the several subjects and literature that had overlapping elements in it to really look at the different studies done and find a research gap and finding a solution for that research gap.

After retrieving the final set of literature that was going to be used, I looked at all the collected literature where I varied them in different columns to help me efficiently go through the literature.

In some of the articles this 'research gap' is being mentioned about the business models typically in processes in the healthcare. In the provided articles we will touch on more on the Business Model Canvas framework. With this knowledge gained we can enhance the effectiveness of the design of the value proposition inside the Business Model Canvas framework. This will also help with the decision making in these complex situations because the reality of the framework is being enhanced.

Studies by Osterwalder and Pigneur have had a significant impact on the field of business strategy, providing managers with an essential tool for analyzing and developing business models. Similarly, Eric Ries' framework for the Lean Start-up method has offered valuable insights into building and growing new business ideas through experimentation, feedback, and continuous iteration. Emphasizing pivoting and customer validation, the Lean Start-up method is especially useful in rapidly changing markets.

Although the standalone value of both the Business Model Canvas and the Lean Start-up method is well-established, there is a noticeable gap in the literature that connects these two frameworks. While they are theoretically compatible, only a limited number of studies explore their integration. This research aims to delve into this gap, investigating how the two methods can be effectively bridged.

Which integrated applications of the Business Model Canvas and Lean Startup Method are necessary to facilitate the successful introduction of innovative medical products in the Portuguese healthcare market?

To establish the roles, we must first observe the roles the business model canvas and lean start-up would fulfil. The Lean start-up focuses on reducing waste and costs and improving patient care and satisfaction (Kristen A. Ramori, 2019). This study goes into a conducted review to analyze business models used in healthcare settings regarding lean thinking in healthcare in matters such as quality models, organizational culture and lean implementation, healthcare delivery method study, clinical services redesign program, process improvement cost model (Kristen A Ramori, 2019). A comprehensive assessment of the literature on lean business models found that the healthcare sector can use models such as numerous process improvement cost models, lean thinking models, management process improvement, and models of care to increase patient satisfaction while reducing waste and expenses. It has also been demonstrated that accountable care organizations can more successfully fulfil customer and competitor expectations for value while maintaining a competitive edge. This research can help firms understand the benefits of implementing lean techniques in the healthcare industry. It may also act as a guide for adopting lean business concepts and procedures. This literature sadly does not contain the specific application of these models and lacks detailed descriptions but gives us a clear understanding of the integration of the lean business models in the healthcare. Another literature that focuses heavily on the critiques of the business model canvas and the lean start up method in practical situations, where it highlights the limitations of the method in hypothesis development and the tendency to promote incremental rather than radical innovation (T. Felin, 2020). The case further states lean start-up's heavy emphasis on easily observed feedback and immediately validated learning minimizes the entrepreneurial scientist's central task of composing a novel theory and hypotheses, prompting instead a search for value and validation only where it is easy to observe it. To put it simply, the literatures' view is that lean start-up unintentionally misrepresents the nature of developing propositions and encourages incremental tests that, in most cases, only produce incremental benefit methods (T. Felin, 2020). On the other hand, in order to assist startups in developing unique, firm-specific hypotheses and crucial experiments for testing theories, the business model canvas is not detailed enough (T It takes the element of creativeness out of the equation following certain steps. This ultimately prevents the users from expressing their innovative imagination through the overemphasis on a certain structure followed by various steps. After following assumptions of existing market knowledge, the business model

canvas may possibly hinder the teams creativity which would lead to missing out on new possibilities and not being able to explore ground breaking innovations.

### 3. DATA COLLECTION

The approach for this process will focus on evaluating the potential of introducing a new medical product into the Portuguese healthcare market. By drawing on the insights gained from the Business Model Canvas, as introduced by Osterwalder, the aim is to support our assumptions and assess the strategic fit of the product. In an increasingly volatile world, strategic planning is not just an additional tool but a crucial element for the success of almost any company. As Rohrbeck and Schwarz (2013) highlight, anticipating future trends plays a significant role in guiding business decisions.

This further supports the fact that organizations often overlook the changes which results in lost opportunities and other social and technological changes (Godet, 2010). With certain technological developments and other market demands that are constantly fluctuating.

The literature reviewed for this research has revealed several key findings regarding the use of the Business Model Canvas (BMC). In a study by Toro-Jarrín (2016), two different approaches were explored for future analysis and visualizing elements for existing businesses: one being the Business Model Canvas, and the other the Technological Roadmap (TRM). While the TRM is particularly useful for decision-makers to identify strategic gaps, it is not relevant to this research due to its non-overlapping instances with our focus. Although the TRM and BMC have complementary components (Toro-Jarrín, 2016), this research will emphasize the Business Model Canvas exclusively, either in combination with or independent of the Lean Start-up method.

After conducting thorough research to identify similarities and differences between these two methods, I will present a conclusion on how their application can facilitate the successful introduction of a medical product into the market.

Having a deeper look into the Business Model Canvas is a good way to start this research as it will give us a transparent idea of how the Business Model Canvas operates in a healthcare setting. Consisting of nine segments which contribute to the greater good of the organization. The different segments of the BMC: customer segments, channels, customer relationships, revenue, key resources, key activities, key partnerships, cost structure and value propositions (Osterwalder and Pigneur, 2010).

All these segments hold their own weight to support the organization.

Customer segments represent the person the service or product is delivered to. Helpful would be to identify the segments within the work area of the product in the Portuguese healthcare market. That would be clear when having tested the product and identify in which way the product could be helpful. Could it be used for national constitutes such as central hospitals or would it rather be used in local private practices for specific client-based instances? These different groups should be segmented clearly. Common goals should be taken into consideration when setting up these different types of segments. This would also set up another domino effect because having the right segments would eventually translate into the value proposition as the service you develop could be different and tailored to their needs and preferences depending on the customer segments. Having stated this correctly is an important step in having a successful business model.

Channels are the various ways the organization can reach the customer. This is important because you want the fastest and most effective way to reach your customers. With medical products it is important to use patient-centered marketing (Quinn, 2009), with social media around it is easier than ever to raise awareness to promote medical products. This is something that should be capitalized on. A lot of people are not educated enough to know everything there is to know about certain diseases. This would encourage people to do more extensive research and get a better understanding of the disease and how it could be treated. It is also important to work with established distributors who have existing relationships that could help you pursue the product to greater heights. This also correlates with the key partnerships. It is important to consider the other segments and make sure everything is aligned.

Customer relationships refer to what kind of relationship the organization has with the customers. This refers to if the process is automated or if the service is face-to-face. This is important because a face-to-face service can reflect a better relationship with its customers. This will ultimately increase the trust the customer has in the organization. Which will further strengthen their attachments followed by loyalty.

Revenue streams showcase all the amounts of generated sales of the product/service. This would also be very useful in gathering feedback and seeing how sales are going and building onward to see if the product performed well, and if it is useful to patients.

Key resources would describe the resources that will be mostly used during the operations of the business. These resources could contain financial or physical resources. This also includes the resources it takes for manufacturing. Having noted the right equipment and for certain cases, the technology is important to organize beforehand. Having the necessary funds to pursue the development to maximize efficiency.

The key activities tell you what the organizations must do to ultimately deliver the services and or products. The whole process is basically displayed in this section. From regulatory issues to marketing of the product. All are showcased in this segment from how the product was put out on the market. The aim should be to do this as efficiently as possible.

Key partnerships refer to the help the organization receives from other parties such as affiliates or other support to make sure the business can operate the services and products successfully. Another key point partnerships address is market penetration; it is important to remember that a good key partnership is a way to successfully enter a market. Due to collaboration with several parties, it is important to manage those relationships to the best of your capabilities by addressing responsibilities and clear goals. Transparent communication also plays a role in ensuring the partnerships are aligned to maximize the development and of course the adoption of the medical product in the Portuguese Healthcare market.

Cost structures have an overview of all the expenses that have been acquired. When developing a product, the financial stability must be consistent, and it must showcase a profitable return to hold the product in balance and make it a success.

Ultimately, the value proposition contains statements that explain what the organization offers and how it can generate value for the customer. This would be a good way of attracting customers (Osterwalder and Pigneur, 2010). Here it also becomes clear what the advantages would generate for the user. A few sentences would state the emphasis of the product and all the other intricacies. This would go hand in hand with the regulatory standards that would also be shown because the relationship between the customer and the organization is mostly

built out of trust. Furthermore, it is of huge essence that the product shows that it is integrated into the best possible state of the market where the product would fit in effortlessly to showcase the ease of adoption and to make it clear that the product is introduced comfortably and that the product cares about the safety of the user. This is the foundation of the knowledge that was established by research on the subject, like Osterwalder and Pigneur's work.

Having a clear value proposition which is clearly emphasized with a positive contribution to sustainability, while also trying to efficiently affect the healthcare system is a valid way of introducing a product the right way which correlates with the study of Osterwalder and being able to set up a strong foundation coming into a healthcare market.

In recent years, there has been an increasing amount of literature surrounding the Business Model Canvas. Through comparing and contrasting various literature, the research that is conducted in this thesis seeks to identify several themes and looks at the development in the literature compared to others. The key idea among the chosen literature is that "using the concept of management "Business Model Canvas" allows the company to comprehensively plan their activities and its main financial results depending on the variability of the influence of external and internal factors. System modelling strength and direction of the effect of these factors as part of this management concept. This enables the company to not only increase the level of revenue and profits but also to ensure the proper level of orientation on the client to maintain the competitiveness and sustainability of the business." (Dudin, 2015)

The creation of startups is mostly mentioned in the literature of Eric Ries' Lean start-up method. The main findings in the literature that were stated beforehand and additionally the build-measure-learn, the MVP and the pivoting are all concepts that will be elaborated on in this section. The MVP is one of the crucial components of the Lean Start-up method, it contains the minimalistic representation of the product that would get the most out of the validated learning out of the users. This means that while testing the minimalistic version of the product would gather information, this data would then go on to be very useful to validate the segments of the Business Model Canvas (Razabillah, 2023). This approach will turn feedback into useful data and will allow the organization to minimize waste and create an opportunity to accelerate the learning process into creating a product that is needed in the market and its users one should not mistake an MVP as an unfinished product and therefore a risk. With still having the core characteristics to form a useable product. It is still able to work as a fully layered product that works without any failures. Pivoting is the next thing that's fundamental to the Lean Start-up method, it involves changing or not. Recognizing things to improve the current product. After certain data is collected from the MVP, the analysis will follow where the feedback is getting analysed to understand what problems the MVP has and accordingly, there will be aspects changed with the goal in mind that it meets customers' demand. The application of the Lean Start-up method in such entrepreneurial projects has been found beneficial, especially when it comes to business modelling and identifying future strategies. (Harianto, 2018)

Not without critique, with potential ideas of generating novelty with its capabilities around radical innovation and the other potentials of the Lean Start-up method and how it can be impactful for business models. There have been several points of critique in the study (T. Felin, 2020). This study will go through the several gaps there has been found in the literature of Eric Ries' Lean Start-up. As mentioned earlier the Lean start-up

method goes hand in hand with the Business Model Canvas where they have been the key to the foundations for entrepreneurship and mostly incubators, which are widely adopted in the world as benchmarks in these matters. Where the Business Model Canvas gives out a display of the business model the organizations build on and the Lean Start-up builds on the framework of the assumptions and hypothesis set by the Business Model Canvas and is more of pushing innovators to undertake these structured assumptions and hypothesis and by incorporating feedback of these experiments (Konietzko, 2020). This would ultimately help the innovator with the process of a rapid iteration of the innovation. The main points of critique Felin mentions are that the tools and mindset from the Lean Start-up method may not be the best fit for radical innovations because startups usually aim to create entirely new products in new industries which is different in this instance. The second critique is that listening to feedback too ambitiously may overemphasize customer feedback which could lead to missing out on truly creative innovative products. Ultimately, the literature states that the Business Model Canvas may be too broad and lacks the specificity to help these startups identify and pursue their hypotheses (T. Felin, 2020). With the Business Model Canvas being a broad spectrum of all the different segments it ultimately fails to focus on the main issue and not being able to provide clear instructions on what to do. As a result, startups that pursue this may lack a compelling theory that is valuable and can direct their experimentation and strategy.

#### 4. RESULTS

Before introducing a medical product in the Portuguese healthcare market, we need to look at the current state of the Portuguese healthcare market. One characteristic of the Portuguese healthcare market is that it has a complex structure. The proof of its complexity is the 3 co-existing systems and contains a multi-layered structure (Simões, 2017).

The first one is the universal NHS, designed to cover the whole population of Portugal where they have services that range from specialized tailored treatments and normal primary hospital care (Barros, 2011). The NHS is mostly a tax-financed system and is based on several principles such as equality and universality. This is meant to help all the residents of Portugal the same. They all have the same type of right to get treated and there should be no divided opinions on this. Promoting fairness and being able to ensure the population of equal access to healthcare products regardless of income etc. Nevertheless, this system has not escaped common challenges such as the rise of costs and an ageing population.

The second system would belong to the health subsystems which is called occupational health insurance. These groups cover a particular side of the population, approximately 16% of the population (Simões, 2017). To be eligible for these certain health subsystems it is typically based on personal situations and various instances that the NHS does not cover for example military or other civil servants. That is why the universal NHS and health subsystems complement each other and fill in with help where the other system cannot offer any help. The way this system is funded is based on contributions and also funding through a crowd that is possibly related to the public sector and individuals who are willing to fund the treatments. The way this system is generally displayed is more often an independent sector where private funding is the focus within the healthcare market.

The third system is private voluntary health insurance, this is where individuals can get additional care options. This is called a premium. When NHS is fully occupied, or if you are just trying

to get faster access to specialists of additional treatments. In general, it just gives the individual a wide range of other healthcare services for a premium. The amount paid for these premiums is often dependent on the level you are trying to cover. With having volatile competitors in the market there are a lot of ways that customers are getting attracted to the service. While being in this type of market there is usually healthy competition between the organizations for the customer as different organizations would want to achieve greater things. For example, because of the fierce competition, the organization must achieve a high level of service quality or be the one service that is the cheapest, to come out on top there are several ways you can attack this market to be the one that gets the most attention and create a high chance that your product is the one that's being adopted the most. This also adds a layer of diversity and complexity to the healthcare service in the country.

Ultimately together these three systems form the healthcare system covering different layers. The layers are operating at different preferences and needs of the customers in Portugal. With the NHS being the broader option and being accessible to the majority of the population, the health subsystem covers a specific type of groups and private voluntary health insurance offering supplementary services for people in the population who want additional services or shorter waiting times with a premium from the healthcare section. Being able to reach out to every single individual in Portugal is a must principle to hold, and that's why it is fundamental to keep this multi-layered structure intact (Tavares, 2020).

The results of this study support the fact that the Portugal Healthcare market is a complex environment. From several factors to regulatory policies, the Portuguese Healthcare market is to be approached carefully. The latest developments need to be constantly looked at to ensure the best position of your product in order to navigate through the complexity of the dynamic market and set it up for success (Craig, 2008).

In the Portuguese healthcare market, there is a regulatory benchmark set by INFARMED (Herdeiro, 2016), which is called the Portuguese Regulatory Agency for Medicines and Health Products. To introduce a medical product, compliance must be ensured with the regulatory requirements that are set by INFARMED. This agency is the main responsible for approving and declining medicines and other health-related products through an approval process (Barros, 2007). It sets guidelines for the product to follow its main goal. To maintain the integrity of the Portuguese healthcare system and protect the health of the population, make sure that the only products that come available in the market are quality products and that have safety as their main concern (Barros, 2007). So, to bypass this maximum compliance is asked from you in order to introduce a medical product in the Portuguese Healthcare market.

One rising problem on the horizon is the ageing population of the Portuguese people. This result may be explained by the fact of its consequences. Older individuals normally need more help, mainly in health services (Rodrigues, 2018). This is mostly the case across the three systems which would have a massive burden on the healthcare system. A price increase has been observed in the study due to a higher demand because there are more individuals in need of medical help. An increase in demand often leads to higher prices due to higher healthcare expenses this is automatically coupled to rising prices due to the costs also getting higher. As the healthcare services are getting fuller, there may follow shortages of facilities or the need for more healthcare workers. More specialized healthcare workers need to be able to stay there long-term. To fund all these processes, there may be a reallocation of funding and that may lead to higher taxes. These

are all problems that affect the population considerably. These social and economic impacts are all consequences we need to consider, so that is why creating a careful planning strategy to prevent these implications in certain processes of introducing a product into these circumstances.

By combining Evidence-Based Practice with the Business Model Canvas and the Lean Start-up Method, we can bridge the existing gaps between the initial research and practice. Implementing Evidence-Based Practice requires changes in education, more practice-relevant research, and closer collaboration between clinicians and researchers (Youngblut & Brooten, 2001). We can bridge the knowledge gap between research and practice and make sure that the most recent evidence is implemented into practical changes by integrating Evidence-Based Practice with the Business Model Canvas and the Lean Start-up Method. Evidence-Based Practice improves patient outcomes, enhances safety, and reduces healthcare costs (Woods, 2013). This strategy can accelerate the adoption of evidence-based procedures, shorten the time it takes for patients to get new treatments, technological advancements, and eventually improve patient outcomes. Evidence-Based Practice is a crucial approach in healthcare that integrates the best available research evidence with clinical expertise and patient preferences to guide decision-making (Purohit Saraswati & Suneel Kumar, 2023). When introducing a product where products have or have not been introduced people tend to choose familiarity over novelty most of the time. Following the findings of the research which suggested that people often choose familiarity over novelty, especially under pressure or when facing perceived endings. Under time pressure or performance stress, individuals tend to select familiar options, even if they are suboptimal, potentially amplifying negative consequences (Litt, 2010)

When coming into a market where certain products already exist one must be aware of not intervening with other products of other owners. These matters are covered through intellectual property. Patents, trademarks, and copyrights. This helps you set up a competitive advantage where it prevents others from profiting from your innovations, while also requiring you to be aware you cannot cross certain boundaries with other products. By having a certain identity, that you create through this intellectual property, you create a presence during the sale or during negotiations and will keep your product safe. Therefore, having this intellectual property secured is a considerable step to take. For reference, the patent is an exclusive right to an invention or product that only the owner has control over. This means if someone is thinking of using the product it must get permission first from the person who holds the patent over the product. A trademark usually contains a logo or slogan that is used by the owner. This is usually used to show the identity of the product where people would recognize it and over time it would create trust in the product which is important. Ultimately, copyright is a referral to the right of the owner of this particular intellectual property. It is a protection of someone's original work, for example, the used software to create the medical product or other medical devices.

When looking at a case study about cardiac devices recently (Kuck, 2014), we can conclude various things. The similarities of regulatory approval, education and validated learning over the years, and the way the market was approached, these similarities can help us in our case. There have been several case studies regarding the introduction of cardiac devices in the Portuguese healthcare market. These devices have grown to such heights that they were seen as devices that could have the potential to significantly improve the treatment of heart failure patients (Kuck, 2014). This stems from the fact that these devices have made such massive improvements that they could be introduced in the healthcare market immediately. Having a solid foundation

and knowing how to approach this environment made the innovation successful. With the devices having such potential, further research and a more personalized approach would suit the device to optimize their effectiveness in the current healthcare market. (Lu, 2020). The findings in this case are similar in their approach to the study that is being conducted. Since this study supports that approaching a Healthcare market with a Lean Start-up method is a way to get the most out of certain products that fit customers' needs.

Based on the analysis of the literature, it is evident that there are various levels of usefulness associated with both the Lean Start-up Method and the Business Model Canvas. One of the main findings of the integrated application of the two methods is one of the stages where the Business Model Canvas familiarizes itself with the nine different segments. The Lean Start-up Methodology focuses on minimalizing uncertainties and enhancing success rates for new ventures by validating business models through iterative testing and customer feedback (Ries, 2022). But that is just merely scraping the surface of the usability of the Lean Start-up, it can serve a bigger and more significant purpose. For instance, you might use the Business Model Canvas to describe your business model and then apply the concepts of the Lean Start-up method to rapidly iterate through the business model and gather feedback to test and validate each of the components.

Due to involving a minimal viable product (MVP), it can shorten the cycle for the business model to recognize the components. It would ultimately add value in the way by providing useful evidence of the implementation of the product in the market and the willingness of the customers, to provide initial feedback and see how the product fits the market standard. One huge upside of the MVP is showcasing the Value proposition and legitimizing it, it is basically an opportunity to see if your product is valid. Just simply offering the basic version of your product would make it clear whether the product would fulfil customers wants and needs to see if your product is a must-need in the current market (Bhattacharyya & Rahman, 2004). To even support this, when developing your Minimum Viable Product, you could take into consideration multiple versions tailored to different segments in the healthcare market. After having several versions, you can test different features at the same time. Giving you a deeper understanding of the product and seeing customers preference to make the product an even better market fit.

By seeing who adopts the product helps you identify your customer segments. By creating an ideal customer profile, you allow the business model to tailor the corresponding value proposition to address these specific needs that belong to this customer profile (Izadfar, 2020). This process is basically an iterative feedback loop. Constant contact with a variety of stakeholders is required for this. Engaging patients, regulatory agencies, and healthcare experts early in the development process allows you to gather important information that helps you make necessary changes to your product (Iqbal, 2016). This is a common practice that is used in today's age, but to make this process even more efficient is by incorporating more frequent feedback loops. This would benefit the organization with identifying issues and thinking of a solution, which leads to a more agile approach. This would help you make sure that the product meets the unique standards of the Portuguese market and would lead to a more successful product development process. All these variables would lead to higher adoption rates and higher revenue.

By creating these the revenue streams would also provide early estimations, or rather indications. Showing statistics regarding the revenue streams would help you make monetary decisions



regarding the product (Remenova, 2020). When allocating money, the initial MVP attracts the other businesses and see who can offer complementary products or services, these partnerships would give you the opportunity to optimize your value proposition. This was made clear in the study of Rohrbeck and Schwarz (2013), where they formed a central focus on anticipating future trends to guide business in decision-making matters which would be key in terms of strategic planning. Achieving rapid experimentation would align effortlessly with the strategic planning of the organization by anticipating future trends. In terms of leveraging the Business Model Canvas as a framework where the business would be able to identify and visualize their strategies and make adjustments through extensive analysis to changing market dynamics, the Business Model Canvas mixed with this side of the Lean Start-up method gives a unique opportunity for organizations to pivot the products in their business models. This demonstrates agility, which is the core value of the Lean Start-up Method while being cautious of uncertainties and being able to capitalize on emerging opportunities is what drives this approach. This approach enables early assessment of customer value, which is crucial for startups and new product development in existing companies (Münch, 2013).

The current Portuguese healthcare market and the adaptation of the Public-Private Partnership model that is used in Portugal can enhance the efficiency and effectiveness of healthcare by making the model adapted to fit the Lean Start-up method. Due to the fact of implications between the different care providers, it is important to improve care coordination between the different groups. Fostering collaboration does not only help improve efficiency, but it also encourages innovation of practices into the care. Additionally, it can help burden financial responsibilities by offering help by combining public and private sectors.

When you integrate the rapid prototyping aspect and iterative testing, the stakeholders can develop pilot projects that allow the feedback from users to fit patients' needs accordingly. The findings of Cruz (2011) align with this which highlight the importance of a strategic framework, which is in this case the SWOT analysis. Which is a framework used to identify the Strengths, Weaknesses, Opportunities, and Threats related to a project. Where in this case this aligns with the importance of a strategic management framework. Where the organization serves a purpose to analyze strength and weaknesses which would help making informed decisions about the implementation of the PPPs internally, and opportunities and threats to help external decision-making. The literature previously discussed the effectiveness of healthcare delivery through the introduction of PPPs in Portugal, where it now emphasizes the conducting of a comprehensive SWOT analysis to enhance public decision-making. This leads right to the meaningfulness of the Lean Start-up method and the Business Model Canvas that would contribute towards achieving this. To comply with the regulatory use has got to be made of the INFARMED organization to ensure product quality and patient safety, which was explained previously in the introduction, Herdeiro, (2016) dives deeper into this subject. After doing comprehensive research in the Portuguese healthcare market, it was stated that it operated in three separate sectors, the universal NHS primary care, the health subsystems and voluntary health insurance all contributing to what is the Portugals multi-layered healthcare structure. This multi-layered system presents both opportunities and implications for efficient resource allocation in namely the primary care. From one point of view, diverse financing sources and suppliers can encourage competition and innovation, which might result in increased efficiency. However, systematic decentralization may lead to inefficiencies and disproportionate

access to care. To enhance the allocation of resources efficiency, the integrated application of the Lean Start-up Method and Business Model Canvas can be influential. Local practices all incorporate perhaps different practices, and each organization might have different insights, occasionally having cultural nuances that might offer a different perspective for the business model. Having a dynamic value proposition which that keeps aligned to the unique needs and preferences of the consumers. Adapting your product ensures that it shares a resemblance to the local market. Due to the Business Model Canvas and the Lean Start-up tools being established on their own and already have a high credibility on their own. One major suggestion was to integrate the SWOT analysis into the research on behalf of introducing medical products in the Portuguese healthcare market. Showcasing the internal and external factors organizations will have a better opportunity to align their business models with market needs, while external opportunities and threats will allow the organizations to guide strategic adjustments to better navigate the competitive landscape. A more nuanced knowledge of how to optimize the Business Model Canvas's nine components in response to identified opportunities and risks is made possible by this integration, which eventually results in a stronger value proposition and customer engagement strategy. Additionally, information from the SWOT analysis can improve the iterative nature of the Lean Start-up method, which prioritizes quick experimentation and consumer feedback, allowing firms to adjust their strategies in response to stakeholder input and real-time market dynamics. In general, this integrated strategy promotes responsiveness and agility, which are essential for success in the dynamic healthcare environment.

## 5. DISCUSSION

While popular in entrepreneurship circles, the Lean Startup method faces challenges in implementation and lacks substantial quantitative data to confirm its effectiveness (Silva & Ávila, 2024). Throughout this research there was always an afterthought of the downside of the tools used in the thesis; the Business Model Canvas and the Lean Start-up Method. Essentially forming a dynamic duo to bring shape to the organization in which they allow the organization to analyze their business strategies effectively and reduce uncertainties by following customers' feedback briefly and trying to minimize waste as much as possible. However, critiques of these frameworks highlight potential limitations such as the Business Model Canvas' broadness, and its straightforward idea of a business model, which may hinder startups that are looking to get through the market or to identify a precise hypothesis. On the other hand, the Lean Start-up Method may put the focus on customers feedback too heavily which would get in the way of radical innovation. The Lean Start-up Method has mostly been critiqued for its tendency of focusing most primarily on incremental improvements rather than fostering radical innovations. Putting most of the emphasis on customer feedback and iterative testing, it could potentially lead to organizations or rather startups becoming too cautious and prioritizing minor adjustments to existing products instead of broadening their horizon and going after the new groundbreaking ideas that would ultimately enter the market with a higher chance of succeeding. If you combine it with the static nature of the Business Model Canvas, you limit your effectiveness within the market. Putting too much focus on little twitches of the product when putting it all aside and starting a newer, more exciting product would be a better overall decision. The Business Model Canvas gives a conservative look at business strategy that organizations can adopt, which is not bad in every case. But when trying to make that one groundbreaking innovation in a turbulent market, it

might be better to consult other tools that might give you the push to attain the ability to adapt to changing market dynamics for that transformative growth that you are searching for. When you as an organization prioritize stability and a low risk aversion instead of radical innovations you should stick to this business model. While both tools could provide valuable insights their limitations can pose challenges when introducing medical products in dynamic markets such as Portugal's healthcare system. What my research has determined is first recognizing the dynamic nature of the landscape, closely followed by the technological advancements, and trying to identify the patients' needs to make a conclusion on whether to use the described tools that have been explained. The intricate systems of the Business Model Canvas would always be open for future research, its broad idea would always leave room for improvements as well as the Lean Start-up Method. The idea of implementing lean principles goes way further in the primary care settings. Setting up a new path for the healthcare sector. Observing the Portuguese healthcare system, one can see that there are various ways to combat the healthcare market. That became clear through observing the data that has been collected through a systematic literature review and other theoretical cases.

Furthermore, the additional integration of a comprehensive SWOT analysis is something that my research has discovered which would help with strategic decision-making, while it is a useful tool for strategic planning it could also disrupt subjectivity. Making choices based on perspectives and biases that come into play of the individuals that are managing this process, which would lead to misinterpretations of the known strengths and weaknesses to combat this is to conduct it by several anonymous individuals so that there would be a similar consensus of what the definitions of the strengths and weaknesses are. Another point my research came across is the potential robustness of the analysis, underestimating the potential effects of reducing situations by overlooking them within the business area. This would be suitable for further research in the future as well as the Evidence-Based Practice, when combining such intricate tools may not have been easy. It surely did give us some practical ways to go about it, as were seen in my research for adding and adapting a variety of tools to the Business Model Canvas and the Lean Start-up Method.

When mentioning the multi-layered structure of the Portuguese healthcare system consisting of the NHS (primary care), health subsystems and voluntary health insurance offers a great variety of care with advantages and disadvantages. By offering a variety of providers of services can encourage competition and enhancing innovation but this complexity does bring its fair share of risks, such as additional inefficiencies it could also mean that individuals do not get the treatment that they deserve. Therefore, a clear path should be cleared for this to flourish. Careful management and top coordination between the sectors are essential according to this research to ensure a successful healthcare market. Also, a factor that plays a huge role in this is the regulatory framework in Portugal that is overseen by INFARMED, the Portuguese Regulatory Agency for Medicines and Health Products. Which should be paid attention to attentively. Offering guidance for new entrants and startups to understand the cultural differences and reimbursement processes to ensure a successful product integration into the Portuguese healthcare market. This research is aimed to fill a research gap by exploring how the Business Model Canvas paired up with the Lean Start-up Method could be adapted as well as combined to support the introduction of innovative medical products in a dynamic Portuguese healthcare environment.

## 6. CONCLUSION

This study aimed to provide a clear overview of how the application of the Business Model Canvas and the Lean Start-up method facilitate the successful introduction of medical products into the Portuguese healthcare market. The main findings indicated that when you combine these frameworks and add other tools, you can significantly enhance the strategic decision-making processes of an organization. After having observed the Portuguese healthcare market, which consists of three multi-layered systems, you could conclude that in such a complex and dynamic environment these tools would have a legitimate purpose. By adding value to every single segment of the Business Model Canvas by following the Lean principles, by applying this you would ultimately streamline your processes, and improve your efficiency in the healthcare setting. With still having its limitations it would remain a significant trend in entrepreneurship, offering tools and techniques to reduce risks associated with launching new products and businesses (Ries, 2022).

One of the tools is a comprehensive SWOT analysis which is one of the components of this research, providing a structured approach to showcasing the strengths, weaknesses, opportunities, and threats when introducing a medical product into the market. This helps stakeholders with the internal and external parts of the processes.

Following the Portuguese regulatory principles, overseen by INFARMED, plays a pivotal role when introducing a product into the Portuguese healthcare market. INFARMED mostly deal with organizations to ensure product quality and patient safety so compliance with these rules is important.

Ultimately, this study provides insightful information about the strategic frameworks that can facilitate the introduction of innovative medical products in the Portuguese healthcare market. Applying the connections between the Lean Start-up Method, SWOT analysis, Business Model Canvas and Evidence-Based Practice, organizations can more effectively navigate the complicated dynamics of the Portuguese healthcare industry, offering enhanced healthcare products to the public.

## 7. ACKNOWLEDGEMENTS

A special thanks goes out to my thesis supervisors, Dr. Vincent Göttel and Dr. Martin Stienstra, for all of their help, advice and criticism.

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## 9. APPENDIX

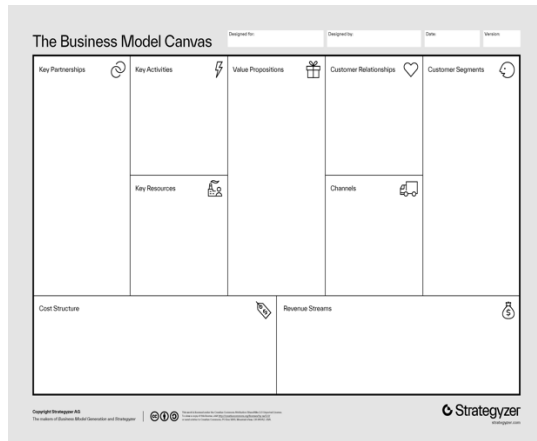


Figure 1, Business Model Canvas.

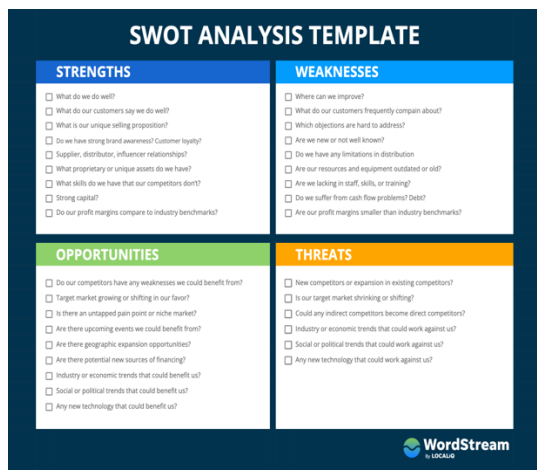


Figure 2, SWOT analysis template.