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Developing A Roadmap How to Bring a New Product to the Market

A Low Risk Medical Device

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Abstract

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The Thesis was triggered by the absence of a clear roadmap in available literature for launching a new low risk medical device to the market, and the lack of practical experience in the case company (a startup), which resulted in the need for creating such a roadmap. The case startup wanted to develop a roadmap that would clearly guide it how to bring a new product to the market, from the initial product idea up to a real, well-working business. In a more global sense, building of this roadmap was inspired by the need to help new startups with a clear path that they can trust and follow, and therefore bring value to the industry as well.

This study used a case study approach and qualitative research methods, especially relying on expert interviews as the tool to explore and find a solution to this problem. The data was collected through interviews with eight industry practitioners and experts and analysis of the documents suggested by them. The current state analysis documented a vision of the road to the market for a new product from the practitioners´ points of view. It helped to better understand the needs of the parties involved into the idea and product development. Based on this initial input, two iterations of the roadmap building were conducted, which resulted in the intended outcome, the roadmap for bringing a new low risk medical device to the market.

This thesis revealed a few important points for the development of the startup's journey that were not indicated in the available studies of startups. A very important part was the topic of medical industry regulations, obtaining patents and licenses, as well as updating internal knowledge by continuously conducting the literature review on a given topic (HealthTech). The outcome of this study is a roadmap that was built based on literature guidance and practical experience of eight experts, which gives reasons for its credibility. Thus, the Thesis brought together two most important elements for a logical and thoughtful roadmap building, the available knowledge and the expertise of practitioners in this field.

By applying the proposed roadmap, the case startup can increase clarity in planning as for the needed actions and next steps, and thus increase its chances for success on the market when bringing the new medical device to the market.

Keywords: New product, low risk medical device, market, product development, roadmap, HealthTech

Contents

1 Introduction

Mankind lives in an age of fast development of technologies. Today, almost any development idea can be implemented, but the duration and cost of implementing it can be too high and not justified if those who are attempting to implement it do not know the shortcuts and best practices of the business world.

This Thesis was born by the need to find a shortcut for bringing a new, very needed, low risk medical device to the market. Along this Thesis journey, there were multiple discoveries made that would otherwise never came to light when planning a breakthrough with a new product by purely business people (without any special HealthTech background) like the start-up´ers of this Thesis. These discoveries can be worth sharing with the people with similar interests who may find themselves in a similar trouble when planning similar attempts. This motivated the thesis researcher to make a detailed report about this case of a new device trying to find its way to the market.

1.1 Business Context

World's markets depend on human needs. But it also works vice versa, people see what is available on the market and suddenly decide that they need some extras for better life. For example, as people work more, they also get tired more. This happens due to many various reasons, such as having a lower level of physical activity, uncomfortable sitting position, boring tasks, etc. In any scenario, it may lead to various health issues as mild but regular as migraines.

Amazingly, 12% of the population – including children – suffers from migraine. Migraine is most common between the ages of 18 and 44 Migraine Research Foundation.org (2020) which is the most active working age. To help these people, the producers of drugs and medical devices innovate various pills and devices. The global medical devices market size was USD 432.23 billion in 2020. Based on Fortune Business Insights (2020) analysis, "the global market exhibited a decline of 3,7 % in 2020 as compared to the average year-on-year growth during 2017-2019. The market is projected to grow from USD 455.34 billion in 2021 to USD 657.98 billion in 2018 at a CAGR of 5.4 % in the 2021-2028 period".

But as lucrative as it may seem, this is a very tricky industry, since “patients must receive the most appropriate medical technology for them in the long term, patient's safety is the industry's main concern” (Fdokuments 2022). This presents a problem for medical device producers and innovators. One of many other problems, which is quite an acute problem especially for novice innovators, is how to bring these new devices to the market, this is the topics for this Thesis.

The case company of this Thesis is a health technology start-up, which is in a very early stage of product development, yet aiming to revolutionize the migraine self-care and professional migraine care with a new high technology solution. The founder of this stat-up is highly qualified sports massage therapist with more than 25 years of professional experience, who launched the first manual migraine clinic in Finland back in 2011. There he achieved the level of 90% positive results in acute migraine care in extremely short times. These promising results are very important in chronic migraine care, as - within more traditional treatment - strong positive results can be reached in appx. 7 weeks.

At this stage, the start-up team is collaborating with Health Innovation Village in Helsinki and other business-related agencies and authorities such as Valvira, which helps in searching the ways for producing the working prototype of this new device, as well as building an application based self-care coaching service. This stage of development called for creating a plan for bringing them to the market in the very nearest future.

1.2 Business Challenge, Objective and Outcome

The business challenge is, thus, to build a clear plan for this low risk medical device and its potential extra added services how to launch them to the market. This plan is needed for the time when the prototype of the device gets ready, and the time comes to take nest steps on its road to the market. Therefore, the need was realized to create the roadmap to the market to help the startup founder to implement it in real business life, based on the small start-up teams’ expertise and experiences.

Accordingly, the Objective of this Thesis is *to draw a roadmap on how to bring the medical device to the market.* The Outcome of the thesis is *a roadmap on how to bring the low risk medical device to the market.*

1.3 Thesis Outline

To gather information about the necessary steps and their sequence on the road of a new product to the market, first, the Thesis focused on an in-depth review of literature and relevant best practice. For this end, this thesis mainly utilized various up-to-date source of literature, articles, business blogs, and industry publications.

Next, to reinforce the theory, it was important to get the opinions of practitioners, that is, to conduct interviews with experts in the field of healthcare technology and healthcare entrepreneurship. The collected data showed a real picture of what happens when new startups want to innovate and bring a new product to the market. Many nuances and comments were revealed, that is, the original map draft required several iterations.

This study consists of seven sections. Section 1, Introduction, describes the background of the thesis. Section 2, Method and Materials, explains how the study is conducted. Section 3, Literature review, reports on the results of search for the existing knowledge and best practice on launching a new product to the market. Section 4, reports on the results from the practitioners´ analysis of the guidance merged from the ideas gathered from literature and best practice for launching new product to the market. Section 5, Building Proposal for the Roadmap, presents the initial roadmap built after the first iteration with the practitioners. Section 6, Validation of the Proposal, reports on the results of the second iteration with the practitioners and leads to the development of the final proposal. Section 7, Conclusions, summarizes the thesis.

2 Method and Material

This section describes the research method and data that were used in this study. Firstly, the section describes research approach, research design and demonstrates how the study was constructed. Secondly, the section discusses the data collection and analysis method.

2.1 Research Approach

Research is the study to establish facts and it is closely related to the creation of new knowledge. The basis of new knowledge creation and its data collection method is usually determined by the researcher. Good data collection practices usually depend on the approach selection and the environment the researcher is exposed to as well as the researchers experience and his target audience. Since most research methods have some sort of boundaries or limitations because of the complexity and the specific nature of research problems, the case study research approach is often the most preferred alternative due to its applicability to little known phenomena and usefulness of its conclusions. (Bonoma 1985.)

The case study approach is often the most commonly used research method also in the filed of business, as it includes a detailed analysis of data that has been collected over time. The value of this approach is recognized in the business, law and policy fields as well as the health sector (Crowe, Cresswell, Robertson, Huby, Avery & Sheikh, 2011). Yin R. being one of the most prominent scholars who have studied this approach in detail has indeed outdone himself. According to him, a case study is an inquiry that investigates a phenomenon in its real-life context especially where boundaries of the object of study and its context are not clear. In his book, he states that the study is a linear but iterative process which he further supports by demonstrating a linear process of case design. He states that each of this process can stand alone but then again it is linked to other stages in the research process. (Yin, 2009). This approach is effective in examining the “why”, “how” and “what” questions. The case study usually has a hard question which poorly explained and now well understood, and its aim is to use the information gained to develop an explanation.

Since case study is usually an in-depth study focused on specific phenomena, it can be viewed as qualitative in nature which can be divided into four different groups which

include observations, participant observations, in-depth viewing and documents review. Qualitative analysis is at times faced with the challenge where it is not greatly understood (Baskarada, 2014).

Case study and qualitative research methods were selected for this thesis due to innovative nature of the research problem, as an effective approach for better understanding of the problem. Case study and qualitative data collection methods were also selected due to the difficulty of obtaining any quantitative statistical data on the selected topic. Case study and qualitative research used together help to explore the given problem deeper. The study focuses on answering different “real life” kind of questions which usually arise during discussions. The research design applied in this study is presented and described in the next sub-section.

2.2 Research Design

This sub-section describes the research design used in this study and explains its key steps. The research design is built as step-by-step process shown in Figure 1 below. It includes several data collection rounds and indicates the expected outcome for each step.

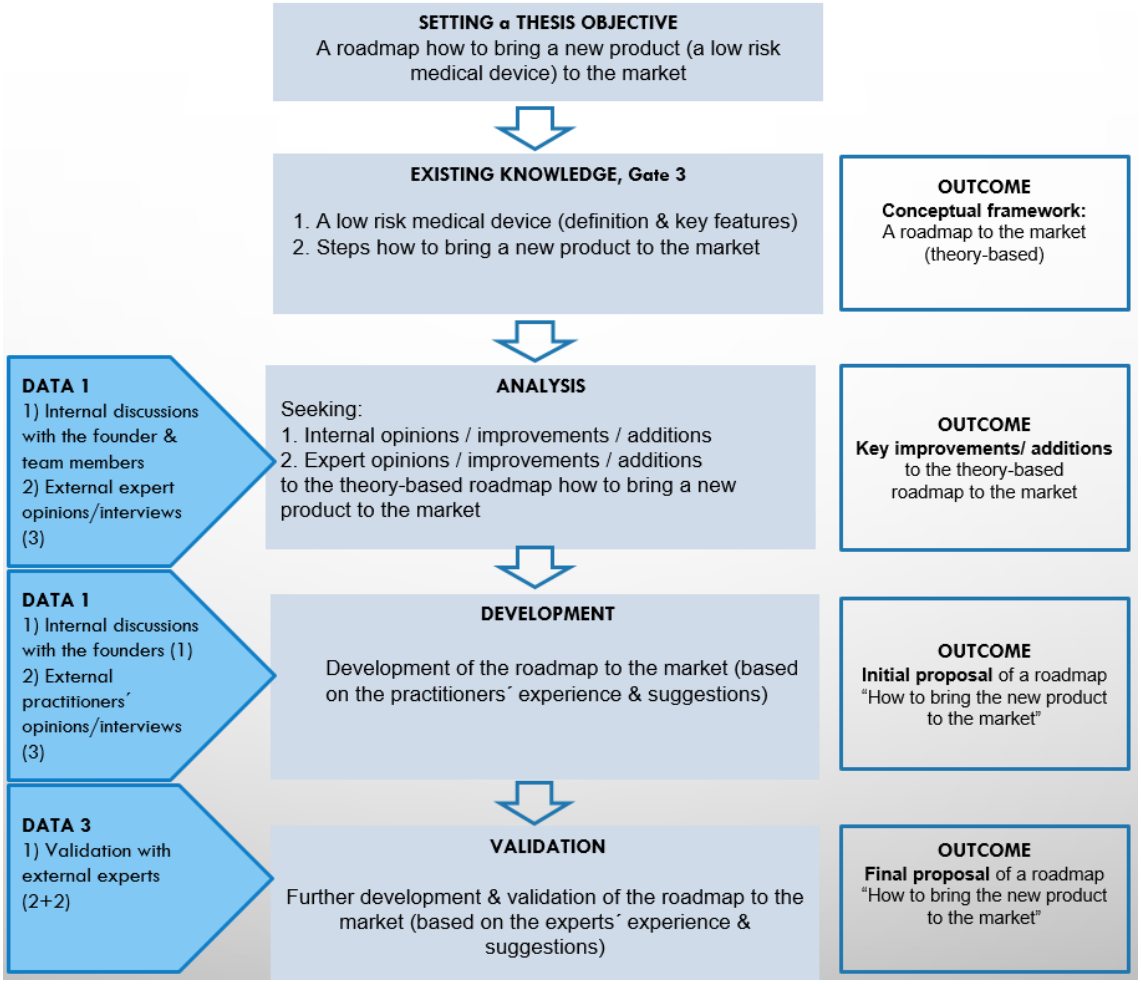


Figure 1. Research design of this study.

As shown in Figure 1, the research design of this study includes five main steps. The first step is defining the objective and outcome of the study. The case startup has determined the business challenge which defines the objective, that is to build a roadmap for a new product (low risk medical device) to the market.

After the objective and outcome were defined, the literature review was conducted to get in-depth understanding of the ideas discussed in available knowledge and best practice regarding how to bring a new product to the market. The literature review helped to identify nine steps of how to bring a new product to the market.

After that, the current state analysis was conducted by interviewing four experts in the field of entrepreneurship and HealthTech. The interview questions focused on discussed the theory-based guidance that was pulled together based on the ideas and concepts from literature and best practice. Based on the ideas put forward by the four experts, on

top of the initial inputs from literature and best practice, the initial proposal for a roadmap was built how to bring a new medical device to the market.

Finally, this initial proposal was discussed and validated by another four experts (Data 2) and then modified into the Final proposal, the roadmap on how to bring a new medical device to the market for the case startup.

2.3 Data Collection and Analysis

In this study, the data was collected from a number of data sources. They are shown in Table 1 below. Data collection 1 was part of the analysis , Data collection 2 was used in the proposal building, and Data collection 3 was gathered when validating the proposal. Table 1 shows details of Data collections 1-3 used in this study.

Table 1. Details of Data collections 1-3 used in this study.

	Participants / role	**Data type**	**Topic, description**	**Date, length**	**Documented as**
	Data 1, for the Current state analysis (Section 4)				
1	Respondent 1: Founder of the case startup	Face-to-face Interview	The roadmap (9 steps) based on literature review	May 2020 60 min	Field notes
2	Respondent 2: Employee of a highly innovative HealthTech startup (AI based)	Video call Interview	The roadmap (9 steps) based on literature review	October 2021 60 min	Field notes
3	Respondent 3: Employee of City of Helsinki, involved in Healthcare Sector Startup development	Video call Interview	The roadmap (9 steps) based on literature review	October 2021 60 min	Field notes
4	Respondent 4: Serial entrepreneur, owning established HealthTech businesses, namely, a health monitoring business abroad (Russia) and a health monitoring startup in Finland	Video call Interview	The roadmap (9 steps) based on literature review	October 2021 60 min	Field notes
	Data 2, for Proposal suggestions (Section 5)				
5	Respondent 1: Founder of the case startup	Face-to-face Interview	The roadmap (9 steps) based on literature review	May 2020 60 min	Field notes
6	Respondent 2: Employee of a highly innovative HealthTech startup (AI based)	Video call Interview	The roadmap (9 steps) based on literature review	October 2021 60 min	Field notes

7	Respondent 3: Employee of City of Helsinki, involved in Healthcare Sector Startup development	Video call Interview	The roadmap (9 steps) based on literature review	October 2021 60 min	Field notes
8	Respondent 4: Serial entrepreneur, owning established HealthTech businesses, namely, a health monitoring business abroad (Russia) and a health monitoring startup in Finland	Tell. call Interview	The roadmap (9 steps) based on literature review	October 2021 60 min	Field notes
	Data 3, from Validation (Section 6)				
9	Respondent 5: Respondent 6: Professionals from a start-up incubator which supports innovations & early phase startups (also in HealthTech)	Video Call Group Interview	Validation, evaluation of the Proposal	May 2022 60 min	Recording & field notes
10	Respondent 7: Respondent 8: High-level experts and practitioners in HealthTech industry, with academic & doctoral degrees	Video Call Group Interview	Validation, evaluation of the Proposal	May 2022 60 min	Recoding & field notes

Table 1 overviews Data collection for this study. As seen from the table, the study mostly relied on one data collection method, interviews. The data which was collected from first round of interviews with four experts used for both, analysis (Data 1) and the proposal suggestions (Data 2).

3 Existing Knowledge and Best Practice on Launching a New Product to the Market

This section starts by discussing the theory behind the features of low-risk medical devices as a product; the medical devices market in general and bringing the low-risk medical device to the market, after a careful analysis of target customers and their needs (presented later in Section 4).

3.1 Definition of a Low-Risk Medical Device and Its Class Characteristics

Presently, a lot of medical research is being conducted to ensure that patients access the new and improved devices as quick as possible and at the same time prevent the counterfeit products from getting into the market. What the producer needs to start with is to define their product (whether it is for medical use) and then identify its class (low, medium of high risk), as it determines the basic certification procedures.

According to WHO (2021), “a medical device can be any instrument, apparatus, implement, machine, appliance, implant, or reagent for in vitro use, or software, material or other similar or related article, intended by the manufacturer to be used alone or in combination for a medical purpose”. The difference between a medical device and any other regular device is its specific purpose of use. Medical devices are beneficial in many ways for regular people and for healthcare organizations.

According to Nectar (n.d.), medical devices can vary from a simple tongue depressor up to surgical lasers and pacemakers. In general, there are main purposes of medical devices: diagnose, prevent, monitor, treat a disease or monitor the condition of the human body. (Therapeutic Goods Administration 2020.)

There are four classes of medical devices in the European Union, They are ranging from low to high risk. Full information is outlined in Article IX of the Council Directive 93/42/EEC and Annex VIII of the EU medical device regulation. As Strålin (2020) explains them:

Class I

This class includes sterile products, devices with measurement function, and reusable surgical instruments, and similar. It has the lowest perceived risk. Accordingly, it is quite

easy to get certified for class I. There are just two things that must be remembered. If the device is not a sterile or measuring device, then the producer takes care of certification himself. If it's a sterile or a measuring medical device, then the producer will need to proceed another type of certification by applying Notified body assessment.

Class IIa

These products constitute low to medium risk. They are hearing aids, surgical gloves, diagnostic ultrasound machines, etc. They are usually used for any period of time less than 30 days. Manufacturers of these devices need a declaration of compliance with a Notified body assessment.

Class IIb

These products constitute from medium to high-risk. They are surgical lasers, defibrillators corrective contact lenses, etc. They are usually used for a period longer than 30 days. Manufacturers need a Notified body to assess technical documentation for compliance with the Medical Device Directive.

Class III

These medical devices have the highest risk possible, they monitored by specialized institutions for their lifetime include an audit of the technical documentation, as well as quality system/product inspection. They prosthetic heart valves, cardiovascular catheters, aneurysm clips, hip-joint implants, etc. (Strålin 2020.)

As soon as these basic characteristics (medial or not, and of which class) become clear with the help of professionals, the next steps in bringing a new product to the market also start emerging. In the next steps, the expertise of business professionals also becomes more critical.

3.2 Bringing a New Product to the Market (Step by Step): Existing Approaches

Creation of a new product to generate organic growth is a key in a business strategy. To bringing a new product to the market successfully, many questions have to be answered, some of them are:

Where to start?

Who is going to buy the product?
Why will they want it?
How much will they pay for it?
If the new product really is very unknown to the public, then it must be demonstrated, but how?
Shall we start from the prototype or from the advertising?
What will be the right price for the product?
What is the best way to distribute it, wholesale, or retail?
What is our advantage?
Shall we really patent the product as soon as possible?
What do we have to offer with this new product to the competitive world?

(Based on: Osterwalder 2010 and 2014.)

Answering these and many other questions will lead to building the step-by-step strategy on how to act on the first stage of the new product development to bring a new product to the market.

There are so many approaches to market strategies nowadays that is useful to get acquainted with some of them. At first look, each approach might have similar steps, but they all are unique and definitely fit exactly in certain business scenarios.

According to McCoy (2021), there are five ultimate steps how to bring a new product to market. He suggests firstly, to hire relevant specialists, secondly, to assess the staffing needs, thirdly, to create a product launch, and then to use key opinion leaders and to build a social media network. In the author's logic, the first step of hiring industry experts can help a new product to succeed in a highly competitive market and bring the necessary learning to the entire organization. In step two, according to McCoy (2021), as soon as the organization adds new products, the sales process will become more complex and highly skilled sales reps will be needed. Their skills will be combined with the product specialist’s knowledge, and this joint effort will help to stay up to speed. In step three, McCoy (2021), the focus is placed on ensuring a successful product launch, which requires well-coordinated teamwork of marketers, product managers and corporate trainers. McCoy (2021) also recommends utilize the possibility of introducing the product to relevant educational institutions which can help to conduct research for future additions to the product. Finally, for catching the attention of potential clients,

McCoy (2021) finds that key opinion leaders (KOLs) who truly believe in the products are paramount for promoting it. According to McCoy (2021), the last step to create is a big stir about bringing the new product to market by building social media presence (online press releases, marketing campaigns etc.) widely shared with the public.

As seen from this 5-step approach, McCoy (2021) believes in hiring big teams with a wide presence of external experts and a significant number of staff. Although informative, this approach could be considered as fitting mostly bigger size companies, as compared to limited resources of SMEs.

In another approach by Expert Panel (2020), thirteen independent experts from different industries highlight the key steps they think are important when it comes to Go-To-Market Strategy.

Brown (2020) suggests, first, to prioritize the needs of potential customers, because meeting their expectations early make them loyal and builds the foundation of successful interaction. Valiulis (2020) suggests to access markets that covers critical customer needs and take care of their pain points effectively.

Miller (2020) second step is to thoroughly understand the market, as deep as it is possible. As step three, Amunategui (2020) advises to have a measurable plan and a disciplined approach. Wise (2020) recommends collect valuable feedbacks and then act accordingly, as step four. In Zaheer's (2020) opinion, one of the most critical steps are align on buyer profiles and well-defined target markets, as the target audience isn't looking for generalists.

According to Shah (2020), building brand equity as step (five) is extremely important for creating that loyalty. Hobson (2020) sees step six as identifying brand standards (mission statement, messaging, goals, font etc.). Thomas (2020) advises that a key step is to collaborate closely with the marketing team for identifying target buyer personas, their problems and objectives effectively. Hicks (2020) suggests to forge authentic connections, as customers trust companies that understand their problems and don't force them to spend their money.

On a more general level, Divinsky (2020) advises to look for and consider different ways to enter a market. Fritsch (2020) sees identifying competitive advantages and deciding how to best exploit them as the key step in the market launch strategy. Merker (2020)

reminds to think forward and consider things like upselling, support, and building long-term relationship with the customer, these actions should help to see the bigger picture.

By reflecting on the above approaches, as well as other suggestions from business professionals and mind leaders (especially Leibson 2018 for the overall framework), the following approach can be summarized.

Relying on Osterwalder (2014) and Leibson (2018), *the first step* could be to identify the target customer groups and competitors. This seems a reasonable step as the company needs to know who to serve with the intended new product. For this end, the company can do segmentation, targeting, positioning and competitor analysis, which make standard business tools for identifying target customers and competitors. Segmentations distributes the customers into segments, while targeting and positioning outlines the proposition idea for each segment.

According to Leibson (2018), and Breschi (2020), *the second step* could be focused on identifying the unserved customer needs of these customer groups. The unserved needs most typically concern functionality/performance, convenience/usability, customer experience, product/service design, price, and other customer needs.

Following the works of Osterwalder (2014) and Leibson (2018), Gierej (2017), *the third step* could be formulated as defining the Customer Value Proposition (CVP). A CVP is structured by Osterwalder (2014) into “the jobs-to-be-done”, “pain relievers” and “gain creators”. These elements will determine the strategy on how to identify and present value to the customer and should help to price the new product based on created value, and thus help to win customers.

Comparing opinions of Leibson (2018), Gierej (2017), Walker (2018), and Ries (2011), *the fourth step* could be defined as refining the feature set for the intended Minimal Viable Product (MVP). It means selecting only those - a minimum set - of features (based on emotional and functional design, usability and reliability) that will create the necessary minimum package of a successful new product. This step is especially important to keep realistic levels about the new product, especially at the early stages of its development. On the contrary, targeting excessive - and expensive - feature sets can simply ruin the product development process, especially for SME companies, due to a simple lack of resources for anything more than a minimal feature set. Thus, this step becomes critically important for all developing companies, but especially for SMEs.

Relying on Leibson (2018), Ries (2011), Pierini (2019) and Moritz (2005), *the fifth step* could be summarized as creating a prototype and testing it. As in any other design process, the prototype is implemented through a cycle of building, measuring, learning & developing, and repeating the cycle until the prototype is ready. Importantly, it relates to both, the prototype for a MVP (a minimal viable product), as well as MVS (a minimal viable service); both need to be tested.

According to Leibson (2018), Ries (2011) and Moritz (2005), *the next, sixth step* should test the MVP/MVS with customers. All these business practitioners stress that, in the test plan, customers should physically try the demo product, followed by in-depth interviews to identify detailed customer feedback and their perceptions.

The seventh step, as inspired by Osterwalder (2014), could focus on building a viable Business Model for the new product or service, which should pull together the value creation, earning logic (how to make profit), partners, channels, and other elements - altogether nice elements for the business model canvas - i.e., a wider product or service picture.

Relying on the opinions of Ries (2011) and Rus et al. (2018), *the eighth step* could relate to launching a lean start-up and brand. This step can also be taken earlier (basically, at any stage), but the experienced business practitioners see the business sense in building a new enterprise only when the key business concerns become thought out and defined (such as customers, competitors, value, porotypes, customer perceptions of the new product, etc). In simple words, the reason for the existence of a start-up should be the new product and the business model, well thought-out before taking this step.

When all the other steps described above are taken, *the last, ninth step* is a brave launch of the product into the market, as a full-size market entry, and streamlining operations. According to Reis (2011) and Datta (2014), a successful market entry will be based on a detailed plan of how to run, finance the operations, and grow.

After outlining this approach summarized from best examples from business practitioners, each step is detailed below. Also, at the end of this section, some gaps in this approach and discussed and further additions are suggested.

3.2.1 Identifying the Target Customer Groups and Competitors

According to Claessens (2019), for correctly marketing a product or a service, it is important to tailor the sales and marketing efforts so that to reach the customer segment that is most likely to purchase the products and services. Claessens (2019) states that - for a startup company to be successful - it needs, above all, to identify its target market. This statement also corresponds to a study by EarlyaPad about the top reasons why the startups are usually failing: first, no market need (42 %) and, second, running out of cash (29%). (Khan 2021.)

Claessens (2019) points out that, the using segmentation, targeting, positioning together has become popular because of ability of reaching niche segments easier. According to Claessens (2019), the key benefits of using the STP model (segmentation, targeting, positioning) are: strengthen company's competitiveness; focusing on marketing strategies; recognizing growth opportunities; effective allocating of resources and as a result better return on marketing investment.

Echoing these views, Quicksprout (2020) points to sequence of steps: first, the need to segment the markets and identify the most attractive segments, and only then developing the positioning strategies and allocating resources, it will prioritize any further development activities.

This sounds very logical and seems as a suitable model for the start-up case scenario especially, due to their limited resources. Nevertheless, it is very important to pay attention at all the constituents, before considering and applying them.

Segmentation

Tow (2019) defines market segmentation as a business practice that identifies the business ability to divide the target market into small groups for easier management and effective communication.

According to Tow (2019), there are four types of market segmentation. First, *Geographic segmentation* is a market segmentation that serves customers in a given area, this type identifies values, interests and other personal details.

Second, it is a *Demographic segmentation* that divides a market by age, gender, education level, family size, occupation, income, etc. This type is popular because some

of the products depends on individual needs very much, one of the most important index is age, as human beings tend to changes their preferences through life time.

Third, *Psychographic segmentation* focuses on the intrinsic traits the target customer possesses. It usually based on different lifestyle features, customer desires vary regularly and marketer's job to know how and when exactly.

Finally, *Behavioral segmentation* focuses on individual customer's decision making and purchasing processes. Tow (2019), argue that customer's attitudes and loyalty towards the brand, as well as recognition in general are good examples of *behavioral* segmentation.

This segmentation method helps to see all the multiple types of customer audience. It is also very good for trying, narrowing and finding the right group of buyers to focus on completely.

Targeting

Expert Program Management (2020) found out that targeting simply decide which of the segments is the most attractive in terms of commercial benefits.

There are several factors that can be considered for targeting, as stated by Expert Program Management (2020). First, it is the size of the segment and its potential. Second, it is the profitability. Targeting usually helps to understand which segments are willing to pay the most; what is the lifetime value of a customer; how easy to reach this segment by applying existed marketing tools and distribution network; what is the cost of acquisition of a customer.

Worth mentioning that various sources point to SWOT or PEST analyses. They are very useful when it comes to identifying risks and opportunities of any targeted market.

Positioning

According to Brainmates (2019), product Positioning is a key marketing tool that helps to make potential customers to choose the product from a range of others. Product positioning is one of development of marketing activities. According to Brainmates (2019), buyers show where the product fits, and the company's competitors usually position their products or services based on it. That is why it is important to spend some time to position the product wisely.

According to Brainmates (2019), once the target segment is picked up, the next step is to prioritise the needs and wants of this segment and cross-check this with the product. Going through all the steps allows to develop a Product Positioning Statement, i.e., a one or two sentence description that articulates why the product is the absolute best solution to the target segment's requirements. (Brainmates 2019.)

These traditional business methods open up a deeper level of the strategy that could be used at this step. Thus, it is key to polish the product and make it the most relevant for the target audience, as well as identify its weak points (cost, efficiency, growth, risks) for the company before mankind any further steps.

3.2.2 Identifying Unserved Customer Needs

Business practice suggests that unserved (or underserved) customer needs make the core point in linking the company with its customers. The difference between the *unserved* and *underserved* needs is quite subtle, but it does exist. Business professionals consider the unserved needs as those needs which are totally ignored, overlooked or unrecognized, while the underserved needs mean the needs that are not met in an expected or convenient way, or in full scope. Korzeniowski (2021) argues that nowadays companies are under pressure to develop additional revenue sources, which they pursue targeting the underserved needs´ markets.

Korzeniowski (2021) also found that close to half (42%) of all failed companies shut their operations down simply because there was no market need for their products. Thus, identifying the true needs for a product or service lies at the very heart of any successful business.

According to Korzeniowski (2021) there are several effective tools that can help at this stage. They include data analytics, mapping software, social media monitoring, and creating personas, among others. According to the Georgia Small Business Development Center, analytics tools bring 15% more sales. It can also reduce costs, increase efficiency, design new products or services, identify and prevent fraud, make smarter business decisions etc. Because big-data technologies are supporting businesses quite well, startups can benefit by using it.

According to Service Corps of Retired Executives (SCORE), half of small business owners (51%) think that big-data analysis is useful, but in reality only 45% of them perform it. Data analyses can help small business owners meet their goals.

It is essential to use suitable tools for big data analyses, there are some of them:

- SAS (manages, retrieves and alters data from different sources – such as web, social media and marketing analytics).
- ClearStory Data (combines a business's internal data with publicly available data for making better decisions).
- Kissmetrics (increases the ROI on their marketing efforts and recognizes customers' behaviors).
- InsightSquared (collects data and generates insights by linking different business softwares). (Ayers 2020.)

Korzeniowski (2021) especially emphasizes *social media managemen*t, as it gives a good read on how customers interact with companies. The biggest part of them are the so-called *social listening tools*, which can detect relevant topics and trends in a market, help to develop social media strategies and differentiate the brand from the competition. Korzeniowski (2021) also stresses the use of *personas*, as they help to clearly portray who exactly makes up that audience. Personas are able to give quite a complete image of a potential client, including a picture of the family status and lifestyle preferences, a range of behavioral characteristics, motives, attitudes, etc.

This approach is echoed by Miller (2020) who outlines the three methods to identify customer needs or jobs to be done.

1. Reflect on Personal Experiences, which means reviewing personal behaviors and experiences to identify patterns in the decision-making process. According to Miller (2020), “it is a good starting point and helps to skip mixing other existing knowledge”.

2. Observing Behaviors, which means analyzing people's habits at various stages of the buying process. According to Miller (2020), “this can be done imaginarily, with a service or a product which does not even exist yet”.

3. Conducting Interviews, with the goal of learning about the decision-making process from current, former or non-customers. As Miller (2020) suggests, it should “cover all the

possible case scenarios: reasons to buy / termination of use or choosing to purchase from a competitor". (Miller 2020.)

Additional questions will help to explore the customer's motivations and the job they hired the product or service to fulfill. At the end of persona building, there should be a clear understanding of customers' unmet needs.

Worth mentionung the urge to recognize the unmet needs, Zak (2019) points out to the opposite phenomenon. According to him, many companies underestimate underserved markets, because of these reasons: design and production are complicated; companies think that some products are not suitable for their brand; as well as "that there simply is not a template to work from, if no one has done it before, it is difficult to know where to start" (Zak 2019). To address these concerns, Zak (2019) reminds that, despite the fact a market has been overlooked, there may be a lot of potential revenue. To address this dilemma, Zak (2019) suggest the following approach:

1. Acknowledge and own the first-mover advantage. According to Zak (2019), any successful startup either creates a new market or enters an old one by doing something differently stated by (Zak, 2019). "Once it is proved an opportunity exists within a market, the door is open for more entrants" (Zak 2019) but there are more benefits for the pioneers.

2. Develop a company's own personality. This step follows the first moves in the market. Here, instead of copying, Zak (2019) suggests to learn from brands and get inspiration from famous brands and be inspired by them. Zak (2019) states that, creative originality develops a unique brand and therefore standards or a new market.

3. Focus on being consumer positive. Zak (2019) also argues that, focusing on an overlooked market provides consumers with more options and choices. If the company is serving these markets successfully, it will create a good revenue opportunity as well as making people happy. These three steps can help companies to approach the new markets more bravely.

Summing up, success of the company comes when it identifies the gaps in the market. The most promising gaps relate to the unserved or underserved customer needs. The success of the move depends on the speed of identifying a problem and finding a profitable solution that will hit the underserved market. As soon as a company

understands *who* and *where* their audience is, it is much easier to reach them out and create awareness about the new product or service. Nowadays the use of modern technologies and strategies - such as business analytics, mapping software, and various tools such as building customer personas - help in identifying and overcoming these gaps. As soon as the company identifies the unserved or underserved customer needs, it is important to concentrate and focus on the product. This topic is discussed next.

3.2.3 Defining a Customer Value Proposition (CVP)

At this stage, the outline of the product or service gets sharpened, verbalized and documented in the form of a Customer Value Proposition (CVP). A CVP answers the question *'why our company'* to the potential customers and *how* the product or service creates value for a Customer Segment by covering their needs.

CVP means a fit, or a successful combination, of the customer's needs with the company's offer. The goal of a CVP is to show how value is created for the customer. Osterwalder (2010 p. 23), states that customer value may be *quantitative* (e.g. price, speed of service) or *qualitative* (e.g. design, customer experience). There is a wide range of elements that contribute to customer value creation.

A company's unique CVP is a key marketing tool, and Osterwalder (2010) argues that the CVP communicates the idea that customers will get a huge value or benefit by purchasing company's products and not the competitor's one.

According to Maverick (2020), the three main CVP elements should point to:

1. Target Market. It means that the company has a clear understanding of the ideal customer is and shapes its value proposition to serve that ideal customer. This element is related to target customer groups discussed earlier and includes key demographics (such as age, sex, family status, income, etc.) and creates a value proposition to attract that target market.

2. Specific Value. This element clearly answers the question of *why* customers should

choose the company's products over any other available options. Some companies offer the lowest price ("cost leadership" strategy), other companies offer high quality or timesaving ("differentiation" strategy).

3. Customer Connection. This element should explain *how the company takes care of* the individual needs or desires. This element helps to identify customers' emotions that are important in building relationship and brand loyalty. As such, it can be compared to the core of the Customer Value Proposition by Osterwalder (2014). Here, success comes from understanding the customer, especially the jobs the customer is trying to get done. According to both, Osterwalder (2014) and Maverick (2020), getting jobs done makes customers to buy a product easier. This thinking is fundamental to the jobs-to-be-done theory (as outlined by Osterwalder 2014). Echoing these views, Strategyn (2020) stresses that, defining the job-to-be-done accurately will predict the success of innovation because the job-to-be-done becomes the center of the entire innovation process. (Maverick 2020.)

In addition to the jobs-to-be-done, this approach by Osterwalder (2014) also identifies *the Customer pains* as the negative outcomes and risks (also in: Tow 2019). *Pain relievers* are the ways your products or services take care of the customer's pain. *Customer gains* are the outcomes or results the customers want to accomplish, as well as benefits they are wishing for. *The gain creators* are the methods of how the products or services share value with customer.

According to VanDerLeest (2021), there are few things and questions, which can help in creating a strong CVP:

Table 3. Example Questions for Customer Value Proposition (VanDerLeest 2021).

1. What exactly does the company do?
2. Who is the company's target audience?
3. What are the audience's pain points?
4. How will the product or service remedy the issue?

Thinking carefully and answering them will define the business uniqueness and resonate with potential customers. It is not only about what the customer wants or needs, it is also about what he fears or how he substitutes the company's product.

Summing up, identification of customer needs, market sizing and segmentation methods depend on defining the job accurately on the first place. If it is not defined correctly, time and money will be wasted. Thus, defining CVP requires serious efforts and an open mind

approach, which should result in deep understanding and confidence of the company about its customers and its products.

3.2.4 Refining MVP's Feature Set

As soon as the company identifies the unserved or underserved customer needs, it is important to concentrate and focus on the product. This topic is discussed next.

According to Breschi (2019), customers need the product to function in the best and individual way and have a convenient solution to solve their unique problem. The user experience needs to be smooth, clear, and easy. Along the lines of experience, the product needs a slick design to make it intuitive to use, as well as the price range must be relatively diverse, as each customer has a unique budget for shopping. The customer experience and the extent to which their needs can be satisfied by a product are always determined at the level of product or service design. In other words, the MVP, and its features level. Yet, choosing the right features can be difficult while working with startups, especially when the picture of the ideal customer is not yet clear.

Mroczkowska (2019), in his study tries to explain a Minimum Viable Product allows team to learn about customer needs with the least amount of effort, while Karnes (2019), argues out that a minimum viable product is the most elementary feature set that allows to get valuable feedbacks during the product development stage.

Lastovetska (2019), in his research gives evidence by quoting Eric Ries:" The power of MVP can be matched only by the amount of confusion that it causes, which is quite hard to do. It certainly took me years to make sense of it." and Steve Blank: "This minimum feature set (sometimes called the "minimum viable product") causes lots of confusion. Founders act like the 'minimum' part is the goal or, worse, that every potential customer should want it."

For defining crucial features for MVP there are two steps: 1. extract core value. 2. define vital features as suggested by (Anoda 2018). First step is quite easy, basically it is a foundation of the product idea. For the second step, it is needed to look at MVP features as for necessary parts of a house and their functions: walls, roof, windows. It is recommended to think about the feature in the following order: functionality, reliability, usability, design. *Functionality* is the quality of being suited to serve a purpose well, in other words the product must be simply practical. According to www.lexico.com (2020),

Reliability is the quality of being trustworthy or of performing consistently well, while *Usability* is ability to perform the tasks of the product safely and effectively with a pleasure for users.

Maksimowicz (2020) describes the product design as a set of properties, consisting of the discrete properties of the form and multiple functions. In includes:

- Emotional design

Emotional design refers to the ability of a design to evoke emotions. It seeks to address the customer's needs efficiently and effectively. Emotional design is a design that aims to foresee and serve customer needs and feedback. www.interaction-design.org 2020

- Functional

Refers to the capacity of a product to work the way it is supposed to. A functional product or service is useful in appliance with its initial purpose.

- Reliable

Reliable denotes the ability of a product or service to work consistently, and according to www.asq.org (2020), a reliable product or service will adequately execute its intended purpose for a given period or operate in a set of environments without failing.

- Usable

Usable refers to the capability of a product or system to work effectively and efficiently. www.interaction-design.org (2020), research found out that a usable product or service allows users to use the product or service in a pleasing, effective, and simple way.

In other words, the sum of the CVP and features set of a new product can also be approached as proof of concept or a principle. The original definition used in 1984 by Bruce Carsten, he was describing a type of prototype “in which the intent was only to demonstrate the feasibility of a new circuit and/or a fabrication technique and was not intended to be an early version of a production design”. (Carsten 1984.)

It allows the company to prove that creating the solution (product/ service/ program etc.) is achievable and explore the general potential of the idea.

Summing up, despite the fact that the cycle of creating MVP seems quite easy and logical, it can get very complicated. The paths of creating MVP and solving the actual problem for customers can unexpectedly go two different ways. The MVP itself is still quite far from the finished version of the product (how the author intended it). So even if the creators are happy with it, it may still look very dubious to a potential audience. That is why prioritizing the functionalities is extremely important.

3.2.5 Creating MVP prototype

Minimal Viable Product (MVP) and BLM loop are best discussed by Ries (2011). According to Reis (2011), an MVP will include:

Building, it entails creating a feature set for an MVP. Here the start-up team addresses and outlines a list of features for the new product. This is done through analysing functionality, usability, reliability, and design aspects for the new product to create a compelling new product minimum package.

Measuring, it involves assessing and considering the viability of a feature set for development. Measuring involves understanding the feasibility of the listed feature set for the new product.

Learning, it entails understanding the requirements or feature set issues while developing. Through learning the start-up team will be able to know whether a feature is necessary or not and how it can be improved and done efficiently.

Developing, it involves the step of refining the existing feature set upon knowledge acquisition. Once the start-up team ascertains and settles on a feature set development phase is undertaken.

According to Moritz (2005), Designing, for example, a Minimum Viable Service will include:

- Design of features

Entails how the features in development will function. The design of features seeks to anticipate and accommodate the desires of the customers and their response.

- Design of client experience

Involves the understanding of the usability of features for the service. It aids in providing meaningful and appropriate experiences to clients.

- Design of processes & systems

Entails establishing the how and practicality of service in hand. Design of process and systems seeks to outline how a service will function and be put into use.

- Design of strategy & policy

Pertains the establishment of a system for dispensing the service. Strategy and policy design includes an outlined set of action on how a service will be undertaken in order to achieve a goal. (Moritz 2005.)

Summing up, creating a prototype allows the company to see how the product will look and how the end-user will interact with the product when it is finished completely. The process of designing the prototype itself helps to notice the errors and act accordingly. The prototype can be tested and developed as long as the best result is achieved, but it can not last forever. The main point there is to get the feedback as soon as possible, and the prototype is a perfect time- and cost-saving solution.

3.2.6 Testing MVP/MVS with Customers

Test plan entails functional testing of the demo product, whereby the customers are afforded the means to test the product physically and then interviewed. This is important since it will help guide the start-up team to learn on what more can be done or what they got wrong and consequently, help them refine the MVP. Testing can be done via customer interviews, demo, landing pages, pre-order page campaigns, explainer videos, surveys, number of new sign ups, etc. (Shah 2020.)

3.2.7 Developing a Business Model

Wladawsky-Berger (2019) and many other researches and business experts share an opinion, that “It’s all about business model innovation, not new technology”, because one of the challenges at this early stage for the start-up is to choose the right business model.

Applying the Business Model Canvas (Osterwalder 2010), helps to find out how different blocks or components shape the business model and what exactly will make it work.

Additionally, discussing and analyzing the five forces model (THE INVESTOPEDIA TEAM 2020), brings an opportunity to see the business from another angle, or using a different tool, which is more applicable for start-ups (e.g., modern business models as described by Osterwalder 2010, 2014). His Direct-to-Customers canvas is meant for:

(a) Physical product sales

(b) Online sales

(c) Renting service. (Osterwalder 2010, 2014.)

There are many ways to do it, and it is extremely important to do it on time, before any decisions have been made. Kavadias, Ladas, and Loch (2016) claim that the business model is a system, which creates and captures value and determines the company’s success. A new business model represents cooperation of the market demand solved by technology. There are few keys components that make the business model transformation successful. Talking about case company, there are three keys, personalized product and service, synergetic ecosystem, and an agile organization. It simply states that, because the start-up aims at bringing unique service and product to the market, to achieve this, the team must be open minded, consider and try different options, collaborate with other similar companies (as a side note, e.g. Health Village provides this opportunity), and often think of the products and services from the customers perspective.

Summing up, a clear Business Model captures the company’s value, the solution of the problem and the potential opportunities. Important not to confused with a business plan, as they have completely different purposes for the company. The business model is the foundation with the main idea of how the company will generate revenue, and the business plan is an explanation of how the business model is working in detail. The business model may seem a simple document, but it is a very good tool to keep the

discipline in the company. At least for the start ups it is a life-saver, as it helps to master the business strategy.

3.2.8 Launching a Lean Start-up and Brand

The first mention of a startup appeared in Forbes magazine in 1976, but it seems that the first famous startup founder lived hundreds of years ago. Every new company expects success when they launch a new idea. But there are a number of challenges on the entrepreneur's path that can cut it very quickly. So, by applying the Lean Startup Methodology (Ries 2011), a new company can see straight away if their business model is practical. Going through each step and coming back to the first step each time (as the methodology is a loop) the company is able to develop the product to a relative perfection. It is an ultimate toolkit that allows companies to build bridges and stairs to their target.

One of the first steps when launching a start-up step entails articulating the *why* and *how* aspects of the lean start-up (most typically known as *Defining the mission, vision, strategy*, etc). Here, a start-up declares its overall goal, informs about the type of product/service it provides, and their desired future position.

The next important concern is *Marketing & Branding*. Reaching the target audience is a big success, but keeping them is a challenge too. There, comes the brand marketing as its main purpose is to grow the number of loyal customers by recognition and reputation. It should focus on the lean start-up’s promotion and advertising aspects. Achieving a wide customer base is another huge success, but understanding them and therefore engaging well (so they could bring more customers) is a complex task and requires a lot of energy. Therefore, *Marketing* is a critical component of any new product or service since it helps to promote its business side. Besides, branding in the business world defines the success or failure of a product or service. Therefore, the way a start-up differentiates itself from its competitors is very important. Customer relationship. It involves the lean startup’s day to day affairs with its customers. (Reis 2011.)

3.2.9 Market Entry and Operations

On the day when the company has its first sale, it enters the market officially. Then the customers get the very first experiences of interacting with the company. At this early

stage, a startup is monitoring all the established processes, reviewing and developing them, if needed. If split into separate elements, the Market entry part includes the five main steps best articulated by Reis (2011), namely:

- Introduction

Introduction entails bringing in the new product into the market. For penetration purposes, the new product gets to be introduced into a new market.

- Commercialization

It means the introduction of a new product and service to the new market. The product is launched, and the marketing data and production cost is observed to determine if the product will earn the company profit if the sales volume is increased.

- Distribution

Distribution is an important component of a marketing mix and is a link between processing and consumption. It involves the sharing of the new product and service to gain publicity in the market. Intermediaries who include the wholesalers, salesperson, and retailers can be used to sell the products to the final consumer

- Promotion

This is the communication made by marketers to persuade and inform, as well as remind the potential customers of a selling product and to influence an opinion. Marketing the product enables a company to afford more customers. Promotion is an essential part of any start-up since not every person is familiar with the new product and service available in the market. Therefore, it is critical to promote the product and service to acquire more customers and be in business.

- Review of performance

This entails evaluating the feedback from customers of the product who have had the chance to use the product and service. Here the start-up assesses the users' reactions, whether positive or negative to gauge what more can be done to stand out in the market. (Ries 2011.)

After the Marker entry, *Managing the operations*, or optimisation of all the processes, comes into focus, and it is a very complex and important stage, which stays relevant for the entire time of business existence. It typically includes staff development, sales productivity, product/service enhancement, etc. If the company manage them well, it gives some hope for the business success.

3.3 Conceptual Framework of This Thesis

This sub-section summarizes the literature review and describes concepts and tools that will be used for building a roadmap in Section 4.

Analysing literature review identified core ideas and concepts of a roadmap how to bring a new low risk medical device. These findings were described individually and summed up, as a result a conceptual framework was formed. It is a visual representation of the roadmap consisting of nine steps. The framework is shown in Figure 2 below.

Nowadays, it is imperative to establish a well-defined target market and to know your industry competitors. Therefore, the first step is to identify the ideal customer groups and rival products in the industry Leibson (2018) Osterwalder (2014). This is essential to understand customer needs, and what the competitors offer. This will aid in coming up with a competitive edge in the long run.

After establishing a well-defined target market, the company should proceed to investigate the unattended customer needs. These are the needs that the competitors have not entirely fulfilled or have failed to address. The needs may also entail customers' desires that are not realized presently. Upon recognition of the customers' needs that are not catered for, the company should progress to describe to the target customer groups(s) what it stands for, the way it operates, and the reason it justifies their business. Here the company summarizes the reasons why a consumer should purchase their medical device.

The fourth step is coming up with a Minimal Viable Product (MVP) which entails creating and refining the feature set for the medical device Leibson (2018) Walker (2018) Ries (2011). At this point, addressing core customer needs is vital, thus selecting key features basing on the functionality, reliability, usability, and design aspects of the medical device.

The company should proceed to test and check for viability of the MVP with the customers and get their review. Upon approval of the feature set for the medical device MVP, the next stage involves physical creation of the prototype and testing it. The prototype will undergo a series of building, measuring, learning, and developing, and repeating the process until achieving a final prototype. The Minimum Viable Service can now be created at this stage while discussing with the customers.

Once the prototype of the medical device is done, the company should proceed and test the device with the customers. The customers need to test the product physically. Then the company should conduct a thorough interview with the customers so that they can be able to find the customers' views. Various techniques can be employed to test customers' opinions, such as creating landing web pages to see the demand for the new product and service.

The seventh step involves coming up with a sustainable business model Osterwalder (2014). This stage is crucial as it determines the success or failure of the start-up. Here the company should reflect on critical business choices such as the way they will sell, the channels, means of delivering the service, payment mode, partnerships etc. As soon as a sustainable business model is established, the company should advance and launch a lean start-up and brand. The lean start-up will encompass a mission and vision that clearly define the company direction.

Finally, the company should proceed and enter the market and full operations. Here the steps entail introducing the medical device into the market for penetration purposes, commercialization, distribution, promotion, and performance review for the product.

Figure 2 summarized the nine steps pulled together based on the selected ideas picked up from literature and best practice as the steps that can guide a start-up launching a new product to the market.

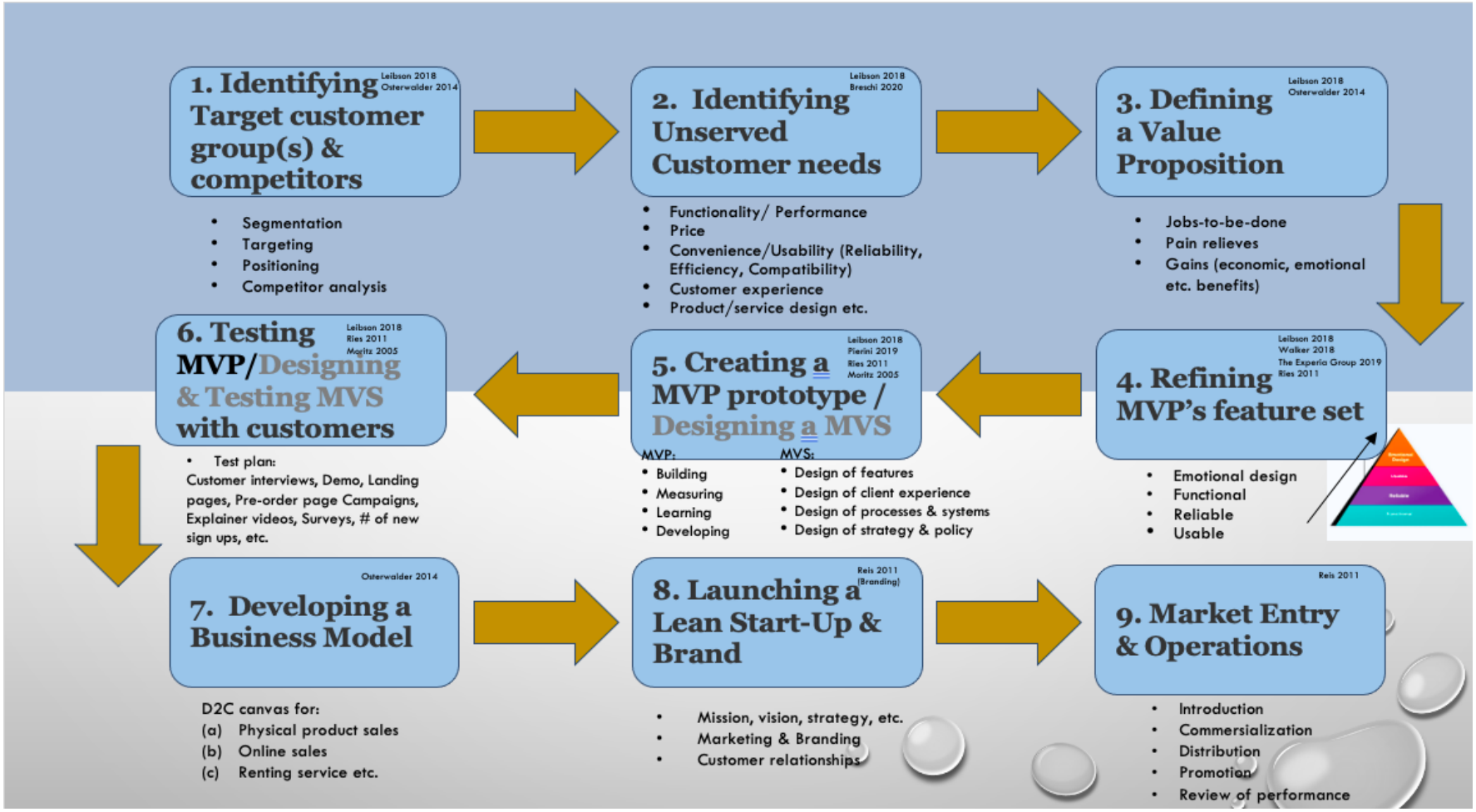


Figure 2. Conceptual framework of this thesis: a roadmap draft how to bring new product to the market. (The thesis researcher published a blog about it here: https://blogit.metropolia.fi/masterminds/2020/06/23/roadmap-to-the-market-for-a-new-medical-device/).

As seen from Figure 2, the conceptual framework includes nine main elements of the roadmap to the market. All steps were chosen and arranged in order logically based on the theoretical literature review. Each step is supported by the list of things that must be went through when applying the roadmap on practice.

To investigate the reliability of this theory-based roadmap, it was discussed with the business practitioners and experts during the next stages of the study. The results from the first iteration of these discussions will be presented in the next Section 4.

4 Analysis of the Theory-based Guidance for Launching a New Product to the Market by Industry Practitioners

This section analyzes the guidance gathered from literature and best practice in relation to launching a new, low-risk medical device to the market. The analysis comes from interviews with four experts in this field.

4.1 Overview of the Analysis

The goal of the analysis was to gather and analyze data about the practices of business professionals working in low-risk medical device start-ups regarding launching their products to market.

The CSA was performed in two steps. First, the relevant start-ups were identified, and business selected practitioners interviewed. Second, the analysis of their responses when discussing the guidance collected from literature and best practice (and summarized as Conceptual framework at the end of Section 3) was done and the findings summarized. The Conceptual framework was used as the theme for the discussion and analysis.

The results are presented in the following way. First, the selected start-ups are briefly presented, and then the business practitioners´ responses are analyzed. For the analysis, two relevant start-ups were selected. **The first one** comes from the early stages of the study, and the data in this case comes from open-type discussions with the founder. This data was gathered in the form of a diary by the thesis researcher that was kept alongside the volunteer work of the thesis researcher for this start-up in 7 months of 2019-2020 years. **The second case** comes from the semi-structured interviews conducted with the expert from another start-up working in the field of medical R&D. **The third case data** comes from an experienced Senior level employee at the social services and health care division (Helsinki City public administration) who deals, among other matters, with start-ups and innovations in healthcare**. The fourth case** is the start-up with extensive experience launching low-medical devices abroad and some initial experience in the same area in Finland, the thesis researcher is currently employed in this start up.

Their inputs regarding the launch of the new product to the market are analyzed. The outcome of the current state analysis is **the currently performed steps by these**

enterprises and opinions of these experts how they bring, or how they believe they should bring, a new medical device to the market.

4.2 Description of the Four Start-up Cases

This section summarizes the analysis results based on the experience of the experts from four cases related to the field of developing or launching low-risk medical devices to the market.

4.2.1 Case 1, a low-risk medical device start-up

This first case comes from the early stages of the study, and the data in this case comes from open-type discussions with the founder. This data was gathered in the form of a diary by the thesis researcher that was kept alongside the volunteer work of the thesis researcher for this start-up in 7 months of 2019-2020 years.

The thesis researcher got acquainted with the founder in one of the business events and, having a business background, got interested and inspired by the founder´s plans to bring their low-risk medical device to the market. The thesis researcher offered help in this endeavor and was included into the project team as a volunteer. The role of the thesis research was exactly to figure out how to bring the new product to the market. At the time of the this cooperation, the new low-risk medical device was at the stage of the prototype and was being prepared by the engineering team for a test and getting approval from VALVIRA. Thus, the goal of the thesis researcher was to figure out and conceptualize the next steps that would be needed for a successful launch of the new product to the market. Since there was a lot of confidentiality involved in the product development, this study will not disclose any further details regarding the product, nor the start-up as it is not considered as having impact on the topic of this thesis, namely, developing the roadmap to the market.

As the necessary minimum context for the case, it can only be added that, by the time of testing and prototyping the new product: (1) the owner had extensive experience as a health professional and a business practitioner (with a long history of the previous start-up and as an entrepreneur), (2) he “gave birth” to the new product based on his multiple years of professional experience, knew the customer base and carefully, critically researched the needs of the customer segments; and (3) had a very clear vision and

strong views how the product should function, look like and be operated on the marker, as a stand-alone product and also via providing relevant services.

An early publication of the thesis research was also part of this study (Berezkina 2019) and it describes the minimum necessary background details as follows:

> *"Back in October 2019 while attending a business event, I met a migraine care specialist who has dedicated 20 years of his healthcare career to creating safe and effective treatment methods for migraine care. Over these years, he has come to the idea of creating an anti-migraine device that could treat a migraine by placing the device on the patience´s head and repeatedly touching sensitive areas, like a massage, until the migraine disappears. The idea of the device is based on his experience of massaging head and neck, which he has proven successful in his practice as a physiotherapist when working with migraine patients. Now, after the idea have matured, the time has come to create this device that can mechanically treat the patient and reach to a much wider audience.*
>
> *Despite the previous experience of being an entrepreneur, the founder was in search of a team who could make the device launch professionally and enthusiastically. After some search, such a team was born: the founder himself; an engineer who has constructed the device prototype as his thesis work; another engineer who is focused on the computer side, and me, responsible for exploring the best way of bringing the device to the market." (Berezkina 2020.)*

Thus, by the moment of the long, open-type discussions with the founder of Start-up 1, many steps had already been done in practice by this start-up, his founder, and the team, which included also some contributions of the thesis researcher into the ideas related to the product launch. All this background allowed for trust in the experience and opinions of the data source (the founder of Start-up 1), and thus, this input can be used as reliable data for the thesis research.

4.2.2 Case 2, an AI medical device R&D start-up

The second case comes from another start-up working in the field of medical R&D. This start-up has a 10-year history of R&D work in the field of AI for prostatic cancer. Again, an expert from this start-up was interview via semi-structured interviews conducted to discuss the steps on the way of the product to the market. This product is now in the final stages of development, and the main challenge before a wide launch to the marker is the final, big-scale medical trials, which are required for this type of pf the product before a commercial launch. Thus, the expert form Start-up 2 was highly knowledgeable in the steps towards the marker launch, but their product had its specifics (a higher risks class in the medical device classification), and therefore, not all the steps on its way to the market were relevant for this study that focuses on launching low-risk medical devices.

The background of Start-up 2 can best be described by citing its expert in his own words:

> *"…Top Data Science (TDS) (is) a company focused on advanced data analytics, Artificial Intelligent (AI) and Machine Learning (ML) solutions. It was stablished in 2004 and acquired in October 2018 by Morpho Inc. TDS has developed an algorithm capable to analyze histopathological images (prostate area) and detect cancerous cells in it. The algorithm has been developed using AI principles.*
>
> *TDS is one of the first companies in Finland researching the usage of AI to analyze histopathological images (prostatic area). The research has been carried out in collaboration with the Helsinki University Hospital (HUS). TDS as a pioneer in the prostate cancer detection using AI has the challenge of proving that histopathological images (prostate area) can be analyzed using artificial intelligent.*
>
> *The pre-clinical test has been successfully carried out in collaboration with the Helsinki University Hospital (HUS) with a 95% approx. of accuracy detection. The current challenge for TDS is to find a new partner to deploy the system and carry out the medical trial." (Vasquez Parada 2021, 1.)*

Thus, by the moment of conducting the semi-structured interviews with the expert from Start-up 2, most of the steps to the market were already done by this case company in practice. The expert, the CEO, and the team, all had very clear ideas related to the product launch. All this background allowed for trust in the experience and opinions of the data source (the expert from Start-up 2), and thus, this input can be used as reliable data for the thesis research.

4.2.3 Case 3, an expert in social services and Health care (public administration office at Helsinki City).

The interview was conducted with Key Account Project Manager from the Social services and Health care division at Helsinki City public administration, who has been involved in multiple projects for 6 years, including those focused on innovations and related to start-ups with similar challenges to this Thesis. The duty of this division, where this responder works, is "to provide wellbeing, health and social security for the residents of Helsinki. The citizens are encouraged to take responsibility for their own and their loved ones' wellbeing and health, while the services of the division guarantee continuous help, when necessary" (https://www.hel.fi/sote/en/presentation/). Since the responder is employed by Helsinki city, he represents this public body. He has experience working with various roadmaps, and therefore knows how ideas are transformed into products. He has not been directly involved in medical products but he has been involved in SOTE sector a lot.

The specifics of his position in the last 6 years were developing trust relationships with a

portfolio of major clients to ensure they do not turn to competition, acquiring a thorough understanding of key customer needs and requirements; expanding the relationships with existing customers by continuously proposing solutions that meet their objectives. Which made him a very desirable responder on the matter of the thesis topic.

4.2.4 Case 4, a low-risk medical device start-up

The data for this case comes from a series of the semi-structured interviews with two founders of the low device medical start-up where the thesis researcher is currently employed.

Start-up 4 is a highly qualified team of engineering and IT professionals with 6 years of experience, engaged in a telemedicine project for round-the-clock remote health monitoring& mostly targeted for companies who would like to track health measurements of their employees. Start-up 4 is developing telemedicine equipment, software, data collection and advanced data analisys. The main goal of the start-up is to provide effective solutions to occupational health and safety. (https://dimeco.fi .)

Thus, by the moment of conducting the semi-structured interviews with the two founders of Start-up 4, most of the steps to the market were already done by this case company in practice. The experts, the CEO and the Managing Director, and their team, all had very clear ideas related to the product launch but had challenges doing it in the new country (Finland). All this background allowed for trust in their experience and opinions (two founders from Start-up 4), and thus, this input can be used as reliable data for the thesis research.

Next, the inputs from these business practitioners and experts in the field of medical devices in relation to the launch of products to the market are analyzed and the results are presented below.

4.3 Analysis and Key Findings from the Current State Analysis

The results of the analysis are presented according to the logic of the Conceptual framework developed in Section 3. The current state analysis looked into the real-life practices of the selected business practitioners and experts according the 9 steps and searched for similarities, deviations and best practices used by the respondents in their

own experience or observed by them from practice. The results start by reporting on Step 1, Identifying the Target Customers and Competitors, as the first step recognized in available knowledge on the way to the marker.

4.3.1 STEP 1, Identifying the Target Customer Groups & Competitors

Respondent 1 believed that the target customers need to be defined first. In this particular case, he could single-out 4 target groups: (a) those who already have problems (individuals), (b) employers (those who want to increase the productivity of their employees), (c) hospitals (since they want a quick solution for patients), as well as (d) those who will have problems in the future (people who take care of their health in advance). Also, Respondent 1 could see the importance of competitor analysis and monitoring the competitors, although in his case; however, at the time of conducting discussions, Respondent 1 did not see any large and significant competitors since he considered this product and idea to be absolutely unique. Respondent 1 could recognize the existing solutions to the problem available currently on the market, but they were completely different from his product idea.

Respondent 2 noticed that he also believes in the importance of recognizing the target segments, and in this case, it looks like a company has kind of a clear target and a clear goal for the device and what the device is supposed to do. Step 1 was also supported by Respondent 3, who said about the customer segmentation:

> *"Yes, that's of course the main thing that we need to do. At first, we must have (…) the number one step that (ends with) number 9 step to go to market. If we put all these to a timeline that would be great because (…) if we want to be a successful at the market, we need to have a clear roadmap and the timeline. The problem nowadays in companies is that they develop, they test, and they forget the customers and the main thing is that when there is a good idea of some device one wants to go to market with, test it right away with customers. (…) Instead, it is vital to test it, pilot it immediately with company's customers. Also, because we do not have to have any license for piloting products (i.e., for low-risk medical devices, E.B.), we do it very often, and that's our job to develop Finnish and foreign (…) devices and solutions for our patients and customers. But of course, we must have a target group. What is our device doing? How it helps our customers and our patients, our medical experts, nurses, doctors? And that's of course demanding, that needs to be cleared".* (Respondent 3)

Interestingly, according to Respondent 4, the starting point is not defining the customer group, but defining *an unserved need*, a problem:

> *"(From my point of view), defining the problem is more important, that's the first thing to do. The second point is to understand what the competitive environment is now. (For instance, on the example of the migraine device from the blog, it would be*

> *asking ourselves how the problem of getting rid of migraine is solved now by others? Then, the company can describe and understand the current competitive situation better; and not just the situation and how many competitors, but what methods they use, and how many types of migraine are there, and other vital details."*

In summary, based on these business practitioners´ and experts´ options, the first step on the road map should relate **to customers**. However, the experts differed in their views what would be the focus of the first step. Some believed that (a) *defining the customers* and customer segments is the first step to do; while others believed that (b) defining *the customers´ unserved need (problem)* is the first step; still others believed that (c) *creating a prototype and testing it with the customers* should make the first step when developing and launching a new product. with a special focus on the competitive landscape.

If summarized, their responses stressed that **the customers are the main people** for whom any company is producing a device to address their problem. Once a company knows **who exactly** is interested in the product, it obtains a better understanding about **the ways of solving these problems.** It becomes the focus of the next steps. The important point, which was highlighted mostly by the last responder, is that the problem should not only be described, but also studied.

4.3.2 STEP 2, Identifying the Unserved Customer Needs

Respondent 1 expressed when talking about his views that in order to pass this stage, a company needs **a ready-made product** so that we can **test it.** Although he also expressed the possibility of identifying additional necessary functions via, for example, using surveys and other types of communication with potential users on an imaginary example of a product.

Respondent 2 stressed that any startup team should have a clear target and a clear goal for the device and what the device supposed to do. Respondent 2 guessed that if a new medical device probably **price wise** might be higher, that's also OK, but **performance wise** this means that after a certain time, the startup team also will need to do calibration and validation of the device and its data to make sure that it is still working as expected.

Responded 3 also thinks, that the step 2 is important. But he also believed that **it is not a concern of a very early stage to identify all possible unserved needs** related to the new product. He suggested that **the key needs should be identified**, while additional needs could come about later:

> *”**When the company tests it**, **the (unserved needs) come along** when by hearing the feedback from customers or patients or nurses. Then company can develop fast and go to the right directions. Of course, the company must have identification, but that doesn't need to take such a long time as it usually does.”*

Respondent 4 had just reviewed the step number 2 and non-verbally agreed on its order right there.

> *“We have the next point (2) Unserved Customer Needs that focuses on identifying the needs to be fulfilled.” - (“Yes”).*

As a summary, based on these business practitioners and expert options, identifying concealed customer needs without testing maybe quite difficult, if not impossible. According to the respondents, there must first be a prototype ready, even if it is not working perfectly. **Any prototype at this stage is a priority**, so the customers could touch it, try it and ask questions. Most of the respondent believed that such questions would fuel the creation process with deep insights and therefore improve, develop and push the product development forward. In the extreme options, trying to identify underserved needs without a somewhat working prototype potentially would waste precious time and possibly would bring the startup team into the wrong direction. There was also an opinion that it - describing the details and asking about the unserved needs in relation to a new to-be-developed product - can lead to giving out innovative ideas, even before a new product is somewhat shaped, which means competitive advantage to, for example, bigger companies who can pass the development stages faster and this win via an early “play” with the unserved needs and other development ideas.

4.3.3 STEP 3, Defining a Customer Value Proposition

Respondent 1 had a very accurate view about the value of his invented product. He believed that this idea should be conveyed to potential users immediately (already at the stage of Step 1). Respondent 2 was not able to give any opinion on this step, as he was engaged with the technical part and did not see much interest in early formulating the CVP of a product. Respondent 3 said:

> *“Absolutely, we need to decide **what we offer and how we can manage** this kind of device, how much does it cost to produce, etc. **The product value proposition is absolutely needed**. Moreover, **the market analysis** in respect to this particular customer value proposition is absolutely necessary, and should be done very early: is it a new market totally that we are we are going? and how many devices do we need? what are the market size, and is it already existing on the market? Is it replacing something old, or this is totally new? That kind of information the company needs to have under consideration. Of course, we need defining value. **However, if***

> ***this is done for the customer mostly, this is a question****, I think. Here, I would argue,* ***it should be done from the company´s perspective first of all****."*

Respondent 4 has reviewed and agreed on that step.

> *"Here, in step 3, we are talking about the fact that we have a hypothetical solution. In other words, we hypothesized that we can solve these unsatisfied needs of clients with such a device or a mechanism, or a treatment regime that this future device should produce. And we begin to describe it (as a CVP)."*

As a summary, according to the opinions of these business practitioners and experts, defining the customer value proposition is important but should not be overestimated and should be done thoughtfully. Defining the customer value proposition of a product has a lot to do with customer interactions in general. It can help customers understand how the company's promises will be fulfilled, the timeline for it, and as a result potential customers should be prepared to pay for this product, since they are sure about their expectations. Even when the product as such does not yet exist, companies can clearly describe it in writing or by any other means of conveying information about what the product carries with all its existing or potential functions, how they can make people's lives better, as well as what details will be developed or invented in the near future. When a clearly structured CVP proposal is communicated to consumers, all subsequent interaction occurs with clarity and with the focus on the product's characteristics and expectations from it.

However, the respondents also stressed that - describing a CVP of a non-existing product to a customer - may lead to confusion; or does not bring up any significant or reliable information as the developers are only "hypothesizing" and are thus not taken seriously, not the responses are serious in their responses; or in the worst case, may mislead the customers and subsequently the developers due to the customers not being able to appreciate the hypothetical information. Thus, the respondents believed that the CVP information should be **focused on the company´s needs and actions**, rather than customers´. Simultaneously, some of the respondents stressed the need to starts **the market analysis** as early as possible and do it from the company's perspective (including the discussion about the customer value proposition that should be done not forgetting the company's perspective).

4.3.4 STEP 4, Refining MVP's Feature Set

Responder 1 related this step with the second step (identifying the unserved customer needs). During the conversations, he stressed an urgent need to create a prototype as soon as possible that should have a feature set of a Minimum viable product. Responder 2 was not able to give any opinion on this step as it was not within his expertise, as he was engaged with the technical production part and not creation or brainstorming. Respondent 3 stated that this step is important but can be clarified later:

> *"If there is some market for a solution in that device, then of course (identifying a feature set becomes important). Alternatively, it is okay to copy someone else's device for a start, or otherwise check how it can be identified (a feature set) via comparing with other devices. That's also a very good move, because we have a market with a lot of solutions and devices that they use already, either as stand-alone solutions or its components. But very rare, seldom, in my experience, the new products come as totally new solutions or devices."*

Respondent 4 has reviewed and agreed on that step.

> *"(In this step), the start-up describes the MVP, its properties, what tasks it solves, and so on. So the **4th** step is more or less ok, I agree."*

In summary, business practitioners and experts believe that defining the feature set is a wise decision to take. This justification can be carried out when the product is already in use with an intent/motive for improvement. The reason is that completely new products rarely appear at this stage of tech development. Unfortunately, these new products are not "new" as thought. This is because they are extended features made from the combination of features from other existing devices. This is to say that defining and improving the set of functions is a very tough one. Therefore, the tech company should be able to balance their myriad priorities like consumers' potential needs and others. Also, the feature set should be made in such a way that small start-ups can afford it. Based on the respondents, a feature will serve the consumer well if the first two moments are joined together like a puzzle successfully.

4.3.5 STEP 5, Creating a MVP prototype

Respondent 1 believed that this step should most definitely be highlighted among any other steps to the market. He was thinking about this step more than about any other step, stressing its importance, and was pointing at its high significance for the fate of the new product.

Responder 2 agreed with the impowas not able to give any opinion on this step as it was not within his expertise, as he was engaged with the technical production part and not creation either brainstorming.

Respondent 3 agreed, as his company already succeeded along this step and moved further, so he could recognize the utmost importance of this step. According to Responder 2:

> ***"****I think the company needs to show customers something concrete, even if at first it is only a picture, need to concrete it, because it's much easier for markets and people to understand it, when it's something tangible, that they can hold in their hands, even if it's a mock device and it is made from wood. So, they can see what the measurements are approximately measuring and that kind of thing the developers mean."*

Respondent 4 stressed the following perspective:

> *"The next steps (5 and 6) are generally logical, i.e. prototype and testing. But look here, even step 4 includes emotional design, functionality, reliability - all these characteristics are not needed at this stage yet.* ***So far we only need a short description of what to do next.*** *Basically, it is possible to use any kind of terrible, ugly device… and test if it works for this client. The most important thing here is that it should be an active and working device. (…). If the device helps…, the person will carry it everywhere and use it all the time. (…) He will not need all these "flowers" (meaning the design is not important at this stage).*
>
> *After step 4, in our experience, we create a laboratory model. Again, the laboratory model should be working, not beautiful. It should be a working functional model of this device, which can then be developed further. (…) After the prototype has been developed, it is necessary to determine the approximate, possible market capacity. In general, this should be decided at the very beginning, in the 1st or 2nd steps, where it is determined who and how often has this particular problem that the innovation will resolve, and what are the existing solutions (i.e. competitors)."*

In other words, the most important thing in a prototype is its functionality. Starting to use the prototype will immediately reveal hypotheses "hidden on paper". There will be only 2 answers: it works or it doesn't work. This step will bring innovators down to earth, it will show the reality. Metaphorically speaking, we will see if the parachute opens. Despite the fact that the respondent spoke about the secondary importance of design, I would replace this meaning with decor, after all, in my understanding, design is much more than appearance, design in its broadest sense is functionality.

Respondent 4 also stressed another important perspective when launching a new product to the market:

> *"In our experience, after we tested the MVP (the working version was tested on ourselves and others, but it hasn't even been out yet, so it's a secret thing yet), as soon as it starts to work,* ***we should start patenting****. Here, I want to draw your attention that t****he steps you described don't say a word about intellectual property.*** *This can be run in parallel with other steps. But this is critically important to start patenting this idea because many solutions, albeit not ideal, already exist and we need to protect our device and future product".*

This expectation made an important input here, since, typically, creating an MVP prototype has been regarded as one of the most important things to do for every business owner. According to this expert, the goal of a product prototype is to let people see, understand, and know what the product is all about. Make the idea become real and tangible in a product form. In addition to the aforesaid, a patent is not only needed to protect the intellectual property, but also at all subsequent stages, product registration, and its interaction in the market. Especially in a time like this, when the same ideas come to the minds of many people at the same time (due to the progressive activity of mankind and technology), hence, every "worthy, marketable" idea should be given enough protection from the early start. Although, this process can take a lot of effort and money to accomplish, which the start-ups should be ready for.

4.3.6 STEP 6, Testing an MVP

Respondent 1 expressed the idea in his talks that testing should follow the previous step. He wondered how long and where exactly it would be possible to do and how to organize it best (testing). For Case 1, negotiations have already been conducted with certain educational institutions. There was already a basis for this step, and the creator was pleased with it.

Respondent 2 had few questions about the testing part, he asked: *"It is very important to know if a company is planning to do it with some hospitals or institution, which is regulating this whole thing."* Respondent 2 also believed that here, when company doing the testing**,** *"it could be good already to start collecting data that could be given to the notified body to say, hey, this is really working."* He also insisted that *"the company needs to build good relationship with customers even before the device is ready."* He believes that *"it will help to back up, when company is doing the validation with a notified body."*

Respondent 3 shared his views as follows:

> *"And testing (step 6) is an ongoing project, it is not possible to have a totally ready device. They evaluate all the time, also older devices we have (blood*

> *measurements) that we know the technology has been the same for decades, but we also know they evolved all the time. (…) The testing is not something companies do in their own laboratory; it needs to be done with the customers all the time - testing and evaluating. (…) I would put it in between steps number 1 and #2 (testing, also piloting)"*

There is an understanding that testing is a process, it is difficult to start and finish, but testing becomes a success when it involves small steps and repetitions. Testing shows the presence of flaws, not their absence. This made the practitioner think that testing can also reveal special benefits. Metaphorically speaking, if at school we are first taught and then given a test, then in the case of product testing, it happens the opposite way.

Respondent 4 was talking about it step earlier, when discussing the previous step. In his opinion, minor changes in the road map needed starting from the 5th and 6th steps.

> *"And at the testing step, again I emphasize - laboratory testing of the simplest device."*

In summary, based on the opinions of business practitioners and experts, testing was seen as important for two main points. Firstly, from a technical point of view - for the development of functionality. Secondly, for entering into communication with people being tested. This is from the point of building relationships with potential customers. These will certainly yield many interesting results and will help to develop the product for its release to the market. Another important addition from a fourth respondent is that testing is needed to confirm the workability of this sample device, and can be patented with great confidence. Thus, testing makes a very significant step in the process of getting a product to market.

4.3.7 STEP 7, Developing a Business Model

Respondent 1 actively studied this issue, he definitely kept pace with the innovation of various business models in this field, and he emphasized and delighted in the fact that new business models are emerging very quickly. This topic has remained in focus all the time. In this particular case, Respondent 1 was also engaged by the idea of renting a device (for example, in pharmacies) at first and thus boosting direct sales to individual customers, and then also probably wholesale to hospitals and clinics.

Responder 2 believed that:

> ***"****I would say nowadays, (…) after a few years users might need to get rid of devices because they are too old. Maybe they are not accurate anymore. I think a good business model could be like a lease. (…) So, the company would lease devices for*

> *a certain period. That means that customers just pay a monthly fee and they don't need to take care of the maintenance or think about the calibration. (…)*
>
> *Instead, the company as a provider, takes care of all that part monthly (…) I don't know how long the lifespan of the device will be. But then it just can be replaced for a new one and the old one utilized (…)"*

There is a very clear idea about the temporality of everything. We live in a century where everything is more profitable, greener and easier to rent. Leasing has many pros and cons, but most importantly, it gives a lot of options to both parties. Customers can try, have time to think, and at the same time enjoy the product without burdening themselves. The company has a monetary profit and may not worry that the product will be returned forever and ask for a full refund. At the same time, they build a connection with the consumer and receive valuable feedback. As a result, they improve the product in a profitable way.

Additionally, Respondent 2 stressed another important perspective when launching a new product to the market:

> *"The thing is, when there is **a business model** or when a company starts **to enter into the market**. It's hard then to change it to a different one. (…). And then for the customer, it's always kind of: Wait, what's going on? Why now it's changing? If it was working fine as it was before, are they looking for more revenue? Are they planning to increase their prices? (…) So, the customer relationship needs to be built already before the **number 7**. Even around #6 I would say. (…) So maybe it can be in parallel now that's going to be the best one."*

This is a very good note. Despite the benefits of leasing, it is worth remembering that the company must be transparent and understandable to its consumers, otherwise it may shake their loyalty; and the relationship with them is the most important thing, especially for a startup.

Responder 3 shared his views as follows:

> ***"**It should be the first step – it needs to be figured out already. (…) If we are doing these steps number one, two and three and if team now in laboratory, and not contacting potential customers and not getting feedback from SOTE sector and so on, then the company is mainly producing something that it thinks it's good, but customers didn't want it or need it or it will go all wrong. So, this is 7th step developing a business model is very important. So step number one should include step #7 if you understand what I mean."*

The importance of customer opinion in this matter was again emphasized. The innovator and his company can come up with whatever product they want, but it won't be a broad enough point of view for big sales. When thinking about creating a modern business

model, the company is not only making its way to the market, but it is building, or at least making its own changes in the market.

Respondent 4, in his turn, saw the situation in relation to Step 7 as follows:

> *"This step should, ideally, include the development of a **business model (7)**, (…) As explained above, we patent, and in parallel, **we must determine the price of this invented solution**. In your steps, it is defined as step 7, but it's not exactly what we need. The price must be determined much beforehand. For example, in your roadmap there is something (functionality, design already discussed), but it's too early, they must come at approximately 8th step, even 9th step. The price should precede them, and significantly, as it will determine them, to a big extent."*

In summary, the development of a business model should keep pace with the very early, initial steps in product development. The business model is part of the sales and product monetization (as well as service) and as such it should be treated as a completely different department in the company. And therefore, should be handled by a separate group of people. The "business model" can be said to be the bridge through which product manufacturers receive money from customers. There are indeed many different types and ways to sell a product today, of which leasing has become increasingly used even by big-name companies as more and more businesses strive to be "green".

Furthermore, one of the respondents talked about the importance of pricing at this stage. Since this is one of the most important aspects of decision-making after the production of the product. A product's price determines the future of the product, the acceptability of the product by customers, and its return and profit. In other words, it is a tool of competition.

4.3.8 STEP 8, Launching a Lean Startup and Brand

Responder 1 stated that the mission and vision were already conceived (at least, on a general level, internally) by this step. But for him it seemed as if they were in the right place in the map as 8th step.

Responder 2, in his turned, explained that:

> *"Step 8 is launching a lean startup brand. I think it might need to start building the brand directly, even before the device is out. (…) I'm saying this because big companies (e.g. Apple) they even release their product before they have enough stocks to be sold out. (…) So, the company is saving time, saying, this is what we can do and this is what we are claiming, and we have the proof that it is working. It has been approved and it can be sold in Europe at least."*

The reality is that the brand has become an integral part of everything in this world, not only products, but also personalities. Brands are a separate niche in the eyes of consumers. They either know this brand or have never heard of it. It may be just one word, but it has a lot to say. Respondent 2 continued to explain this view as follows:

> *"Yes, to create a brand, make it well known in the market or just known in the market, it takes sometimes. For example, there is a big fair in Germany, once a year, it is about medical equipment and medical devices. (…) There are vendors from all over the world. So let's say there is a launch of the product in December and the fair already happened in November, the company will need to wait one year to get a bigger market or bigger audience to get to know this device."*

This is an important note, since building a brand takes not only time, but patience and perseverance. With the help of the brand, the company shapes its whole strategy. Therefore, also other associations with the brand will be important here (e.g. who are the companies partners, where or from whom the potential consumer first heard about the product, etc) can influence the customer´s decisions.

Respondent 3 stressed another important perspective when launching a new product to the market:

> *"Launching (step 8) is, naturally, important. You know, like Apple told us when it launched, new iPhone or iPad go big, as we say it. But that's I think not the way to do it, if we want to make a medical device, because of course the 1st question customers ask - how secure is it? How safe is it? We don't have to make it right away according to every standard (…). After piloting and getting feedback from customers, we need to maybe develop features. And then we can put it on the pipeline for the licensing of medical devices and get the license from Finnish. (…) Then it is very good for the public sector to be sure about safety. (…) Then we need to focus on marketing and contacting potential customers and go for it."*

Here, the respondent's thoughts are focused only on security, which is true especially for medical devices, no matter which risk group they belong to. Safety of the product is a big part of the success of such a product on the market. In simple words, product safety is quality.

Respondent 4 has not given any comments exactly about this step, as he suggested another case scenario.

> *"So the company patents. And in parallel, the price of this invented solution must be determined. It is in your steps, in step number 7, but it's not exactly what we need. The price must be determined beforehand. For example, in your roadmap there is something (functionality, price). But it's too early, there's nothing to count yet. It must be approximately in 8th step, even 9th step."*

From the comments, it follows that the lean startup is a very popular and logical model to be used in our time. Although Information technology and medicine/HealthTech differ a great deal (in specific requirements and restrictions), when it comes to lean startups, the medical device company learns a lot from them. Even though the lean startup is not ideal for medical device startups, this enterprise form keeps focused on making production cheap, i.e. to spend money wisely.

4.3.9 STEP 9, Market Entry and Operations

For Responder 1, this topic seemed a little distant, since his real case (his own startup) was still at the stage of prototype development, and also, due to the lack of practical experience in launching any products yet. In other words, this was exactly the area where Respondent 1 was hoping to get more team members to take care of the operations so that he himself could be more focused on product development. Respondent 2:

> *"I'm thinking ahead. When a potential company gets to* ***the market entry operations.*** *As it is planning to, this* ***device needs to be used as medical equipment****. As early as the company sta****rts collecting data that can be a proof*** *that this is really doing what it's intended to do. It will help you in the validation with the company's notified body. (…) And about the* ***market entry operations.*** *(…) In the medical equipment area, I believe promotion like a 50% discount, or something doesn't work like that. So, the prices are very stable, and the "discount strategy" will give mistrust for branding because the company is looking after the money (even though it might be the reality). (…) I guess that it will also depend on the volumes of how many devices they might be interested in. And again, the introduction of this product needs to happen already quite early so that people will get to know what this is about even before it has been launched into the market. (…)*
>
> *Because hospitals or clinics are very old fashioned and traditional when doing things. So they cannot just bring the device and start using it with people. People or patients will also need to understand it well. (…) Plus, there's a whole regulation behind how the patient needs to be informed. There is a whole board analyzing who is doing what, following the projects and so on. So, it's not so straightforward. Unfortunately for us. (…) From my experience our company has never got to the number 9 which is distribution, but it was Software as a Service, it was kind of free of infrastructure.*

Unfortunately for innovative startups, the market for medical devices is not as simple as it might seem. It is tightly controlled with special state regulations, as well as the presence of multiple competitors. This market is far from being a comfortable place for young entrepreneurs; experience and knowledge are clearly required here. Respondent 3:

> *"Marketing, entry and operations (step 9). It needs to be figured it out on the step number 1. What's the market then? Who are the customers?*
>
> *Does this medical device goes directly to the consumers, or healthcare professionals, nurses, doctors? (…) For instance, blood/sugar measurements nowadays, the manufacturers go directly to consumer markets, but also the*

> *professional markets, and that's not a huge difference between Apple products or other digital equipment markets, it's quite the same.*
>
> *If the company has the license, they need to use it and say that the device is safe and easy to use and apply all the certifications needed. After that, the company can re-consider the pricing. If the pricing is too high but there are no other devices on the market that can define the market price, then the company can keep it (for some time). But they will still need to monitor the situation closely and think about it. The pricing needs to be set correctly!"*

From this answer, a picture emerges of two of the most important things in the medical device market. They are, first, the availability of official license and, second, a competitive price. It sounds right, as the license itself ensures the solution of the consumer's problem and safety, and the pricing makes it available (or even tempting) for customers.

Respondent 4 has not given any comments exactly about this step, as he suggested another case scenario.

> *"The company must calculate the minimum cost (price) and details. And after that you can think about design. What are the costs for the design project. Maybe it's expensive and not worth doing it at this stage. Further, we calculate the approximate cost, for example, the production of 100,000 pieces. What will be the approximate prime cost (net cost) of these pieces?*
>
> *After that, we need to conduct a* ***comparative analysis of the current competitors.*** *First, they are medicines, such as aspirin, amidopyrine, and any other headache remedies. You think like this: the cost of aspirin, for example, 1 euro per pack. It contains about 12 tablets, that is, theoretically enough for a couple of months. (…) Everyone understands that aspirin is running out, but the device works anytime, just needs to be plugged in. But here it is important to develop an exemplary model for entering the market. What are your competitive advantages over aspirin? For example, aspirin affects the kidneys and liver."*

Here the importance of correct pricing is especially emphasized. The price of a product decides the success of entry into the market. As a result, no matter how high the quality of the product is, the price must be reasonable. According to the interviewed practitioners, the company must work hard to find this balance. Thus, it can be said that pricing is an art that, together with marketing, make an effective tool for selling a product.

Summing up, experts have helped to understand the dangers of entering the market without proper planning. In the case of a complex product such as a medical device, documents and certificates must be ready, without which entering the market and establishing sales processes for goods will be impossible. Thus, based on the previous steps proposed by the fourth respondent, entering the market practically is another way to penetrate the market, and the company must understand the pros and cons that can help its buyers to make the purchasing decision.

4.4 Summary of the Analysis Results

Table 2. Similarities and differences from the Conceptual Framework identified in real practices and opinions of the practitioners from Case companies 1-4.

Steps to the market (based on CF and available knowledge)	*Similarities in opinions and practices (based on inputs from the respondents)*	*Differences in opinions and practices (based on inputs from the respondents)*
STEP 1, Identifying the Target Customer Groups & Competitors	One way or another all responder agreed about the first step. Customers are the main people for whom any company is producing a device to address their problem.	The only difference there is how all the responders knew and felt about this step, as all of them had different background in business as well as current or potential roles in the given organizations.
STEP 2, Identifying the Unserved Customer Needs	This step caused concerns for all the responders, as it clearly was not the right time to do it.	The types of concerns seemed to be quite different. The responder 1 was thinking about the future steps and focusing on present, the responder 2 was overthinking about other different aspects and responder 3 simply thought that it not very important at all.
STEP 3, Defining a Customer Value Proposition	Only two out of three responders were commenting on this step, but they both agreed on this one. Value proposition is extremely important, especially nowadays, when companies are fighting for customers.	The difference here was about the level of professionalism, as the responder 1 was talking about it from a very imaginary perspective and the responder 3 knew how exactly to move the process here.
STEP 4, Refining MVP's Feature Set	Only two out of three responders were commenting on this step, but they both agreed on this one. MVP's feature set is required to at least present the idea of a prototype (and later a product).	Again, the difference here is that the Responder 1 only knew how to implement it theoretically, and the Responder 3 were already involved in this type of processes, so he had very clear ideas about this step.
STEP 5, Creating a MVP prototype	Without hesitation, the most important step was described by all the responders with enthusiasm.	The responder 1 was overthinking about this step, as it was in the stage of making it already with another student (engineer), and the other two responders dealt with the prototypes already at some point in their career, so they just knew that this stage would bring a great outcome.

STEP 6, Testing a MVP	This step is a continuation of the previous discussion, all three agreed on the importance and need to implement it as soon as possible, as it would move the project forward.	The responder 1 was a little stressed about the idea of implementation, the responder 2 were wondering about some details and the responder 3, as an experienced professional was quite confident about it.
STEP 7, Developing a Business Model	All the responders only agreed on its importance.	The esponder 1 was still studying this topic, the responder 2 was talking about it from a very global point of view and the responder 3 stated that it is too late for this step being number 7, so to say he highlighted the importance.
STEP 8, Launching a Lean Startup and Brand	All the responders saw this step as the right thing to do.	The responder 1 was hypothetically thinking about it a long time ago, he did not pay attention that is would have been probably happen earlier. The responders 2 and 3 would place it in parallel with other steps earlier.
STEP 9, Market Entry and Operations	All agreed that this step should have been happen earlier.	Again, all of them thought of it from different perspectives. The responder 1 was a little far away from knowing how exactly all the operations must be organized. The responder 2 and 3 had a lot to say about all the possible details that are important here, as they been more experienced as the responder 1.

To investigate the reliability of this roadmap, the practitioners´ comments and suggestions were built into the proposal. The proposal was created using the pattern of the initial roadmap during the next stage of the study and is presented in Section 5.

5 Building Proposal for the Roadmap How to Bring a New Product to the Market

This section merges the results of the analysis and the conceptual framework towards the Proposal for the roadmap based on co-creation and discussions with four experts reported in Section 4.

5.1 Overview of the Proposal Building Stage

During the CSA, several weakness and strength areas were identified regarding the build roadmap. After the detailed analysis with the experts, they were reviewed again and the key findings from the CSA investigation were noted. The main issue, identified during this stage was that the order and stressed importance of some of the steps did not match with the experience and knowledge of the experts. At the same time, the finding from the interviews confirmed that the developed roadmap is well presented and covers most of the things to be considered when entering market.

The focus for the process development in the next proposal building stage is aimed at correcting the identified weaknesses, the order of the steps and stressed significance of some of the steps. The initial proposal was built in several stages. First, based on the literature review was the first roadmap was developed. Second, the first round of interviews was conducted (Data 1 and Data 2), and the roadmap was discussed together with the experts to increase the reliability of the conducted study. The collected material was used during the creation of the new roadmap, with determination of importance of each step.

5.2 Findings from Data 2 (pulling together CSA, CF and Data 2 for the Proposal)

This section report on the main *inputs* from the four experts for re-building the guidance built on literature and best practice into the practical Roadmap. The main inputs for the proposal building will be: (1) CF (input from literature), Data 2 (findings from CSA, discussed earlier in Section 4, as an analysis and co-creation round), and (c) merging them into the updated Roadmap for further discussions. Figure 3 below shows the starting point for the discussions.

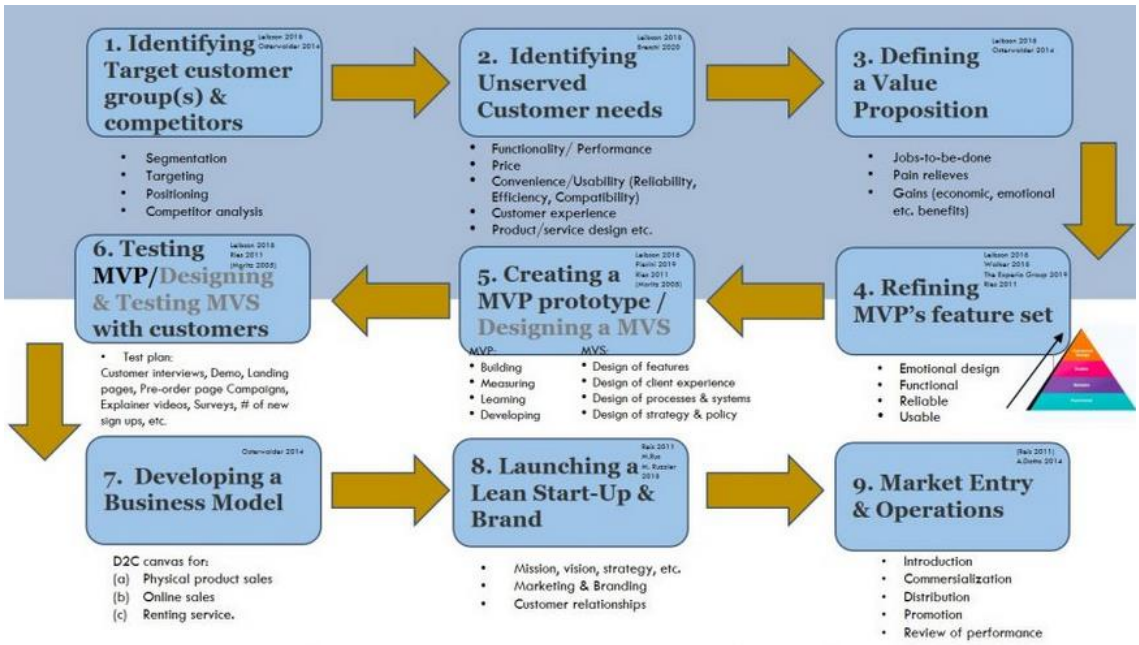


Figure 3. Conceptual framework as a starting point for the expert discussions (repeated from Section 3).

Table 3 below shows the inputs for the practical Roadmap (proposal).

Table 2. Key stakeholder suggestions (findings of Data 1) for Proposal building in relation to the Conceptual framework.

*Input from literature (**CF**)*	*Suggestions from experts for the Proposal, summary (**Data 1**)*	*Description of their suggestion (in more detail)*
STEP 1. Identifying Target customer group(s) & competitors	STEP 1. Identifying competitors & doing market research 1) To divide the identification of customers and competitors into 2 different steps 2) To add the Market Research	1) Experts suggested to move the identification of target customers to a later stage (to the third step). It is important to learn about potential competitors first. From studying the competitors company benefits by a huge amount of knowledge about many different aspects of the existing business. 2) Market research is critical for the start-up as it identifies new opportunities and existing solutions, therefore helps to reduce risks.
STEP 2. Identifying Unserved Customer needs	STEP 2. No major change, but a refinement	*Refining a problem and outlining a potential solution* means that the team gets clear with what they want to build.

	STEP 3. Identifying Target customer group(s)	Experts suggested to move *the identification of target customers* to this later stage (to the third step), when more is known about the existing solutions (from the Market research, Step 1) and Unserved customer needs (Step 2).
STEP 3. Defining a Value Proposition	STEP 4. Defining a Value Proposition	1) Experts pointed to the need for exclusivity, attractiveness and crystal-clear explanation of the product idea. Everything that the start-up broadcast about the product should be true. 2) This action brings customer closer to the start-up, without communicating directly. The portraits of potential customers may be found through many different studies and surveys available online. Identifying groups of customers helps a start-up stay more focused on moving forward, as well as emerge networks and attract similar groups, opportunities, and ideas.
STEP 4. Refining MVP's feature set	STEP 5. Refining MVP's feature set	Functionality, reliability and ease of use must be combined and always follow together. These are the most important components for the feature sets. Other additions are good, but not that important on the early start up development stages.
STEP 5. Creating a MVP prototype	STEP 6. Creating a MVP prototype	The importance of creating a functioning prototype as soon as possible is high. The key here is the focus on working condition, additional things may be forgotten for a while. Also, the prototype attracts attention of customers, investors, while at the same time not wasting the money of the creators.
STEP 6. Testing MVP prototype	STEP 7. Testing MVP prototype	Testing implies a process that repeats over and over again, up to the highest quality, this should happen automatically, until it brings one hundred percent confidence in the suitability of the product in order to show this invention to the world officially.
	STEP 8. Patenting and Licensing	Patenting and Licensing reserve a place in the market, even if they don't guarantee profits and demand. The meaning of patenting is great, this is also a re-verification of the product, as it includes the testing stage by another instance. The patenting stage is also a test for the creators of the product, if they survive it, then future challenges are easily passable.
STEP 7. Developing a Business Model	STEP 9. Developing a Business Model	It need to do carefully as when a decision about business model made, it will be difficult for a company to change it. The change may require company to go a few steps back and revise all goals and strategy, also revise management, costs, and more. Also there have been added two important thing to focus on, first is the calculation a market capacity, as it can be very useful for showing to the potential investors. And the second is *setting competitive pricing strategy*, in other words need to strike a

		balance and find *the right price for the product*, as low price can be considered as a low quality.
STEP 8. Launching a Lean Start-Up & Brand	STEP 10. Finding the Funding & Launching a Lean Start-up	
	STEP 11. Building a Brand & Boosting Awareness & Building Customer Relationships	In the previous map, building a brand was part of a lean start-up, however, the significance of this methodology was not discussed or raised, probably because all the people interviewed had quite a long experience and adhere to proven methods. But it is known that the main difference between a Lean startup and a traditional one, quick solutions and ability to adapt to circumstances. The customer experience of any company has come to the fore. Therefore, building strong, trusting relationships becomes the key to the demand for the product.
STEP 9. Market Entry & Operations	STEP 12. Developing a Business Model	The main task is to organize all the processes of production, sales and interaction with the outside world as a whole. The importance of this step is again on the very last place. As in general any business professional is able to organize these processes easily.

As seen from Table 4, there were three main changes identified in the structure of the road map. The first step requires separating the identification of competitors and customers, as well as adding deeper market research.

The step number four (Refining MVP's Feature Set) is losing its breadth and importance described earlier in the literature, its role now determined by practicality and becomes secondary, following the urgency of creating a prototype and testing it. The most important and completely overlooked step of patenting and licensing appears, it is now number eight.

Other steps were moved around these changed steps but were not affected and remained at their meaning and importance.

5.3 Initial Proposal

This Proposal re-thinks the conceptual framework (presented at the end of Section 3) that was built based on the ideas pulled from business literature and best practices by Breschi 2020, Leibson 2018, Moritz 2005, Osterwalder 2010, Osterwalder 2014, Pierini

2019, Reis 2011, Walker 2018, etc. Their ideas about launching a product to the market were reflected against practice and put together into one route (i.e. roadmap) for launching the product to the market, based on two perspectives: the theory-based and the practice-based ones. It was done with the intention to guide the start-ups in their actions *more reliably,* when facing challenges of a product launch.

In the current state analysis, the theory-based conceptual framework was brainstormed with 4 experts coming from 4 companies that faced similar challenges in their real-life business practice, and their ideas were gathered about the “theoretical” approach to launching a product (summarized at the end of Section 4). In short, practitioners working in the field of medical R&D and low-risk medical devices found the proposed “theoretical” approach prone to various challenges and sometimes questionable. These discussions led to the conclusions that the criticism of these 4 practitioners point to the same direction, more or less, and their views can be considered for building a new version of the roadmap, based on the practical experience of these business practitioners, for this specific business area (low-risk medical devices by start-ups).

Therefore, the Proposal presented below pulls together the practice-based ideas of the 4 practitioners for building a roadmap to the market for a low-risk medical device that would be “closer to life”, as these start-up representatives see it. The four experts had a little different specializations, but one way or another they have been involved in development of start-ups in the field of production or promotion of low-risk medical devices/innovations. Each interview, conducted for the CSA and Proposal building phases, lasted about an hour and all but one of the experts were able to comment in detail on each of the steps presented earlier. An analysis was made of all comments, as well as all suggestions and questions. Based on their responses, it was clear that they especially helped and contributed to the formation of new steps, rather than blindly following the “theoretical” construct built from literature.

Accordingly, a new “construct” was pulled together, based on the steps proposed by the four practitioners in such a way that there were as many points and angles incorporated as possible, so that the result would be a roadmap built from experience in the field of low-risk medical devices by these 4 start-ups´ers. Each specific interview, as a separate case, has become a unique link in the chain of development. The total number of steps in this new roadmap increased to twelve by following the suggestions from the experts. The Proposal is shown in Figure 4 below.

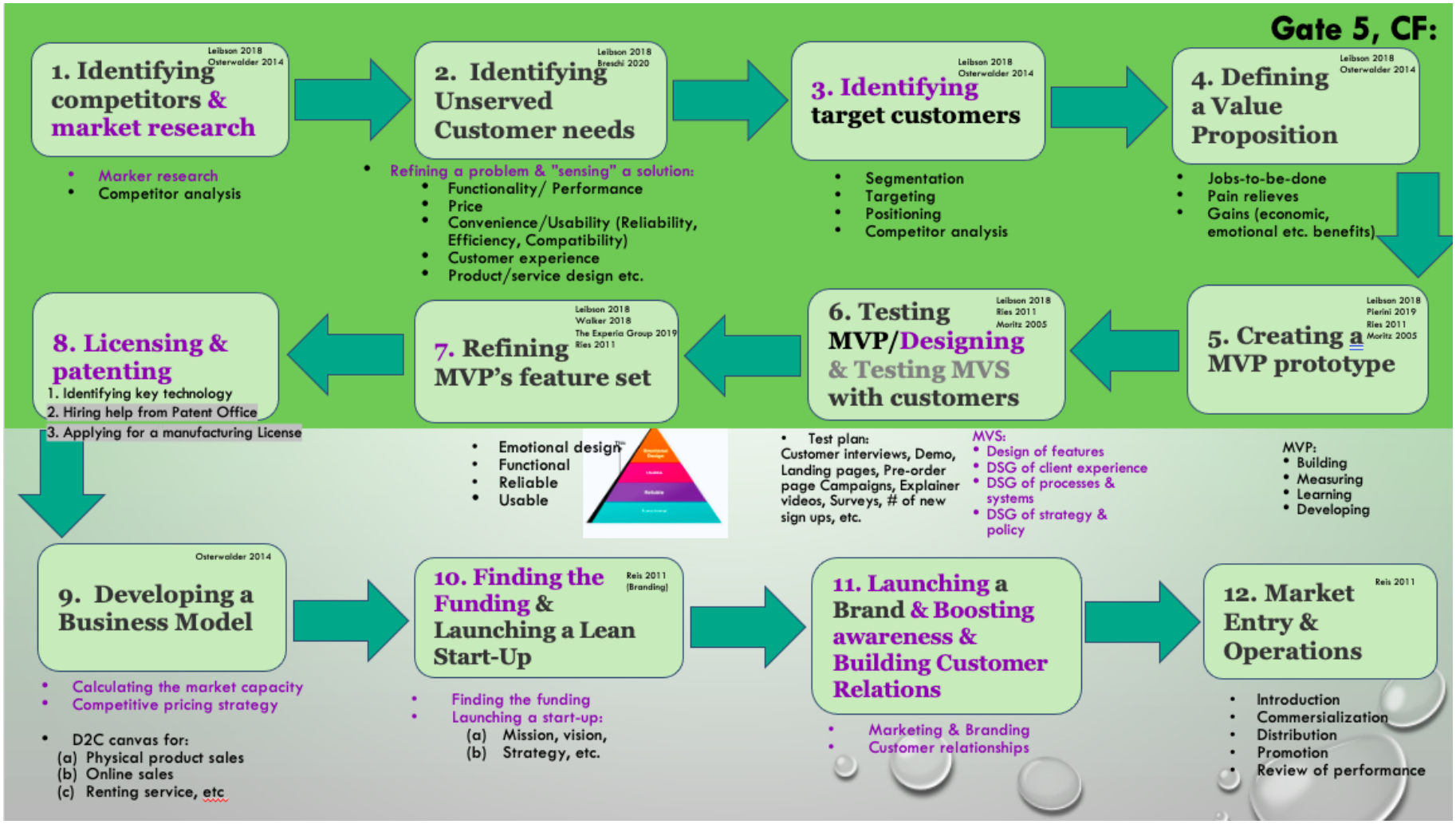


Figure 4. Initial proposal (the lilac colour shows the additions to the theory-based roadmap that came from 4 practitioners).

Figure 4 shows the summary of the steps proposed by the 4 experts, formed into *the revised practice-based roadmap for the field of low-risk medical devices on the experience from start-ups.*

Phase one. This phase includes 4 steps: Step 1, market research and competitor analysis; Step 2, identifying the unserved customer need via finding a problem and outlining ("sensing") a possible solution; Step 3, identifying the target customers, and Step 4, defining the Value proposition. The proposed steps are described below, based on the earlier construct from Section 3 (theoretical) and the comments to it by the interviewed experts (practice-based inputs).

Step 1. Identifying competitors & Market research

Step 1, as based on knowledge from the literature, was the first step which aimed to identify competitors as well as target customer groups.

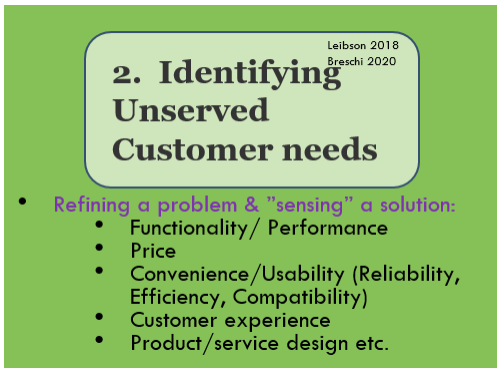
This is necessary because the company needs to know what kind of offerings are already on the market and who is behind them. A company can perform segmentation, targeting, positioning and competitor analysis, which are standard business tools for identifying both competitors and customers. Competitors are other companies with which you obviously compete for the end consumer. But a competitor can be not only another company itself, but its separate brand (product or service). As a result of the analysis of competitors, a competitive offering is formed - these are goods or services that buyers may prefer (or already prefer). So, the analysis of competitors in general makes the first true and mandatory stage in the development of a marketing strategy for a product (this strategy will be discussed a little later).

A correct assessment of the company's competitive environment allows the company to create a sustainable competitive advantage for the product, for example, choose the right communication channels and reduce risks. A company's unique proposition is the primary marketing tool, and it's designed to convey the idea that consumers can get the

highest possible value or benefit from buying a company's products—more value or benefit than they can get from them competitors' products.

Step 1, experts´ inputs. In addition to this theoretical description, the inputs from the 4 practitioners can be summarized as pointing to the need for a thorough "*Market research".* This research should be based on some *preliminary idea*, and such ideas can come from different sources, mostly from personal or professional experience. The idea itself does not mean much (and it may change later), but the market research acts as a very first step, which, in most of the cases, require nothing except search on the Internet. It can be done in many ways and bring different results, but it is important, precisely because it helps to see the big whole picture, to notice opportunities, potential risks and learn about trends. Unlike the CF in this step here was a deliberate separation of the analysis of competitors and the target group of customers, the latter will be discussed a little further, namely in the third step.

Step 2. Identifying unserved customer needs



Step 2. Available literature and business practice suggests that unserved customer needs make the core point in linking the company with its customers. They also stress that the unserved needs are often totally ignored, overlooked or unrecognized, while the underserved needs mean the needs that are not met in an expected or convenient way, or in full scope. Nowadays companies are under pressure to develop additional revenue sources, which they pursue targeting the underserved needs´ markets. Close to half (42%) of all failed companies shut their operations down simply because there was no market need for their products. Thus, identifying the true needs for a product or service lies at the very heart of any successful business.

Literature and best practice suggest many effective tools: data analytics, mapping software, social media monitoring, and creating personas, among others. For example, analytics tools can bring 15% more sales. It can also reduce costs, increase efficiency, identify weaknesses, design new products and services, identify and prevent fraud, make smarter business decisions etc. It is essential to use the right tools for big-data analyses. For example, best practice emphasizes social media management, as it gives a good read on how customers interact with companies; as well as using personas, as they help to clearly portray who exactly makes up that audience.

Summing up, the true focus in product development of the company comes when it identifies the gaps in the market. As soon as the company understands who and where their audience is, it is much easier to reach them out and create awareness about the new product or service. Nowadays the use of modern technologies can greatly help in identifying and overcoming these gaps.

Step 2, experts´ inputs. In addition to this theoretical description, the inputs from the 4 practitioners can be summarized as pointing to the need for articulating and refining *the problem* at this step. In other words, the problem gets clarified here (and in relation to what element, functionality, usability etc, as described in the theoretical approach). *Refining a problem* (i.e. clarifying *the unserved customer need) and outlining/"sensing" a potential solution* means that the team gets clear with what they want to build. In some cases, the problem itself can immediately point to a solution, but the market research can make it clearer, also help to see it from a different angle as well as urge add knowledge about existing alternatives and other potential solutions. In other cases, the problem is so important, but the solution is not immediately visible, that the problem needs extensive research before any solution can be outlined. Outlining/"sensing" a solution for one specific problem can be challenging, there might be many possible solutions, which no one ever tried to use or there might be too many, but all too complicated. Most likely, it would require puzzling bits of information, mix, blend and infuse them into one working (new, own, innovative) solution.

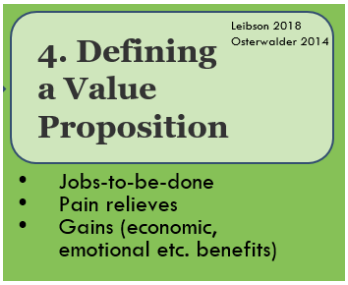
Step 3. Identifying target customers

Step 3. What was found out from literature, is that some theorists suggest to go for the path of least resistance and look for product markets that address the mission-critical needs of the customer and impact their pain points in a positive way. It is important to forge authentic connections, as customers are searching for companies that understand them rather than those that push them to simply buy.

All these notes seem reasonable as the company needs to know who to serve with the intended new product. For this end, the company can do segmentation, targeting, positioning and competitor analysis, which make standard business tools for identifying target customers and competitors. Segmentations distributes the customers into segments, while targeting and positioning outlines the proposition idea for each segment. When the target customers are identified, it means that the company has a clear idea and understanding of who its ideal customer is and shapes its value proposition to appeal to that customer. This element includes key demographics (such as age, sex, family status, income levels, etc) and then designs its value proposition to speak to that target market.

Step 3, experts´ inputs. In addition to this theoretical description, the inputs from the 4 practitioners can be summarized as pointing to the need for identifying groups of people, and getting closer to them (or bringing them closer to the start-up), even without communicating directly with the people. Just looking closer at their needs can already tell a lot about the potential customers, especially nowadays, when there are many studies on people's behavior and their classifications. Identifying one or more groups of potential customers also helps a start-up stay more focused on moving forward, which will certainly add "points" to the overall treasury of success. Also, often when a group of potential clients is defined, additional associations and connections come along, they may have not been imagined previously, so new opportunities begin to form too. As a result, emerging networks, like a magnet, attract similar (albeit different) groups, opportunities, and ideas.

Step 4. Identifying target customers



Step 4, here, theorists remind about long-term value and the relationship with the customer, which should help to understand the bigger picture better. Defining the Customer Value Proposition consist of “the jobs-to-be-done”, “pain relievers” and “gain creators”. These elements will determine the strategy on how to identify and present value to the customer and should help to price the new product based on created value, and thus help to win customers. The most important questions to ask here include: what segments are prepared to pay the most for this product or service? and what is the lifetime value of a customer (LTV)? At this stage, the outline of the product or service gets sharpened, verbalized and documented in the form of a Customer Value Proposition (CVP). A CVP answers the question 'why our company' to the potential customers and how the product or service creates value for a Customer CVP means a fit, or a successful combination, of the customer's needs with the company's offer. The ultimate goal of a CVP is to show how value is created for the customer.

A company’s unique CVP is “a primary marketing tool, and it is crafted to communicate the idea that consumers can receive the highest possible value or benefit from purchasing the company’s products — greater value or benefit than they can receive from competitors' products” (Investopedia, CVP). There are three main CVP elements should point to:

1. Target Market. It means that the company has a clear idea and understanding of who its ideal customer is and shapes its value proposition to appeal to that customer.

2. Specific Value. This element clearly answers the question of why customers should choose the company’s products over any other available choices.

3. Customer Connection. This element should explain how the company meets the individual needs or desires of its customers.

In addition to the jobs-to-be-done, a CVP also identifies *Customer pains* that are the negative outcomes, blockers, risks, and setbacks that relate to the jobs. *Pain relievers*, in turn, are the ways your products or services take away the pain from your customer. *Customer gains* are the ultimate outcome your customers want to accomplish or the specific benefits they are looking for. *Gain creators* are the ways your products or services add value to your customer. (Osterwalder 2014.)

Step 4, experts´ inputs. In addition to this theoretical description, the inputs from the 4 practitioners can be summarized as pointing to the need for exclusivity, attractiveness and crystal-clear clarity that must be added. In practical terms it means that, after seeing even a little information about the product, a potential client can no longer forget about it, this should be associated with his problem, which worries him so much all the time. Indeed, everything that the start-up broadcasts about the product should be true, as this will already be the first brick for building relationships between the company and the client.

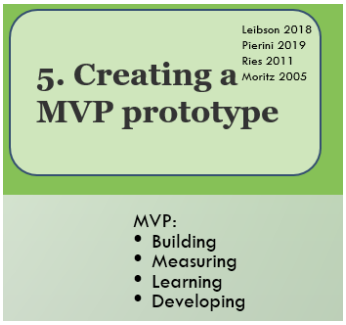
The experts insisted that these 4 steps can be done *either* in this logical order, *or* this order can be changed as seen necessary as every entrepreneur's backgrounds vary, and some decide to make a product out of their own pain, while others get ideas from what they hear from other people (customers, partners, or general public), or still others just "see the potential" for a new product in the market by analyzing the existing, available products. By doing the first three steps, the start-up prepares for defining their customer target group and a value proposition. After that, the start-up can move into Phase 2, but it is worth remembering that 4 experts stressed that some of the steps of Phase 3 can be done in parallel with some steps from Phases 1 and 2, so there is no fully "fixed order".

Phase two. After the team has decided on the goals and a clear idea for the product, it is the time to create a prototype in the shortest possible time. Phase two includes 4 steps: Step 5, Creating the product porotype (NB! without the service prototype yet, unlike in the theoretical approach); Step 6, the most important factor for the prototype is its ability to solve the initially outlined problem, have the necessary functions. At this stage, its looks and additional functionalities are completely unimportant. They will be refined by the end of this Phase two.

After that, the start-up team begins to actively test it and fix all possible bugs, testing is an ongoing process, so you should not focus on it and wait for the end of this task. At the same time, start up makes all the necessary calculations, such as market capacity,

to determine the potential sales volume. Also, the company needs to take care of licensing, because to sell a product, it must be done legally and have proof that it is safe. Be sure to patent the product to protect intellectual property, the patent itself has great power to move the invention far ahead.

Step 5. Creating a MVP Prototype



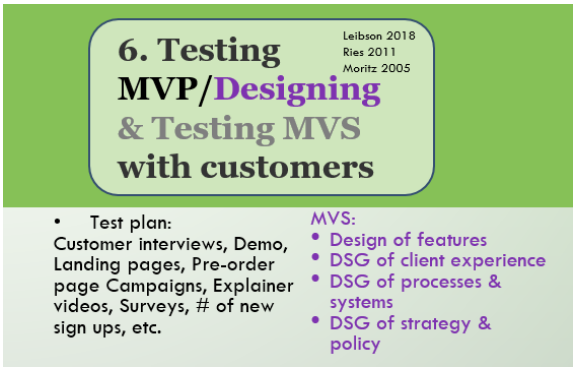
Step 5, in any design process, the prototype is implemented through a cycle of building, measuring, learning & developing, and repeating the cycle until the prototype is ready. The original definition of prototype was “in which the intent was only to demonstrate the feasibility of a new circuit and/or a fabrication technique, and was not intended to be an early version of a production design”. The prototype will undergo a series of building, measuring, learning and developing, and repeating the process until achieving a final prototype. The Minimum Viable Service can now be created at this stage while discussing with the customers.

Summing up, creating a prototype allows the company to see how the product will work and how the end-user will interact with the product when it is finished completely. The process of designing the prototype itself helps to notice the errors and act accordingly.

Step 5, experts´ inputs. In addition to this theoretical description, the inputs from the 4 practitioners can be summarized as pointing to the need thinking about the prototype from a different angle. For example, they make an example of a designer who should make a chair. It seems that this is the simplest construct, but designers around the world have been managing to make amazing chairs for decades. The meaning here is simple, just drawing a chair is not enough, it must be real, as well as perform its functions, and they are also quite limited. A chair is primarily a support for sitting, but it can also serve as a support to stand when a person wants to change a light bulb or dust off a closet, a

chair can also serve as a book stand, lamp and even piles of clothes. The same story happens to the prototype of any product. It is important to create a functioning prototype as soon as possible, the key here is the focus on working condition, while its appearance, material and other additions should be forgotten for a while. Also, the prototype does two important things: simulation and thus attracting attention. Simulation is an act of pretense, it is not yet real, but already tangible and visible; it undoubtedly attracts people, customers, investors, while at the same time not wasting the money of the creators.

Step 6. Testing the MVP Prototype & Designing and Testing MVS with customers

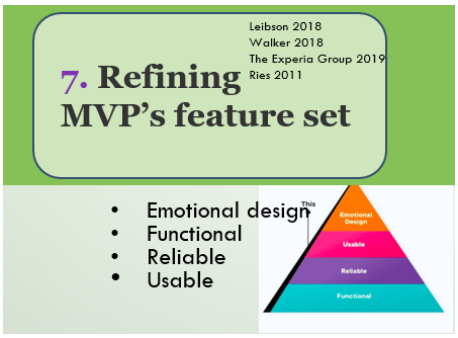


Step 6, the next step is testing the MVP with customers. Best practice stress that, in the test plan, customers should physically try the demo product, followed by in-depth interviews to identify detailed customer feedback and their perceptions. There must be an accurate test plan, which entails functional testing of the demo product, whereby the customers are afforded the means to test the product physically and then interviewed. This is important since it will help guide the start-up team to learn on what more can be done or what they got wrong and consequently, help them refine the MVP. The prototype can be tested and developed as long as the best result is achieved, but it cannot last forever. The main point there is to get the feedback as soon as possible, and the prototype is a perfect time- and cost-saving solution.

Step 6, experts´ inputs. In addition to this theoretical description, the inputs from the 4 practitioners can be summarized as pointing to the need for looking very seriously at this stage because testing will open the door to applying for a patent and all kinds of licenses. Testing implies a process that repeats over and over again, up to the highest possible quality results, until it brings full confidence in the workability and suitability of the product in order to show this invention to the world officially. It is also needed to stress that the

service creation was meant for this stage, after the product is more or less defined and the company knows that it is working.

Step 7. Refining the MVP´s Feature Set



Step 7, customers need the product to function in the best possible way, and have a convenient solution in order to solve their problem or desire. For this end, user experience needs to be smooth, clear and easy. Along the good experience, the product needs an appealing design to make desirable and easy to use. The customer experience and the extent to which their needs can be satisfied by a product are determined at the level of product or service design. In other words, the MVP and its features level.

Choosing the right features can be difficult while working with startups in many ways. A minimum viable product should possess the most elementary feature set that early adopters will use and contribute feedback during the product development phase. *"This minimum feature set (sometimes called the "minimum viable product") causes lots of confusion. Founders act like the 'minimum' part is the goal or, worse, that every potential customer should want it".* (Blank 2009.)

For defining crucial features for MVP, there are two steps described in literature and best practice: 1. extract core value. 2. define critical features. It is recommended to think about the feature in the following term, including its functionality, reliability, usability, design. Functionality is the quality of being suited to serve a purpose well, in other words the product must be simply practical. Reliability is the quality of being trustworthy or of performing consistently well, while usability is the capacity of a system to provide a condition for its users to perform the tasks safely, effectively and efficiently while enjoying the experience. Emotional design refers to the ability of a design to evoke emotions. It seeks to address the customer's needs efficiently and effectively. *Emotional* design is a design that aims to foresee and serve customer needs and feedback. *Functional* refers

to the capacity of a product to work the way it is supposed to. A functional product or service is useful in accordance with its intended purpose. *Reliable* denotes the ability of a product or service to work consistently, a reliable product or service will adequately execute its intended purpose for a given period or operate in a set of environments without failing. *Usable* refers to the capability of a product or system to work effectively and efficiently. Usable product or service provides the user with the ability to use the product or service in a pleasing, effective, and simple way.

Step 7, experts´ inputs. In addition to this theoretical description, the inputs from the 4 practitioners can be summarized as pointing to the need for very practical aspects is much more important at this stage, it certainly does not include emotional and external design. All additional functions fade into the background if the main task is not performed well and quickly. Indeed, the features of this or that product can be useful for marketing and for the presentation of the product as a whole. Moreover, interesting and special features can certainly attract the attention of additional groups of customers (probably not previously identified). A wide list of functions can also be useful in the battle in the market and a significant advantage over competitors, but again, the main function or even the main duty of the product is to solve the previously identified problem, so in fact there can be only one function. However, if the startup team indicates the exact order of importance in the arrangement of features and functions, then, *as soon as* the main function comes clear for the user (for example, the interface), only *then* the design, color, and so on gain any importance. In other words, the previously described functionality, reliability and ease of use must be *put first* and always follow together. The rest is *secondary*. It is also a good practice to have this list of priorities as a clear, realistic check list for the testing phase.

Step 8. Licensing and patenting

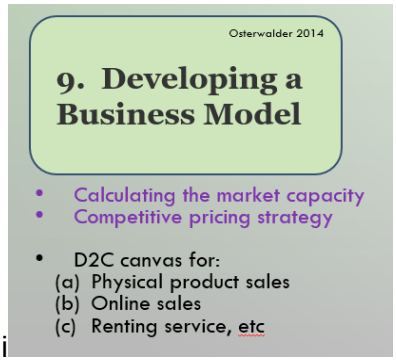
Step 8 was a new step suggested by experts as missing in the theory-based roadmap. There is a hunch that theorists have missed this moment from the big picture, since

initially this process does not relate directly to the development of the medical product, and very much related to entering the market as a whole.

Step 8, experts´ inputs. In addition to this theoretical description, the inputs from the 4 practitioners can be summarized as pointing to the need for patenting as it simply gives a reserved place in the market, even if it does not guarantee profits and demand. But the meaning of patenting is much greater, as is the process of its approval. This is also a re-verification of the product, as it includes the testing stage by another instance. It is important to understand that patenting is also a test for the creators of the product, since in most cases it costs a big amount of money, and also finding the funding for this is a serious test of how the creators themselves are confident to go forward. If this is so, then the coveted seal and a reserved place in the market are well deserved. And start up can move on to the next phase, namely, to calculate the market capacity.

Phase three. This phase includes 4 steps: Step 9, developing a business model; Step 10, finding the funding and launching a lean start up; Step 11, launching brand, boosting awareness and building customer relationship, and Step 12, market entry and business operations. The proposed steps are described below, based on the earlier construct from Section 3 (theoretical) and the comments to it by the interviewed experts (practice-based inputs).

Step 9. Developing a Business Model



Step 9 in CF. The old saying “It’s all about business model innovation, not new technology” is common among business practitioners since one of the challenges for the start-ups at this early stage is to choose the right business model. Business model is a system, which creates and captures value and determines the company’s success. The new business model serves as the interface between what technology enables and what

the marketplace wants. Applying the Business Model Canvas (Osterwalder), in the case study will enable to find out how different blocks or components shaped this particular business model and what exactly will make it work.

Additionally, discussing and analyzing the five forces model (Porter), brings an opportunity to see the business from another angle, as well as using a different tool, which is more applicable for start-ups, for example: Direct to Customers canvas for: (a) Physical product sales, (b) Online sales, (c) Renting service. A clear Business Model captures the company's value, the solution of the problem and the potential opportunities. It is not to be confused with the Business plan, as they have completely different purposes for the company. The business model is the foundation with the main idea of how the company will generate revenue, and the business plan is an explanation of how the business model is working in detail.

Step 9, experts´ inputs. In addition to this theoretical description, the inputs from the 4 practitioners can be summarized as pointing to the need for two more additional things:

Calculation a market capacity. The market capacitys formula is simple, it is very easy to calculate, but this step is very important, as it will give even more confidence. The capacity calculation is also the first important document that can be shown to potential investors, as this is a very important aspect that will quickly and clearly prove the importance of the product, investors may not even see the product itself, but the numbers will describe the volume, size and demand, this is definitely guarantees their interest. It will also help company compare itself to other companies, show own value and possibly foresee the future in the market.

Setting competitive pricing strategy. Nowadays, pricing has become more than just a label on a product, as it is important to strike a balance and find the right price for the product. Indeed, the pricing begins after the cost has been covered, but if it is initially too high, then the product may not find enough customers. Here again, it is important to remember that in this map it is proposed to devote time to calculating the price already in parallel with building a prototype, when the company will roughly understand the cost of the finished product. In the previous version of the roadmap, it was proposed to study the price at the stage of identifying unserved needs, but this tactic seems to move the company to put the focus on price, rather than quality and other important foci.

Developing a profitable business model. Business models appear and are created very quickly in our time. There are no rules in this aspect, often companies play with different models, transforming and even mixing them with each other. One of the experts well noted that having decided on a business model, it will be difficult for a company to change it if it suddenly decides to do so. Despite the fact that there is a convenient template for developing a business model (Osterwalder, 2010), the change itself in the model may require company to go a few steps back and revise all goals and strategy, also revise management, costs, and more.

Step 10. Finding the Funding & Launching a Lean Start-up

Step 10. Mission, vision, strategy, etc. This entails the why and how aspects of the lean start-up. Here a start-up declares its overall goal, kind of service it provides, and their desired future position. Every new company expects success when they launch a new idea. But there are a number of challenges on the entrepreneur's path that can cut it very quickly. So, by applying the Lean Startup Methodology a new company can easier to see if their business model is practical. Going through each step and coming back to the first step each time (as the methodology is a loop) the company is able to develop the product to a relative perfection. It is an ultimate toolkit that allows companies to build bridges and stairs to their target.

Finding the funding was not separately covered as vividly and in detail as other steps; and there is a hunch that theorists have missed this moment from the big picture, since initially this process does not relate directly to the development of the product, although of course this has a direct and very important role to entering the market.

Step 10, experts´ inputs. In addition to this theoretical description, the inputs from the 4 practitioners can be summarized as pointing to the need for finding the funding (multiple financing sources). This is a new step that was not previously included. Indeed, at this

point the discussion is focused on taking care of the cash flow, since at first the profit will be small under any given conditions, but the expenses will also require payments. But there are other possible strategies (e.g. fundraising). In addition, sponsoring a startup certainly helps and increases its viability in the market. It is also worth remembering that making new connections can be useful not only for money, but for other things, as network means a lot.

Setting a mission, vision, and goals. This step describes how a start-up communicates with the outside world and answers the questions, "who are we? What are our values? Why are we doing this? Where are we going?". Clear understandable answers to these questions are the basis for further brand building, but it is important to give this step proper time first and not confuse with other steps. In the previous map based on the literature, this step was in 8th place, here it is in 9th place, but as already mentioned, the steps from the third phase can be discussed in parallel.

Step 11. Launching a Brand & Boosting Awareness, Building Customer Relationships

Step 11. Branding involves the lean start-up's promotion and advertising aspects. Marketing is a critical component of any new product or service since it helps to promote its business side. Besides, branding in the business world defines the success or failure of a product or service. Therefore, the way a start-up differentiates itself from its competitors is very important.

Customer relationship as a day-to-day affair with its customers is a great part of the lean startup. Reaching the target audience is a big success but keeping them is a challenge too. There comes the brand marketing as its main purpose is to grow the number of loyal customers by recognition and reputation. Achieving a wide customer base is another success but understanding them and therefore engaging them (so they could bring even more customers) is a very complex endeavor and requires a lot of effort and resources.

Step 11, experts´ inputs. In addition to this theoretical description, the inputs from the 4 practitioners can be summarized as pointing to the need for *Launching a brand and boosting awareness.* Building a brand is a complex task. A brand is like a passport of a person, it can tell a lot of things besides the name, for example, belonging to a country, age, partners, etc. The brand plays a great role in recognition, sometimes it is inexplicable, what makes customers choose this particular product. Very often, the brand overshadows the benefits of marketing and advertising itself, and vice versa, some brands are just as famous and strong, only because of their marketing advertisements. The company decides which strategy to choose. A brand is an important decision, which of course takes time not only for approval, but also for immediate implementation.

In the previous map, building a brand was part of a lean start-up, however, during these interviews, the significance of this methodology was not discussed or raised, probably because all the people interviewed had quite a long experience and adhere to proven methods. But it is known that the main difference between a Lean startup and a traditional one, quick solutions and ability to adapt to circumstances. However, this method is more suitable for products of a different type and severity.

Building customer relationship. The customer experience of any company has come to the fore. Therefore, building strong, trusting relationships becomes the key to the demand for the product. Especially at the beginning of a startup path. The product may not be produced yet, but potential customers may already receive information in various forms, only the sky is the limit here, a startup can use their creativity to its advantage. Interaction with the client, answering their questions, observing people who are interested, all these things can be done in parallel with the first two phases. After all, communication with customers for the most part occurs through digital tools.

Step 12. Market Entry and Operations

Step 12. Introduction entails bringing in the new product into the market. For penetration purposes, the new product gets to be introduced into a new market. *Commercialization* entails the introduction of a new product and service to the new market. The product is launched, and the marketing data and production cost is observed to determine if the product will earn the company profit if the sales volume is increased. Then distribution is an important component of a marketing mix and is a link between processing and consumption. It involves the sharing of the new product and service to gain publicity in the market. Intermediaries who include the wholesalers, salesperson, and retailers can be used to sell the products to the final consumer.

Promotion is communication made by marketers to persuade and inform, as well as remind the potential buyers of a given product so as to elicit a response or influence an opinion. Marketing the product enables a company to afford more customers. Promotion is an essential part of any start-up since not every person is familiar with the new product and service available in the market. Therefore, it is critical to promote the product and service to acquire more customers and be in business.

Review of performance entails evaluating the feedback from customers of the product who have had the chance to use the product and service. Here the start-up assesses the users' reactions, whether positive or negative in order to gauge what more can be done to stand out in the market.

Step 12, experts´ inputs. In addition to this theoretical description, the inputs from the 4 practitioners can be summarized as pointing to the need for management organization.

Business operations management. The main task is to organize all the processes of production, sales, and interaction with the outside world as a whole. In a word, increase the efficiency of the organization. This is a complex task, but these days there are many smart tools that make the task easier. It must be remembered that start-ups differ from serious large organizations mainly in the atmosphere inside. A few things to look out for are open communication between start up participants, considering all ideas, automating all processes as much as possible, using the latest smart technologies, breaking big projects down into many small ones, ongoing learning, and creativity in general.

As seen from Figure 4 and the description above, the proposed roadmap includes in addition to already existing roadmap several changes and steps.

The main goal of newly proposed roadmap is to find out the best possible scenario how to bring a new product to the market backed by knowledge and experience of practitioners described in detail.

In summary, the newly proposed elements of a roadmap enable to establish more precise route and specify the details of the required actions when bringing a new product to the market that was not possible from the theory-based construct.

Next, the Thesis proceeds to validating this initial proposal.

6 Validation of the Proposal

This section reports on the results of feedback and validation of the initial proposal, presented in Section 5. First, this section overviews the validation stage to display the logic of its creation. Second, the section discusses findings from Data 3. Third, the section reports on the development to the initial proposal with presentation of the final proposal.

6.1 Overview of the Validation Stage

The goal of this section was to build the final proposal for the roadmap how to bring a new product (low risk medical device) to the market. The purpose of this stage was to evaluate the steps in the initial roadmap (i.e. Initial proposal, Section 5). The key focus of the validation discussion was on the general order of the steps and the level of importance of each of them.

The validation of the proposal was done in two steps. First, the initial proposal was presented to the experts from expert organizations involved into the startup development, also in HealthTech, and subsequently, two more experts were invited to the brainstorming and validation discussion with top class expertise in HealthTech and also academic degrees in this field. These experts brought the most valuable insights as they possess both eh industry and academic experience. Their inputs were focused on evaluating the initial proposal and suggesting desirable changes. Based on the comments and recommendations, the final proposal was created.

6.2 Developments to the Proposal (based on Data Collection 3)

Data Collection 3 concentrated on identifying improvements / developments that resulted from testing/piloting/try-out or proposed by the validation experts/ key stakeholders to the Initial proposal in Section 5. What the experts say should be further developed in the Initial proposal? Data Collection 3 is strictly focused on the Proposal contents and seeks to finalize it based on the expert/company feedback.

Table 4 below shows the inputs from validation (example).

Table 3. Expert suggestions (findings of Data 3) for the Initial proposal.

*Input from CF, CSA and Proposal (**CF + Data 1&2**)*	*Suggestions from experts for the Proposal, summary (**Data 3**)*	*Description of the comment/ feedback by experts (in more detail, Data 3) + developments to the Initial proposal*
STEP 1 Identifying competitors & market research	STEP 1 Identifying competitors & market research **+ literature review** a) To go through "Running Lean" and "Scaling Lean" books and apply finding accordingly.	The experts suggested to go through these critical sources which should shed light how the company communicates with the potential clients and various stakeholders. These sources should improve early understanding whether a given idea is good. As well as studying various useful metrics and how to track them.
	b) Continues literature review and finding other similar products/ services existing on the market.	Experts suggested that studying the available products through literature and the Internet (persistently and continuously, at all stages of development). This should help effectively monitor available products, new entrances, and innovations, and better follow the situation on the market and in science.
STEP 2 Identifying Unserved Customer needs	STEP 2 Identifying Unserved Customer needs This step is well situated on its place. Need to find out the nature of customer's problem.	Experts suggested to study characteristics of potential customers individually of by groups supposedly divided by profession, place of residence, gender, hobbies, and so on. They also advised to look at the problem from different angles. These actions should help to better understand the nature of the problem and compare it to existing or potential solutions. In general it will define/pin-point the problems they solve.
STEP 3 Identifying target customers	STEP 3 Identifying target customers Paying attention to solving the problem, through scanning and researching customers.	The experts suggested the approach of getting to know the target and potential customers better and studying them with greater detail. This move should make it easier to solve the problem.
STEP 4 Defining a Value Proposition	STEP 4 Defining a Value Proposition Need to stress an importance of a concept.	The experts suggest to re-think the concept carefully, visualize, and present the CVP in clear terms. It should help company to see the idea clearly and protect it from unnecessary and costly actions.
STEP 5 Creating an MVP prototype	STEP 5 **Exploring regulations** Need to dive deep into medical device regulation system.	Experts suggest to learn the regulations and standards from key existing documents, as well as possibly to find an outsourcing service for this matter. By doing it right, the medical device manufacturers hold a great competitive

		advantage and creates the baseline for a successful business.
	STEP 6 Creating an MVP prototype Need to see and create the closest-to-perfect prototype.	Experts suggested creating a prototype as real as possible, so that it is easy to use and modify. The MVP prototype is the basis of the final product, it is the model that will be multiplied in large/scale production.
STEP 6 Testing MVP prototype	STEP 7 Testing MVP prototype	This step is a continuation of the previous step, all experts agreed on the importance and need to implement it as soon as possible, as it would move the project forward.
STEP 7 Refining MVP's feature set	STEP 8 Refining MVP's feature set	Functionality, reliability and ease of use must be combined and always follow together. These are the most important components for the feature sets. Other additions are good, but not that important on the early start up development stages.
STEP 8 Licensing and Patenting	STEP 9 Licensing and patenting Need to 1. Identify the key technology 2. To hire help from Patent Office 3. Apply for a manufacturing license	Experts reminded that patenting and licensing are lengthy processes, the company need to prepare in advance, starting by looking out the other existing similar products. Patented technologies are much easier to commercialize. Patents protect and thus adds value to product in general.
STEP 9 Developing a Business Model	STEP 10 Developing a Business Model To go through "Running Lean Startup " book carefully	Experts reminded to rely on the book and the Lean Canvas, that are very good tools for creating a business model. Applying Lean Canvas allows a problem-solution strategy to be easily described. It should help the startup avoid many possible mistakes.
STEP 10 Finding funding & Launching a Lean Start-Up	STEP 11 Finding funding & Launching a Lean Start-Up It is principal step, but not the most important.	Experts suggested not to rush with finding funds, first the idea must be developed into the physical prototype and have a decent presentation. Large investors reject most pitches, as they look at the company from a different angle and are interested in a product that makes profit. The company must make every effort to show a working product. It makes no sense to look for large capitals from outside, it wastes time
STEP 11 Launching a Brand & Boosting awareness & Building Customer Relations	STEP 12 Launching a Brand & Boosting awareness & Building Customer Relations a) Evaluate the product from the	a) Experts reminded that often brand is made not by the advertising only, the quality of a product and a world of mouth can work for the company as much effectively. b) Experts remind to pay attention to the type of the product. Focusing on big clients (other businesses) is the good way.

	marketing point of view b) Consider a B2B model	Choosing the right brand and marketing strategy will bring business the right relationships naturally.
STEP 12 Market Entry & Operations	STEP 13 Market Entry & Operations	The main task here is to organize all the processes of production, sales and interaction with the outside world. This steps open the way to “business as usual”, i.e. optimization of all operations and processes (i.e. end of the product launching phase).

As seen from Table 3, there were several main things suggested by the valiadation experts, in addition to the Initial proposal.

First, particular importance of literature review was emphasized. It is necessary to search, check and supplement knowledge from the very beginning, from the idea stage and continuing constantly during the development of a startup, the founders and employees must be aware of all the changes and news on the market and in the scientific community to move forward successfully. It was added to the step number one.

Second, finding help from best practice was approved and revised, and in this revision, the book ”Lean Start Up” (cited cited previously) was suggested by the experts as a good source of help. Also, other books were suggested (“Running Lean” and “Scaling Lean”) which strengthen the theme of Lean Startup, although they were written by a different author. The knowledge and advice from these books are especially suitable for the step where the Business Model (step number 10) is being developed.

Third, most of the discussion was related to the issue of medical devices regulations (MDR). Additional materials were strongly advised to be used, as - according to the experts, - understanding the regulation at a professional level and following them with accuracy is CRITICALLY important for the very survival of the product idea, let alone any success of the company in the market.

Other comments, suggestions and ideas were also extremely valuable but not affected the outline of the roadmap.

6.3 Final Proposal

This description pulls together the final version of the “Roadmap for bringing a new low medical device to the market”. It contains 13 steps that are summarized below.

Step 1. Identifying competitors, market research and literature review.

In the initial proposal, based on knowledge from the literature and expert opinions, the first step was to identify competitors as well as target customer groups. Typically, a company uses standard business tools such as segmentation, targeting, positioning, and competitor analysis. As a result of the analysis, a competitive offer for buyers is formed, which is also a competitive advantage, and the correct choice of a communication strategy and risk management. Also, the company's unique offer is the main marketing tool that visualizes the benefits and difference from competitors.

In practice and the experience of experts, it is very necessary to carry out "market research" of the main idea. This helps to see the big picture, notice opportunities, potential risks, learn about trends, and so on. Here it turned out there is a need to separate the analysis of competitors and the target group of customers, as it was in the third part.

Step 1, second round of experts´ discussion. Initially, experts agreed that the first three steps were the most important. Next, the experts recalled the suitability in denouncing the topic of the books that they use in their daily activities often. Both books are a logical continuation of the previously mentioned book "Lean Start Up". While "Running Lean" is more about how the company communicates with the potential clients, "Scaling Lean" is more focused on the interaction of the company with various stakeholders. The main points described in the books cover the questions about early validation, understanding whether a given idea is good, studying various useful metrics and how to track them, as well as taking them all the way to product market fit and then scale.

Another addition came up from a conversation with the second pair experts who are not only practitioners but also academics in HealthTech. It was stressed that the company needs to constantly search and screen for other (similar) products/ services on the market and study what makes the purpose and competitive edge of these products. Experts stress that, from their experience, many established firms (not start-ups), keep

forgetting about the literature reviews and therefore the big picture gets hidden from them, which ends up in significant financial losses when competitors suddenly come up to the scene. This kind of companies also miss on spotting innovations. Another important thing is that the company has to do literature review again and again, continuously. Any product require continuous developing process, and a thorough literature review should be done several times a year.

Step 2. Identifying unserved customer needs

Step 2. In the initial proposal, based on knowledge from the literature and expert opinions, the unmet needs of customers are the main point in establishing a connection between a company and its customers. Often, underserved needs mean needs that are not met in the expected/convenient ways or in full. Business practice suggests that about half of all bankrupt companies ceased their activities due to the fact that their products were not in demand by the market. Thus, identifying the true needs for a product or service is at the core of any successful business. Currently, there are several effective tools for identifying unmet needs, for example, analytics tools bring in more sales, reduce costs, increase efficiency, help develop new products and services, and generally make better business decisions. The real success of a company comes when it identifies gaps in the market. Once a company understands who and where their audience is, it becomes much easier to reach them and raise awareness of a new product or service. And of course, the use of modern technologies and strategies are the best helpers in overcoming these gaps.

The experience of experts also proves the need to formulate and clarify the problem at this stage. After all, this is where the problem becomes clear (and with regard to which element, functionality, usability, etc., as described in the theoretical approach). And clarifying the problem (i.e. finding out the customer's unmet needs) and identifying/"feeling" a potential solution means that the team has a clear understanding of what they want to build. And this can already be said half the battle.

Step 2, second round of experts´ discussion. Startup experts continue to support the importance of the first three steps. This step allows to delve into the essence of the problem much deeper, and first determine the pattern of occurrence of the problem. Whether it happens at a certain time, or when interacting with something / someone. Perhaps the company will be able to find out whether the problem relates more to the individual characteristics of people or whether this problem occurs in certain groups of

the population, divided, for example, by profession, place of residence, gender, hobbies, and so on. The company will also look at the problem from different angles, compare existing or potential solutions to this problem, and will more able to determine exactly what problems they solve, because a detailed close look is a more professional and wise approach.

Step 3. Identifying target customers

Step 3. In the initial proposal*,* based on knowledge from the literature and expert opinions, it is most important to seek markets for products that meet critical customer needs and positively impact customer pain points. It is also important to make good connections as clients look for companies that understand them and genuinely care about them. This is true because the company needs to know who to serve with the proposed new product. Accordingly, it is very advisable to carry out a series of measures to determine the portraits of a potential buyer, as indicated earlier, there is currently a wide range of different tools for this, suitable for companies according to their preferences and budget.

When the target customers are identified, it means that the company has a clear idea and understanding of who its ideal customer is and shapes its value proposition to attract that customer. It helps startups in many aspects of development. New opportunities, connections and ideas begin to form.

Step 3, second round of experts´ discussion. The startup experts continue to support the importance of the first three steps. They suggest that more attention be paid to the approach to solving the problem, through thorough scanning and research of customers in general and of course target customers. The reason for this is that, usually when a company defines its target customers, it serves as immediate confirmation that the problem being solved is, in fact, fundamental, and the needs of customers do exisit and can be addressed.

Step 4. Identifying target customers

Step 4. In the initial proposal*,* based on knowledge from the literature and expert opinions, value proposition answers potential customers´ question “why should you choose our company”, also sets the value and cost of the product, which will ultimately help win customers. In other words, a CVP is a demonstration how value is created for

a customer. A company's unique CVP is the primary marketing tool, and it is designed to communicate the message that consumers can reap the greatest possible benefit. There are three main elements of CVP: target market, specific value, customer connection. Customer benefit is the end result the customers want to achieve or the specific benefits they are looking for. Profit Creators are how the products or services create value for customers.

The experience of experts shows that such things as exclusivity, attractiveness and crystal clearness for the client are also important. It is these points that will make the client think about the product constantly. Unconditionally, all information about the product must be true, this will also become the first brick of customer loyalty.

Step 4, second round of experts´ discussion. Here, the startup experts recalled the importance of the concept as a whole. There was a suggestion that before creating a prototype, concepts of multiple solutions to a problem should be thought out and presented. On the one hand, this will protect the company from unnecessary and costly actions, on the other hand, it will help to make a more informed decision regarding the construction of a prototype, as well as other decisions in this business as a whole. In general, visualization of concepts is also useful for illustrating the highest value of a product. Customers and the market will see that in fact the problem to be solved is real, not only exists, but it is also serious, and there are multiple ways to solve it, and this is the best moment for the company to present their best solution.

Step 5. Exploring regulations

Step 5. In the initial proposal*,* there was no discussion about this step, as there was no request from the start up to go deep inside this topic and therefore there was no understanding of the great importance of this element (medical industry). The start-up only requested the business roadmap, and was focusing on the prototype construction, thinking that the regulation part will be taken care later.

Step 5, second round of experts´ discussion. The HealthTech experts pointed to the important to “customize” the initial proposal for medical devices specifically; not for launching products, in a general sense. It included the importance of defining a real medical device, its risk class, etc. and especially including multiple special regulations and directives into the development process. The HealthTech experts shared the most critical document, a 110-page booklet ”European Medical Device Regulations MDR &

IVDR" available at https://www.leanentries.com/wp-content/uploads/european-medical-device-regulations-mdr-ivdr-a-guide-to-market.pdf The document was created in collaboration of two big organizations, Business Finland and Lean Entries Ltd.

The aim of this brochure is to provide guidance to the Finnish medical device manufacturers regarding the new European regulatory requirements so they can avoid being non-compliant as a potential market barrier in the HealthTech sector. This consultancy paper, that includes links to other most critical regulations and directives, gives valuable insights on topics that are not easy to comprehend for the newcomer and which require extensive practical experience in this field. This information may save months, if not years, of time by turning confusion into clarity, as it is the manufacturer especially that holds responsibility that all relevant regulatory requirements are followed. By doing it right the first time, the medical device manufacturers hold a great competitive advantage and create more chances for success for their products. There are three main points summarized from this document:

1. The medical product must become a CE marked medical device, so everyone are sure that device is safe and effective. The CE marking itself includes 8 steps along this way:

a. Defining the intended purpose
b. Identifying applicable Legislations
c. Determining the Device Classifications
d. Identifying the Relevant Requirements
e. Demonstrationg Confirmity
f. DoC and CE Marking
g. Device Registration
h. Compliance Throughout the Life Cycle. (European Medical Device Regulations MDR & IVDR 2021.)

2. The device must meet all related requirements and hold a complete Technical Documentation.

3. The manufacturer must meet all Quality Management System (QMS) requirements. By running an efficient QMS, the manufacturer comes to control its processes to create highly performing medical devices and to manage their commercial activities throughout the life cycle of the device. (European Medical Device Regulations MDR & IVDR 2021.)

Summing up, the manufacturer's journey starts from their marketing and regulatory strategy, how the innovation is turned into a medical device that is eventually placed on the market. To craft the strategy, the first step is to define whether or not the product is regulated as a medical device, and the answer is not always as easy as it may seem. The intended purpose of the device, as defined by the manufacturer, is decisive when solving this problem. The risk classification and the type of the device define the extent of the conformity assessment and the amount of work ahead prior to placing the device on the market. It all seems as a very complex thing to do, but experts reassured that There are a lot of consultation organizations, so it is possible partly outsource taking care and monitoring the progress on applications/documentations. But it is important choose these organizations and control that they are following the MDR guidelines anyway.

Step 6. Creating a MVP Prototype

Step 6. In the initial proposal, based on knowledge from the literature and expert opinions, the prototype is realized through a cycle of build, measure, design and develop, and the cycle is repeated until the prototype is ready. Initially, a prototype is needed to demonstrate the feasibility of a new scheme and / or manufacturing technology. As a result, a Minimum Viable Product may already be created during discussions of the effectiveness and suitability of the prototype with customers. That is, creating a prototype allows you to see how the product will look like and how the end user will interact with the product. The detection process itself contributes to the detection of errors.

Experts talked about the prototype from a different angle. Just creating it is not enough, the company must make sure that it functions under all conditions for all users. As it turns out in practice, the appearance, material and possible additions are completely unimportant at this stage. An important note is that the prototype will already perform the function of imitating the real product and therefore attract attention. It can already be touched / tried on and played in solving a client problem.

Step 6, second round of experts´ discussion. When a company has a concept-based closest-to-perfect way to solve a problem for their customers, an MVP is created. This term implies a minimum viable product, but it is already exactly what satisfies the consumer's need. This is an already existing product that you can test, try to change,

and of course improve. The concept is difficult to perfect because it is still not real, and the MVP is a physical product. This MVP is already the basis of the final product for large-scale production and sales.

Step 7. Testing the MVP Prototype & Designing and Testing MVS with customers

Step 7. In the initial proposal*,* based on knowledge from the literature and expert opinions, there must be a precise test plan, customers must physically try out a demo product, followed by an in-depth interview to get detailed customer feedback and perceptions. The plan is important because it helps the startup team understand what else they can do or where they went wrong, and therefore will help them improve both testing and interviews, as a result of the MVP itself. As a result, the prototype as a whole is the ideal solution to save time and money.

The experience of experts compared testing to passing an exam that will help to get into the patenting and licensing phase. Testing implies a process that is repeated over and over again, to the highest quality, this should happen automatically until one hundred percent confidence in the suitability of the product in order to show this invention to the world officially.

Step 8. Refining the MVP´s Feature Set

Step 8. In the initial proposal*,* based on knowledge from the literature and expert opinions, customers want a lot more than just a working product, they want it to function in the best and most personal way. The user experience should be smooth, clear and easy. The product needs a nice design to make it intuitive to use. The list of all functions as determines the level of capabilities of the profit center. However, choosing the right features can be quite difficult. It is recommended to consider a feature in the following order: functionality, reliability, usability, design.

The experience of experts says that, at this stage, very practical aspects are much more important, all additional functions fade into the background if the main task is not performed efficiently and quickly. Indeed, the features of a particular product can be useful for marketing and in the battle with competitors, but again, the main function or even the main responsibility of the product is to solve a previously identified problem. If the company specifies the exact order of importance of the location of functions, then, of course, after the main function comes understandability for the user (for example, an

interface) and only then design, color, and so on. In other words, the previously described functionality, reliability and ease of use must be combined and always go together.

Step 8, second round of experts´ discussion. Refining MVP was not a big part of the discussion, since based on experts´ experience, other points (for example, the regulation of medical devices) are much more important and this is where most of the team's energy should be directed. Refining the MVP feature set is, so to say, a natural thing to do that would be done during the process anyway.

Step 9. Licensing and patenting

Step 9. In the initial proposal, based on knowledge from the literature and expert opinions, this process is not directly related to product development, although, of course, it is essentially a ticket to the market. The experience of experts confirms that patenting itself reserves a place in the market, even if it does not guarantee profit and demand. The meaning of patenting is great, as is the process of its approval. It is also important to remember that patenting also costs a lot of money, and of course is very dependent on funding.

Step 9, second round of experts´ discussion. Experts pointed out that the alleged invention can be patented only if it is of a technological nature, that is, it is a technical solution. It can also be a method or process but is usually a device or a product. It could also be a new way to use existing technology. The invention must also be novel and, of course, must be industrially applicable.

The second point is that technologies that are already protected by patents are much easier to commercialize, since the patent itself is a universal language. That is, customers will understand that there is a technology behind which there is a patent, respectively, the value of the product is already increasing. Also, a patented product is always easier to license, and in general a patent is a strong protection for a product. It is worth remembering here that patenting is always an expensive process. Therefore, if a particular technology is applied not only in Finland, but also on an international scale, it should have this very protection in the form of a patent.

All the same, patenting and licensing are lengthy processes, so you can prepare in advance. That is, throughout the entire process, you need to keep track of which technology is the key, which can be protected by a patent. Experts suggested literally

looking at patenting as a landscape and towers on it, towers are kind of hot spots for key technologies in this industry. The closer a company can get to them, the more valuable the patent will be.

The other side of the coin that needs attention is having much more capital and much more powerful sophisticated technology elsewhere. There are millions of patents in the system, which will require a huge investment of energy and time, it will be easier to do this with a commercial assistant from the Patent Office. In addition, it is important to find out what other technologies already exist that are covered by fairly similar patents. This will also give confidence in the popularity and interest in this kind of technology. It's called traction. This implies the possibility that just such a solution is insufficiently valuable or insufficiently developed, or can be done better. However, if the new product looks like a completely unique technology, there are two options. Either this is a very breakthrough innovation and perhaps a world-wide discovery, or, on the contrary, many have considered it, but for some reason have not yet materialized, and then you should find out why.

Step 10. Developing a Business Model

Step 10. In the initial proposal*,* based on knowledge from the literature and expert opinions, "It's all about business model innovation, not new technology". A business model is a system that creates and captures value and determines the success of a company. And the new business model serves as a link between the capabilities of technology and market needs. Applying the business model canvas to a case will allow you to figure out how the various building blocks or components have shaped that particular business model and what exactly will make it work. It should not be confused with a business plan, as they have completely different goals for a company.

Expert’s experience also confirmed that the business model better depicts the market capacity, and this information in itself serves to attract potential investors. It will also help the company compare itself to other companies, show its value and possibly foresee the future in the market. When developing a profitable business model, there are no rules, often companies play with different models, transforming and even mixing them with each other. Having decided on a business model, it will be difficult for a company to change it if it suddenly decides to do so.

Step 9, second round of experts´ discussion. The startup experts suggested studying business modelling in carefully. They also refer to the books like Lean Startup, as well as its sequels by another author, where there an advanced Lean Canvas can be found. They also suggest rearranging the steps, or move the business model step before the patenting and licensing.

Step 11. Finding the Funding & Launching a Lean Start-up

Step 11. In the initial proposal, based on knowledge from the literature and expert opinions, by defining a mission, vision, strategy, a startup announces its overall goal, the type of services it provides, and its desired future position. By applying the Lean Startup methodology, a new company can immediately see if its business model is practical. By going through each step and returning to the first step each time (because the methodology is a cycle), a company can develop a product to relative perfection. This methodology is a set of tools that allows companies to build bridges and ladders towards their goal.

Covering the topic of financing, the experience of experts in its search is based on pre-seed and seed financing. The main task is to take care of the cash flow, since at first the profit will be small under any given conditions, but the expenses will also require payment. It is also important to highlight the fact that sponsoring a startup certainly attracts attention and increases its recognition in the market. It is also worth remembering that new connections can be useful not only for money, but also for other things, in our time the network means a lot. Expanding those very connections, and presenting a start-up, clear mission, vision and goals will again be needed. This is a personal presentational description of how a startup communicates with the outside world and answers the questions: “Who are we? What are our values? Why are we doing this? Where are we going?".

Another addition came up from a conversation with the HealthTech experts. They pointed out clearly that any commercialization of HealthTech innovation will undoubtedly require a very large amount of money. Whether funds coming from own sources, private investor or any organization, it is a serious issue that needed to be taken care of, as it is not only drives the processes forward, but also adds extra confidence. Despite the fact this particular field of business is quite expensive, HealthTech sector will always be important to society, no matter what, especially at some critical moments, as we all observed in 2020. Also, the funds add extra protection on the prototype creation an testing stage, as

if something goes wrong (equipment failure/ personnel injury), company has it all covered if the funds are sorted well.

Step 11, second round of experts´ discussion. Experts from the start-up organization shared that many business start-ups often have It is a misconception that you need to immediately move from identifying the idea and target customers to finding finance. However, despite the fact that financing is a very important point, finding it can still wait, especially since approaching that phase, the company will most likely already have all the necessary knowledge and skills for easier obtaining finance, it has been weeks on the first steps. The amount of funding, of course, depends on the complexity and uniqueness of the technology itself. Of course, health-related innovations that require special precision, safety, require higher amounts than any other product.

Step 12. Launching a Brand & Boosting Awareness, Building Customer Relationships

Step 12. In the initial proposal*,* based on knowledge from the literature and expert opinions, a brand defines the success or failure of a product or service. Therefore, how a startup differs from its competitors is very important. Customer relationships, like day-to-day customer relationships, are an important part of a lean startup. Reaching your target audience is a big success, but retaining it is also not an easy task. Brand marketing is coming, as its main goal is to increase the number of loyal customers through recognition and reputation. Reaching a broad customer base is another huge success but understanding them and therefore engaging them well (so they can bring in more customers) is a very complex system that requires a lot of live energy.

In addition to this theoretical description, the contributions of the four practitioners can be summarized as pointing to the need to launch the brand and raise awareness. Building a brand is an extremely difficult task. A brand is like a passport of a person, besides the name it can tell a lot, for example, about belonging to a country, age, partners, etc. A brand plays a big role in recognition, sometimes it is inexplicable that this encourages buyers to choose this particular product. Very often, a brand overshadows the benefits of marketing and advertising itself, and vice versa, some brands are just as famous and strong only because of their marketing advertising. The company decides which strategy to choose. A brand is an important decision, which, of course, requires time not only for approval, but also for immediate implementation. But it is known that the main difference between the Lean Startup and the traditional one is

quick decisions and the ability to adapt to circumstances. The Lean method may be more suitable for products of a different type and complexity.

Finally, as for building relationships with clients, the customer experience of any company has come to the fore. Therefore, building strong, trusting relationships becomes the key to the demand for the product. Especially at the beginning of the starting path. The product may not be produced yet, but potential customers can already receive information in various forms, there is no limit only to the sky, a startup can use their creativity to its advantage. Interaction with the client, answering questions, observing those who are interested, all this can be done in parallel with the previous steps. After all, communication with customers for the most part occurs through digital tools, so it is easy to perform.

Step 12, second round of experts´ discussion. One of the startup experts looked at this idea in comparison with the start of a different type of business - restaurants, which begin to advertise themselves much earlier than the direct opening of doors for customers. It is worth seriously considering whether it is really worth it. The risk to this step is added by the fact that what the clients expect can only be an illusion, and in the end will not bring the proper result later, although of course it will cost resources. There is also a memory of another hair dryer startup that had a rather long and thorny path to success, but now does not require advertising at all, one name instead of thousands of advertising companies sell the product around the world.

The other pair of experts, from HealthTech, stressed that from a business point of view, the markets are usually somewhat different, meaning that medical devices are not very often customer to customer type of products. Usually they are Business-to-Business (B2B). One of the reasons is because B2B form as a whole has many advantages, such as more global large sales, with a big business partner/ client it is easier to build long term relationships. Also, reducing concerns about customer service on an individual level will obviously add energy and resources to other important tasks like product improvement.

Step 13. Market Entry and Operations

Step 13. In the initial proposal*,* based on knowledge from the literature and expert opinions, after the presentation of the finished product, its commercialization begins, and its sales and distribution expand. Many other processes are connected to these

processes, at first glance hidden processes. For example, distribution is an important component of the marketing mix and a link between production and consumers. Product promotion is communication to persuade and inform, and to remind potential buyers of a given product in order to generate a reaction or influence opinion. Product marketing allows a company to afford more customers. A performance review entails evaluating customer feedback on a product that has had the opportunity to use the product and service. With this help, the startup evaluates what else can be done to stand out in the market.

The experience of experts confirmed the need for management organization. After all, the processes of production, sales and interaction with the outside world as a whole increase the efficiency of the organization. It is important to remember that startups differ from serious large organizations mainly in the very organization of supporting processes and the atmosphere inside. It is worth paying attention to the mandatory interaction within the startup team, consideration of all ideas, the maximum possible automation of all processes, the use of the latest intelligent technologies, breaking large projects into many small ones, constant learning and creativity in general.

Step 15, second round of experts´ discussion. The four experts did not make any significant corrections to this proposed step, as they considered part of “business as usual” where the innovative product development ends, and thus it is a simpler step to manage.

Summing up the discussion above, Figure 5 below shows the summary of the steps proposed by the four experts in the second round of the interview as their corrections or developments it the Initial proposal. These steps formed the revised *practice-based roadmap for bringing a new low-risk medical device to the marker* formulated based on the experience of professionals in the startup and HealthTech sectors.

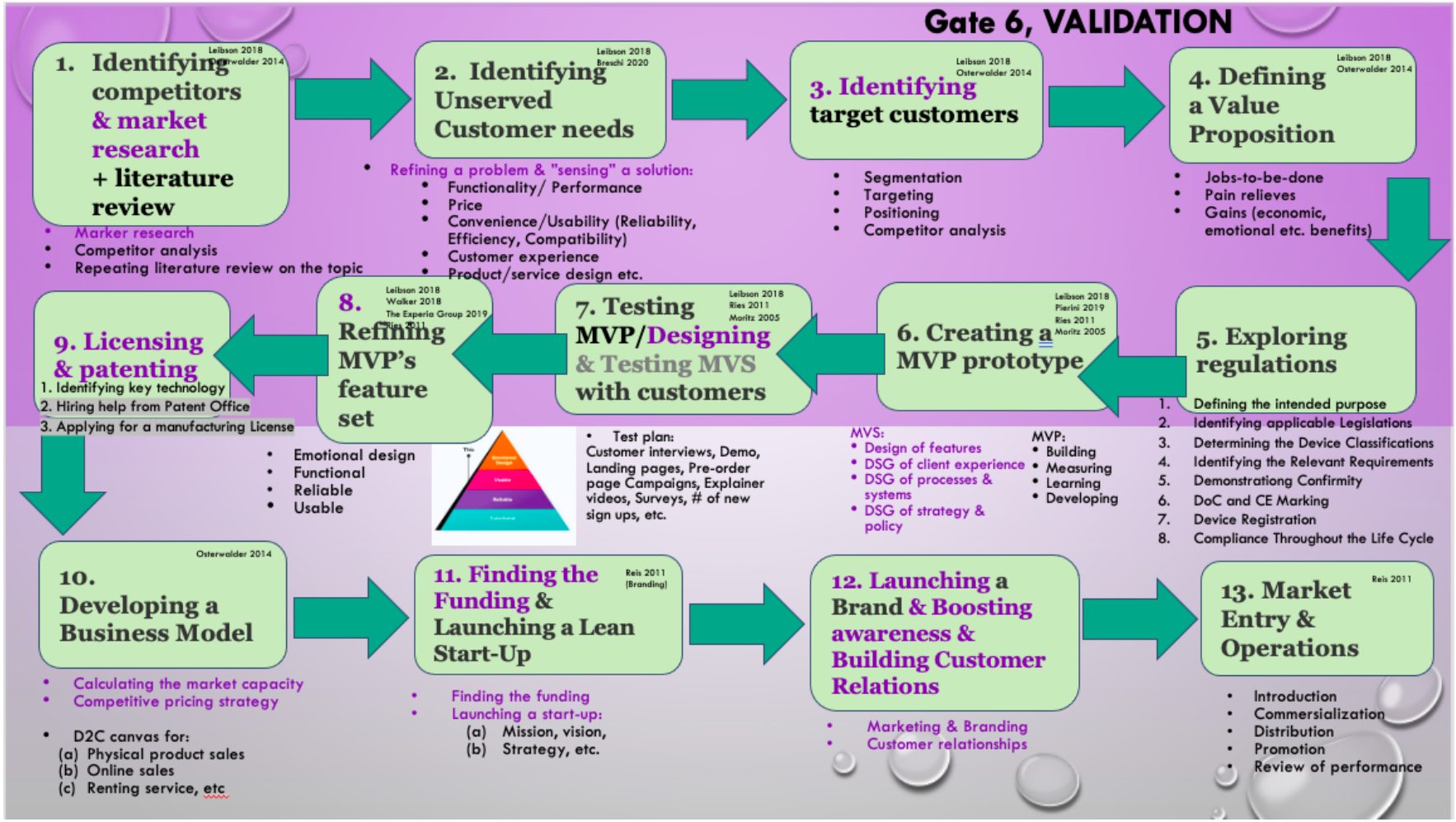


Figure 5. Final proposal.

As seen from Figure 5, the proposed *roadmap how to bring a new low-risk medical device to the market* consists of thirteen steps.

In general, any roadmap makes part of strategic planning and makes a tool for communicating these plans to team members and other stakeholders. The planning process also needs monitoring and evaluating the situation continuously, from many different perspectives. Following this roadmap can be a good support in terms of tracking the progress, which is the crucial component of successful implementation.

The final proposal was made based on comments and suggestions from the experts who have been involved in launching many startups and HealthTech products, represent the attempt to describe the way a new low risk medical device to the market. According to the experts, the proposal is reasonable and realistic, and it has some potential in leading to successful implementation. Although it will definitely require re-evaluating each step carefully to fit a particular startup and its current situation individually.

Next, Section 7 presents the conclusions from the study.

7 Conclusion

This section summarizes the key findings of this study and suggests further steps for the case start up. Afterward, the section proceeds with evaluation of the Thesis.

7.1 Executive Summary

Today, humanity lives in an era of rapid technological development. People choose to live in comfort and enjoyment. Any problem, inconvenience or interference with a person's life is perceived as unbearable. The solution to people problems, if not exists at the moment, will appear in the next season. People are divided into two camps: those who consume and buy these solutions, and those who create them. It is one thing to come up with a new smartphone model idea and use it for entertainment or high-quality pictures; and it is another thing to come up with a solution to a really important problem, such as pain relief or a cure for an ailment.

Traditional medicine does not welcome self-treatment, but it also does not solve the problem of all diseases and the physical condition of people. Real innovators do not stop and dare to solve these problems. Today, people are happy to use various devices to eliminate pain, clamps, symptoms, or simply to monitor their health at home, measuring temperature, blood pressure, pulse etc. Medical devices solving health problems powered by light, temperature, vibrations, imitations, and so on. The variety of technologies is amazing. However, there are too many barriers, time, patience, and self-education behind the implementation of the idea into a real working product in the medical devices sector. Therefore, technology innovators often have a slightly different mindset from business professionals. This is the moment when the merging of two different worlds is necessary to solve the problem of bringing a new medical device to the market. Thus, the objective of this Master’s Thesis was to develop a roadmap how to bring a new (low risk) medical device to the market.

The research process in this Thesis was conducted by applying the case study approach and qualitative research methodology. The main stages in the research process were the literature review followed by the current state analysis and proposal building. The data was collected within four case startups and from four other experts in the fields of entrepreneurship and health technology by using data collection methods such as interviews and document analysis.

Using the best practice found from literature, first, a map with 9 steps was developed. As a result of this initial literature review, nine steps and their sequence were identified. A reference and the description of each step were found in the materials of various theorists, so the initial outcome was backed up with existing literature, and the first draft of the map how to bring a new low risk medical device was developed. After that, the first round of the discussions with experts followed, about this theory-based roadmap. The data from four real-life startups related to the order of the steps and needs to add new ones in order for the roadmap to look closer to reality, according to the experience of these professionals. After the first iterations of improving the roadmap, another round of the interviews with another four experts with HealthTech implementation experience was necessary, so that to ensure that these initial improvements were enough and the roadmap is ready for implementation in a real-life start-up. In this second development iteration, the study got even more valuable suggestions, and the ultimate roadmap how to bring a new medical device to the market was drafted.

This Master's Thesis revealed the difficulties and importance of practical experience in developing a step-by-step roadmap on how to bring a new medical device to the market. By applying the proposed steps, the case startup can rely on the higher probability of successful when launching their market entry.

7.2 Thesis Evaluation

The objective of this Master's Thesis was to build a roadmap how to bring new (low risk medical device) product to the market. The expected outcome of this study was a step-by-step roadmap how to bring a new low risk medical device to the market, and this intended outcome was achieved.

The main purpose of building this roadmap was to visualize the framework of transforming the idea to market entry through creating a physical product, considering all the legal conditions, as patenting, licensing, and other necessary regulations. During the study, a roadmap was developed and then was modified twice, with the help of experts´ opinions. The resulting roadmap can now be used by the case company, as well as by similar healthcare technology startups as a guide.

The initial need for the development of the roadmap was based on the absence of a clear roadmap in literature and the lack of practical experience of the case startup´ers,

including the thesis researcher. In a more global sense, building of the roadmap was primarily aimed at helping new startups to have a clear plan that they can trust and follow, and therefore bring value to the healthcare technology industry as well.

The research design helped the study to proceed according to the identified stages, and to reach the objective of the Thesis in the most effective way. The literature review helped in acquiring deeper knowledge of the startup development process, as well as clarified the role of marketing in product development. The data collection method was selected to fit the framework of the Thesis; it was handy to analyze and understand all the nuances and suggested corrections against the initial draft of the theory-based roadmap. The current state analysis showed the practitioners´ points of view, and thus helped to better understand the needs and opportunities of the parties involved into the idea and product development. In general, the Thesis research process brough together all the most important elements for a logical and thorough roadmap building.

The originally proposed nine steps were modified, first to twelve, and then to thirteen steps. Despite the apparent complexity and lengthening of the roadmap, it was done in order to clarify the most important steps for a startup in such a real life case. It is worth noting that the first modification (Figure 4) was based on the experience of individual expert practitioners, recalling the experience of their single cases. While additional changes from the second modification (Figure 5) were added as a result of brainstorming in a group conversation with experts who absorbed the knowledge of startup development by interacting with dozens of different start-ups and had a deeper professional knowledge of the HealthTech industry regulations.

The most important remark, which brought a deep insight, was that, despite the necessity of each step in the roadmap, the most important steps are *constant literature review, knowledge of the regulations* in the field, while obtaining a patent and a license afterward. This is truly remarkable because it has not been touched or mentioned by any of the theorists, and thus could get unnoticed, had the startup of this study only to relied on theory.

In this study, the case startup has identified the business challenge which defined the objective of the Thesis. The expected outcome was identified by the objective itself which led to the research design and approach selection. According to Albert Einstein, “In theory, theory and practice are the same. In practice, they are not.” Therefore, the thesis researcher was driven to gather the deepest insights from the practitioners not in order

to support theory findings, but to make the outcome of the Thesis applicable and reliable in real business life.

7.3 Closing Words

This Thesis emphasized the importance of having a step-by-step roadmap for new startups when entering a market. Equally important was to build this map with experts in both business and industry environments. This study showed the logic and implications of building a roadmap in the context of innovative and highly regulated industry. During the research process, the study revealed dependence of external organizations and importance of replenishment of knowledge in the field of building a business. According to observations, many novice businessmen for some reason believe that the most important thing is to get as much funding as fast as possible, although on a logical way to enter the market, according to the experience of experts, it only becomes important when all the other details are resolved, and the main intention of the businessman to release the product on the market is still in force.

With the help of the developed roadmap, it is now possible to spread knowledge based on experience among newcomers to the business, thereby increasing the chances of developing truly outstanding ideas into high-tech products and getting them to the market faster and more efficiently.

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