Universiteit Utrecht

Scientific Entrepreneurship in the Medical Technology Sector

Investigating the problem of scientific entrepreneurs lacking business knowledge and competences in the medical technology sector

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Abstract

Key words: scientific entrepreneurship – medical technology sector – lean start-up approach – business knowledge – innovation barriers and challenges in medtech

One of the causes of the hampering innovation in the medtech sector is the lack of business knowledge and competences of the scientific entrepreneurs, managing the medtech firms. Building a medtech firm is a challenge, and the required entrepreneurial skills are out of the comfort zone of a scientist. The Lean Start-up approach could be the solution to this problem, challenging scientific entrepreneurs to go outside their comfort one in order to gain this knowledge. However little scientific evidence exists for the practical success of this approach in the medtech sector.

The aim of this research is to explore, analyze, and explain the use of the Lean Start-up approach within medtech start-ups. The main research question is *"How do medtech start-ups apply the Lean Start-up approach, and how does this LSA support the business knowledge creation process within these start-ups?"* 7 Dutch medtech firms that apply the approach have been investigated, as well as a deviant case that does not apply the Lean Start-up approach. The perspective of 3 incubators have also been taken into account. The ultimate goal is to build a theoretical framework of how the Lean Start-up approach is applied in the medtech sector. It is interesting to fill this gap in literature and investigate how scientific entrepreneurs operate in their uncertain high risk environment. Gaining these insights can lead to more innovative medtech innovations in a quicker and cheaper way, with the ultimate goal of lowering healthcare costs and an increase in quality of life.

Results show that the Lean start-up approach appeared to be a suitable approach for scientific entrepreneurs to gain knowledge about entrepreneurship in the medical technology sector. The Lean start-up approach contributes to the awareness of the complexity of the market, but the step towards the market and business competences to get them out of the comfort zone seems to remain hard-to-reach. For gaining these skills support is required. Testing the medtech product in the market is where the biggest challenges can be found for the medtech industry. A recommendation for start-ups is to search for help. Search for people who can help in validating the business model and support in the step towards the market.

Samenvatting

Kernwoorden: wetenschappelijk ondernemerschap – medisch technologische sector – lean start-up approach – business kennis – innovatie barrières en uitdagingen in de medtech

Een probleem met innovatie in de medisch technologische sector is dat wetenschappelijke ondernemers business kennis en competenties missen die nodig zijn voor het managen van medisch technologische bedrijven. Het bouwen van een medisch technologisch bedrijf is een uitdaging en de benodigde ondernemerschapsvaardigheden bevinden zich buiten de comfort zone van een wetenschapper. De Lean Start-up approach heeft in theorie de potentie om de wetenschappelijke ondernemers de missende business kennis bij te brengen. Echter is er geen wetenschappelijk bewijs van het succes van de Lean start-up approach toegepast in de medische sector.

Het doel van dit onderzoek is om het gebruik van de Lean Start-up approach te analyseren in de medisch technologische sector. De onderzoeksvraag luidt: "*Hoe passen medisch technologische start-ups de Lean Start-up approach toe en hoe draagt deze approach bij aan het creëerden van business kennis binnen deze start-ups?"* 7 Nederlandse medisch technologische bedrijven die de Lean start-up approach toepassen zijn onderzocht, evenals een afwijkende case die de Lean start-up niet toepast. Ook zijn de perspectieven van 3 incubators meegenomen in het onderzoek. Het uiteindelijke doel is het bouwen van een theoretisch raamwerk dat inzicht geeft in hoe de Lean Start-up approach wordt toegepast in de medisch technologische sector. Het is interessant om deze toevoeging te geven aan de huidige literatuur en om te kijken hoe wetenschappelijke ondernemers opereren in hun onzekere en risicovolle omgeving. Het verkrijgen van deze inzichten kan leiden tot meer innovatieve medtech producten op een goedkopere en snellere manier, wat uiteindelijk leidt tot lagere kosten in de medische sector en een verhoogde kwaliteit van leven.

Resultaten van het onderzoek laten zien dat de Lean Start-up approach een passende manier is voor wetenschappelijke ondernemers om kennis over ondernemerschap op te doen in de medisch technologische sector. De Lean start-up approach draagt bij aan de bewustwording van de complexiteit van de markt, maar de stap naar de markt en de vaardigheden om uit de comfort zone te stappen blijft lastig voor wetenschappelijke ondernemers. Voor het verkrijgen van deze vaardigheden is begeleiding nodig. Het testen van de producten in de markt blijkt de grootste uitdaging in voor de medische industrie. Een aanbeveling voor start-ups is om begeleiding te zoeken. Het is belangrijk om hulp te krijgen van mensen die ervaring hebben met het valideren van business modellen en de stap naar de markt begeleiden.

Table of Content

1. Introduction

"Scientific entrepreneurs lack business knowledge and competences"

Health related spending grows each year. Costs and pressure on the healthcare system lead to significant challenges and opportunities for businesses, especially for high-tech small firms in the medical technology sector (Kaiser, 2009). Innovation is widely regarded to be the key to solving these challenges and opportunities for businesses and healthtech is seen as a potential way to improve the quality of life and reduce health care costs (Foray et al., 2012; Chatterji, 2009). Medtech covers all systems, procedures and devices developed to solve health problems and improve quality of life. However, innovation within the medical-technology (medtech) sector is not easy, since this sector is complex and fragmented (Faulkner, 2009). It takes years to develop a fully designed medical technology and around 50% of all medical patents never end up in a commercialized product (Metcalfe et al., 2005; Mattes et al., 2006). The medtech market is highly regulated, certification is needed to sell a medtech product in the Dutch market. A medtech product must be validated by manufacturers, test houses, inspection for health care and the medical instrumental department of a hospital (Medical Technology, n.d.). Besides certification and validation medical ethical comities need to give approval to all medical scientific research (UMCUtrecht, n.d.).

1.1 Problem description

A problem with medical innovations is that breakthrough technologies often have difficulty finding their way through the path from solution in the laboratory to economically viable health care products (Davey et al., 2011). Innovation speed is failing to keep up with the growing demand by our society (NLC accelerating healthtech inventions, n.d.).

Complex medtech environment

This failing innovation speed can be explained by the uncertain nature of the sector. This uncertainty is due to both complexities of the environment as well as the increase in technological complexity. Davey et al. (2011) argue the medtech sector has a multi stake-holder environment and is *"highly fragmented, constantly changing, heavily regulated and global in nature"* (p810). Foray et al. (2012) argue there is a high level of uncertainty and risk associated to medtech development: *"medical technologies face high uncertainty in both demand and technology"* (p25). This increase in technological uncertainty can be assigned to the phenomenon that several technological fields come together, a phenomenon is called 'converging technologies' (Doorn, 2006). Mainly progression in the fields of biology, nanotechnology, social sciences and material engineering are of importance in this development. Several medical applications that are developed that cannot be classified according to existing systems and they need new implementation strategies (Doorn, 2006). These implementation strategies require innovative business models. However scientific entrepreneurs (SEs) find it hard to experiment and validate innovative business model (Foray et al. 2012).

Required innovation management competences

This high risk environment of medtech firms requires specific innovation management skills (Furr and Dyer, 2014). According to Miron-Schatz et al. (2014) it is hard to manage ideas into successful companies: "*Today, psychologists, physicians and other academics are increasingly developing interventions for health improvement and disease prevention, yet the leap into large-scale implementation of these interventions usually requires business knowledge"* (p.2). The most common failure factors of medtech start-ups are the lack of focus, misunderstanding of customers, too high product prices, too complex organizational structures and lacking knowledge of the reimbursement dynamics (Miron-Schatz et al., 2014). A medtech firm is a challenge, and the required entrepreneurial skills have are out of the comfort zone of a scientist or technician.

Many small firms within the medtech sector are managed by entrepreneurs with a highly scientific or technical background, instead of experience innovation managers (Brown and Sonderstorm, 2002). These SEs lack deep knowledge about how they should commercialize their technology (Boussaroua and Deaking, 1999). Scientific entrepreneurs have a simplified view of business and management issues, and are putting too much energy in the technical product development (Brown and Sonderstorm, 2002). Taken together, most researchers with a scientific or technical background lack understanding of the business world and do not have the right competences to develop their ideas into a viable business (Miron-Schatz et al., 2014). In general, the lacking business knowledge and competences of SEs is one of the causes of the hampering innovation in the medtech sector.

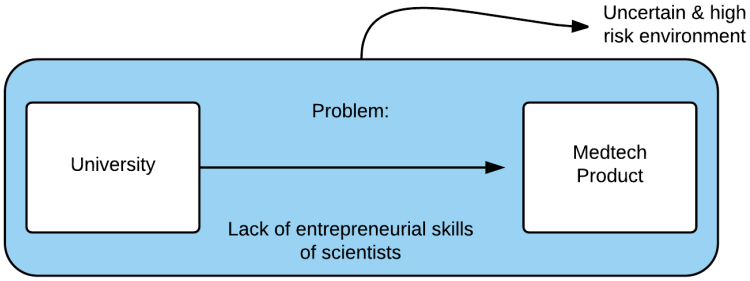


Figure 1. Problem visualization

1.2 Potential solution

In 2011 a method has been developed to break down the barriers and limiting failing factors for start-ups, called the *Lean Start-up Approach* (Ries, 2011; Blank, 2013). The main goal of the LSA is to build and test a 'minimal viable product' (MVP) as quickly as possible, and by that validate and refine the business model of a start-up. The principles can be summarized in the 'Build Measure Learn feedback loop'. The goal is by minimizing the total time through this loop, and keep release products iterative by incremental innovations. After one MVP the feedback from the customer must be taken into account when building the next MVP (Ries, 2011). One of the most important lessons of the scientific lean method: if you cannot fail, you cannot learn (Ries, 2011). The LSA will be explained in more detail in the theory section.

This approach has in theory the potential to help the SEs to gain the needed business knowledge, because it is a scientific based approach to test hypotheses, and validate risky assumptions by means of experimenting. As the LSA is a scientific approach it is likely to fit within the absorptive capacity of SEs. The LSA is originated from the software and ICT entrepreneurship, but according to Ries (2011) this scientific entrepreneurial approach works across all industries and sectors. However, little scientific evidence exists for LSA's practical success in the medtech sector.

LSA as deductive method of testing

Because the LSA is based on the statement that valid knowledge can only be created by constant testing the hypotheses and assumptions with the empirical world, it can be seen as a knowledge creation tool, just like science. Science and knowledge creation are cycles of conjectures and refutations, which are similar to the hypotheses and experimenting of the LSA. The LSA shows similarities with the deductive method of testing (Popper, 1959). He argues the deductive method of testing is the proper way of doing science. Science should not start with observations, but start with theories, and scientists should try to falsify statements which can be logically derived from these theories (Popper, 1959). It must be possible for a scientific system to be refuted by experience; a theory should be confronted with experiments to find out whether the new consequences of the theory are able to stand up to the demands of practice (Popper, 1959). If no reason can be found for discarding the theory the theory can be verified. *"I refuse to accept the view that there are statements in science which we have to accept as true merely because it does not*

seem possible to test them" (Popper, 1959 p48). Taken together, the LSA has the potential to be a knowledge creation mechanism, because the LSA shows similarities with the deductive method of testing and theoretically seems to be within the absorptive capacity of SEs.

1.3 Aim of the research

This research has an explorative approach and looked at whether, and under what conditions, it is possible for SEs to take advantage of the LSA by means of gaining business knowledge and competences. For this research we define medtech start-ups as firms that are involved with the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of live (WHO, n.d.). The following research question has been developed:

"How do medtech start-ups apply the Lean Start-up approach, and how does this LSA support the business knowledge creation process within these start-ups?"

Three sub questions have been developed in order to assist in answering the main research question. First of all it was interesting to investigate whether the problem of the lacking business competences is recognized by the SEs: 'How do scientific entrepreneurs experience their own business knowledge and competences?' Secondly there has been analyzed whether the SEs experience a growth in business knowledge and competences by actively applying the LSA: 'Do scientific entrepreneurs experience a growth in business knowledge and competences by applying the LSA, and if so what sort of knowledge is gained?' Ultimately it was interesting to find out what insights can be gained about the complex medtech sector by observing medtech start-ups applying the LSA: 'What insights can be gained about the complex medtech sector by observing medtech start-ups applying the LSA?'

The goal of this research was to strive for a more intensive theorizing along the lines set out in the theory section. Thus to build theoretical explanation around existing models of the lean start-up approach. To meet this aim, an explorative qualitative research design (Eisenhardt, 1989) was selected to obtain the experiences of the SEs. There has been chosen to analyze and observe 7 medtech start-ups in detail. One of these companies is a deviant case, a firm that is not familiar with the LSA. Furthermore the results of the experiences of the SEs have been discussed with incubators in the Netherlands that have a proven track record in supporting medtech ventures. The opportunities for the data collection have been made possible by the extensive network of NLC (NLC accelerating healthtech inventions, n.d.). NLC is a company that co-founds medtech companies and accelerates the business development of these medtech companies. An internship at this company made it possible to study and analyze the cases of this research in detail, and gaining deep insights about the medtech and start-up sector in the Netherlands.

1.4 Justification

The relevance of this thesis is in twofold. First of all it contributes to the relatively unexplored field of scientific entrepreneurship in the medtech sector. A lot of management literature has been written about the innovation process of large companies, for example by Christensen, Chesbrough, Osterwalder et al. and von Hippel (Blank, 2013). Despite the difficulties in investigating SEs, the understanding of the micro foundations of scientific entrepreneurship for smaller companies is also increasing (Menzies, 2012; Smart and Conant, 1994; Ziman, 1984; Morris et al., 2002; Mathieu et al., 2008; Miron-Schatz et al., 2014; Louis et al., 1989; Shane, 2004). The role transition of researchers becoming an entrepreneur isn't easy and business knowledge and skills are lacking in the early phase of the commercializing process (Rasmussen et al., 2011). This research will contribute in this strand of literature on role transitions, by means of studying whether the lacking business knowledge hindering the role transition into entrepreneur can be gained by experimenting and validating innovative business model using LSA principles and tools. In this thesis there has been investigated whether applying the, for other sectors proven, lean start-up approach can support the role transition from scientists to entrepreneur.

The societal relevance of this research can be explained by economic arguments. High tech start-ups play a prominent role in the current economy (Clarysse and Moray, 2004). Getting more insights about what business knowledge and competences the SEs lack, and whether they can gain it by applying the LSA, could eventually lead to a lower start-up failure rate in the medtech sector. This lower medtech start-up failure rate could lead to an economy that is driven by the expansion of start-ups. This research could help SEs by the decision whether or not to apply the LSA as innovation management philosophy, and can give insights in what business competences and knowledge scientists lack for managing a medtech company in the uncertain high risk medtech industry. If the LSA proves to be a good tool for gaining business experiences, it can be applied more frequently by SEs. This can at the end help develop medtech innovations more quickly and cheaper than when applying traditional management. Gaining more insights in the medtech industry and in the competences of SEs can furthermore help incubator programs in improving their strategy for supporting medtech start-ups. If innovative medtech innovation can be developed quicker and cheaper, this leads to lower healthcare costs and increases of quality of life.

The next section will provide theoretical background on scientific entrepreneurship, business models and the lean approach. In the method section the case selection, operationalization, empirical approach and data analysis of this research will be explained. The result section gives results of the analyzed SEs and incubators. In the discussion the proposed theoretical framework will be presented. In the conclusion an answer will be given to the research question. Finally a management implication will be given to NLC.

2. Theoretical framework

"Creating business models under conditions of high uncertainty"

The ultimate goal of this research was to analyze how scientific entrepreneurs apply the LSA in their uncertain and complex sector, and how effectively this LSA is as a process of gaining the lacking entrepreneurial knowledge and competences. First there will be given some definitions about the medtech industry and medical devices, followed by an overview of the current literature on scientific entrepreneurship. Then an overview about literature on business models will be presented. This because it is important for SEs to understand how to validate a business model, since the business model ensures that the technological core of an innovation delivers value to a customer. The goal of the LSA is to validate business models as quickly as possible with deep information about the market and customer. Lastly there will be given a description of the ideas and concepts behind the LSA.

The medtech industry is complex, highly fragmented, paradoxical, obscure, uncertain in both demand and technology, risky, constantly changing, and heavily regulated (Faulkner, 2009). The uncertainties of the medtech market can be related "*to the technology, uncertainties concerning the existence of sufficient demand, significant fixed costs that are not easily recoverable etc.*" (Colombo et al., 2010 p3). The medtech industry encompasses "*therapeutic, diagnostic, screening, inert and powered technologies" (*Faulkner, 2009 p28*)*. The WHO states about medical devices: "*means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software material or other similar or related article"* used in healthcare and not working by "*pharmacological, immunological or metabolic means" ,* in other words not a drug (WHO medical device, n.d.). Medical devices are multisided, and have to do with doctors, patients, hospital, insurance, reimbursement, FDA and clinical trials (Blank, 2013).

2.1 Scientific Entrepreneurs

Most founders in complex high tech firms are technical entrepreneurs without deep knowledge of how they could commercialize their technology (Boussouara and Deakins, 1999). Scientific entrepreneurs recognize their lack of management background as a potential barrier to success (Samson and Gurdon, 1993). Scientific entrepreneurs are hard to study since they are rare, and it is difficult to recruit scientific entrepreneurs for a research project (Oliver, 2004; Göktepe-Hultén, 2008; Menzies, 2012; Aldridge and Audretsch, 2011). Despite these difficulties, the understanding of the micro foundations of scientific entrepreneurship is increasing (Menzies, 2012; Smart and Conant, 1994; Ziman, 1984; Morris et al., 2002; Mathieu et al., 2008; Miron-Schatz et al., 2014; Louis et al., 1989; Shane, 2004).

Samsom and Gurdon(1993) zoomed into the career life of scientists who are taken an entrepreneurial role. The role transition from scientist to entrepreneur is related to character, competence, knowledge and cultural differences. Star scientist played a disproportionally significant role in the commercialization of bioscience inventions (Zucker and Darby, 1996). The world of commercialization is for most scientists a non-trivial challenge (Jain et al., 2009). *"Such involvement typically requires these individuals to modify their role identity – which is defined in the social psychology literature as a self-view of a meaning attributed to oneself in relation to a specific role"* (Jain et al., 2009 p923). The culture of the scientist appeared to be different from the culture of business. "*Businessmen appear to feel that scientists demonstrates unwarranted perfectionism in trying to achieve further technological development which goes beyond marketplace needs and demands" (*Samsom and Gurdon, 1993 p66).

There can appear conflicts due to the different normative cultures of the university and business world (Jain et al., 2009). *"It may require a fundamental reassessment of their abilities, belief and priorities, and even their view of meaning of their work"* (Jain et al., 2009 p923). See table 1 for the comparison of the role identity of scientists and entrepreneurs. Menzis (2012) also investigated the differences between

the role of the entrepreneur and scientist: *"scientists are recognized as being impartial, methodical and analytical and having good intellects and deep technical knowledge and skill. In contrast to entrepreneurs they are often seen as introspective, perfectionist and vey autonomous to the point of being somewhat isolated" (p13).* Menzies (2012) described the needed competences for an entrepreneur: "*entrepreneurs need a considerable amount of social and interpersonal skill to build and cultivate networks and other social capital that will enable them to glean the information and resources they need"* (p3). Entrepreneurs need to be creative, visionary, opportunistic, intentional and controlling (Smart and Conant, 1994). Scientists, who are insiders, may have to become outsiders when they start building a business (Ziman, 1984; Morris et al, 2002; Mathieu et al., 2008).

Table 1. Academic and Entrepreneurial role identity compared (Jain et al., 2009)

	Academic	Entrepreneurial
Norms	Universalism	Uniqueness
	Communism	Private Property
	Disinterestedness	Passion
	Skepticism	Optimism
Process	Experimentation	Focus
	Long-term orientation	Short-term orientation
	Individualistic/Small group	Team management
Outputs	Papers	Products
	Peer recognition/Status	Profits

There can be concluded that there is a difference between entrepreneurs and scientists speaking of character, competences, experience and knowledge. The role transition of researcher becoming an entrepreneur isn't easy, and business knowledge and skills are lacking in the early phase of the commercializing process. Being a SE asks for an exceptional combination of experience and skills. The scientists need to learn a lot when they start commercializing their invention. A broad set of different competencies is needed, but are not readily available (Rasmussen et al., 2011). They have to be developed or acquired during the role transition and early phase of the commercialization process (Rasmussen et al., 2011). The scientist need to learn how to be an entrepreneur when starting a medtech company (Ziman, 1984; Morris et al, 2002; Mathieu et al., 2008).. This appears to be hard, and the highly scientific entrepreneurs have an overly simplified view of business issues. This research will contribute in this strand of literature by means of investigating whether the lacking business knowledge can be gained by building, experimenting and validating innovative business models, using proven LSA principles and tools.

2.2 Business model as unit of analysis

The LSA is based on validating and experimenting with business models. In this paragraph the scientific background will be given on what business models are and how it is related to innovation and time. 'Business model' is a term that has occurred since the internet boom (Magretta, 2002). Since the mid-1990s dot-com firms had to pitch their business model to attract funding (Shafer et al 2005). New communication and computing technology led to more customer choices, and the need of customers became more centric (Teece, 2010). "*Internet has raised fundamental questions about how businesses should deliver value to the customer, and how they can capture value from delivering new information*

services that users often expect to receive without charge….and customer power has increased as comparison shopping has been made easier" (Teece, 2010 p172). These developments asks for a re-evaluation of value propositions that firms present to customers. A well-developed business model is needed in many sectors. There has been performed research into the origin of business models, the function of business models, their importance and about the reshaping of business models (Magretta, 2002; Teece, 2010; Shafer et al., 2005; Osterwalder et al., 2005; Morris et al., 2005; Chesbrough and Rosenbloom, 2002; Clarysse and Moray, 2004; Linder and Cantrell, 2000; Hamel, 2000).

Business models are a new unit of analysis that can be observed and compared (Osterwalder et al., 2005). There are a lot of definition of the term 'business model' used in the literature in papers found between 2002 and 2010. There is no consensus regarding the definition and evolution of business models (Morris et al. 2005). Chesbrough and Rosenbloom (2002) for example mention that a business model is a focusing device that mediates between technology development and economic value creation. For this research the most recent definition of business models will be used: "*a business model reflects management's hypothesis about what customers want, how they want it and why they will pay, and how an enterprise can organize to best meet customer needs, and get paid well for doing so*" (Teece, 2010 p191).

Business models have several functions, such as articulation of the value proposition, identification of market segment, definition of the structure of the value chain, estimation of cost structure and profit potential, description of business within the larger value network and the formulation of the competitive strategy (Chesbrough and Rosenbloom, 2002). The crucial role of a business model is eventually to ensure that the technological core of an innovation delivers value to a customer (Chesbrough and Rosenbloom, 2002). Since this value creation is not only a matter of technical uncertainty, but also of economic uncertainty, it is important to identify all possible different models, which requires knowledge of both the technology and the market (Chesbrough and Rosenbloom, 2002). A formal and modular business model approach can foster innovation (Osterwalder et al., 2005). The creation of new organizational forms and business model innovation get too little attention in advanced technologically progressive societies (Teece, 2010). It is important for SEs to understand how to validate a business model since the business model ensures that the technological core of an innovation deliver value to the customer.

Business models are not a snapshot of the description of a specific moment in time, but they change rapidly (Hamel, 2000; Linder and Cartrell, 2000). This reshaping of business models creates possibilities to discover new opportunities for technical and economic value (Chesbrough and Rosenbloom, 2002). It is important to experiment with business models, and there is never an ultimate model (Morris et al., 2005; Shafer et al., 2005). The adoption of new business models and the change of existing ones is visualized in figure 2. A conceptualized model is needed to modify certain elements of an existing model. "*Modification is, without doubt, essential in an uncertain and rapidly changing competitive landscape*" (Osterwalder et al., 2005 p15). Teece (2010) explains adjusting and improving business models is a complex art. Business models must morph over time and change just like technologies, legal structures and markets do (Teece, 2010). Reshaping business models is a key foundation of dynamic capabilities (Teece, 2010). When SEs learn how to adapt, validate and experiment with business models, this can possibly help them in their role transition from scientist to entrepreneur. By validating the business model they can learn what entrepreneurial activities they should perform.

A lot of models fail because of faulty assumptions about customer behavior. "*They are solutions in search of a problem"* (Magretta, 2002 p6). Within the early phase of a high tech start-up, the most important activity is to develop the technology while using customers as the major source of information (Clarysse and Moray, 2004). The lean start-up approach has a strong focus on shaping business models by involving the customer.

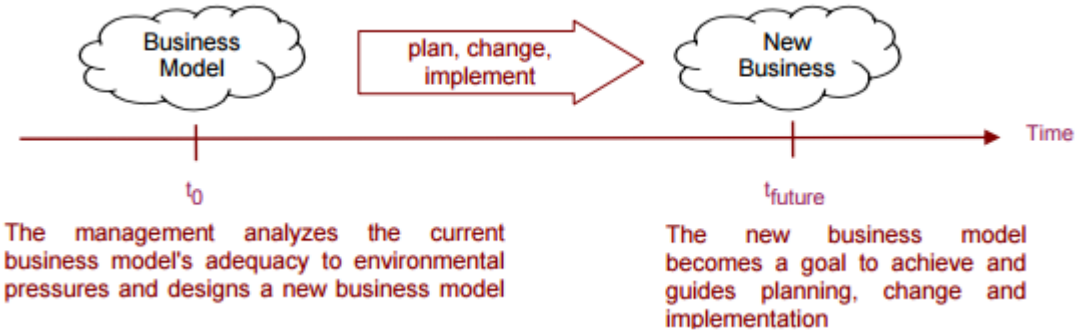


Figure 2. Reshaping business models (Osterwalder et al., 2005)

2.3 Lean start-up approach as solution

Validating and experimenting with business models is a possible way to help scientists identify themselves with entrepreneurs. However keep experimenting and adjusting the business model appears to be a complex art. The Lean Start-up approach is a scientific entrepreneurial approach that helps entrepreneurs to be aware of the importance of keep reshaping their business models. The goal of the LSA is to validate business models as quickly as possible with deep information about the market and customer. Thus it helps to keep reshaping business model over time and by that breaking down the barriers of failing factors for start-ups (Ries, 2011; Blank, 2013). The LSA has the potential to be a way for SEs to support the role transition from scientist to entrepreneur. The support in reshaping the business model can be a mechanism of business knowledge creation, and guide the SEs in what entrepreneurial activities they should perform. It guides the SEs in validating their business model under circumstances of high uncertainty (Ries, 2011). Since it is a scientific based approach, it can possibly fit within the absorptive capacity of the SEs.

Ries (2011 p31) states that *"Innovation is a bottoms-up, decentralized, and unpredictable thing, but that doesn't mean it cannot be managed"*. The LSA has been developed with the goal to make the process of starting a company less risky (Blank, 2013). "*It favors experimentation over overelaborate planning, customer feedback over intuition, and interactive design over traditional big design up front development"* (Blank, 2013 p4). The goal is to improve the chances of success for new ventures by fail and learn fast. The LSA provides a scientific based approach to test hypotheses, validate risky assumptions of start-ups and consequentially breaking down the barriers of failing factors for start-ups. The LSA reduces high costs caused by long development cycles and getting the product wrong. The LSA has the goal to help launch ventures with products that customers actually want, in a quicker and cheaper way. Blank (2013) even claims that the lean start-up approach can also be applied to large companies. He gives examples including General Electric, QUALCOMM, and Intuit that all have started to implement the lean start-up approach (Blank, 2013).

According to the LSA all entrepreneurs must accept that all they have in the first phase of their start-up is a series of untested hypothesis. These untested hypotheses are summarized in a 'Business Model Canvas'. The BMC is a tool to systematically invent, design and implements new business models. The BMC thus provides a visual, easily understandable summary about the business model of a start-up. The elements within the business model canvas are: key partners, key activities, key resources, value proposition, customer relationships, channels, customer segments, cost structure and revenue streams. This business model canvas is a document with the key business model assumptions in a portable format, which can be discussed and shared with others (Maurya, 2012).

SEs should get out of the building and test the hypotheses that are visualized in the business model canvas. The goal is to get early customer feedback on several prototype versions. To learn what customers really want, validated learning should be applied. "*Validated learning is the process of demonstrating empirically that a team has discovered valuable truths about a start-up's present and future business prospects. It is more concrete, more accurate, and faster than market forecasting or classical business planning"* (Ries, 2011 p38). The LSA is initiated from the software industry and ICT entrepreneurship. The goal is to eliminate waste time and resources, and develop products incrementally hand in hand with customer development

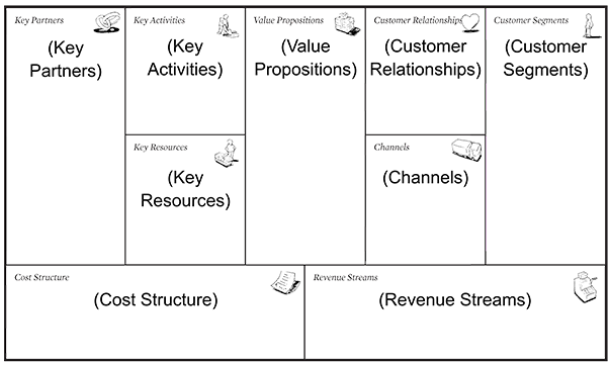


Figure 3. Business Model Canvas (Osterwalder & Pigneur, 2010)

The main goal of the lean start-up is to build and test the Minimal Viable Product (MVP) as quickly as possible, and by that validate and refine the business model of a start-up. The abovementioned principles off the LSA can be summarized in the Build-Measure-Learn feedback loop (BML) feedback loop, see figure 4. "*The build measure learn feedback loop is at the core of the Lean Start-up model" (Ries, 2011 p76).* It is important to minimize the total time though this feedback loop, the essence of steering a start-up (Ries, 2011). After one loop it is not over, after one MVP the feedback from the customer must be taken into account and immediately work on the next iteration (Ries, 2011). According to Ries (2011) one of the most important lessons of the scientific lean method: if you cannot fail, you cannot learn. In the build phase the MVP is build. In the measure phase the MVP will be tested on the market to get early feedback. In the learn phase there is the most important step, the pivot. It is the phase in which the difficult question comes up for every entrepreneur: "*Whether to pivot the original strategy or persevere"* (Ries, 2011 p77). Pivoting is needed when one of the assumptions/hypotheses in the business model discovered to be false.

The LSA is thus intended to create and validate business models under conditions of uncertainty. Since the LSA focuses on testing hypotheses in an experimental way, it shows similarities with Popper's ideas of conjectures and refutations (Popper, 1959). The LSA is an approach that by experimenting with hypotheses and assumptions may help by creating business knowledge for SEs that have a lack of competences on managing. This research is about investigating whether applying the philosophy of the BML feedback loop, and using the BMC contributes to the business knowledge creation of SEs. The goal of this research was to strive for a more intensive theorizing along this BML feedback loop.

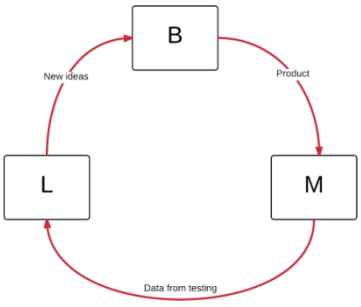


Figure 4. BML loop (Ries, 2011 p75)

3. Methodology

"Analyzing perceptions of scientific entrepreneurs and incubator manager"

The ultimate goal of this research was to build a theoretical explanation of the phenomenon of LSA applied to the medtech industry. For obtaining the experiences of the SEs a qualitative approach (Eisenhardt, 1989) is required for this research. This qualitative approach is needed to elaborate on theories about scientific entrepreneurship and the LSA principles, and zoom into the internal dynamics, activities and perspective of medtech firms. First, the case selection and data collection are discussed. Followed by the analysis and scientific quality criteria.

To identify and explain how LSA is applied within the medtech sector, this research is based on grounded theory. The LSA is used as a guideline for the interviews (Blumer, 1954). Important concepts of Ries and Blank will be used as sensitizing concepts. These sensitizing concepts will be used as starting point for analyzing the LSA within the medtech industry. The concepts that are used are: *'testing hypotheses', 'testing risky assumptions', 'fast-failure', 'learning,* and *'business model canvas', 'customer development'*. These concepts have been chosen as sensitizing concepts since they reflect the key principles of the LSA. These sensitizing concepts gives a general sense of reference and guides the empirical research (Blumer, 1954). For instance the interview guide is developed using those sensitizing concepts, to make sure the interviewee will be questioned about all the important aspects of the LSA. Those concepts are continuously kept in mind while analyzing the findings, writing the results and answering the research question.

3.1 Case selection

This explorative research makes use of purposive sampling to select research subjects of which data is extracted. Bryman (2008) explains that purposive sampling means that researchers select cases relevant for their research question. Only those cases were selected that most likely generated optimal insights into the knowledge creation mechanisms of the LSA.

Search criteria purposive sampling

To make sure only relevant cases were selected in the process of purposive sampling, clear selection criteria have been established. An overview of these criteria can be found in table 1. Data for this research has been collected from medtech start-ups as well as from incubators. The search criteria for the data from the medtech start-ups were: early stage start-ups, located in the Netherlands, developing a medical technology, apply the lean start-up approach, and have a founding manager with a highly scientific background.

The goal of analyzing medtech ventures with the abovementioned profile is to get insight into the perception of SEs that apply the LSA. There has been chosen to analyze one firm that is a deviant case as well, a firm that is not familiar with the LSA. This is because it is interesting to compare the perception of the SEs that apply the LSA with the perception of a SE that does not apply the LSA. Thus this deviant case has the selection criteria of being an early stage start-up, developing a medical technology, not applying the lean start-up approach and having a founding manager with a highly scientific background. The SE of the deviant case will be interviewed and comparable topics will be discussed, finding out how this medtech start-up functions without applying the LSA. By taking this case into account patterns can be found that differs from the start-ups that apply the LSA.

After interviewing the medtech firms, it appeared to be interesting to discuss the results of the perceptions of the SEs with experts in the field of medtech. There has been chosen to conduct the interviews with medtech entrepreneurial experts as a second round of data collection to reach theoretical saturation and to discuss the insights gained by the observation and interviews with the SEs. People with the profile of medtech entrepreneurial experts have been found by incubators, in the function of program managers and

business developers. It was interesting to discuss the result of the observations and interviews of the SEs with these people, because they have seen a lot of SEs applying the LSA principle and using LSA tools such as the BMC. These experts have more comprehensive notion of what entrepreneurship entails. Since all the SEs were in a quite early stage of commercialization, the incubators could give additional insights into what barrier the SEs could run into in later phases of their entrepreneurial process and role transition. The search criteria for the data from the incubators were: incubators located in the Netherlands, who have a proven track record in supporting medtech firms, supporting the firms by applying the LSA, supporting medtech firms that have a SE, see table 2.

The opportunities for the data collection, both for the medtech businesses as well as the incubators, have been made possible by making use of the extensive network of NLC (NLC accelerating healthtech inventions, n.d.). NLC is a firm that co-founds medtech companies and accelerates the business development of these medtech companies. They have experience in applying the LSA for rapid validation of business models. NLC has a strong network within the medtech sector, including entrepreneurs, scientists, start-ups, innovators, incubators and investors.

Table 2. Selection criteria case selection

Medtech cases	Deviant case	Incubators
Early stage	Early stage	Proven track record
Located in the Netherlands	Located in the Netherlands	Located in the Netherlands
Developing a medical technology	Developing a medical technology	Supporting medtech firms
Applying the LSA	Not applying the LSA	Supporting firms by applying LSA
Highly scientific CEO	Highly scientific CEO	Supporting firms with a highly scientific CEO

Overview case selection

The medtech start-ups that have been analyzed and thus fulfill the abovementioned criteria are CTcue, Innofuse, Incision, Wind Tales, Haermoincs, Hapticore and NIColab. The incubators that have been interviewed and fulfill the criteria are ACEVentureLab, UtrechtInc and YES!Delft. These 3 incubators are all incubators in the Netherlands that have experience with supporting medtech start-ups.

The interviews were in-depth semi-structured interviews. All these interviews have been recorded and transcribed. Besides interviews there have been made field notes while attending meeting of the start-ups. In table 3 there is an overview of what data has been collected from what firm. For instance from the firm Haermonics only field notes have been collected, the firm CTcue has been interviewed, and the firm Wind Tales has been researched by both an interview combined with field notes from meetings.

Table 3. Overview of data sources firms

Case	Code	Name	Product	Data source	Initial source
Medtech firm	1	CTcue	Matches patient data with clinical trial criteria	Interview Founder/CEO	ACE
Medtech firm	2	Innofuse	Disposable IV set improving drug administration in neonates	Interview Founder/CEO	UtrechtInc
Medtech firm	3	Incision	Online knowledge program for surgical care	Interview Operational manager	CTcue
Medtech firm	4	Wind Tales	Game for children with respiratory diseases	Interview Founder and field notes several meetings	NLC
Medtech firm (not LSA)	5	Haermonics	Flushing device open heart surgery	Field notes multiple meetings	NLC
Medtech firm	6	Hapticore	Hand and wrist rehabilitation platform	Interview Founder & Co-founder	ACE
Medtech firm	7	NIColab	Services for neurovascular multicenter clinical trials	Interview Founder/CEO & Co-founder	ACE
Medtech firm(s)	8	Bootcamp ACE	Bootcamp workshop	Field notes 3 start-ups	ACE
Incubator	A	YES!Delft	Incubator TUDelft, 21 medtech firms	Interview Incubation and growth manager	NLC
Incubator	B	ACEVentureLab	Incubator UVA, VU & HvA, 11 medtech firms	Interview Project manager	ACE
Incubator	C	UtrechtINC	Incubator Utrecht University, 8 medtech firms	Interview business developer	NLC

Below a short description of all seven firms and three incubators will be given. Here they will be only described to account for their apparent suitability for this research, based on online available information.

CTcue

CTcue was founded in late 2013. CTcue has a solution for the challenging search for clinical trial patients. CTcue matches patient data with clinical trial criteria and alerts about eligible patients. They have developed a large pool of patients. CTcue implements a multi-center patient recruitment process. CTcue has a platform with inclusion[1] and exclusion[2] criteria that can be matched with patient data in local electronic patient records. Research nurses of multi center trials can be informed about the presence of patients that fulfill the inclusion criteria of a study. CTcue is free for hospitals and researchers, and life sciences organizations need to have a license fee to use it. (CTcue, n.d.). CTcue is founded by a SE who has a background in Mechanical Engineering. For this research this scientific CEO has been interviewed.

Innofuse

Innofuse was founded in 2011 as a spin-off company from the UMC Utrecht. Current available intravenous-sets cannot perform a stable drug administration. This results in

[1] Characteristics the prospective subject must have if they are to be included in the study
[2] Characteristics that disqualify prospective subjects from inclusion in the study

unexpected fluctuations in the patients' blood pressure, heart rate and long waiting times before the effect of the medicine is noticed. These consequences are hazardous in Neonatal Intensive Care. Innofuse saw this critical need for innovation, and developed a disposable IV[3] set, improving accuracy and immediacy of drug delivery in neonates. This leads to a significantly increased patient safety. The IV set of Innofuse is designed from a user-centered perspective and suits the needs of highly specialized NICU[4] care professionals. They now have developed a totally closed infusion system to minimize risk on infections, providing the user with an ultimate sense of control in the care they can provide. Innofuse has developed this product with their partners UMC Utrecht and Pontes Medical. (Innofuse, n.d.). Innofuse was founded by a SE with a MSc in Biomedical Engineering and published several articles about IV pump systems. For this research this scientific CEO has been interviewed.

Incision

Incision has been founded in December 2014. Incision improves surgical care worldwide by changing and restructuring the way surgeons are being trained. They provide an extensive knowledge program online. They develop 3D videos of surgical procedures, filmed from a surgeon's point of view and complemented by lectures from experts. 3D is the best way to visualize a procedure. Incision produces its educational material by partnering with LUMC, UMCU, Braun, Turtle Beach and Perceptum. (Incision Group, n.d.). Incision was founded by four SEs, who all have a medical background. A MD PhD, who is surgeon and trainer in surgical oncology for almost 30 years. A MD MSc PhD, who is specialized in the integration of healthcare and science. A MD MBA, and healthcare entrepreneur in the Netherlands for more than 20 years. Finally a MSc, President and CEO of Delft Imaging Systems. For this research one of the team members, MD, has been interviewed. He has spent 7 years in med school and now joined INCISION as its operational manager.

Wind Tales

Wind Tales is a serious game developed for children with Cystic Fibrosis. Cystic Fibrosis is a pulmonary disease which thickens mucus produced by the body. To clear this thickened mucus in patients, doctors prescribe physiotherapy based on breathing exercises. Wind Tales is a game designed to make these exercises fun and exciting using a spirometer as a controller (Wind Tales, n.d.). The children breathe their way through levels and defeat bosses on either mobile devices or PC. The progress of the patient can be measured and send to the therapist. Wind Tales aims to reduce the burden of Cystic Fibrosis for both patients and their parents, by improving the compliance of the therapy in a fun way. Wind Tales develops this product with their partners 'Nederlandse Cystic Fibrosis Stichting', 'UMC Utrecht', and 'UMC st. Radboud' (Wind Tales, n.d.). Wind tales is founded by a SE, who has experience in the gaming industry and has a background in Interaction Design with a specialization in Gaming. The co-founder has a MSc in Health Food Innovation Management. This scientific co-founder has been interviewed for this research.

Haermonics

By open heart surgery excess blood needs to be drained off by the surgeon. Today, drainage systems become congested, causing blood to flow towards the pericardium[5]. This leads to complications for patients. Haermonics has developed a system that continuously flushes the wound leading to reduced risk of complications and lowers the required amount of blood transfusions. (Haermonics, n.d.). Haermonics develops this system with their partners 'AMC Amsterdam' and 'University of Amsterdam'. A SE, MD and cardiac surgeon at the Centre for congenital

[3] Intravenous
[4] Neonatal intensive care unit
[5] Tough double layered fibroserous sac which covers the heart

heart diseases Amsterdam Leiden founded Haermonics. For this research there have been made field notes during multiple meetings of the Hearmonics team.

Hapticore

Hapticore develops a rehabilitation platform for hand and wrist rehabilitation. Their system consist of three basic elements, a device, training software and a communication system. Currently there is a lack of affordable rehabilitation devices for home use, while these exercised are important for functional recovery. Hapticore enables wrist and stroke patients to perform a customized exercise program in the comfort of their own home. There is a market in the Netherlands of 40.000 trauma and 30.000 stroke patients annually that require hand/wrist therapy. The WHO even estimates that the stroke patients will increase with 30% over the next decade. (Hapticore, n.d.). Hapticore is founded by a SE who is doctor of medicine (MD), and currently performing a PhD research at the VU medical center. For this research both the SE and his co-founder have been interviewed.

NIColab

NICo-Lab

NIColab enhances clinical research by providing services in medical image management, image analysis, cloud services and scientific consultancy. NIColab develops and validates image processing techniques to enable high throughput analysis of neurovascular data. Their goal is fast processing of big neurovascular image data. NIColab aims to set new industry standards in neuroradiology. They believe in the future of health, saving lives and money. (NIColab, n.d.). NIColab is founded by two SEs. One of them has a MSc degree in Technical medicinal and Medical signaling and currently performing a PhD research at University Twente and Academic Medical Center. The other founder is master student of the Neurobiology and Neuroscience master of the University of Amsterdam. For this research both scientific entrepreneurial founders have been interviewed.

YES!Delft

YES!Delft

YES!Delft, is known as Europe's best technological incubator, with strong relationship with the TUDelft. *"With the help of innumerable colorful post-its and tables with a Business Model Canvas-print participants take a closer look at their plans"*. YES!Delft offers workshops, coaching, consultation, an investor network, events, facilities, partners and sponsors. Stakeholders of YES!Delft are the TUDelft, City of Delft and TNO. Furthermore YES!Delft is supported by the European Regional Development Fund. Before 2009 YES!Delft had 6 acquired companies within the medical technology field, and since 2009 another 12 (YES!Delft, n.d.). From YES!Delft *the Incubation and Growth Manager* has been interviewed.

ACE venture Lab

Amsterdam Center for Entrepreneurship ACE VENTURE LAB

ACE Venture Lab is an initiative of the Amsterdam Center of Entrepreneurship, which stimulates entrepreneurship and entrepreneurial behavior by students and performs research towards successful entrepreneurship. ACE is a collaboration between the UVA, the VU University and the HvA. (ACEVenturelab, n.d.) ACEVentureLab has three programs, and in all those three they focus on the Lean start-up approach, namely lean product development, business models, business assumptions and building a MVP. ACE Venture Lab has currently 10 medical related start-ups in their portfolio. From ACE Venture Lab *the Project Manager* has been interviewed.

UtrechtInc

UtrechtInc is an incubator with a strong relationship with the University Utrecht. UtrechtInc has 8 medical start-ups in their portfolio. UtrechtInc has several partners, such as the University Utrecht, Hogeschool Utrecht, UMCU Utrecht, and the Rabobank. UtrechtInc works and support start-ups according to the lean start-up method (UtrechtInc, n.d.). From UtrechtInc the *Business Developer* has been interviewed.

3.2 Data collection and analysis

The data collection and analysis took place as an iterative process in which additional data was collected to complement the provisional concept and patterns found in the first few data analysis (Bryman, 2008). Two data sources have been used to analyze the cases, interviews as well as observations.

Interviews

Interviews were semi-structured, to make sure there was some coherence between the cases. These semi-structured interviews were based on the questions listed in the interview guide in the appendix. During these interviews several topics came across, such as challenges, risky assumptions, business model, customers, finance, and validated learning. Overall, the interviews were thus focused on the LSA principles and tools, with a main focus on the business model canvas. The questionnaire was mainly used as a checklist whether all topics has been covered. In total 11 respondents were interviewed, which an average of roughly 45 minutes per interviewee. This interviewing process was restricted due to the availability and willingness of useful respondents. It was hard to find suitable medtech firms with a profile according to the selection criteria, and it wasn't easy to arrange the interviews and ask time from the entrepreneurs. Interviews were recorded and transcribed to enable the analysis afterwards. The firm Incision is a company that does not apply the LSA. During interviewing Incision, the same questions and interview topics came across as by the other scientific entrepreneurial interviews. Thus topics such as their product, mission, challenges, team formation, successes, competences, business model and risky assumptions have been discussed during the interviews. The topic of contribution of the LSA and LSA & the medical sector has however not been discussed, since Incision is not familiar with this approach.

Observations

A method that has been used to collect data was participant observations (Taylor and Bogdan, 1984). Participant observation is described by Cassell and Symon (2004, p154) as "*the idea being to allow the observer to study first-hand the day-to-day experience and behavior of subject in particular situations, and, if necessary, to talk to them about their feelings and interpretations*". An internship has been performed at the company NLC, which is a co-founding company that has the goal to accelerate the business development of medtech companies. By performing this internship a lot of opportunities appeared to observe start-ups in the medtech sector. This accounted for both inside the company as well as outside the company. First of all internally, it has been made possible to attend in meetings that were planned with the start-ups within the portfolio of NLC. Furthermore external, is has been made possible to attend in conference and events.

Meeting were attended when they appeared interesting to the study. However the possibility to visit such a meeting dependent on the approval of the participants. There were four meetings attended in the past 9 months. The research identity during the observations was as a 'participant-as-observer', which means I formed relationships and participated in activities, but did not made secret of an intention to observe the event (Burgess, 2002). One meeting was an expert meeting of the firm Wind Tales. With several medtech experts the prototype and business of Wind Tales was discussed. Furthermore another meeting of the same firm has been attended, in which the BMC has been discussed. From the firm Haermonics an expert meeting has been visited a well. During this expert meeting the several prototypes has been discussed, as well as their BMC. Finally a Bootcamp session of the ACEVentureLab has been incorporated in this research as well. During this workshop for start-ups several start-ups pitched their business model canvas

to each other and a jury. The focus during this workshop was on the revenue stream and cost focus of the start-ups. Observing these events helped extracted valuable additional information, and helped grasping the opinions that exists among SEs. Field notes have been made during these meetings which have been coded in the same way as the transcripts of the interviews.

There appeared several opportunities to attend lean start-up and or medtech related conferences. The goal of visiting these events was not to observe several stakeholders within the medtech sector and to make sure I understood the medtech sector and mechanism within the sector. The interaction during the participant observations was less intense compared to the above described meetings. Thus the research identity during these observations can be described as 'observer-as-participant', which means I maintained only superficial contacts with people being studied (Burgess, 2002). The sector is seen as complex, and the SEs have to do with quite a lot of different stakeholders. Visiting these events and talking to different people in the sector gave me more insights into the start-up-scene, the popularity of the lean start-up and the role of SEs in the medtech sector. Gaining these insights helped in the data analysis, and helped structuring and steering the interviews. By understanding the sector and understanding challenges and hurdle in the new product development system for SEs, the interviews were more in-depth then when these were only based on a literature study. Since the LSA is a practical approach, it appeared to be a good way to gain more qualitative insights of the sector by attending the start-up meetings and events. Furthermore a study tour to several universities, incubators and medtech related start-ups in San Francisco gained insights into the application of the Lean principles in the city where the LSA originated from. Seeing and understanding how the approach is applied by start-ups that have been guided by the founders of the LSA, contributed in estimating and understanding how the LSA is applied in Dutch medtech firms. The events that have been visited have been described in table 4.

Table 4. Overview events and gained insights

Name	Location	Gained insights
Innovation for health	Rai Amsterdam	Issues on cost saving in the health sector
Uprise festival	Roest Amsterdam	Understanding the Dutch start-up scene and get insights into challenges of start-ups outside the medtech sector
Eric Ries in Amsterdam	Life on Demand Amsterdam	Getting to know and see one of the founders of the LSA. Understanding the popularity of the approach in the start-up scene, across all sectors. Getting insights into the shift towards corporates that now also want to apply the LSA, such as Philips
Zorg & ICT beurs	Jaarbeurs Utrecht	The enormous amount of suppliers in the Health ICT
Dutch Life Sciences conference	Nijmegen Novio Tech Campus	Medtech will also become important in the pharma industry, focus will become more on self-monitoring of patient
Eureka Mega Challenge	UMCUtrecht	Enormous amount of valuables ideas that come from specialists and medical teams in the academic hospitals
Sustainable Healthcare challenge	Medique	Enormous amount of valuables ideas that start-ups have, but the enormous lack on finance, skills and competence to make a valuable product out of it
500 Start-ups (visiting incubator)	San Francisco	The enormous role the LSA plays in the start-up and incubators sector in San Francisco
Transence (visiting start-up)	San Francisco	The enormous role the LSA plays in the start-up and incubators sector in San Francisco. Furthermore the more aggressive way the start-ups are pushed to use and apply the LSA principles and tools compared to Dutch incubator programs.

Analysis

Theoretical coding has been applied. Theoretical coding is defined by Flick (2009, p296) *as "the procedure of analyzing data, which have been collected in order to develop a grounded theory"*. Flick (2009) also emphasizes that data collection is closely linked to interpretation, which is *the "anchoring point for making decisions about which data or cases to integrate next in the analysis and how or with which methods they should be collected"* (Flick, 2009 p296). First of all open line by line coding was applied, using sensitizing concepts has been used to develop codes. These codes were further developed into categories by applying axial coding (Flick, 2009). While coding, constant comparison has been carried out, by continuously discussing the resulting codes and categories. Also, initial categories have been adjusted, old ones eliminated and new ones added account to new details. During this axial coding strategy, a cross case analysis has been made to search for other cases in which the same learning mechanisms appeared. This axial coding finally resulted in 2 tables with the most important and promising preliminary categories, one for the medtech firms, and one for the incubators. Thereafter, by applying a more selective coding strategy (Flick, 2009), these categories have been merged into three higher level themes. The goal was to finally reach theoretical saturation. The software program NVIVO has been used to perform the abovementioned analysis steps. For the field notes the same coding principles have been applied, and the results of these field notes have been integrated in the final category table of the SEs. Eventually the results of the main themes of the medtech ventures and incubators have been merged in order to answer the sub questions and the main research question. See table 5 for a coding example.

Table 5. Coding example

Step in analysis	Interview/meeting	Transcript/field notes	Codes	Categories	3 higher level themes
Theoretical coding strategy	Interview guide	Typing	Open line by line coding	Axial coding	Selective coding
Example	What do you think medtech start-ups can learn from the use of the LSA, from applying those principles?	*"…Well it begins with identify the pains. And identify who is your customer. That way of thinking is lacking by the medical scientist…."*	'Identify pain & customer'	'Usefulness lean start-up'	'Contribution LSA'

3.3 Scientific quality criteria

It is important to meet the quality criteria of scientific research (Bryman, 2008). The internal and external reliability as well as the internal and external validity of this research will be checked.

External reliability explains the degree to which the study can be replicated. It is about *"if you apply the same procedure of measuring something, you will end up with the same results if nothing else has changed that could influence that"* (King et al., 1994 p25). It is about explaining how to move from concept to operationalization so other scholars can replicate the research and check the results (Hanké, 2009). This external reliability is met by describing the case selection and discussing the data analysis in detail, including several examples. Thus the external reliability can be guaranteed by giving insights into the coding strategy and analysis of the data. The internal reliability is about whether multiple researchers of one research team interpret their results the same (Hanké, 2009). The internal reliability of this research will be guaranteed by the fact that the coding, categorization process, developed concepts and analysis will continuously be discussed with the supervisor of this projects, as well as with colleagues of NLC, the firm where the internship took place.

Validity can also be split up in internal and external validity. Internal validity explains to which degree the observations match with the theoretical ideas (Hanké, 2009). In other words internal validity refers to whether the concepts defined are correctly expressed in the measurements that are used (Hanké, 2009). This is ensured by a critical self-evaluation, as well as iterative contact and collaboration with colleagues of NLC. Furthermore the external validity reflects the generizability of the research. The generizability of this explorative research is limited. The culture and characteristics of the medtech industry might differ outside of the Netherlands. This makes it hard to generalize the results of this research to other countries in for instance Europe or the US. Furthermore this research may inspire other researchers to also conduct a research on the LSA as knowledge creation mechanism with other case studies, which can contribute to a coherent theory about product development within the medtech industry.

4. Results

"Knowledge creation, medical barriers to innovation and complex environment"

In this chapter the results of investigating the start-ups and incubators will be presented. The findings will be discussed following the three main themes that emerged. The SEs have explained in great detail how they applied the LSA and how it contributed to their business knowledge creation process. 13 Categories have been organized in three higher level themes: *'Knowledge creation LSA', 'Medical Barriers to Innovation*', and *'Complex Environment '*. The incubator managers have also explained in detail how their experiences are with supporting medtech start-ups that apply the LSA. The emerged ten categories have been organized in the same three higher level themes as the findings of the perception of the SEs.

The theme *Knowledge Creation* LSA explains what the SEs learn about entrepreneurship in general. So this theme explains what entrepreneurial knowledge the scientists gain when applying the LSA. The theme *Medical Barriers to Innovation* clarifies what barriers the SEs face when applying the LSA in the medtech sector. It shows what conflicting issues there are with the principles and tools of the LSA when applying it in this sector. The theme *Complex Environment* explains what the SEs learn from the complex sector they are in when applying the Lean principles. These three higher level themes will be discussed in detail below.

4.1. Knowledge creation LSA

First of all a common view amongst the SEs was that they do agree with the fact that most researchers lack understanding of the business world and do not have the right competences to develop their ideas into a viable business. When asking the companies what they could have been doing better in the past, almost everyone says that they regret they didn't look for help in an earlier phase. A good example is the following quote of firm 2: "*you should quickly look for help. I am very happy now that I work together with other people. It helps for accelerating. It can be help from for instance incubators, or entrepreneurs who already have been through the phases you're in.*" Company 5 explained talking to people maybe makes them vulnerable. But they see it is required to make sure new ideas and insights will be gained from outside the company. Furthermore when searching for help, a lot of competences are needed in the firm. The SEs '*underestimated entrepreneurship*' and they admitted they have a '*lack of entrepreneurial experience*'. According to venture 7 "*no one of us is an experiences entrepreneur, I think it is really different from what we all expected it to be*". Besides missing the basic entrepreneurial background, concrete competences that are mentioned by the firms that are lacking are sales, marketing, communication and finance skills. The deviant case also admits they do not have all competences within their team. However they mainly mentioned specific surgical skills they are missing, instead of specific business competences. It seems that they are trying to solve this issue by hiring the knowledge, skills and people they are in need for.

When asking the incubators what the SEs lack in business knowledge and experience, they overall mention '*an entrepreneurial way of thinking*.' For instance SEs don't think about collaborations with partners, about how to spend certain resources and what their competitive advantage is. As incubator C confirms: "*we talk about entrepreneurship, which is something really different from what a scientist is thinking about usually.*" According to the incubators another problem with the skills of SEs is the courage of them to step towards customers. According to incubator B the SEs do not have enough attitude to actually perform the process of approaching the customer. Incubator C confirms "*they need to get used to it which takes time, you should get out of your comfort zone.*" There are several scientist who are ambitious about stepping out of their comfort zone. But even if SEs are ambitious about making the step towards the market it appeared to be hard because of the accessibility of people in the market. Other, by the incubators identified, lacking knowledge and skills of the SEs are that they have no focus on their competitors, they lack sales skills and have difficulty in understanding the complex medtech market. The ambition of the SE differs per entrepreneur and start-up. According to incubator A there are two sorts of entrepreneurs;

entrepreneurs that want to make an impact and entrepreneurs that want to make money. According to incubator A in the medtech industry you will mainly find SEs that want to make an impact on the health system. However according to incubator B there is not enough ambition to reach this impact on the health system: "*the ambition of the Dutch scientific entrepreneurs is insufficient.*"

SEs have been asked about what role the LSA and associated tools can play in this lack of understanding and lack of entrepreneurial skills. The SEs appeared to be all well aware of their most risky assumption. They can all mention what their most risky assumption is. For instance finance, market, time, profitability, subsidies, acceptance, and long prototyping. This shows that the SEs understand what risky assumptions are, and shows they have been thinking about what the risky assumptions and hypothesis for their businesses are. There are multiple SEs who are not certain if and what their exact market is, and thus are in a phase of identifying customer and customer need. Furthermore getting finance and subsidy is an issue for a lot of interviewees. According to venture 1 money is always an issue. Company 2 mentions about finance that it is important that the production of the product does not become too expensive. The SEs could also explain how they are planning to test these assumptions. According to venture 4 the period of testing depends on the assumption that has been tested. The firms test their assumptions by mapping expectations, talking to people. It is important to map the expectations of targeted customers, finding out what the customers expects from a product and what he or she is willing to pay for it. Firm 7 explained "*it is mainly talking to people, show them we exist.*" Thus looking at these results, there can be suggested that since all the companies are clear about what their risky assumption is and how they are going to test it, they become aware of the biggest hurdles and risks of their start-up, and they have a plan of how to test this assumptions.

Every company mentioned they learned the importance of getting in touch with the customers when testing risky assumptions. For example interviewee of company 1 told: "*One of the most important things you have to do, it to get in conversation with your customer, with the potential users".* By getting in touch with the customers, the SEs learn to help identifying the pains and gains from the customer. The SEs explained that the LSA helps them getting out of the comfort zone of the product development. It helps understanding the market, identify risky assumptions, testing hypotheses and formulate solutions. The SEs argue that entrepreneurship is practice. The deviant case does not apply the LSA, but they do work together with their customers to get feedback. They talk to a lot of different parties, of which their end customer are the teachers that choose the learning materials. Furthermore they perform evaluations, both when they have meetings with groups of people, but they have now also processed their feedback part in the online e-learning tool. This can be due to the more experienced SEs that founded the company, that are already known with the fact that these activities are important to perform.

Incubators also mentioned the LSA has a role in understanding the customer. The LSA contributes in understanding the customer perspective, identification of the pain of the customer and possible customer segments. For instance incubator C told: "*make sure that the firms develops products that fits with the needs of the users.*" Furthermore incubator B explained that "*the LSA, including the business model canvas, learns them to look at other possible customer segments and ways to sell the product.*" Besides the importance of the customer segment the LSA ensures a better understanding of the market. First of all understanding when a product is market ready and the market ready for paying for the product. The LSA also learns thinking strategically about how to bring the product to the market. As incubator A explains: "*the fact that SE are aware of all the important stakeholder and who to convince that their product is a good product.*" According to the incubators the LSA also leads to a better understanding of the entrepreneurial process, identifying risky assumptions and helps thinking like an entrepreneur.

The SEs and incubators have been deeply questioned about the use of the business model canvas. First of all, several SEs explained they used and filled in the business model canvas because it was part of an incubator program or a start-up challenge. For instance firm 6 "*yes because it is here (ACE venture Lab)*

in the program". Furthermore in almost every interview it appeared that the SEs completed the business model canvas by using feedback from customers. Interviewees not only stressed the importance of customer contact, but also the number of customers talking to, as illustrated by company 1: "*you have to speak a lot of people"*. SEs do not see the use of the LSA and BMC tool in first instance. Using and applying the principles has a lead time. SEs are skeptical about the entrepreneurial approach. They do not all give immediately priority towards the principles, and are critical about putting time and effort in it. Firm 7: "*in the beginning I though what is it, a business model canvas?"* It takes usually a few weeks, and they see the importance and use of the BMC and principles of the BML loop after filling in the canvas after a few times. Commercializing a technology is a complex art for the SEs, and the SEs have a very busy schedule, especially when they combine being an SE with performing a PhD research. Because of this busy schedule, they prefer putting effort and time in writing a subsidy application or working on the technical developments over filling in canvasses and contacting customers. As company 2 states: *"I noticed that because of the usual issues of the day I am too busy to take time to really analyze the canvas"*. So if the firms have deadlines or other priorities, the business model canvas does not get the full attention.

Most firms have several versions of the business model canvas. Firm 1 explained: "*yes I have been shifting in my model."* Venture 7 has not only shifted in the model, but the current version of the canvas is completely new compared to the first version. They modified it "*at least two times a week"*. They will even never stop using the canvas. They are one of the few companies that archived all versions of their canvasses. Applying and testing the business model canvas gives the entrepreneurs guidance. Company 7 explained about the canvas: "*yes, it visualizes all aspects of entrepreneurship."* Venture 1 highlights the business model canvas makes them learning from mistakes. The business model canvas is seen as a tool that visualizes the risky assumption and entrepreneurial activities. The SEs mentioned both LSA and associated BMC tool as useful since it brings them structure in entrepreneurial activities: "*What entrepreneurs do with a bit of gut feeling, the lean start-up approach brings structure" (firm1)*. Thus SEs get insights about what entrepreneurial activities they should perform in order to validate their business model. The deviant case does not make use of the business model canvas, but they do use posters and think strategically about how to make money out of their business. This result implies that the BMC is not a unique way or tool to think about the business model.

All the incubators agreed that the BMC is a tool that gives guidance and structure for ventures. As incubator C states: "*firms use it as a helpful tool, the advantage of the business model canvas is that you can see how the business looks like at a glance."* And according to incubator B "*scientific entrepreneurs have no clue where to start, which becomes with the business model canvas really concrete."* Incubator C told start-ups that use the BMC learn who their customers are, and how to earn money. According to incubator A the BMC is a tool used by start-ups mainly when there is an overload of information. When there is chaos the BMC is used to provide the needed structure to move forward with the business. The incubators told that the final goal of applying the BMC is a faster and cheaper market validation, and to make sure the start-ups do not fall back on technology. They also mentioned the importance of the value proposition element of the BMC, mainly in the beginning of the process. To make sure the pain and gains of the customer and the gain creators and pain relievers of the start-ups are clearly defined. Incubator B explained that the SEs learn to stop their technological product development and start earlier with selling the product. Incubator C argues it is the most important part of the LSA, learning to involve the customer into the product development process and make sure the implementation of the technology takes place earlier. Besides identifying and testing risky assumptions and getting in contact with the customer, the SEs learn about the network importance in the medical world. Since understanding the complex environment and the importance of networking is such a big requirement in the medtech sector, it is described as a separate theme: '*Complex environment'*.

An interesting insight from the incubator perspective is they are arguing start-ups need support when using the business model canvas tool. They cannot make full use of it all by themselves. As incubator B told "*it is not in their character to apply the lean process and using the BMC, they can understand it in theory and fill in the canvas, however it is hard to keep applying the method and tool in practice.*" Incubator A even states that without their program the start-ups would fail using it and fall back on their product development, and they argue they are absolutely an important guidance in the process of using the BMC. The main point where the start-ups need this support is in approaching the customer and understanding the market, or in lean terms '*getting out of the building'*. The start-ups also need support in validating assumptions. This because two out of three incubators explained that a pitfall is to validate assumptions too fast. According to incubator A " *they often think something is achieved, but if you ask deeply it appeared that it is actually not validated at all."* Another finding is that incubators stated that support is needed for testing risky assumptions. This support is needed since it appeared that the SEs find it hard to test assumptions. The venture should receive methods of how to validate customers, and how to build and test an MVP. The fact that only the incubators mentioned the importance of support can be explained in two ways. This can mean that the SEs underestimated the usefulness of the support. However this is unrealistic since the SEs all state they underestimated the business activities in first instance. Furthermore it can be due to the fact that the interviews with the SEs were not as much directed into questions about support. The role of support and education in the LSA principles might be an interesting topic to investigate for further research.

Despite the lead time and skepticism, overall the SEs are positive about the contribution of the LSA on gaining business knowledge competences. The incubator managers agree on the fact that the LSA and BMC gives the SEs structure and guidance and leads to faster market validation, however they stress the importance of support by using the LSA and associated tools. They argue without this support the start-ups will fail in learning from using the LSA tools. The fact that the incubators and entrepreneurs agree in what the SEs learn from the LSA shows that the SEs do not under or overestimated themselves in terms of knowledge creation.

4.2. Medical barriers to innovation

Overall the incubators argued the LSA is good applicable for the medtech sector, and applying the LSA helps selling the products earlier. As the following quote of incubator C illustrates: "*yes it is definitely applicable, I even think it is applicable for every market. However viewed from the build measure learn loop, you do should check the specific market requirements.*" There has been taken a look into those specific market requirements and possible barriers to innovation.

The LSA has, as described in the theme *Knowledge Creation LSA,* a strong focus on interaction with customers. This interaction with the customers is one of the most important conflicting issue between the LSA and the medical sector. This is a remarkable result since the conversation with the customer is also mentioned as something the SE learns from applying the LSA. Several customers segments have been identified: insurance companies, patients, hospitals (doctors), pharma and research companies. Firm 6 told that their product "*improves compliance of patients, which is interesting for the health insurer companies, since it can reduce costs"*. According to company 2 the customer segment is quite complex in a hospital environment when the doctor or nurse is the customer. Those members of the medical team can obstruct the commercialization process along the way. They can do this by not participating in giving feedback, not taking time to discuss prototypes and eventually by rejecting to buy and use the new product. The support of the medical team is needed, especially when the doctor and hospital is the direct customer of the product. Firm 1 mainly focuses on the pharmaceutical companies, since they solve a big problem for those firms and by that can accelerate the clinical trial procedures. The identified customer segments in the medtech sector have a big influence and important voice, and by that they can obstruct the commercialization process along the way.

The incubators mentioned the customer segment as well, and more specific the availability of people in the market, as a problem in the medtech sector. This limited accessibility of people leads to longer validation times of hypothesis and business models. Incubator B explained *"while web start-ups can validate their business model in three months, it can take at least a year in the medical sector"*. This has to do, according to incubator B, with the fact that the medical sector is a niche in which not everybody is available to talk to. Furthermore the other market characteristics appointed by the incubators which make applying the LSA harder compared to other industries are that the sector is complex, multiple customers, highly regulated, usually no consumer products, depended on IP, capital intensive, and long time to market (accounts mainly with hardware products).

Regulation can be seen as an conflicting issue when applying LSA in the medtech industry. For example from field notes of venture 4 it appeared that '*clinical validation is needed for getting CE marking'*. Regulation can hamper the acceleration, while acceleration is the goal of the LSA. Firm 6 explained that it takes at least six months before the certification is arranged. This certification is needed because it is not possible to sell a medtech product in the Dutch market without this CE classification. This CE classification is a risk classification, the lower the number, the lower the risk and the easier is the route to the market. A medtech product must be validated by manufacturers, test houses, inspection for health care (IGZ), the medical instrumental department of a hospital as well as the user (Medical Technology, n.d.). Field notes of firm 5 shows that medical ethical approval is an issue, and there are a lot of protocols that are taken into account by a medical ethical comity of an academic hospital. This medical ethical comity needs to give approval to all medical scientific researches. These protocols have to do with for instance how the participants of the research have been informed (art.6) and the way in which insurance is regulated (art.7) (UMCUtrecht, n.d.).

A common view amongst the interviewees was that it is hard to fail fast and learn fast in de medical sector. Developing an MVP is not possible for every medical technology. This has to do with both long prototyping times as well as the abovementioned regulatory affairs. It is not possible for every product to test and use an unfinished product. For example firm 2 is developing a product which is difficult to test in an early phase due to the high risk for the patients: "*infections play a major role and the impact of mistakes has to be minimal"*. This has to do with the fact that in the medical technology sector '*expensive complex products'* are developed. For firm 2 it was not easy to develop a prototype, "*it took more than two years before we had a working prototype*". Because it is hard to fail fast and learn fast, it is hard to pivot in the medical industry. According to incubator A it differs per start-up and per SE how frequently they work with the BMC. There is according to the incubators always a danger for the SEs to fall back on their technology. There is a lead time, and it takes a while until the start-ups are familiar with the BMC. Usually it takes a while, but when the start-ups come to a point of frustration, due to an overload of information, they are really willing to use the canvas to give them structure. Whilst the majority of the businesses were positive about the LSA, there was also one firm (6) that commented that the LSA was is not at all appropriate to apply to the medical sector because of this complexity, arguing the LSA is meant for mass products, and products in the medical sector are no consumer products.

Several SEs explained that the LSA is a very new way of thinking compared to the current research and hospital culture. Hospitals and science do have a focus on product development, but not at all on the implementation of those products and thus to use the products in practice. As company 7 explained "*the academic center is focused on product validation and publications."* A firm of the bootcamp session explained about the implementation of products: "*what happens in a PhD stays in a PhD and university."* This hospital culture will furthermore be discussed under the theme '*Complex Environment'*. The deviant case commented it is a challenge in the medtech sector to be a commercial firm. "*A firm that wants to make profit and help people, that's sometimes looks conflicting."* They use bodies that are donated for science, so they need to make sure their way of working is ethical accepted.

When asking the incubator what they would like to see changed in the structure of the business model canvas, not many improvements were mentioned. They however did had some remarks and observations on the use of the canvas. First of all, two of the three incubators mentioned the business model canvas is not sector specific in itself. The most specific modification recommended was by incubator B, who suggested there should be a bigger focus on IP in the canvas. He told there is not enough attention for IP within the key resources while validating the business model. It should become a specific element in the process. "*It is important for start-ups to check whether they have freedom to operate…that should be made very explicit within key resources, which should get more attention in validation the resources of medical start-ups.*" Furthermore incubator A stated if a start-up has more than 1 product, they need also to fill in more than 1 business model canvas for validating their different products. Incubator C explained it is important for an entrepreneur to have vision, and the final vision of the start-up is not a single element of the canvas. The canvas does also not pay any attention to the personal characteristics and development of the SE. So the start-ups should be aware that the canvas is really about the elements of the business, and does not pay any attention to the team and or scientific entrepreneurial skills and vision. Finally, incubator C explained besides the business model canvas the lean model canvas can be a valuable canvas to use in the beginning of the entrepreneurial process.

Interestingly, the interviewee of the deviant case did not mention as many medical barriers to innovation as the other interviewees did. This can be due to the highly experienced founder of the firm. The founders have more experience with entrepreneurship in the field, for example one of them is the founder of the consultancy firm 'Plexus'. By having more experience with entrepreneurship in the field it is possible the firm is more experiences with the barriers to innovation, and has less problems with overcoming those barriers.

These findings show that are conflicting issues between the principles of the LSA and the medtech industry, as well as conflicting issues between the BMC, and the medtech industry. First of all, the issues between the LSA principle and the medtech sector are the customer segment, regulation, limited opportunities for fast failing, research culture, and hospital culture. Furthermore the conflicting issues between the BMC tool and the medtech industry is feasibility in terms of priority and shifting times. It appeared the SEs mainly apply and used the BMC because they are enforced doing so by a certain incubator program. They fill it in by using feedback from customers and learned to talk to a lot of them. The canvas does not always get priority. It appeared to be hard to pivot in the medtech industry and prototyping times are long. Filling the canvas and keep applying the principles of the LSA seem time consuming for the SEs. It is also not always useful in their perception because the sector and market is not suitable for quick pivoting and adapting business model by default.

4.3 Complex environment

A third important theme emerging from the data is about what the SEs learn from their complex environment by applying the lean principles. About gaining awareness of the complex environment of the SEs in the medtech sector. When asking the SEs about risky assumptions and what a tricky part of entrepreneurship is, a frequently mentioned problem turned out to be understanding and handling the complex environment.

The SEs gain knowledge about the network importance of the medical world. This network is important for the entrepreneur for understanding the market and to be sure who to speak to. As firm 6 explains: "*That is the main problem in the medical world. It's about your network…. If you haven't been performing a PhD in a hospital it is difficult.*" Incubators agreed on the fact that it is important to approach different networks, as the following quote of incubator B shows "*the most important thing to pay attention to is networking with companies, investors and experienced entrepreneur.*"

One of the principles of the LSA is measuring a MVP, and validate the business model. This should be done by getting out of the building (testing with customers). By filling in the business model canvas, one of the elements of the canvas is channels. Channels towards the customers. Talking about this issue firm 1 explained: "*first I have been working on understanding the sector…what is actually going on in the sector?"* Field notes of business 5 showed that they need a better understanding of the market. They argued the LSA is a good approach to become aware of the importance of paying attention to the business model of the firm. It is important to talk to a lot of people when validating the business model: "*understanding the game better, why they are in it and how"*. The LSA forces thus to think about channels, however a majority of the firms still has difficulty in understanding the sector and finding suitable channels and stakeholders of within the sector. Incubator managers mentioned reaching these channels is hard for the start-ups. It is easier to talk to customers when making a consumer product, but this is rarely the case in the medtech sector. According to incubator B "*in healthcare, it is usually a niche product in a market where you cannot question everybody easily with an online questionnaire or so…"*

By applying the LSA, the SEs created awareness of the big influence of a medical team on the medical product development. The LSA force to talk to people and go to the market. For instance ventures 1,2 and 4 learned it is important that key opinion leader within their domain, endorses and supports the product. As interviewee of firm 2 said: "*there are some doctors conservative in the introduction of new products, and too busy to be actively engaged in the introduction of new innovative medtech products"*. Furthermore company 1 fiercely stated if the doctor is not enthusiastic about the product, he immediately quits, since without the blessing of the doctor he will not get it done. Not every hospital and doctor is thus open to innovation. Incubator A and B both emphasize the key opinion leaders have a big influence on the start-ups developments. "*In the medical world you can function faster if the key opinion leaders are in favor of you"(*incubator A).

Lastly, by applying the LSA, the firms gained knowledge about the importance of collaboration with the academic hospital when developing and testing a medtech product. Company 4 mentioned that is important that universities have thrust in your product and firm from the beginning. Not only for the network and doctors, but what can be seen in the field notes of the bootcamp is that the academic centers are also important for subsidies that come from universities that can play a major role in financing the start-up. Thus SEs, by forcing them to test their MVP, understand the priority of networking with the academic hospitals. They encounter the hospitals as important for the success rate of the technologies.

Just like the other start-ups, the deviant case has experienced difficulties with their complex environment. Just like for the lean start-ups, the external stakeholders is a frequently returning topic in the interview. They acknowledged the hierarchy and reserved culture in the hospitals. "*There are few institutions in the Netherlands as bureaucratic as the academic hospitals"*. Furthermore the deviant case has a problem with the attitude of surgeons. According to the interviewee "*the surgical world is very isolated."* All surgeons have their own way of carrying out surgeries. Firm 3 standardizes the procedures and needs to make decisions which way is the good way for carrying out those surgeries for making the e-learning movie material. Firm 3 sees this isolated world and attitude of surgeons as a big challenge. They are aware they should handle those doctors with care. This awareness can be explained by the strength of the team and by the experience within the team, which is more than the experience of the other SEs.

Looking at the theme *complex environment*, the SEs explained that they learned several aspects of the complex environment of medtech by applying the LSA. By being forced to test in an early phase, they become aware of the complexity of the market, understand the influence of the key opinion leader in medical teams, and learn the value of collaboration with academic hospitals. It is thus hard to network in the medical sector, but the incubator managers do come up with several suggestions. For instance using an existing network of for instance an incubator, trying to think differently and try speaking to the sector in another country. All the entrepreneurs, including the deviant case, understand the importance of

networking. This results might indicate, since the LSA applying entrepreneurs find the networking hard, the LSA is not by default a method that actually helps the start-ups with networking in the complex medtech industry. The results show the incubators agree on the fact that the networking is difficult for the entrepreneurs that apply the LSA. The LSA thus gives guidance and stresses the importance of networking and talking to people, but it remains a complex activity for the SEs.

Table 6. Themes and associated finding perception

Theme	Important findings
Knowledge creation LSA	Identify risky assumptions
	Understanding the market
	Understanding how to test risky assumption
	Getting into touch with customers
	Out of comfort zone product development
	BMC structures and gives guidance
	BMC support needed
	Structures entrepreneurial activities
	All aspects of innovation
Medical barriers to innovation	Complex customer segment
	Availability of people in the market
	Regulation
	It is hard to fail fast
	Complex products
	Long prototyping times
	Hard to pivot
Complex environment	Network importance
	Influence key opinion leader
	Collaboration academic hospital

5. Discussion

"The measure phase is the phase where the biggest challenges can be found for the medtech industry"

In this chapter a theoretical framework will be proposed. Furthermore a critical reflection on the sample, analysis and quality of the research will be given, followed by recommendations for further research. Finally some implication of this research will be discussed.

5.1 Proposed Theoretical Framework

First of all the results of this research will be linked back to the theoretical section. First the results will be coupled to the business model canvas, followed by the proposed theoretical framework in which the results will be linked to the Build-Measure-Learn feedback loop. The BMC can be seen as the most important tool of the LSA for validating the business model and testing the prototype, and the BML loop is a visualization of the process of validating. In the BMC the characteristics of the sector are visualized, and in the BML loop is linked to the contribution of the LSA as well as the medical barriers to innovation and the complexity of the environment of the SEs.

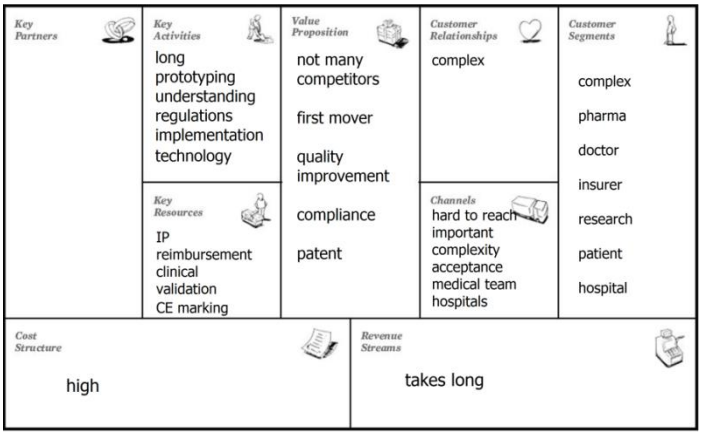


Figure 5. Business model canvas for medtech sector

Business model canvas

The most important result about this BMC tool of the LSA is that validation of the business model takes longer compared to other sectors. It can take at least a year, whereas the validation for other industries appeared to be shorter. This has to do with the accessibility of people in the market to talk to. Furthermore there appeared to be a lead time, and it takes a while until the start-ups are familiar with the BMC. It is easy to fill the canvas in a single time, however the challenge is to keep applying this tool in practice.

In this research several specific characteristics have been identified which make fast and cheap validation of the business model in the medtech sector complex, summarized in the BMC in figure 5. First of all the medical devices have high development costs. It takes long before revenue comes up. This is due to long prototyping and testing phases. Medtech products are complex both in development and regulation. The IP should have a bigger role in the business model canvas. When asking the SEs about their unique value they mention that they have not many competitors, they (think they are) first mover in the industry, several products focus on improving the compliance of certain therapies and it differs per product if there is a patent or not. There appeared various customer segments, namely: hospitals, patient, insurers, pharma, doctor and research purposes. A remarkable result within the canvas is the importance of the element channels. This part of the canvas is of very high important in the medical sector. The channels are hard to reach, and there are a lot of stakeholder. This complex stakeholder environment is perceived as complex by the SEs, by which the LSA can give structure and guidance.

Build Measure Learn loop

In the theory section the Build-Measure-Learn (BML) feedback loop has been explained, which is the core of the Lean Start-up approach. In the build phase the Minimal Viable Product (MVP) is built, in the measure phase the challenge is to measure this minimal viable product by getting feedback from customers. The learn phase is to decide whether to pivot or to persevere with the current strategy. The main goal of the LSA is to minimize the total time through the loop, and by that validate the business model of a start-up as quick as possible.

The results of the contribution of the LSA and the barriers to innovation identified in this research can be connected to the phases of the BML-loop. The main result is that the LSA does help the SE to understand the key elements of entrepreneurship, and help identifying barriers to innovation in the market. However there is no evidence the LSA directly contributes in gaining needed competences to test product in the market. The step towards the market and business competences to get them out the comfort zone seems to remain absent. When looking at the main goal of minimizing the total time through the loop of Build-Measure-Learn, it is important to look at the identified barriers to innovation in de medtech sector, and look at where these barriers have influence on this BML loop.

First of all, in the build phase the goal is to produce a minimal viable product as fast as possible. This is where the first problems appear when looking at the medtech sector. A barriers in this build phase is the long prototyping times. It appeared to be hard to build a complex product that it capital intensive in a short time. The second phase is the measure phase. This is where for the medtech industry the biggest problems appear. The measure phase is the phase that is out of the comfort zone of the scientist. Testing in the market does not always gets the priority of the SEs. If it does get the priority of the entrepreneurs it appeared to be complex because of the following hurdles they cannot handle: the complex customer segment, understand the regulations, to collaborate with academic hospitals, and to speak to key opinion leaders. Early measuring is outside their comfort zone, and communication with the customer is hard in the medical sector. The contribution of the LSA is in this phase that the SEs become aware of customers, markets, assumptions, and the importance of fast validations and getting out of the comfort zone. However although they are aware of these important activities, they do not have enough experience to handle these issues. Because there are such major problems in the medtech industry with testing the medtech products with the customers, in the learning phase there are hurdles as well. The main barrier in this learning phase is that it is hard to pivot and change strategy. This is because changing strategy is hard because the technology as well as the regulation might change as well when changing strategy. Furthermore it is hard to fail fast, due to earlier mentioned regulatory policies and technological complexity of the products.

Overall there can thus be stated when looking at the BML loop, the main problem can be found in the measure phase. Measuring and getting data from the customers appeared to be hard in the medtech industry. The LSA helps in gaining awareness of the characteristics of the industry that makes measuring hard. However, although the SEs gain this awareness, they still lack the experience and attitude to handle these problems. A possible and suggested solution for this problem is that the start-ups should get support. This support can for instance be provided by incubators. This support is required when SEs want to benefit from the LSA. Without support the SE distrusts the LSA, and validating business models does not get enough priority within the firms. The SEs underestimate entrepreneurship and lose themselves in the major difficulties of the medtech sector when they do not get help.

Thus the LSA can be applied to the medtech sector, and SEs can benefit from the approach. However they do need support to handle the barriers and difficulties they run into during the three phases. Support is a requirement when applying the LSA, and the measure phase is the phase where the biggest challenges can be found for the medtech industry. The abovementioned phases and associated barriers and contributions

of the LSA can be found in figure 6. Figure 6 shows the BML-loop for the medical technology industry, which has been created by combining the observations, insights from the SEs and incubators.

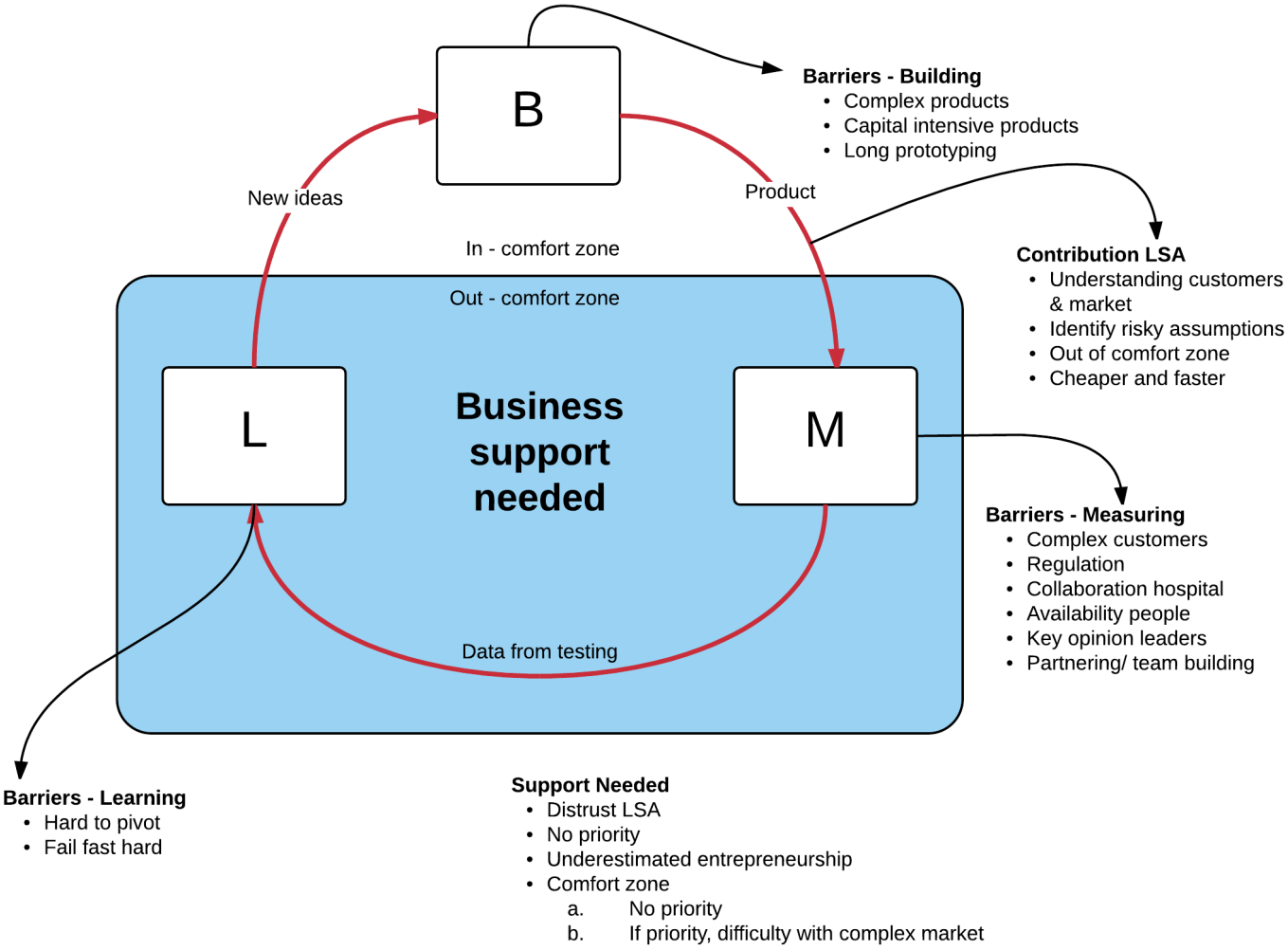


Figure 7. Proposed Theoretical Framework: BML loop for the medtech industry

5.2 Limitations

This research was a case study of the Dutch medical technology sector with a focus on early stage ventures that are managed by a SE. 7 Dutch medtech start-ups and 3 incubator managers were interviewed, and the data was complemented by field notes from meetings of the start-ups. One of the 7 Dutch medtech ventures did not apply the LSA. By choosing these interviewees, I made sure representatives of both LSA applying SEs, a not LSA applying entrepreneur as well as incubator managers were included in the research. However some notes should be made with regard to this sample of ventures.

First, one of the representatives of the venture has a more experiences entrepreneurial background compared to the other LSA applying firms. The CEO of firm 1 had more experience with entrepreneurship compared to the other interviewed CEOs, and the current firm was not the first firm he founded. However his insights about applying the LSA were so detailed and useful that there has been chosen to nevertheless

take this case into account. Furthermore it appeared that the deviant case was founded by several SEs, however they were more experiences compared to the other SEs. The founders had more experience within the entrepreneurial medtech field than expected. Because of this it was hard to compare the LSA entrepreneurs with the deviant case. This has been solved by not highlighting this case as much in the result chapter, and mainly use the other cases for interesting insights for the result section. Furthermore when performing further research, one should try to arrange more interviews with non LSA applying SEs. This might provide some additional insights in the way entrepreneurs that do not use the specific LSA approach organize their activities and routine in their start-up. Unfortunately it appeared hard to find entrepreneurs that want to cooperate in this research, since they are busy with their daily entrepreneurial activities. Due to the limited time available it was necessary to use snowball sampling to reach enough representatives of each perspective type. The network of NLC and the incubators were an important link for reaching the entrepreneurs, and helped in finding entrepreneurs that wanted to cooperate. This might have caused a bias among the results of mainly the SEs, as the interviewed people of the scientific entrepreneurial perspective were found via the network of NLC. This led to the fact that most medtech firms that have been interviewed are headquartered in Amsterdam or Utrecht area. For further research it might be interesting to involve cases from the areas of Brabant and Gelderland as well, since there are a lot of interesting medtech developments as well.

By including at least three representatives for the perspectives of the SEs and the incubator managers, triangulation was possible and therefore outliers were not taken into account when assessing an barrier to innovation or contribution of the LSA. As only one representative of each venture or incubator was interviewed, triangulation at this venture level was not possible. However, since only small-sized companies were interviewed, it is assumed that interviewing more representatives would not have resulted in much different answers. Therefor it is expected that this has not affected the results significantly.

The fact that all interviews were fully transcribed, and all full transcripts are archived to be viewed on request, and the coding and labeling process has been discussed with colleagues and the supervisor and the coding tables are presented in the appendix, in combination with a clear presentation of the final important finding, combined with a detailed analysis section in which the perspectives have been compared, makes the analysis of this research as transparent as possible. Furthermore the fact that this analysis has been so transparent, made it possible to relate the conclusions to the theoretical concepts of the BMC and the BML-loop in a structured way.

The external validity of this research is limited. The culture and characteristics of the medtech industry might differ outside of the Netherlands. This makes it hard to generalize the results of this research to other countries in for instance Europe or the US. I nevertheless hope that this research inspires other researchers to conduct similar research with other case studies, which could ultimately lead to a more coherent theory of scientific entrepreneurship in the medical technology sector.

5.3 Future research

Several medtech firms have been analyzed, and it appeared to be hard for the medtech companies to validate their business model. Therefore, a recommendation for further research is to investigate how exactly pivoting and changing strategy works in the medtech industry. It might be interesting to investigate how the business model canvasses change over time. Archiving several versions of the business model canvasses to see what changes are made in the business model. So a more longitudinal approach to see how long it takes to validate a business model exactly. This was unfortunately due to time limitation no option for this research.

Furthermore a striking result of this was that the insight that medtech firms need support in applying the LSA. The LSA appeared to be a good tool for acquiring business knowledge, however experience and skills have to be supported and educated by for instance incubators. Another suggestion for further research is to investigate what support the start-ups exactly need, and how to gain experience and business competences, since that seems to keep lacking despite applying the LSA.

5.4 Implications

Based on the results of this research, there are several managerial implications for start-ups, incubators and universities.

First of all, this research shows entrepreneurs can benefit from the LSA, however under the condition of support and education in how to get out of their comfort zone of product development. The LSA creates awareness under the scientists about the characteristics of the medtech industry. SEs find their high risk environment complex and hard to handle. A combination of applying the LSA and use the business model canvas with support from experiences business people might help SEs in managing their medtech company. Thus a recommendation for start-ups is to search for help. Search for people who can help in validate the business model, support in the step towards the market and always be aware of the danger of falling back on focusing on only the technological developments.

Furthermore implications for incubators is that they should be aware that there is always a risk for start-ups to fall back on the technological product development. It is hard for SEs to get out of the comfort zone. If they are eager to step towards the market, it appeared to be very hard. Incubators that support medtech companies should be aware of the fact that building an MVP and measuring this MVP in the market is hard in the medtech sector. Thus the start-ups should get extra support and attention in this process, and achievable goals should be set when applying the LSA in the medtech industry.

Since the LSA appeared to be a good tool for gaining knowledge about entrepreneurship, a recommendation for universities is to educate and inform students and researchers that want to start a company about the LSA and associated tools. For instance by providing guest lectures from previous researchers that successfully applied the LSA and have successful start-up that has validates the business model due to the LSA. Furthermore the universities could, if desirable in combination with governments or institutions, think about how to make the medtech industry more accessible for SEs that want to test their prototypes. For instance organizing an network event in an academic hospital where the inventors or entrepreneurs can meet with doctors and staff members of the medical team.

When the abovementioned implications are taken seriously by start-ups, incubators and universities, hopefully a more healthy entrepreneurial and innovative climate can be created for SEs. Thus eventually more innovative medical technologies will be developed under less uncertainty in a quicker and cheaper way. This could reduce health care costs and increase quality of life.

6. Conclusion

"Business knowledge can be gained by applying LSA, but help is needed for gaining competences"

The main research problem was that building a medtech company is a challenge, and the required entrepreneurial experience are about a range of skills and competences outside of the comfort zone of scientists. One of the causes of the hampering innovation in the medtech sector is due to the lack of this business knowledge and competences. This research had an explorative approach and looked at whether, and under what conditions, it is possible for SEs to take advantage of the Lean start-up approach by means of gaining the lacking business knowledge. 7 Dutch medtech start-ups and 3 incubators have been analyzed in detail in order to explore, analyze and explain how SEs apply the LSA and how effectively this is for gaining knowledge and experience. In this chapter first an answer on the three sub question will be given, followed by an answer on the main research question: *"How do medtech start-ups apply the Lean Start-up approach, and how does this LSA support the business knowledge creation process within these start-ups?"*

6.1 Lacking business knowledge

This study shows the SEs agree that most researchers do not have the right competences to develop their ideas into a viable business initially. Besides missing the basic entrepreneurial background, concrete missing skills that are mentioned by the firms are sales, marketing, communication and financing experiences. Additional findings from the incubators is that they argue the SEs lack an entrepreneurial way of thinking, they don't think about collaborations with partners, about how to spend certain resources and what their competitive advantage is. SEs need support in continuously applying the lean principles, and continuously using the associated LSA tools. The scientists themselves agree with the fact they lack skills, and they highly recommend that other SEs should look for help. The incubators argue the SEs do not have enough attitude to actually perform the process of approaching the customer. Even if SEs are ambitious to get out of their comfort zone, this step appeared to be hard because of the availability of the people in the market.

Taking into account above described conclusions, an answer can be drawn on the first sub question: *How do scientific entrepreneurs experience their own business knowledge and competences?* The SEs experience their own business knowledge and competences as insufficient, and are critical and aware of missing entrepreneurial experience. The SEs do not have enough attitude to approach the market.

6.2 Gaining business knowledge

The results of this research support the idea that entrepreneurs can learn from the LSA speaking of understanding customer and market. Results show furthermore that the lean entrepreneurial approach contributes to a better understanding of identifying risky assumptions, and helps them getting out of the comfort zone of product development. Incubator managers told the LSA gives the entrepreneurs structure and guidance.

The LSA forces the SEs to test the prototype in the market. It encourages the entrepreneurs to get early feedback and use that feedback to modify and validate the business model. Both the principles of early testing, and the BMC tool to validate the business model of the firm contributed in gaining business knowledge. First of all the LSA contributes in a better understanding of risky assumptions. The SEs are aware of what their risky assumption is and how to test this risky assumption. Frequently mentioned risky assumptions are finance, market, time and profitability. The SEs, by testing the MVP in the market, learn the importance of talking to customers. By getting in touch with the customers, the SE learn to help identify pains and gain from the customer. The LSA helps the SEs out of the comfort zone of product development. Validating the business model by using the BMC give the entrepreneurs guidance. The

entrepreneurs furthermore get insights about what entrepreneurial activities they should perform in order to validate their business model. Besides identifying and testing risky assumptions and getting in contact with the customer, the SEs learn about the network importance in the medical world. One of the most important conclusions is that the incubators stress that support is needed when applying the LSA.

Looking at the abovementioned conclusions, the answer on the second sub question can be formulated: *Do scientific entrepreneurs experience a growth in business knowledge by applying the LSA, and if so what sort of knowledge is gained?* This study indicates that the LSA SEs are positive about the contribution of the LSA on gaining their business knowledge, and they learn about all different aspects of innovation. The SEs learn what entrepreneurial activities they should perform in order to test their prototypes and validate their business model. This research however also highlights the importance of supporting start-ups in using and applying the LSA and associated tools, since without this support there is a big chance that entrepreneurs do not keep applying the LSA principles, and thus the learning process will hamper.

6.3 Understanding of the complex medtech sector

The findings of this research gave insights in the medical barriers to innovation. This research gave insights about what SEs learn by applying the LSA, and furthermore by observing the LSA applying medtech firms there have been gained insights about the medtech sector in general. First the conclusion about what SEs have learned, followed by what insights this research has created about the medtech sector.

The SEs learn about their complex environment by applying the lean principles. The SEs create awareness of the complex environment of the medtech sector. A frequently mentioned problem turned out to be understanding and handling the environment. By getting out of the building and testing and measuring a MVP, the SEs must get into touch with customers. By filling in and using the BMC, one of the elements in the BMC is channels towards the customer. The LSA forces to think about channels, however a majority of the firms still has difficulty in understanding the sector and finding suitable channel and stakeholder within the sector. By applying the LSA, the SEs create awareness of the big influence of the medical team and key opinion leaders. The SEs learn it is important to start early with networking and building relationships with the medical sector, and in particularly with important doctor in the field. Also networking with academic hospital is important when developing and testing a medtech MVP. Thus since the LSA is focused on testing an MVP in the market, the SEs understand the priority of networking. By being forced to test in an early phase, they become aware of the complexity of the market, understand the influence of the key opinion leader in medical teams, and learn the value of collaboration with academic hospitals.

Observing the LSA applying medtech firms has created interesting insights into the medtech sector. The SEs from the cases in this research do not have references with other sectors. However observations during events and being in the environment of startups and incubators made it possible to evaluate the application of LSA in the medtech sector. Insights from literature as well as gained knowledge from observation shows that validating business models and the turnaround time of the BML loop are way shorter in other sectors, such as within ICT entrepreneurship. For example regulations, IP, long prototyping times, and complex expensive products, and a diverse customer segment make applying the LSA in the medtech hard and result in longer turnaround times of the BML loop. Incubator managers mentioned that networking is difficult for SEs, also when the entrepreneurs apply the LSA. These results might indicate, since the LSA applying entrepreneurs find the networking as hard and complex as the not LSA applying entrepreneurs, the LSA is not by definition a method that actually helps the start-ups with networking in the complex medtech industry. The LSA thus gives guidance and stresses the importance of networking and talking to people, but it remains a complex activity for the SEs.

An answer can be drawn from the abovementioned conclusions on the third sub question: '*What insights can be gained about the complex medtech sector by observing medtech start-ups applying the LSA?*' Overall, the LSA contributes in the awareness of the complexity of the market. Furthermore the LSA stresses the importance of networking and approaching the market in an early stage. Unfortunately there is no evidence that the LSA helps the SEs in guiding them to approach the industry. In other words, the LSA does help the SE to understand the key elements of entrepreneurship, as well as helping to identify barriers to innovation in the market. However there is no evidence from this research showing the LSA contributes in gaining related competences needed to test products in the market. The experience with the cases in this research show that the LSA is a tool for gaining knowledge in theory, but the step towards the market and business skills to get them out of the comfort zone seems to remain absent.

6.4. Applying Lean Start-up approach

The SEs are aware of the fact that they lack entrepreneurial experience, they mainly lack an attitude to approach the market. The start-ups apply the LSA by mainly working with tools such as the business model canvas. The LSA SEs are positive about the contribution of the LSA on gaining their business knowledge competences, and say they learn all aspects of innovation, such as understanding customers, market, risky assumptions and getting out of the comfort zone. Although the SEs are positive about gaining knowledge, this research also highlights the importance of supporting start-ups in using and applying the LSA and associated tools, since without this support there is a big chance the entrepreneurs will not learn from applying the LSA. There is no evidence that the LSA helps the SEs in guiding them to approach the industry. There is only a suggested that there is an important role for the LSA in creating awareness of the complex elements of the industry. An important result is that building an MVP, testing the MVP and reducing the turnaround time of the BML loop is challenging for the medtech sector. Validating business models takes longer for medtech start-ups compared to other sectors.

To conclude, the Lean start-up approach is a suitable approach for SEs to gain knowledge about entrepreneurship in the medical technology sector, but the step towards the market and business competences to get them out of the comfort zone seems to remain hard-to-reach. Overall, looking at the uncertainty of the sector, the LSA contributes in the awareness of the complexity of the market, and makes entrepreneurs aware of IP, regulations, stakeholders and customer segments. But for gaining skills it seems to be very important for start-ups to look for support while applying the LSA. Combining insights from observations, SEs, incubators and the proposed theoretical framework, and answer can be given to the main research question. "*How do medtech start-ups apply the Lean Startup approach, and how does this LSA support the business knowledge creation process within these start-ups?*" The LSA does help the SE to understand the key elements of entrepreneurship, and helps identifying barriers to innovation in the market. However there is no evidence that the LSA directly contributes in gaining related competences needed to commercialize their product. Looking at the role transition from researcher to entrepreneur, the LSA might help the researchers to identify themselves in entrepreneurs. It helps in visualizing and creating awareness about important entrepreneurial activities to perform. The LSA should be accompanied by support, to make sure the SEs get out of their comfort zone and become an entrepreneurial scientist. SEs need support to handle the barriers and difficulties they run into during the three phases of the BML feedback loop. Support is a requirement when applying the LSA, and the measure phase is the phase where the biggest challenges can be found for the medtech industry.

7. Management Implication

NLC is a co-founding company that has the goal to accelerate the business development of medtech companies. They have experience with the LSA for rapid validation of business models. Their concept consists of model that provides start-ups in need 3 types of help, namely the 'TMF' model, which represents team, business model and finance. NLC matches an entrepreneurial manager with an inventor, and furthermore adds the team when desk analysts are needed. The goal is that the entrepreneurial manager together with the inventor builds the business according to the LSA principles. NLC has a strong network in the medtech sector, including entrepreneurs, scientists, start-ups, innovators, incubator and investors.

The results of this research confirms the usefulness of the LSA. These managerial implications for NLC are based on the proposed theoretical framework and main conclusions of the research.

NLC must keep applying the LSA principles. It appeared to be a useful entrepreneurial approach for gaining knowledge about entrepreneurship. It is recommended to make sure the principles of the LSA will be known by all employees, new start-ups and by the entrepreneurial managers. NLC should be a role model in applying the LSA principles and tools. More time and effort should be put in implementing the principles of the LSA. Just like what happens in the start-up firms in this research, NLC does not give enough priority in using and modifying the BMC.

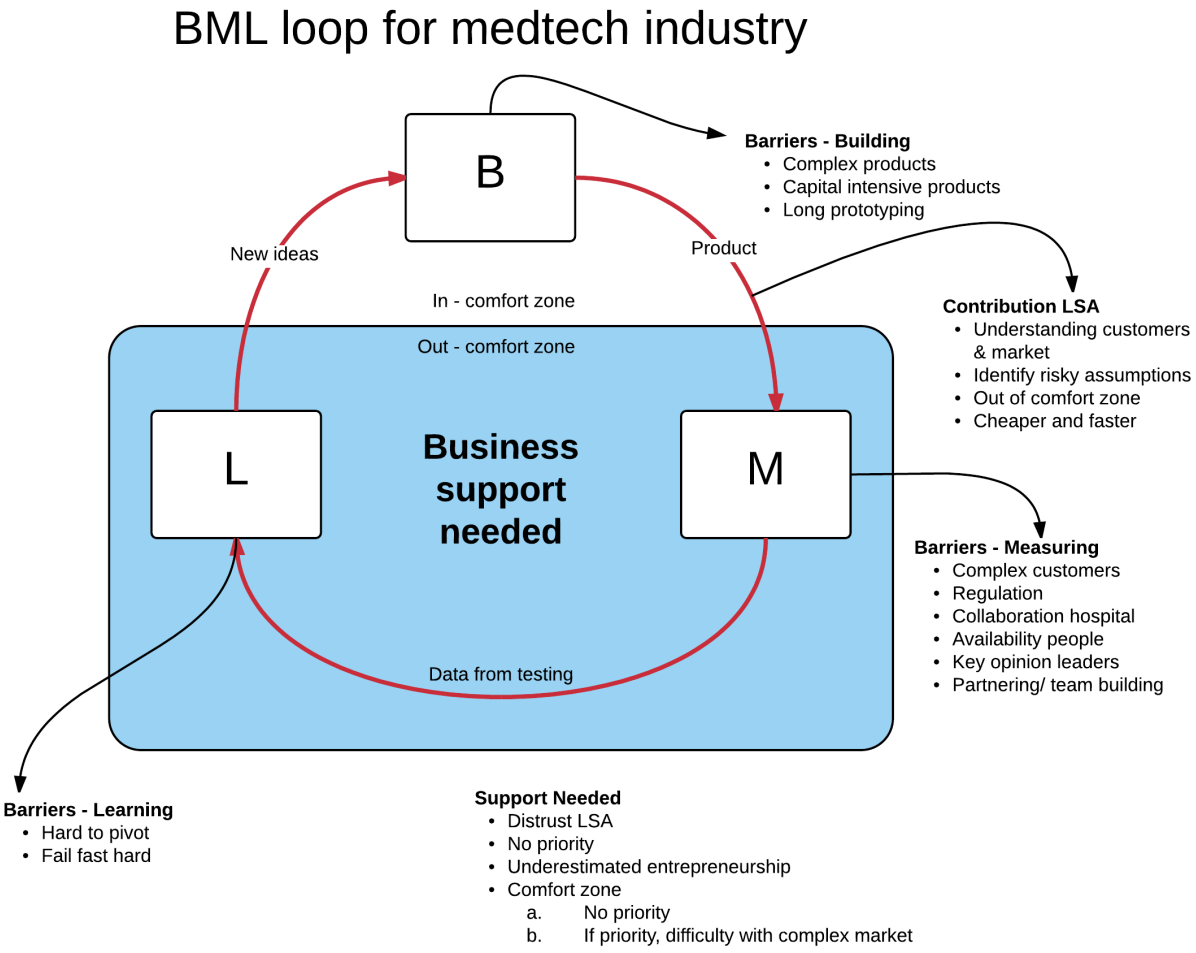
This research shows that support is needed in applying the LSA principles and tools. This support in the LSA can be given by the entrepreneurial managers. But it is required that the entrepreneurial managers understand and are experienced with the LSA principles. They must manage the start-ups using the BMC. They must help the start-ups and need to create trust by the inventors that this is the way to do. The entrepreneurial managers should get more education and workshops in the lean principles. If the start-ups get support by the entrepreneurial managers, these entrepreneurial managers should be really good aware of the importance and usefulness of the approach. Furthermore they must take a look at the barriers that have been indicated in this research in the BML loop, so they are aware of the challenges for the LSA in the medtech industry.

There is no evidence that the LSA helps the SEs in guiding them to approach the industry. It is thus important for the entrepreneurial managers to understand the medtech industry. The entrepreneurial manager should support and help the inventors in the barriers they will face during the BML loop. The biggest challenge appeared to be the measure phase, thus the biggest value the entrepreneurial can add should be in this face. During the recruitment process it is thus important to check whether the entrepreneurial managers have experience in the medtech industry. The entrepreneurial managers should have competence to handle and guide the inventor through challenge in the field of IP, regulations, complex customers segments and building a testable MVP. Furthermore the entrepreneurial manager should have a motivating role in helping the inventor out of the comfort zone. In the strategic concept of NLC the main focus of the inventor should be on the invention and developing the MVP, however it is important for the inventor to understand the LSA principals as well. The inventor should be aware of the importance of the customer feedback, and should give priority to implement this feedback in a new MVP.

By starting collaboration with a new venture and a new entrepreneurial venture it is important to set achievable goals in the beginning. It is interesting to brainstorm and think about the application of the LSA and BML loop. It is useful to apply the LSA in every start-up; however the support must be start-up specific. There must be taken a look into what product the start-up is developing, and what this means for deadlines, when to measure, who to talk to people and when to start building a new MVP. There should be taken a look at the risks of the product, and what an achievable product development time is for the first MVP. There should be made a list of risky assumptions and people whom to talk to when testing the MVP. There cannot be set one general development time for a new product, since it is very product specific how

long this should take. Thus the goal of the LSA is to minimize the total turnaround time of the BML loop. By setting achievable goals, the team can stay motivated and resources can be reduced at the same time.

Thus NLC has probably found a very interesting combination of putting knowledge and competences of inventors and entrepreneurial managers together. NLC should be a role model in applying the LSA principles and tools, in which still progress can be made. Furthermore the focus of the entrepreneurial managers should be mainly on helping the inventor into the challenging phase of measuring in the medtech sector. Helping them handle the barriers they will phase. If the abovementioned implications are taken seriously, NLC can help create a healthier entrepreneurial and innovative climate for SEs, and by that realize more innovative medical technologies under less uncertainty in a quicker and cheaper way.



References

ACE Venture Lab. (n.d.). Retrieved May 19, 2015, from http://www.ace-venturelab.org/

Aldridge, T. T., & Audretsch, D. (2011). The Bayh-Dole act and scientist entrepreneurship. *Research policy*, *40*(8), 1058-1067.

Blank, S. (2013). Why the lean start-up changes everything. *Harvard Business Review*, *91*(5), 63-72.

Blumer, H. (1954). What is wrong with social theory?. *American sociological review*, 3-10.

Boussouara, M., & Deakins, D. (1999). Market-based learning, entrepreneurship and the high technology small firm. *International Journal of Entrepreneurial Behavior & Research*, *5*(4), 204-223.

Brown, A., & Soderstrom, E. (2002). Start-up and equity primer. *Yale: Association of University Technology Managers Publication*.

Bryman, A. (2008). *Social research methods*. Oxford university press.

Burgess, R. G. (2002). *In the field: An introduction to field research*. Routledge.

Cassell, C., & Symon, G. (2004). *Essential guide to qualitative methods in organizational research*. Sage.

Chatterji, A. K. (2009). Spawned with a silver spoon? Entrepreneurial performance and innovation in the medical device industry. *Strategic Management Journal*, *30*(2), 185-206.

Chesbrough, H., & Rosenbloom, R. S. (2002). The role of the business model in capturing value from innovation: evidence from Xerox Corporation's technology spin-off companies. *Industrial and corporate change*, *11*(3), 529-555.

Clarysse, B., & Moray, N. (2004). A process study of entrepreneurial team formation: the case of a research-based spin-off. *Journal of Business Venturing*, *19*(1), 55-79.

Colombo, M., Mustar, P., & Wright, M. (2010). Dynamics of science-based entrepreneurship. *The Journal of Technology Transfer*, *35*(1), 1-15.

CTcue. (n.d.). Retrieved May 17, 2015, from http://www.ctcue.com/

Davey, S. M., Brennan, M., Meenan, B. J., & McAdam, R. (2011). Innovation in the medical device sector: an open business model approach for high-tech small firms. *Technology Analysis & Strategic Management*, *23*(8), 807-824.

Doorn, M. (Ed.). (2006). *Converging Technologies: Innovation patterns and impacts on society*. The Hague: STT.

Eisenhardt, K. M. (1989). Building theories from case study research. *Academy of management review*, *14*(4), 532-550.

Faulkner, A. (2009). Medical Technology into Healthcare and Society: A Sociology of Devices. *Innovation and Governance. London: Palgrave Macmillan*.

Flick, U. (2009). *An introduction to qualitative research*. Sage.

Foray, D., Mowery, D. C., & Nelson, R. R. (2012). Public R&D and social challenges: What lessons from mission R&D programs?. *Research Policy*,*41*(10), 1697-1702.

Furr, N., & Dyer, J. (2014). *The Innovator's Method: Bringing the Lean Start-up Into Your Organization*. Harvard Business Press.

Göktepe-Hultén, D. (2008). Academic inventors and research groups: entrepreneurial cultures at universities. *Science and Public Policy*, *35*(9), 657-667

Haermonics. (n.d.). Retrieved May 19, 2015, from http://www.nlc.nl/portfolio/haermonics/

Hamel, G. (2000). Leading the Revolution Harvard Business School Press.*Boston, MA, USA*, 343-354.

Hancké, B. (2009). *Intelligent research design: a guide for beginning researchers in the social sciences*. Oxford University Press.

Hapticore. (n.d.). Retrieved May 17, 2015, from http://hapticore.com/?page_id=9

Incision Group. (n.d.). Retrieved May 14, 2015, from http://incisiongroup.com/about-2/about-us/

Innofuse. (n.d.). Retrieved May 17, 2015, from http://www.innofuse.nl/wat-wij-doen/

Jain, S., George, G., & Maltarich, M. (2009). Academics or entrepreneurs? Investigating role identity modification of university scientists involved in commercialization activity. *Research policy*, *38*(6), 922-935.

Kaiser, H. (2009). Healthcare costs: A primer, key information on healthcare costs and their impact. Retrieved December 10, 2014, from http://www.kff.org

King, G., Keohane, R. O., & Verba, S. (1994). *Designing social inquiry: Scientific inference in qualitative research*. Princeton University Press

Linder, J., & Cantrell, S. (2000). Changing business models: Surveying the landscape. *Acenture Institute for Strategic Change*.

Louis, K. S., Blumenthal, D., Gluck, M. E., & Stoto, M. A. (1989). Entrepreneurs in academe: An exploration of behaviors among life scientists.*Administrative Science Quarterly*, 110-131.

Magretta, J. (2002). Why business models matter.*Harvard Business Review,* 1-8.

Mathieu, A., Meyer, M. and de la Potterie, B. v. P. (2008) 'Turning science into business: A case study of a major European research university', Science and Public Policy, 35: 669–80.

Mattes, E., Stacey, M. C., & Marinova, D. (2006). Predicting commercial success for Australian medical inventions patented in the United States: a cross sectional survey of Australian inventors. *Medical Journal of Australia*,*184*(1), 33.

Maurya, A. (2012). *Running lean: iterate from plan A to a plan that works*. " O'Reilly Media, Inc.

Medische Technologie. (n.d.). Retrieved June 9, 2015, from http://www.medischetechnologie.nl/regelgeving.html

Menzies, M. B. (2012). Researching scientific entrepreneurship in New Zealand.*Science and Public Policy*, *39*(1), 39-59.

Metcalfe, J. S., James, A., & Mina, A. (2005). Emergent innovation systems and the delivery of clinical services: The case of intra-ocular lenses. *Research Policy*, *34*(9), 1283-1304.

Miron-Shatz, T., Shatz, I., Becker, S., Patel, J., & Eysenbach, G. (2014). Promoting Business and Entrepreneurial Awareness in Health Care Professionals: Lessons From Venture Capital Panels at Medicine 2.0 Conferences. *Journal of medical Internet research*, *16*(8).

Morris, M., Schindehutte, M., & Allen, J. (2005). The entrepreneur's business model: toward a unified perspective. *Journal of business research*, *58*(6), 726-735.

NIColab. (n.d.). Retrieved May 17, 2015, from http://www.ace-venturelab.org/en/start-ups/nicolab/

NLC accelerating healthtech inventions. (n.d.). Retrieved June 3, 2015, from http://www.nlc.nl/

Oliver, A. L. (2004) 'Biotechnology entrepreneurial scientists and their collaborations', Research Policy, 33: 583–97

Osterwalder, A., & Pigneur, Y. (2010). *Business Model Generation: A Handbook For Visionaries, Game Changers, And Challengers Author: Alexander Osterwalder, Yves."* (p. 288). Wiley.

Osterwalder, A., Pigneur, Y., & Tucci, C. L. (2005). Clarifying business models: Origins, present, and future of the concept. *Communications of the association for Information Systems*, *16*(1), 1.

Popper, K. R. (1959). The logic of scientific discovery. *London: Hutchinson*.

Porter, M. E. (2011). *Competitive advantage of nations: creating and sustaining superior performance*. Simon and Schuster.

Rasmussen, E., Mosey, S., & Wright, M. (2011). The evolution of entrepreneurial competencies: A longitudinal study of university spin-off venture emergence. *Journal of Management Studies*, *48*(6), 1314-1345.

Ries, E. (2011). *The lean start-up: How today's entrepreneurs use continuous innovation to create radically successful businesses*. Random House LLC.

Samsom, K. J., & Gurdon, M. A. (1993). University scientists as entrepreneurs: a special case of technology transfer and high-tech venturing.*Technovation*, *13*(2), 63-71.

Shafer, S. M., Smith, H. J., & Linder, J. C. (2005). The power of business models. *Business horizons*, *48*(3), 199-207.

Shane, S. A. (2004). *Academic entrepreneurship: University spinoffs and wealth creation*. Edward Elgar Publishing.

Smart, D. T., & Conant, J. S. (2011). Entrepreneurial orientation, distinctive marketing competencies and organizational performance. *Journal of Applied Business Research (JABR)*, *10*(3), 28-38.

Taylor, S. J., & Bogdan, R. (1984). Introduction to qualitative research methods: The search for meaning.

Teece, D. J. (2010). Business models, business strategy and innovation. *Long range planning*, *43*(2), 172-194.

UMCUtrecht. (n.d.). Retrieved June 8, 2015, from https://www.umcutrecht.nl/nl/Subsites/Medisch-Ethische-Toetsingscommissie/Onderzoeksdossier-formulieren

UtrechtInc. (n.d.). Retrieved May 13, 2015, from http://utrechtinc.nl/over-ons/

WHO medical device. (n.d.). Retrieved June 3, 2015, from http://www.who.int/medical_devices/full_deffinition/en/

WHO. (n.d.). Retrieved March 21, 2014, from http://www.who.int/topics/technology_medical/en/

Wind Tales. (n.d.). Retrieved May 17, 2015, from http://www.nlc.nl/portfolio/windtales-2/

YES!Delft. (n.d.). Retrieved May 18, 2015, from http://www.yesdelft.nl/About-us

Ziman, J. M. (1987). *An introduction to science studies: The philosophical and social aspects of science and technology*. Cambridge University Press.

Zucker, L. G., & Darby, M. R. (1996). Star scientists and institutional transformation: Patterns of invention and innovation in the formation of the biotechnology industry. *Proceedings of the National Academy of Sciences*,*93*(23), 12709-12716.

Abbreviations

LSA	Lean Start-up Approach
BMC	Business Model canvas
Medtech	Medical technology
MVP	Minimal viable product
SE	Scientific Entrepreneur
BML loop	Build-Measure-Learn loop

Appendix

Scientific poster

Scientific Entrepreneurship in the Medical Technology Sector

Universiteit Utrecht

Introduction

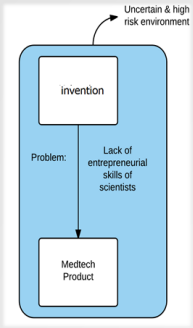
Pressure healthcare system - One of the causes of the hampering innovation in the medtech sector is the lack of business knowledge and competences of the scientific entrepreneurs that are managing the medtech firms.

The Lean Startup approach - has in theory the potential to be a way for the scientific entrepreneurs to gain the business knowledge they are lacking, however little scientific evidence exists for the practical success of this approach in the medtech sector.

The aim of this research is to explore, analyze, and explain the use of the Lean Startup approach within medtech start-ups.

"How do medtech startups apply the Lean Startup approach, and how does this LSA support the business knowledge creation process within these start-ups?"

Problem visualization



Theory

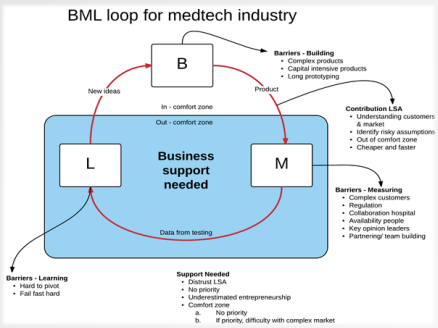
Scientific entrepreneurs - being a sientific entrepreneur asks for an exceptional combination of experience and skillls"

Business model - "business model reflects management's hypothesis about what customers want, how they want it and why they will pay"

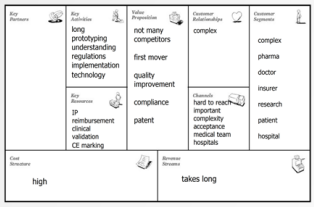
Lean start-up approach - originates from ICT entrepreneurhip, scientific based approach to test hypothesis, validate risky assumption and breaking down the failing facators for startups

Build measure learn feedback loop - iterative product releases, incremental innovations, fail fast learn fast,

Proposed framework

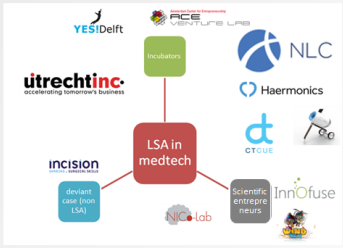


Business model canvas



Methods

Explorative qualitative approach
Analyzing perceptions – of 7 Dutch medtech firm that apply the LSA approach, 1 deviant case and 3 incubators that have experience in supporting medtech firms
Data made possible by using network of NLC



Conclusion

Results show that the Lean startup approach appeared to be a **suitable approach** for scientific entrepreneurs to gain knowledge about entrepreneurship in the medical technology sector. The Lean startup approach contributes in the **awareness of the complexity** of the market, but the step towards the market and business competences to get them out of the comfort zone seems to remain hard-to-reach. For gaining these skills support is required. The measure phase of the BML loop appeared to be the biggest challenge for medtech firms. A recommendation for startups is to search for help. Search for people who can help in validate the business model, and can guide the step towards the market.

The LSA does help the scientific entrepreneurs to understand the key elements of entrepreneurship, and helps identifying barriers to innovation in the market. However the LSA does not seems to contribute in actually gaining the related competences needed to test their products in the market. **Thus the LSA should be accompanied by support,** to make sure the startups and scientific entrepreneurs get our their comfort zone and do not continuously fall back on the technical product development.

References

- Blank, S. (2013). Why the lean start-up changes everything. Harvard Business Review, 91(5), 63-72.
- Faulkner, A. (2009). Medical Technology into Healthcare and Society: A Sociology of Devices. Innovation and Governance. London: Palgrave Macmillan.
- NLC accelerating healthtech inventions. (n.d.). http://www.nlc.nl/
- Teece, D. J. (2010). Business models, business strategy and innovation. Long range planning, 43(2), 172-194.

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Questionnaire scientific entrepreneurs

Introductie

1. *Wat voor product is (bedrijfsnaam) aan het bouwen?*
2. *Hoe kwam je op het idee voor (bedrijfsnaam)?*
3. *Kun je de missie/doel van (bedrijfsnaam) omschrijven?*
4. *Zijn uitdagingen die je tot nu toe gehad hebt gerelateerd aan de sector van health technologie?*
5. *Hoe heb je het team van (bedrijfsnaam) bij elkaar gekregen?*
6. *Wat zijn tot nu toe de grootste successen geweest van (bedrijfsnaam)?*

Competenties

7. *Welke aspecten in het bedrijf houden je wakker?*
8. *Wat is de lastigste beslissing die je hebt moeten maken in de laatste maanden?*
9. *Heeft (bedrijfsnaam) wel eens het idee gehad competenties te missen om dit bedrijf en product succesvol te maken?*
10. *Heb je wel eens advies of hulp gekregen van buiten (bedrijfsnaam) op het gebied van ondernemerschap?*

Business model

11. *Hebben jullie je business model wel eens gevisualiseerd? Wanneer voor het laatst?*
12. *Hebben jullie je business model wel eens aangepast of herziend? En hoe regelmatig? Waarom wel/niet?*
13. *Welk probleem van gebruikers lossen jullie op, en welke oplossing hebben jullie hiervoor?*
14. *Is jullie klant ook de directe gebruiker van het product?*
15. *Wat maakt het product van (bedrijfsnaam) verschillend van eventuele alternatieve oplossingen of producten?*
16. *Wat is het unfair advantage van (bedrijfsnaam). Wat kan niet makkelijk worden overgenomen/gekopieerd?*
17. *Hoe zit het verdienmodel van (bedrijfsnaam) in elkaar?*
18. *Waar komt de financiering voor (bedrijfsnaam) vandaan? Hoe kom je aan deze investeringen?*
19. *Wat zijn de huidige kanalen die jullie hebben richting beoogde klanten?*
20. *Wat is de meest risicovolle aanname? (product/klant/markt)*
21. *Hoe zijn jullie deze aanname aan het testen?*
22. *Waar zie je (bedrijfsnaam) over tien jaar?*

Leren

23. *Als je terug in de tijd kon reizen naar dag één van (bedrijfsnaam) en je had 15 minuten om door te brengen met jezelf om welke les dan ook bij te brengen over de afgelopen tijd, wat had je jezelf dan geleerd om fouten te voorkomen?*

Overig

24. *Zijn er nog vragen die ik niet gesteld heb die je wel verwacht had? Wat moet nog zeker genoemd worden wat we nog niet besproken hebben?*

Questionnaire incubator managers

1. *Wat is jouw ervaring vanuit (incubator) met het begeleiden van medisch technologische start-ups?*
2. *Grote uitdagingen die de medische start-ups hebben, zijn die gerelateerd aan de medische sector?*
3. *Wat denk jij dat medtech start-ups kunnen leren van de lean start-ups methode?*
4. *Denk jij dat de lean start-ups methode goed toepasbaar is voor medische start-ups? Waarom wel/niet?*
5. *Geeft een canvas de start-ups sturing/richting?*
6. *Hoe intensief werken start-ups met de canvas? Passen ze het vaak aan? En wat is hun incentive om er mee te werken?*
7. *Wat zou jij veranderen aan de canvas om het beter toepasbaar te maken voor de medische sector?*
8. *Merk je dat bedrijven intensief bezig zijn met het bepalen van risicovolle aannames en het testen van deze assumpties?*
9. *Wat is het belang van netwerken in de medische sector? Met welke mensen zouden medisch technologische start-ups moeten netwerken en waarom?*
10. *Welke skills merk je dat medtech start-ups missen?*
11. *Hoe zijn de medtech start-ups bezig met concurrentie?*
12. *Wat zien de start-ups als grote successen?*
13. *Wat zijn de ambities van de bedrijven? Zijn die meer lange of korte termijn? En op groei, omzet of georgrafische spreiding gebaseerd?*
14. *Zijn er vragen die je wellicht wel had verwacht maar niet zijn gesteld? Oftewel wat zou ik sowieso moeten meenemen in mijn onderzoek wat we nog niet besproken hebben?*

Coding table entrepreneurs

Category	Code	Data source [6]
Usefulness LSA	Identifying pains & gains	1
	Conversation customers *	1,7,8,3,1,8,6
	Comfort zone product	1
	Helps understanding market	1
	Structures entrepreneurship	1
	Making experiences scientific	1
	Identifying risky assumptions	5
	Testing hypotheses	5
	Entrepreneurship is practice	8
	Formulate solution	5
LSA & medical sector	Communication customer hard	5,5,1
	Regulation *	5,7,6,6,6
	Inappropriate application	7
	For mass products	7
	Expensive complex products	8,8,3
	Hospital have product focus	8,6
	Science not focused on implementation	8,2
	Medical team acceptance product	8
	Fail fast hard	3,7
Usefulness BMC	Understanding customers *	5,3,8
	Network importance medical world *	7,2,1
	Gives direction *	8,1,7
	Checklist selling what to whom	1
	All aspects of entrepreneurship	8
	Visualization previous process	7
	Learn from mistakes	1
Modifying BMC	Using it not for incubator/challenge *	7,3,5
	Use feedback customer *	4,7,1,1,1,2,2,1,8,8
	Canvas outdated *	5,1,2,2
	No priority *	3,5,2,6,5
	Uninteresting	7,2
	Feasibility modification	1

[6] 1=ctcue 2=ace 3=innofuse 4=incision 5=wind tales 6=hearmonics 7 = hapticore 8=nicolab

	Distrusting in fist instance	8
	Use other posters	4
	Archived all versions	8
	Never stop using it	8
	Completely changed	8
	Modified several versions *	1,5,8,7,5
Improve BMC	More than 1 canvas	8,5
	Too simplistic	7,7
	Lean for mass products	7
	Risking inaccuracy	5
	Risk shifting too fast	1
	BMC product not business	8
	Decision trees missing	7
Risky assumptions	Team member dependent	8
	Change over time	5
	Not about technology	1
	Is there market?	7,7,8
	Finance *	1,7,5,4
	Profitable	3,6
	Getting subsidies	8,5
	Care/commerce conflict	4
	Partner choice *	4,7,1,5
	Acceptance	3
	Taken seriously	8
	Time	8,2
	Success fear	7
	Long prototyping	3,4
Testing risky assumptions	Testing period varies	5
	Mapping expectations	8
	Willingness to pay	8
	Hard because of regulations	3
	Talking to people	8
Channels	Need for understanding market *	6,1,3
	Medical sector complex	8
	Big role doctor *	1,5,5,3,1

	Relation doctor important	3,3,3
	Reputation doctor importance	1,4,1,4
	Negotiations academic hospitals	8,8
	Hierarchy hospital	8,8,4
	Hospital reserved	1,1,8
	Collaboration academic hospital	5,2
	Hospital complex	3
Customer	Customer research	8
	Customer side complex	3
	Search for customer needed	8
	Customer insurance company *	1,5,7
	Customer patient	7
	Customer hospital	2
	Hospital complex	6
	Customer pharma	6
Lack Skills	Search for help *	3,7,6,6,1,8,4
	Underestimated entrepreneurship	8,2
	Lack of entrepreneurial experience	8,5,8
	Centipede needed	3
	Sales	2
	Marketing	8
	Communication	5
	Software	2
	Medical	5
	Finance	5
Unique value	Not many competitors	5
	Competitors not fulltime	1
	First mover *	6,4,1,7
	Not scared competition	1
	Improving quality	7,8
	Compliance	7,5
	Patent	3
	No patent	8
Success	Awards/prices	3,5
	Finance	3

	Big (international) demand	8,8
	Product validation	8,5
	Open innovation environment	1
Ambition	Unclear long term goal	2
	Short/long term	4
	Ambition & strategy important	2,2
	Other applications technology	5,5
	Geographic spread *	7,4,1
	Growth	8
	Becoming not too big	6
	Sell company	7,3
	Implementation of technology	1

Empirical results entrepreneurs

After the first data collection of seven firms and one bootcamp, a lot of concepts appeared. These concepts can be explained by 13 categories. These 13 categories shows the perception of the (mostly academic) entrepreneurs within the medical technology field on the value of the LSA. They have explained how they apply the LSA and how it contributed to their business knowledge creation process.

Categories that have emerged are: usefulness lean start-up, LSA & medical sector, usefulness lean canvas, modifying lean canvas, improve lean canvas, risky assumptions, testing assumptions, channels, customer, lack skills, unique value, success, ambition. Every category emerged out of several codes, which can be seen in table X (appendix).

Usefulness LSA The first category is the *'usefulness of the LSA'*. The most important code that is linked to this category is '*conversation customers'*. For example interviewee of company 1 told: "*One of the most important things you have to do, it to get in conversation with your customer. With the potential users"*. Furthermore interviewees explained that the LSA helps identifying the pains and gains from the customer. The scientific entrepreneurs explained that the LSA helps them getting out of the comfort zone of the product development. It helps understanding the market, identifying risky assumptions, testing hypotheses and formulate solutions. Scientific entrepreneurs state that entrepreneurship is practice, but that the LSA is useful since Steve Blank made his experiences with entrepreneurship scientific, and brings structure in entrepreneurial activities. Entrepreneur of company 1 admits that the LSA gives structure in entrepeneurship: *"What entrepreneurs do with a bit of gut feeling, he (steve Blank) brings structure"*.

LSA & Medical sector The scientific entrepreneurs gave a critical reflection on the use of the LSA within the medical sector. First of all the code '*regulation*' was an conflicting issue with the LSA. For example from field notes of firm 5 it appeared that '*clinical validation is needed for getting CE marking'*. Regulation can hamper the acceleration, which is eventually the goal of the LSA. Firm 7 explained that it takes at least six months before the certification is arranged. Furthermore field notes of firm 6 shows that medical ethical approval is an issue, and that there are a lot of protocols within the medical sector that need to be taken into account.

The *'communication with the customer'* is not always easy within the medical sector. First of all the communication language. Firm 5 explained that it is important to take into account that a medic has other communication language than paramedic. Just like a doctor has another language than a physiotherapist. Besides the communication language the '*availability of customers'* appeared to be an issue. It appeared

not to be easy to get an appointment with a doctor for asking him/her about his needs and problems. This is problematic, since the medical team can have a big influence on the sales. Even when the product is not directly sold to a member of the medical team, they however do have an influence on the acceptance in the sector.

Furthermore the interviews have shown that is can be hard in some cases to fail fast and learn fast in de medical sector. Developing an MVP is not possible for every medical technology. For example firm 3 is developing a product that needs to be approved and needs to go through regulation since the products has a lot of risks for the patient when it there it does not function: "*infections play a major role and the chance of mistakes have to be zero".* This has to do with another code called '*expensive complex products*'. Several firms explained that within the medical sector expensive and complex products are developed. For firm 3 it was not easy to get an prototype, "*it took more than two years before we had a working prototype*". There was even one firm, firm 7, that commented that the LSA was not at all appropriate to apply to the medical sector because of this complexity. They explained the LSA is meant for mass products, and products in the medical sector are not.

Several scientific entrepreneurs explained that the LSA is a very new way of thinking compared to the current research and hospital culture. Hospitals and science do have a focus on product development, but not at all on the implementation of those products and thus to use the products in practice. As firm 8 explained "*the academic center is focus on product validation and publications."* A firm of the bootcamp session explained about the implementation of products: "*what happens in a PHD stays in a phd and university."*

Usefulness lean canvas Just like for the usefulness of the LSA, for the usefulness of the lean canvas '*understanding the customer*' is an important code. Furthermore the '*network importance medical world*' came across. This network is important for the entrepreneur for understanding the market and to be sure who to speak to. As firm 7 explains: "*That is the main problem in the medical world. It's about your network. … If you haven't been performing a PhD in a hospital it is difficult."* Several scientific entrepreneurs told the lean canvas gives them direction. Firm 8 explained about the lean canvas "*yes, it truly are all aspects of entrepreneurship."* Furthermore firm 7 told the lean canvas is a visualization of previous processes, and firm 1 explained it makes them learning from mistakes.

Modifying lean canvas The scientific entrepreneurs have been deeply questioned about how they have been working with the lean canvas. About whether they modified it a lot, why and how. First of all, several scientific entrepreneurs explained they used and filled in the lean canvas because it was part of an incubator program or a start-up challenge. For instance firm 7 "*yes because it is here (ACE venture Lab) in the program".* Furthermore in almost every interview it appeared that the scientific entrepreneurs completed the lean canvas by using feedback from customers. This is what is also explained by the category *'usefulness LSA'* with the code '*conversation customers*'. It is not only mentioned that it is important to have a conversations, but "*you have to speak a lot of people"* (firm1).

Most firms have several versions of the lean canvas. Firm 1 explained: "*yes I have been shifting in my model."* Firm 8 has not only shifted in the model, but the current version of the canvas is completely new compared to the first version. They modified it "*at least two times a week".* They will even never stop using the canvas. They are one of the few companies that had archived all versions of their canvasses.

There are several scientific entrepreneurs who distrusted the canvas method in first instance. Firm 8: "*in the beginning I though what is it, a business model canvas?".* And still there are interviewees who stated that they have several versions of the canvas, but that the current version is outdated. This because modifying the lean canvas does not always gets priority in the firm. As firm 3 states: *"I noticed that because of the usual issues of the day I am too busy to take time to really analyze the lean canvas".* Furthermore it appeared that for instance subsidy application influence the willingness to work with the lean canvas. For instance firm 5 told that "*for a subsidy application a project description was needed, which had no common ground with a canvas."* So if the firms have deadlines or other priorities, the lean canvas does not get the full attention.

There is only one firm not enthusiastic about the canvas. He told the canvas was uninteresting and he questions the feasibility of modification. This because it is hard to pivot in the medical industry and because of the long prototyping times.

FEASIBNILITY

Improve lean canvas Within this category some interesting improvements for the lean canvas were suggested by the interviewees. Two firms came with the conclusion that one lean canvas is not sufficient. This because "*the canvas is not a firm but the product if the firm has more than 1 product. And that needs to be structured in a way.*" So one concrete point is that firms should be working with more than one canvas if they have more than 1 product.

Second, a reviewing point is that the lean canvas is too simplistic. It is mentioned for mass products and not for complex and expensive medical technologies. This could however be resolved by making the canvas more detailed. For instance by adding decision trees, for example in the customer segment. This because the customer segment is always a choice between several segments, such as patient, doctor, pharma, or the insurer.

Furthermore the scientific entrepreneurs highlighted some dangers they experiences when working with the lean canvas. These include risking inaccuracy and the risk of shifting too fast. People using the canvas should be aware of the fact that when using it a lot and repeating it, there is a change of becoming inaccurate. Furthermore it is risky to shift a lot and very fast. Entrepreneurship is namely also about being confident about your product and making decisions.

Risky assumption The scientific entrepreneurs have been asked about identifying and testing risky assumptions. Interesting codes that emerged by this category are '*is there market*', *'finance'*, and *'partner choice'*. The scientific entrepreneurs are not all certain if and what their exact market is. Thus still in a phase of identifying the customer and customer need. Furthermore getting (enough) finance is an issue for a lot of start-ups. According to firm 1 money is always an issue. Firm 3 mentions about finance that it is important that the production of the product does not become too expensive.

Partner choice and team building seems quite hard for the scientific entrepreneurs. It is hard to find suitable team members, and it is also hard to fire people when needed. As firm 3 explains: "*that are difficult decisions on the business level. Which people are you going to cooperate with, hiring people*". Furthermore company 7 experienced the same difficulty, "with *(personx) it was an awkward situation, we just didn't thought about who we offered a job, we just quickly needed someone*".

Besides these three frequent mentioned codes risky assumptions that are identified by the scientific entrepreneurs are: profitability, getting subsidies, acceptance, time and long prototyping. TIME UITWERKEN

Testing risky assumptions About the category testing risky assumptions the scientific entrepreneurs explained that '*testing period varies*'. According to firm 5 the period of testing depends on the assumption that has been tested. Furthermore the assumptions are being tested by '*mapping expectations*' and *'talking to people'*.

The scientific entrepreneurs told that it is important to map the expectations of the targeted customer, finding out what the customer expects from a product and what he or she is willing to pay for it. These expectations are being mapped mainly by talking to customers. Thereon firm 8 explained that it is mainly "*talking to people, show them we exist*".

Channels The category channels is a frequently and constantly returning topic in all the interviews with the scientific entrepreneurs. By this category the following key codes emerged: '*need for understanding market', 'big role doctor',* and '*collaboration academic hospital*'.

For instance firm 1 explained: "*first I have been working on understanding the sector…what is actually going on in the sector?" F*ield notes of firm 6 showed that they needed a better understanding of the market. They understood it is important to pay attention to the business model and risky assumptions, and for validating those it is important to talk a lot about it and they wanted to "*understanding the game better, why they are in it and how".*

Besides the first importance of understanding the market, it appeared that there is within the medical technology (business) development a big role for the doctor. For instance firms 1,3 and 5 clearly explained that it is of importance that the doctors, or key opinion leader within their domain, endorses and supports the product. Firm 3 explained: "*you should have luck with a doctor that is open to innovation, however there are a lot of them who are not interested in innovation and new products, then you have bad luck".* Furthermore firm 1 fiercely stated that if the doctor is not enthusiastic about the product, he immediately quits, since without the blessing of the doctor he will not get it done. Not every hospital and doctor is thus open to innovation. The firms explained and give as a tip for other start-ups that it is very important to start early in the beginning with networking and building relationships with the medical sector, and in particularly with important doctors in the field.

Besides collaboration with the doctors, collaboration with the academic hospitals is mentioned. Firm 5 mentioned that is important that universities have thrust in your product and firm from an early stage. Not only for the network and doctors, but what was can be seen in the field notes of the bootcamp is that the centers are also important for subsidies that come from universities that can play a major role in financing the start-up. Thus the academic hospitals are important for the success rate of the medical technologies since there is money and people needed for building the product and business.

Customer While talking to the scientific entrepreneurs, it appeared that for within the medical technological sector there are several customers segments. The following customers are mentioned by firms: insurance companies, patients, hospitals (doctors), pharma and research companies. Thus the medtech products can be sold to several customers.

However the insurance companies are mentioned by the most interviewees. Firm 7 told that their product "*improves compliance of patients, which is interesting for the health insurer companies, since that can reduce costs".* According to firm 3 the customer segment is quite complex in a hospital environment when the doctor is the customer. This because not only the doctor, but also nurses have a say in it. And those nurses and doctors can obstruct your process along the way. And firm 1 mainly focuses on the pharmaceutical companies, since they solve a big problem for those firms and can accelerate the clinical trial procedures.

Thus the customer depends on the goal and features of the medical technology the start-ups are developing, and for whom in the medical sector they solve a problem, and thus who is willing to pay for that.

Lack Skills When looking at the category lack of skills, the most important code that emerged is '*search for help'*. When asking the companies what they could have been doing better in the past, almost everyone says that they regret they didn't look for help in an earlier phase. A good example is what firm 3 explained: "*you should quickly look for help. I am very happy now that I work together with other people. It helps for accelerating. It can be help from for instance incubators, or entrepreneurs who already have been through the phases you're in.*" Firm 6 explained that talking to people maybe makes them vulnerable, however it is needed to come up with new ideas and insights from outside the company.

Furthermore when searching for help, a lot of competences are needed in the firm. The scientific entrepreneurs '*underestimated entrepreneurship'* and they admitted they have a '*lack of entrepreneurial experience'*. According to firm 8 "*we are all not entrepreneurs, I think it is really different from what we all expected it to be".* Besides missing the basic entrepreneurial background, concrete competences that are mentioned by the firms that are needed are mainly within sales, marketing, communication and finance.

Unique value An interesting outcome of the category 'unique value' is that the most frequently mentioned unique value of the start-ups is having a '*first mover advantage'*. The firms say they are the only one in the market, and if they are not that they are ahead in development and thus will enter the market earlier than the competitor. Firm 1 explained that there is "*no reason to be scared for competition*." It is important that you are sure you're making a better product and that you can launch it in time. He has a competitive product, however developed by the government where people are not working full time, while he and his team is. Besides being a first mover the start-ups talked about developing a better quality product, and two firms explained they are building a product that will enhance the compliance of a therapy of patients.

A striking result for this category was that while asking about unique values, the focus was thus on being a first mover and making a better product, instead of having a patent or not. Firm 3 was the only firm explaining that that is a big advantage for their firm. However for instance firm 8 explained they have not patent and don't need one. The rest of the firms did not explained about it at all as a unique value.

Success When asking the firms about their successes in the past, several codes emerged. '*Awards and prices'* was one of them. In the Netherlands there are a lot of competitions held for start-ups. Winning those venture challenge prices and awards appeared to be important for the firms for both gaining finance and reputation. '*Product validation'* is also seen as a success for firms. It is for the firms very important that the technology works without any errors. Furthermore finance and international demand are mentioned as successes.

Ambition When asking the firms about ambitions, it differs what the company tell. The ambitions vary from not having clear ambition to growth and geographic spread to selling the company. They are aware that ambition and strategy is important, but it is not always clear. 'Implementation of technology' is seen as important, as well as 'other applications technology'. So these ambitions are technology related. There are also business related ambitions such as geographic spread, growth and selling.

Conclusion perception scientific entrepreneurs Thus from the perception of the scientific entrepreneurs the LSA helps them getting out of the comfort zone of the product development. It helps understanding the market, identifying risky assumptions, testing hypotheses and formulate solutions. The scientific entrepreneurs gave some conflicting issues for the LSA and the medical sector, which were mainly about communication with the customer, regulation, culture of the hospitals, and hard to fail fast and learn fast. It was quite diverse how intense the start-ups work with the lean canvas. The canvas does not always has the full priority within the firm. There were suggested some improvements of the lean canvas by the interviewees, mainly since the canvas is focused on consumer products instead of complex business to business products. Risky assumptions for the firms were mainly to identify whether there is a market, to get finance and to choose the right partners. The scientific entrepreneurs test these assumptions by mapping expectations and talking to people. Channels appeared to be very important within the medical sector. There is need for understanding the market and for having acceptance of the medical team for the product. There are several customer segments, such as patients, doctors, hospitals, insurance companies, pharma and research. The scientific entrepreneurs have a lack of skills in their teams. They underestimated entrepreneurship, mainly within the business field. They perceive a first mover advantage and are not scared for competition.

Coding table incubator

Category	Code	Data source
Usefulness LSA		1,2,3
	Focus on technology is wrong	1
	Hope on sales	1
	Fear unfinished product	2
	Understanding process	2
	Customer perspective	1,3 *
	Pain identification	1
	Customer identification	2
	Understanding market	1,3 *
	Identify risky assumptions	3
	Think like a entrepreneur	3
LSA & Medical sector		
	Medtech complex market	1,1
	Multiple customers	1
	Regulation	1,1
	No consumer products	1
	IP issues	1
	Capital intensive market	1
	Hardware market	1
	Long time to market	1
	Also general problems	1
	Medtech not the only complex market	1
	less waste	2
	Validation BMC takes longer	2
	Niche	2
	Selling product earlier	2,3 *
	Less product focus	3
	Good applicable	2,3 *
	Lean not the most important one	3
Usefulness lean canvas		
	Fall back on technology	1
	BMC instead of LMC	1
	Never bores	1
	Faster & cheaper market validation	1

	Understanding process	2
	Canvas as tool	1,2,3 *
	BMC gives guidance	1,2,3 *
	Use differs per person	3
	BMC brings structure	1,3 *
	Value proposition use	1,3 *
	No use validation board	1
	Support by BMC use needed	1,2 *
	Supporting get out of the building	3
Modifying lean canvas		
	Contstant modification	1
	Use differs per person	1
	Focus back on technology	1
	Lead time canvas	1
	Point of frustration	1
	Overload information	1
Improve lean canvas		3
	Standard completion	1
	Specific steps medtech	1
	More products more canvasses	1
	More focus on IP	2
	LMC instead of BMC	3
	BMC nog sector specific	1,3 *
	Personal development missing	3
	LMC ipv BMC	3
	Vision missing	3
Risky assumptions		3
	Assumption testing from BMC	1
	Support needed for testing assumptions	1
	Testing assumptions not easy	1
	Pitfall to fast validation	1,2 *
Channels		
	Talking to a lot of people	1
	Hard to get into the network	1
	Understanding complex environment	1

	Importance network incubator	1
	Thinking different	1
	Foreign countries also possible	1
	Financing complex in medtech	1
	Channels consumer product easier	1,2 *
	Approaching different networks	1,2 *
	Importance key opinion leaders	1,2 *
Lack skills		
	Language barrier	1
	Market specific	1
	Availability of market	1,2 *
	Out of comfort zone several reasons	1
	Ambitious to get out of comfort zone	2
	No focus on competitor	2
	Entrepreneurial way of thinking lacks	1,2,3 *
	Big step from scientist to entrepreneur	3
	Lacking courage for step towards customer	2,3 *
	Incubator should create expectations	3
	Medtech engineers same as other engineers	1
	Sales skills lack	1,3 *
	Dirve towards market missing	2
Success		
	Phase specific	1
	Subsidy	1
	Prototype	1,2 *
	Marketing	1
	Reimbursement	1
	Geographic spread	1
	Business sucess	3
Ambition		
	Depends per entrepreneur	1
	Impact/ money entrepreneurs	1
	Ambition lacking in the Netherlands	2

1=Yes!Delft 2=AceVlab 3=UtrechtInc

Empirical results incubators

Usefulness LSA With the incubator managers the usefulness of the LSA has been discussed. First of all, mentioned by all incubators was the customer. The LSA helps by understanding the customer perspective, identification of the pain of the customer and possible customer segments. For instance incubator 3 told: "*make sure that the firms develops products what fits with the needs of the users.*" Furthermore incubator 2 explained that "*the LSA incuding the business model canvas learns them to look at other possible customer segments and ways to sell the product.*".

Besides the importance of the customer segment the LSA ensures a better understanding of the market is discussed by two of the three incubators. First of all understanding when a product is market ready and the market ready for paying for the product. And thinking strategically about how to bring the product to the market. As firm 1 explains: "the fact that you be aware of all the important stakeholder and who to convince that your product is a good product."

According to the incubators the LSA also leads to a better understanding of the entrepreneurial process, identifying risky assumptions and helps thinking like an entrepreneur.

LSA & Medical sector The incubator managers have also been asked about the application of the LSA specifically towards the medical sector. Overall they explained the LSA is good applicable for the medical industry, and it helps selling the products earlier. As the following quote of incubator 3 illustrates: "*yes it is definitely applicable, I even think it is applicable for every market. However viewed from the build measure learn loop then you do should check the specific market requirements.*" Incubator 2 explained that the scientific entrepreneurs learn to stop their technological product development and start earlier with selling the product. Incubator 3 even states that he thinks it it the most important part of the LSA, learning to involve the market into the product development and make sure the implementation of the technology takes place earlier.

However the incubators do are aware of certain market characeristics that make applying the LSA somewhat complex. First of all validation of the business model takes longer. Incubator 2 explained that *"while web start-ups can validate their business model in three months, it can take at least a year in the medical sector"*. This has to do, according to incubator 2, that the medical sector is a niche where not everybody is available to talk to. Furthermore the other market characteristics are that the sector is complex, multiple customers, highly regulated, usually no consumer products, depended on IP, capital intensive, and long time to market (accounts mainly with hardware products).

Usefulness BMC The most important outcomes of the usefulness of the BMC are that it is used as a tool, that gives guidance, structure. And that support is needed by using the BMC. As incubator 3 states: "*firms use it as a helpful tool, the advantage of the business model canvas that you can see how the business looks like at a glance.*" All the incubators agreed that the BMC is a tool that gives guidance and structure for ventures. As firm 2 explained "*they have no clue where to start, that is now with the BMC really concrete.*" And incubator 3 told that start-ups that use the BMC learn who their customers are, and how to earn money. According to firm 1 the BMC is a tool that is used by start-ups mainly when there is an overload of information. When there is chaos the BMC is used to provide the needed structure.

However the stratups do need support when using the business model canvas tool. They can not do it all by themselves. As incubator 2 told "*it is not in their character to apply the lean process using the BMC, they can understand it in theory and fill in the canvas, however it is hard to keep applying the method and tool in practice.*" Incubator 1 even states that without their program the start-ups would fail using it and fall back on only their product development, and they say they are absolutely an important guidance in the process of using the BMC. The main point where the start-ups need this support is in getting out of the building and starting to speak with the customer and understanding the market, or in lean terms '*getting out of the building*'.

The incubators told that the final goal of applying the BM is a faster and cheaper market validation, and to make sure the start-ups do not fall back on technology. They also mention the importance of the value proposition, mainly in the beginning of the process .To make sure the pain and gains of the customer and the gain creators and pain relievers of the start-ups are clearly defined.

Modifying lean canvas The incubators have been asked about how frequently the start-ups they support modify their business model canvas. According to incubator 1 it differs per start-up and per scientific entrepreneur how frequently they work with the business model canvas. There is according to the incubators always a danger for the scientific entrepreneurs to fall back on their technology. There is always a lead time, and it takes a while until the start-ups are familiar with the canvas. Usually it takes a while, but when the start-ups come to a point of frustration, due to an overload of information, they are really willing to use the canvas to give them structure.
Improve lean canvas When asking the incubator no what they would like to see changed in the structure of the business model canvas, there were no big possible improvements mentioned. They however did had some remarks and observations on the use.

First of all, two of the three incubators mentioned that the business model canvas is not sector specific in itself. And the most specific modification recommended was by incubator 2, who suggested that there should be a bigger focus on IP in the canvas. He told that there is not enough attention for IP within the key resources while validating the business mode. It should become a specific element in the process. "*it is important for start-ups to check whether they have freedom to operate…that should be made very explicit within key resources, that should get more attention in validation the resources of medical start-ups.*"

Furthermore incubator 1 stated that it is important if a start-up has more than 1 product, they need also to fill in more than 1 business model canvas for validating their different products. Furthermore incubator 3 explained that it is important for an entrepreneur to have vision, and the final vision of the start-up is not a single element of the canvas. Furthermore the canvas does not pay any attention to the personal characteristics and development of the scientific entrepreneur. So the start-ups should be aware that the canvas is really about the elements of the business, and does not pay any attention to the team and or scientific entrepreneurial skills, competences and vision. Finally, firm 3 explained that besides the business model canvas the lean model canvas can be a valuable canvas to use in the beginning of the entrepreneurial process.

Risky assumptions The most important finding of the category risky assumption is the fact that two of the three incubators explained that a pitfall is to validate assumptions too fast. According to incubator 1 " *they often think something is achieved, but if you ask deeply it appeared that it is actually not validated at all."* Another finding is that incubators stated that support is needed for testing risky assumptions. This support is needed since it appeared that the scientific entrepreneurs find it hard to test assumptions. The venture get methods of how to validate customers, how to build and test an MVP.

Channels From the incubator perspective it appeared that they also stress the importance of the network in the medical sector. Incubator 1 and 2 both emphasize that the key opinion leaders have a big influence on the start-ups developments. "*In the medical world you can function faster if the key opinion leaders are in favour of you."* Besides the importantce of key opinion leader the incubators agree on the fact that it is important to approach different networks, as the following quote of firm 2 shows "*the most important thing to pay attention to is networking with companies, investors and experiences entrepreneur.*"

Although the importance of networking is mentioned by the incubators, they also mention that it is hard for the start-ups to network. This because talking to as much people possible is hard in the medical industry. And it is easier to talk to consumers if you make a consumer product. This is however rarely the case in the medtech sector. And according to firm 2 "*in healthcare, it is usually a niche product in a market where you cannot question everybody easily with a online questionnaire or so…*

It is thus hard to network in the medical sector, but the incubator managers do come up with several suggestions. For instance using an existing network of for instance an incubator, trying to think differently and try speaking to the sector in another country.

Lack skills When asking the incubators what the scientific entrepreneurs lack in entrepreneurial competences, they overall mention '*an entrepreneurial way of thinking*.' For instance they don't think about collaborations with partners, about how to spend certain resources and what their competitive advantage is. They have never learned to think in such an entrepreneurial way. As incubator 3 confirms: "*we talk about entrepreneurship, and that is something really different from what a scientist is thinking about usually*."

Another problem with the skills of scientific entrepreneurs is according to the incubators the courage of them to step towards customers. According to incubator 2 the scientific entrepreneurs do not have enough attitude to actually perform the process of talking to the customer. And incubator 3 confirms "*they need to get used to it and that takes time, you should get out of your comfort zone of scientist.*" However there are a lot of scientist who do are very ambitious about stepping out of the comfort zone. But even if they are ambitious about making the step towards the market it appeared to be hard because of the abovementioned availability of the market.

Other, by the incubators identified, lacking skills of the scientific entrepreneurs are that they have no focus on the competitor, they lack sales skills and have difficulty in understanding the complex medtech market.

Success the incubators explain that what the start-ups mention as success depends per phase they are in. mentioned successes for start-ups mentioned by the incubators are: subsidy, a working prototype, marketing, reimbursement, graphic spread and other business successes.

Ambition also the ambition of the scientific entrepreneur differs per entrepreneur and start-up. According to firm 1 there are two sorts of entrepeneurs, namely entrepreneurs that want to make an impact, and entrepreneurs that want to make money. According to incubator 1 in the medtech industry you will mainly find scientific entrepreneurs that want to make an impact on the health system. And according to incubator 2 "*the ambition of the Dutch scientific entrepreneurs is way too little.*"