How can MedTech start-ups overcome the second Valley of Death?

A holistic multiple case study to identify factors that potentially affect the duration of the commercialization phase of MedTech start-ups that focus on exploiting new & innovative medical devices.

Master Thesis Business Administration
Specialization: Entrepreneurship, Innovation & Strategy
Faculty of Behavioural, Management and Social Sciences

Bram Gerhardus Jacobus ten Bok

S1501666

Contact e-mail: b.g.j.tenbok@student.utwente.nl

First supervisor:	PD Dr. Rainer Harms
Second supervisor:	Dr. Tamara Oukes
External supervisor:	Jurgen Kruiper
In cooperation with:	Oost NL
Date:	25-10-2018

UNIVERSITY OF TWENTE.

oost nl

Preface

This thesis represents months of blood, sweat and tears (sometimes of joy), ups, downs, and everything in between. It represents the personal growth from a young student towards a young professional. Finishing this thesis means that an 'era' has come to an end and that a new part of my life is about to start. Before moving on to the thesis itself, I would first like to thank a couple of people.

First, I would like to dedicate this Master Thesis to my father, who showed me that giving up is never an option for a ten Bok to consider. Second, I would like to thank the rest of my family and friends for supporting me for the past 8 months when things were quite rough. Third, I would like to thank my internal supervisors, PD Dr. Rainer Harms and Dr. Tamara Oukes for their time and feedback. And last, but certainly not least, I would like to specifically thank my external supervisor Jurgen Kruiper and all my other colleagues at Oost NL who made me feel more than welcome during my stay and gave me the opportunity to improve my professional capabilities.

B.G.J. ten Bok
Utrecht, October 2018

Glossary

Clinician: *A clinician is a health care professional that works as a primary care giver of a patient in a hospital, skilled nursing facility, clinic, or patient's home. A clinician diagnoses and treats patients.* https://en.wikipedia.org/wiki/Clinician

End-user: *in line with the literature of Shah & Robinson (2009), the researcher often refers to the patient as 'end-user'.*

CE-marking: *The letters 'CE' appear on many products traded on the extended Single Market in the European Economic Area (EEA). They signify that products sold in the EEA have been assessed to meet high safety, health, and environmental protection requirements. When you buy a new phone, a teddy bear, or a TV within the EEA, you can find the CE mark on them. CE marking also supports fair competition by holding all companies accountable to the same rules.* https://ec.europa.eu/growth/single-market/ce-marking_nl

Clinical study (trial): *are research studies performed in people that are aimed at evaluating a medical, surgical, or behavioral intervention. They are the primary way that researchers find out if a new treatment, like a new drug or diet or medical device is safe and effective in people. Often a clinical trial is used to learn if a new treatment is more effective and/or has less harmful side effects than the standard treatment.* https://www.nia.nih.gov/health/what-are-clinical-trials-and-studies

Holistic case study: *a case study in which the researcher looks at the entity of interest as a whole and does not focus on specific sub-units as objective of analysis (Yin, 2003).*

Lead-user: *in line with the literature of Shah & Robinson (2009), the researcher often refers to the clinician as 'lead-user'.*

Medical Technology: *Medical technology can be considered as any technology used to save lives in individuals suffering from a wide range of conditions. In its many forms, medical technology is already diagnosing, monitoring and treating virtually every disease or condition that affects us.* http://www.medtecheurope.org/what-is-medtech

Medical device: *Medical device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:*

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury,*
- *investigation, replacement, modification, or support of the anatomy or of a physiological process,*
- *supporting or sustaining life,*
- *control of conception,*
- *disinfection of medical devices*
- *providing information by means of in vitro examination of specimens derived from the human body; and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.* http://www.who.int/medical_devices/full_deffinition/en/

Operational cashflow break-even: *The point at which a firm's net cash inflow resulting directly from its regular operations (disregarding extraordinary items such as the sale of fixed assets or transaction costs associated with issuing securities) is equal to the total amount of fixed and variable expenses.* https://www.nasdaq.com/investing/glossary/c/cash-flow-from-operations https://study.com/academy/lesson/accounting-break-even-operating-cash-flow.html

Abstract

With over 12,200 patent applications filed with the European Patent Office and currently 27,000 active medical technology companies in Europe, one could say that the medical technology industry (€385bn in Europe) is not only practically relevant, but also economically (MedTech Europe, 2017). Nevertheless, the path towards successful commercialization is, compared to other industries, extremely long, complex and difficult. The speed at which a start-up is able to complete the stage from regulatory approval up to commercial success is not only very important for the entrepreneur, but it will also tell participating investors how soon, and if, they will be able to make a return on their initial investment. For MedTech start-ups this specific stage can be identified as what Wilson, et al. (2018) would describe as the 'Second Valley of Death'. The alarming large variance in the length of this stage for MedTech start-ups, 1 to 10 years, indicates that this stage is a rather unclear and complex one that needs more investigation (Wijk, van. M., 2014). Chiesa & Frattini (2011) acknowledge this problem by stating that although the commercialization phase is a critical stage in the technological innovation process, it is still considered as the least well managed phase of the entire innovation process.

This study will specifically focus on MedTech start-ups that develop rather new and highly innovative medical devices. These devices are interesting, because these are the ones that are mainly plagued by complex reimbursement routes and time-consuming clinical tests. Furthermore, due to their innovativeness, it is also harder to establish acceptance of the clinician for these devices, than for devices that show similarities with existing solutions. Finally, it are specifically those new and innovative medical devices that seem to fall into the trap of the 'Second Valley of Death' and are facing a rather long commercialization trajectory.

In order to overcome the commercialization phase, more in-depth knowledge is needed on what factors play an important role during this stage and affect its duration. Therefore, the following research question will be addressed: "What factors affect the duration of the commercialization phase (from the point of adopting CE-marking up until the point of operational cash flow break-even) of MedTech start-ups that focus on exploiting new, innovative medical devices?" To put some more focus on this research, this study looked at the commercialization phase from two perspectives, namely that of investment professionals and that of healthcare(-related) professionals. Ultimately, the purpose of this study was to: **(1)** Build a conceptual model that visually represents the commercialization phase from the point of CE-adoption (regulatory approval) up until the operational cashflow break-even point (commercial success), **(2)** which is linked to the factors that according to the literature and experience of investment & healthcare(-related) professionals play an important role during this phase and **(3)** can serve as a guide for investors/entrepreneurs to successfully move through this phase without having to encounter unnecessary delay.

To answer this research question, the researcher first conducted an extensive systematic literature review on the topic of medical technology commercialization. Based on this systematic literature review, several propositions were initiated that form the foundation of this research. These propositions were subsequently used as a guideline for the 10 semi-structured interviews that followed. In total, 9 factors were found that could possibly affect the duration of the commercialization phase (from the point of CE-marking up until operational cashflow break-even), namely: *the added value ; the active use of social media ; attending conferences ; the business acumen of the management team ; the quality of the clinical study design ; the understanding of the cost structure ; the understanding of the reimbursement landscape ; the understanding of stakeholders ; the quality and diversity of the key opinion leaders.*

Finally, these 9 factors were linked to the level at which they presumably are the most influential and were incorporated into a conceptual model that could be used to see what aspects of the business deserve (more) attention in each specific phase of the lifecycle. Altogether this could help entrepreneurs to take all the necessary hurdles that are needed to succesfully commercialize their medical device. In that same light, this conceptual model could also be used by investors as an easy handhold for their own portfolio companies. For future research it would be interesting to statistically test the 9 factors as proposed in this study and to see whether the conceptual model is perceived as useful in practice.

Table of contents

1. Introduction

1.1. Background & problem statement

With over 12,200 patent applications filed with the European Patent Office and currently 27,000 active medical technology companies in Europe, one could say that the medical technology industry (€385bn in Europe) is not only practically relevant, but also economically (MedTech Europe, 2017). Nevertheless, the path towards successful commercialization is, compared to other industries, extremely long, complex and difficult. Not only should end-user preferences and needs be understood, but also requirements of hospitals, insurance companies and government should be taken into consideration during the development process of the medical technology. What makes it even harder to assess these needs is that before a MedTech start-up can bring its device to the market, it must first obtain a certificate (e.g. CE or FDA) to proof user-safety and effectiveness and in some occasions is also plagued by time-consuming clinical tests (Pellikka, et al., 2007). Due to this the medical technology industry faces large uncertainties until devices are tested in the actual environment (Pietschz & Paté-Cornell, 2008). As a result, the average time-to-market for a MedTech start-up is generally longer than that of regular technology startups (Lettl, et al., 2008). According to information from Wijk, van, M. (2014) the phase from regulatory approval up until commercial success can vary between MedTech start-ups from 1 to 10 years.

As known from a variety of sources, adopting regulatory approval is a very important milestone for a MedTech start-up, because after certification they are allowed to start selling their product on the market (Kramer et al., 2012). This means that the start-up can start to make its own revenues and is not solely reliant on the financial resources of investors. Therefore, the speed at which a start-up completes the stage from regulatory approval up to commercial success is not only very important for the entrepreneur, but it will also tell participating investors how soon, and if, they will be able to make a return on their initial investment. The longer it takes before a start-up can fully rely on internal financial resources, the more external finances are needed to keep the start-up running and the riskier these investments will become. For MedTech start-ups this specific stage can be identified as what Wilson, et al. (2018) would describe as the 'Second Valley of Death'. The alarming large variance in the length of this stage for MedTech start-ups, 1 to 10 years, indicates that this stage is a rather unclear and complex one that needs more investigation.

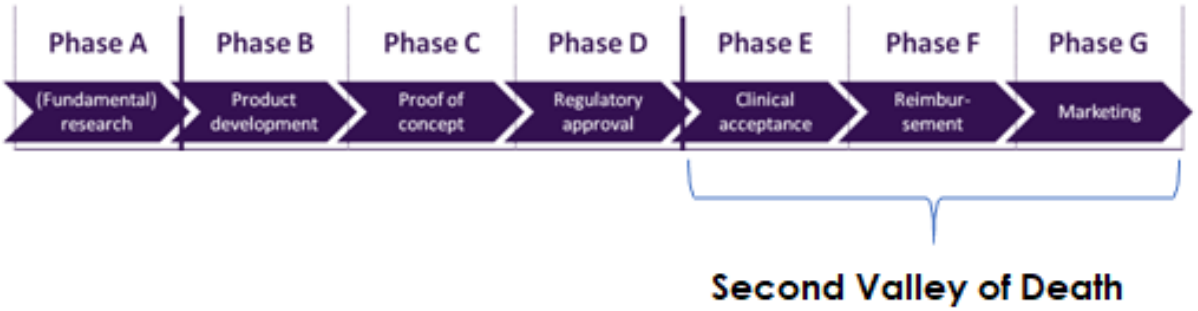
What makes this situation even more worrisome is that innovative science, such as medical technology, is usually developed by academia and scientists that lack an understanding of this commercialization process and the basic skill set that is required for success (Scanlon & Lieberman, 2007). Innovators usually have little experience in the market and thus lack the necessary 'know-how'. The problem is thus not the invention itself, but how to translate this invention into a stream of economic returns (Gans & Stern, 2003). Chiesa & Frattini (2011) acknowledge this problem by stating that although the commercialization phase is a critical stage in the technological innovation process, it is still considered as the least well managed phase of the entire innovation process.

This study will specifically focus on MedTech start-ups that develop rather new and highly innovative medical devices. These devices are interesting, because these are the ones that are mainly plagued by complex reimbursement routes and time-consuming clinical tests. Furthermore, due to their innovativeness, it is also harder to establish acceptance of the clinician for these devices, than for devices that show similarities with existing solutions. Finally, it are specifically those new and innovative medical devices that seem to fall into the trap of the 'Second Valley of Death' and are facing a rather long commercialization trajectory.

1.2. Research goal, scope & question

As mentioned in the problem statement by Wijk, van, M. (2014) the phase from regulatory approval up until commercial success can vary from 1 to 10 years, which brings a lot of uncertainty for not only the entrepreneur, but also the investor. This research will thus focus on this specific part of the commercialization phase (see figure 1), namely on the phase between the MedTech start-up adopting regulatory approval up until the moment of commercial success. Furthermore, this study will focus on those MedTech start-ups that tend to commercialize rather new and innovative mecical devices as they are often plagued by complex reimbursement routes and time-consuming clinical trajectories. It are namely those new and innovative medical devices that seem to fall into the trap of the second Valley of Death and are facing a rather long commercialization trajectory.

Figure 1: the development cycle of medical devices (Wijk, van, M., 2014)



As this research is conducted under European legislation, regulatory approval for this research is equal to the start-up *adopting a CE-mark* for its product. Adopting regulatory approval is an important milestone for MedTech start-ups, because after certification they are allowed to start selling their product on the market and can start to make their own sales revenues.

As commercial success is a rather subjective term and in order to make this success measurable, in this study one will use the moment of the start-up achieving *operational cashflow break-even* as a measurement point for commercial success. This point is chosen, because achieving operational cashflow break-even means that there is enough traction within the market for the start-up to fully rely on internal finances, instead of relying on external financing from investors. As a result, this stage is not only very important for the entrepreneur, but the course of this stage will also tell involved investors whether they will be able to get a return on their investment.

Nevertheless, the supposed variance in the length of this stage of 1 to 10 years, indicates that this stage is a rather complex one. For MedTech startups this specific stage can be identified as what Wilson, et al. (2018) would call the 'Second Valley of Death'. In order to overcome this stage, more in-depth knowledge is needed on what factors play an important role during this stage and affect its duration.

Therefore, the following research question will be addressed:
"What factors affect the duration of the commercialization phase (from the point of adopting CE-marking up until the point of operational cash flow break-even) of MedTech start-ups that focus on exploiting new, innovative medical devices?"

To put some more focus on this research, this study will look at the commercialization phase from two perspectives. First, investment professionals from different backgrounds (e.g. investment managers from venture capital funds, government funds and business angels) will be interviewed to identify factors that according to these investors play a crucial role during this part of the commercialization phase. As a result of these interviews, one will not only identify important factors but also try to point out the discrepancies between the existing literature and the knowledge from everyday experience. Secondly, the same will be done again, only this time the healthcare(-related) professionals will be interviewed. These professionals are closely related to the procurement-, acceptance- and diffusion-processes of the medical technology and can provide the researcher with in-depth and essential insight in the commercialization process.

Finally, the purpose of this study is to:

(1) Build a conceptual model[1] that visually represents the commercialization phase from the point of CE-adoption (regulatory approval) up until the operational cashflow break-even point (commercial success), **(2)** which is linked to the factors that according to the literature and experience of investment & healthcare(-related) professionals play an important role during this phase and **(3)** can serve as a guide for investors/entrepreneurs to successfully move through this phase without having to encounter unnecessary delay.

1.3. Academic & practical relevance

As mentioned in the previous section, not a lot of knowledge exists on how MedTech start-ups can successfully commercialize their products. Next to that, most of the existing literature focuses on the first valley of death, which is the phase in which a start-up must attract enough financial resources to move from proof-of-concept into a marketable product. Nevertheless, not much is known about the second valley of death that most MedTech start-ups seem to struggle with, which is the phase in which the start-up must start to generate a steady source of sales. This research will try to add to the existing literature about the second valley of death for start-ups. This study has practical relevance as it will give MedTech start-ups a better impression of how to validate their own product and how to achieve market wide adoption by approaching the commercialization phase with more knowledge than in past endeavors. Furthermore, it will also give investors (e.g. venture capitalists, business angels, banks and government) more hold on how they should approach MedTech start-ups. This study could help investors to get a better understanding on the validation of MedTech start-ups and in what way they could help their portfolio companies to commercialize their products and work towards a successful exit.

1.4. Outline of the thesis

The rest of the research is structured as follows. In the next chapter a systematic literature review will be performed to see what factors might influence the commercialization phase of MedTech start-ups/medical devices, according to the literature that is currently existing. At the end of the systematic literature review a selection will be made of the factors and frameworks that will be used in this study. Chapter three contains the methodology and will explain how the factors from chapter two will be analyzed and will give more information about the sample used for this study. Chapter four will describe the results and the analyses performed on the interviews. The final chapter of this research will provide the overall conclusion of the study and will touch on the limitations, implications and directions for further research.

[1] Conceptual, meaning that it is based on qualitative data and has yet to be statistically validated, which can be done in an additional study.

2. Theoretical Framework

In this section a systematic literature review will be conducted, to see what factors according to the existing literature could play a role during the commercialization phase of the MedTech start-up.

2.1. Systematic literature review

According to Wolfswinkel et al. (2013) a better legitimization of the choices made during the review process of the literature enhances the value of the review as it makes the research more useful and replicable. Thus, instead of just picking some frameworks in a rather random fashion a more systematic approach will be used as proposed by Wolfswinkel et al. (2013) which finds its roots in the Grounded Theory approach of (Glasser & Strauss, 1967). The article of Wolfswinkel et al. (2013) proposes five-stages for conducting a good systematic literature review. The review consists of the following stages: *define, search, select, analyze and present.*

2.1.1. Define

In this step of the systematic literature review, one will define the criteria for either inclusion or exclusion of a certain article in the dataset (Wolfswinkel et al., 2013). To set a certain time-frame, all the articles under consideration must have been published within the last five decades. Furthermore, the *relevance*, *times cited,* and *impact factor* have a leading role throughout this systematic search. These variables will be especially important when it comes to the selection of theoretical frameworks. When searching for articles to only get an impression on the status quo of medical technology or to start a certain exploratory stream of thought this is of less importance. In that case also less prominent articles or white papers can be taken into consideration. During this search journals will be preferred over books. Next to that this systematic research will focus on the fields of *Business*, *Management*, *Policy*, *Innovation*, and *Healthcare, Medicine* and *Biotechnology.* Subsequently this study will only take articles into consideration that are derived from Web of Science, Google Scholar and Scopus.

Finally, one can state that this research basically evolves around two central themes, namely 1) medical technology and 2) the commercialization/adaption/acceptance/assessment of (high) technology. Articles that fall into the general theme of 'medical technology' will not be considerate if there is no sign that it may possess any valuable information that is connected to the aforementioned second theme. Therefore, a search will be done on the following individual or combination of keywords: MedTech, medical technology, innovation, diffusion of innovation, technology commercialization, break-even, venture capital, technology acceptance, technology adoption, product-market strategy, exploitation, start-up and time-to-market. A combination of the above used keywords would look as follows; e.g. 'medical technology' AND 'start-up' or 'medical technology' AND 'commercialization'.

2.1.2. Search & Select

In the first part of this section the actual *search* in previously described databases will be performed. When a certain article already seems helpful at first sight, further search with forward/backward citation will be immediately applied. Furthermore, if during the search it is already noticed that an article has been already adopted in the dataset, then it will be left out already on purpose. Initially (see table in appendix A) a total sample of 85 articles were found. For now, the last box of the table will not be filled in yet. In the *select* section the articles (85) found in the previous section will be selected accordingly to whether they fit the criteria mentioned in section 2.1.1. Furthermore, all the doubles that were not identified during the search-phase will now be filtered out of the dataset. In this section

one will also check the last box of the previous table to determine whether, after a quick first scan, an article seems to be useful or not (see appendix A).

After scanning all the articles individually and filtering out the doubles the total sample of articles in the dataset consists of 54 articles. These 54 articles fit the boundaries of the research setting as described earlier. See appendix A for an overview of all the exact combinations of keywords.

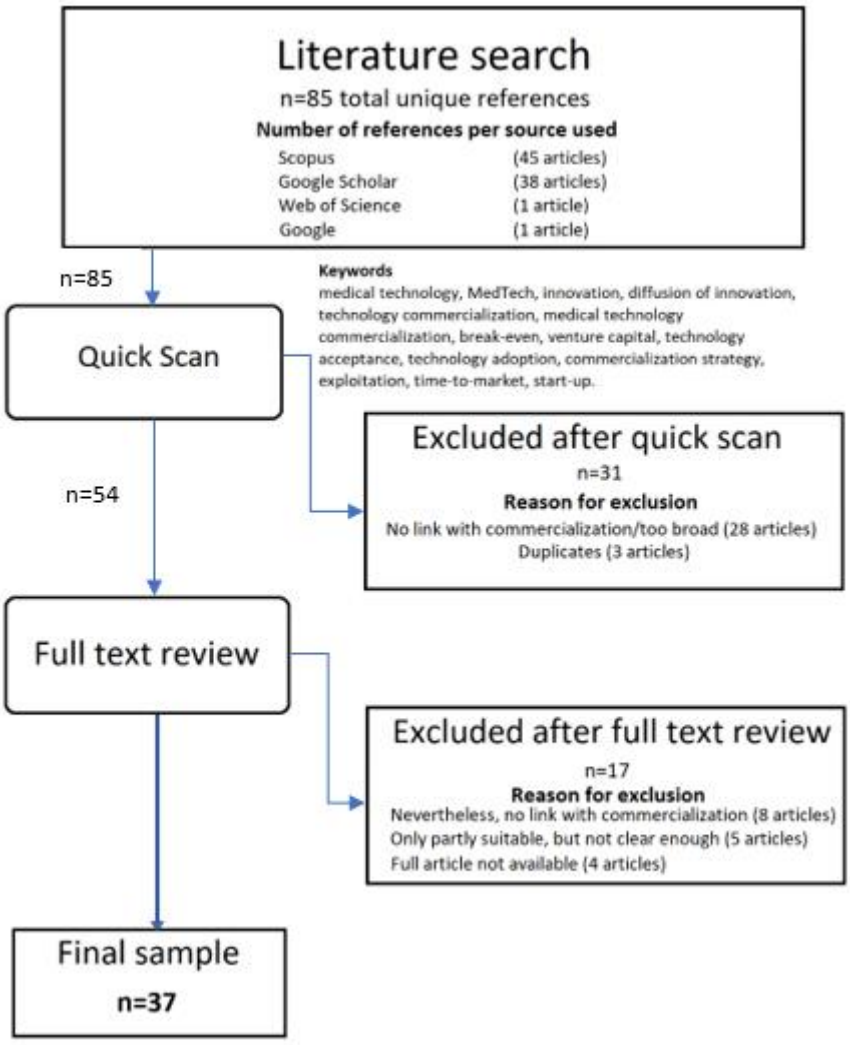
2.1.3. Analyze

After the previous section one ended up with an unstructured stack of the articles, thus in this phase one will perform the 'analysis' based on the Grounded Theory. In this phase the articles will be analyzed by using open coding (Wolfswinkel, et al. 2013). In short this means that the author will read all the articles very closely and look what the underlying concepts of the articles are and how they fit the research question of this study. "The ultimate goal of open coding is to identify a set of categories or a bird's eye image of the study's findings, with a set of theoretical and methodological insights attacted" (Wolfswinkel, et al., 2013, p. 50).

In appendix B, an overview is given of the articles in which they are categorized and connected to concepts that have been developed after analyzing the articles as proposed above. The articles, concepts and the connections between the individual articles will be explained in detail in section 2.1.4. If an article is marked red, this means that after a more careful analysis it appeared not to be useful for this research. When an article is marked orange, this means that the article is only partly applicable for this research, or only under certain conditions. In total 37 articles appeared to be useful for this research, of which 5 can only be deemed as useful under certain conditions.

The complete systematic literature review is visually presented in the following flowchart:

Figure 2: SLR Flowchart



2.1.4. Present

In this section the articles, concepts and connection between the individual articles will be explained more in detail. Each of the following paragraphs will try to give more insight about a specific piece of theory that, according to the literature and the rationale of the author, could possibly affect the duration of the commercialization phase of the medical devices. Thus, after each paragraph a proposition will be formulated to reflect how a specific factor might influence the commercialization process according to the current perception of the researcher. Subsequently, to give some more structure and to show the different layers of this research, each proposition will be connected to the level (e.g. hospital level, start-up level, etc.) on which it seems to have an effect. Finally, these propositions will be used during the interviewing process to challenge the participants about these different topics and to get a better understanding of what role they play during the commercialization phase and how they are intertwined with each other.

2.1.4.1. Development rationale & hospital adoption

In order to know how to commercialize medical technology in a successful way, one must know on what grounds a certain technology is adopted by hospitals. The article of Greer (1985) proposes that hospitals generally make this decision based on three distinctive streams of rationale, namely: *medical-individualistic*, *fiscal-managerial* and *strategic-institutional*. The medical-individualistic perspective puts the most emphasis on the value that is created for the patient by looking for technologies that maximize patient welfare and minimalize risk. In this case, classic literature such as the diffusion of innovations of (Rogers, 1965; 2003) seems best applicable. The fiscal-managerial perspective puts emphasis on values such as profitability and predictability and proposes a manner of decision-making that is based on rational and quantitative analysis. The strategic-institutional perspective embodies a broader view and looks at how a certain technology might change the organization as a whole.

Teplensky et al. (1995) later questioned this theory of Greer (1985) by stating that these decision systems are not as much mutually exclusive, but complementary to each other. Teplensky et al. (1995) proposed three views that in some way resemble the perspectives of (Greer, 1985). The *first* perspective, links hospital adoption to the anticipated financial returns. In this case expected profitability is the prominent value that depends whether a hospital will adopt a new medical technology. Thus, technology under consideration should be able to shorten patients stay at the hospital or decreases costs. In the *second* perspective, cost does not seem to play a role per se. What is specifically important in this perspective is that the technology under consideration must boost the hospital its image. Thus, capital-intensive technology is adopted in order to claim the position of technological leader in the hope that it will attract physicians and patients. The *third* perspective puts most emphasis on the needs and wishes of the patient. Hospitals and physicians in this case look at the clinical needs of the patients they serve and do not consider alternatives that are financially a better choice or would add more to the hospital its image.

A very clear statement that can be found in most of the literature is that new medical technologies have a lot of upsides when it comes to improving patient value, but on the downside, they are also raising healthcare cost at a tremendous speed (e.g. Greer, 1985; Teplensky et al., 1995; Greenberg, 2003; Egeland et al., 2017). The articles of Cosh (2007) and Egeland et al. (2017) even emphasize that cost and cost-effectiveness are becoming more and more important in order for a medical technology to even be taken into consideration. Egeland et al. (2017) states that hospital financial stakeholders signal that clinical superiority and support from the physician are still important but are no longer sufficient alone as it is becoming very challenging for innovative devices to be adopted if they add cost to tight budgets. This same message has recently also been adopted by the 'Centraal Plan Bureau' that in their policy paper stress that more emphasis should be put on the cost-effectiveness of new medical

technologies before they are being taken into consideration for reimbursement (Mot, et al., 2017). To conclude, it could be that MedTech start-ups mainly look to provide the perfect clinical solution to an existing problem or need from the perspective of the patient. By doing that they forget the importance of cost on an organizational level. Eventually one ends up with an excellent product that is too costly for hospitals to adopt. This mismatch could explain why the path towards successful commercialization is for some start-ups very long and difficult.

- **Proposition 1:** It could be that there is a mismatch between the a) rationale on which the product is developed by the start-up and b) the rationale on which new technology is adopted by the hospitals.

Based on the above, the researcher expects that the rationale on which the product is developed by the start-up will mainly have an influence on the **hospital-level.**

2.1.4.2. The role of end- & lead-user involvement

Another aspect that receives a lot of attention in the existing literature is the role that lead-users/end-users should have in the development phase of the medical technology in order for it to become a success (Shah & Robinson, 2007, 2009 ; del Campo et al., 1999 ; Lettl et al., 2008 ; Cain & Mittman, 2002 ; Chatterji et al., 2008).

In their research Shah & Robinson (2009) classify medical device users in two categories, namely: 1) end-users (patients) and 2) lead-users (professional users). In Shah & Robinson (2009) they built on their previous work, again stressing that the acceptance by end-users is crucial for the device its longevity. Even if the product is perfectly manufactured or recommended by healthcare professionals, it will only work if it is accepted by the end-user, the patient. In that same article they use the example of how asthma patients played a crucial role in the development phase of building what we now know as the inhaler. Nevertheless, the importance for this study is aimed at the commercialization phase. Thus, it would be valuable to test in what way patients can influence the diffusion of the medical technology in the commercialization phase. In that line of thought the article of Cain & Mittman (2002) propose that due to the increased access to medical information via the Internet, patients are more aware and involved in what is going on in the field of healthcare. Subsequently, patients are also better informed when it comes down to their own medical conditions and thus could take a pro-active role in expressing their needs for a certain treatment towards their physicians.

To conclude, it could be that medical technology start-ups are not making a lot of use of social media to engage with both lead- and end-users. If that is the case, then they might also not benefit from the possible positive side effects such as engagement with key opinion leaders and early adopters, whom can increase their chances of diffusion & market adoption and thus a timely commercialization.

- **Proposition 2:** It could be that MedTech start-ups do a) not make enough use of social media and thus are b) not sufficiently engaged with both end- & lead-users.

Based on the above, the researcher expects that the engagement with social media by the start-up will mainly have an influence on, both, the **end- & lead-user level** (patient & clinician).

The research of del Campo et al. (1999) showed that it is important for medical technology companies to validate the clinical benefits of the technology, which can be done by collaborating with physicians. These interactions can give better insight in the cost and other issues and concerns that could play a role if a company wants to get considered for reimbursement. Knowing that it is not allowed to just put medical technology on the market, lead-user involvement is the only way how MedTech companies can test whether their product has the potential to be adopted. According to del Campo, et al (1999)

understanding the needs of not only patients but also of the physicians that actually use the technology, will increase the potential for commercial success. The article of Chatterji et al. (2008) also acknowledges that practicing doctors are an important source of external knowledge on unmet needs and customer preferences. Furthermore Chatterji et al. (2008) also discovered that innovations that are patented by doctors or with the participation of doctors, receive more citations and had higher generality scores than corporate inventions.

Nevertheless, again, a lot of the focus is put on the early development phase of the medical technology. For this research, it would be particularly interesting to see what role physicians could play in the commercialization phase. To discover what impact physicians can make on the purchase-decision of hospitals it thus would be interesting to see in what way physicians engage with medical technology and how they inform themselves on new technology. The article of Escarce (1996) proposes that the main sources of information for physicians about new medical technologies are journals, conferences and informal discussions with peers. Journals and conferences are particularly important as the first sources of information for a physician to become aware of a new technology. Discussion with peers become valuable in a later stage, namely to diffuse a certain technology from one hospital to another (Escarce, 1996).

Whereas the latter is quite difficult to influence, a company can proactively make an effort into getting published and to make an appearance at conferences. First, a publication in a well-known journal could give a medical technology start-up the chance to prove clinical validity. When clinical validity is proved, this could make the device more eligible for reimbursement which could spark the interest of clinicians and motivate them to recommend the device to the hospital they work for. Second, attending conferences could not only give the start-up the opportunity to present their product, but also to extend their professional network and to team-up with credible partners. Being present in those surroundings could therefore also be perceived as a measure of validation for clinicians. This altogether could indicate that both, publications and appearances at conferences could function as catalysts for a timely commercialization.

- **Proposition 3:** It could be that a publication in a journal a) is seen as a measure of validation that could lead to b) a better chance of being adopted by clinicians.

- **Proposition 4:** It could be that attending conferences a) is seen as a measure of validation that could lead to b) a better chance of being adopted by clinicians.

Based on the above, the researcher expects that, although getting published and attending conferences could ultimately affect the hospital its adoption decision, it will first and foremost have an influence on the **lead-user level** (clinician).

2.1.4.3. The role of the academic background of the entrepreneur

The final stream of literature mentions the importance of forming strategic alliances in order to obtain unique capabilities and successfully commercialize new products (Hsu, 2006; Mitchel & Singh, 1996 ; Gans & Stern, 2003 ; Teece, 1988 ; Scanlon & Lieberman, 2007). What not should be forgotten is that start-ups are relatively small ventures that often lack all the necessary 'know-how' to successfully exploit a new technology (Gans & Stern, 2003). Another aspect that sometimes is overlooked is that the entrepreneurs behind the medical technology are not business-minded per se. In fact, most of the times, if not always, medical technology is invented by academic researchers. The paper of Scanlon & Lieberman (2007) acknowledges two fundamental commercialization problems, namely; 1) the ability of the academic community to change the culture of the scientist to commercialize technology and 2)

the ability of the business community to successfully communicate with the scientists to exploit their innovative ideas.

As medical technology is often developed by either researchers or clinicians, it could be that their main focus is on doing research and development of the technology itself, but that there is a lack of attention for the commercial aspect of the business. Therefore, it could be that they are not sufficiently informed on the market, its competitors and are not able to set up a good sales operation. This lack of business acumen could possibly explain why the path towards successful commercialization is for some start-ups very long and difficult.

- **Proposition 5:** It could be that most of the entrepreneurs behind the MedTech start-ups have a) a strong research background which leads to b) a lack of business acumen and subsequently c) a bad sales operation.

Based on the above, the researcher expects that the strong research background of the entrepreneurs will mainly manifest itself in how successful the start-up will be in its commercial endeavours and thus that it will be influential on the **start-up level**.

3. Methodology

3.1. Research Design

In order to know what type of research design is applicable for this specific research, one first must determine the *nature of the research*. Robson (2002) points out that the research design is based on its research purpose, which can be either: exploratory, descriptive or explanatory. Nevertheless, it is also possible that a research can have more than just one purpose.

To be clear, this study revolves around the following research question:
"What factors affect the duration of the commercialization phase (from the point of adopting CE-certification up until the point of operational cash flow break-even) of MedTech start-ups that focus on exploiting new medical devices?"

This question is asked with the purpose to:

(1) Build a conceptual model that visually represents the commercialization phase from the point of CE-adoption (regulatory approval) up until the operational cashflow break-even point (commercial success), **(2)** which is linked to the factors that according to the literature and experience of the investment & healthcare(-related) professionals play an important role during this phase and **(3)** can serve as a guide for investors/entrepreneurs to successfully move through this phase without having to encounter unnecessary delay.

This research is therefore on the one hand an exploratory study, but on the other hand a descriptive one. Firstly, it is exploratory as it tries to find out "what is happening; to seek new insights; to ask questions and to assess phenomena in a new light" (Robson, 2002, p. 59), by investigating what factors might play a role on the phase mentioned above. Secondly, it is descriptive as it tries to "portray an accurate profile of persons, events or situations" (Robson, 2002, p. 59), by describing the possible role of these factors and by developing a visual representation of this specific phase in order to provide more in-depth insight for investors and entrepreneurs.

After having determined the nature of this research, it is possible to select a *research strategy* (Saunders et al., 2009), e.g. experiment, survey, case study, action research etc. The most suitable research strategy for this study seems to be a case study, which is defined by (Robson, 2002, p. 178) as "a strategy for doing research which involves an empirical investigation of a particular contemporary

phenomenon within its real-life context using multiple sources of evidence". Case studies can be applicable to: individuals, communities, social groups, organizations and institutions and events, roles, relationships and interactions. Saunders et al. (2009) describe that a case study is able to answer the questions 'why?', as well as 'what?' and 'how?'. As we want to explore 'what?' factors seem to play a role in the commercialization phase and describe 'how?' they seem to affect the commercialization phase in the eyes of investment & healthcare(-related) professionals, a case study seems to be the right research strategy for this study.

Yin (2003) describes that a case study can have four types of design, that consist of two dimensions. First, a case study can either analyze a singular case, or multiple cases. Second, the unit of analysis can be of either a holistic (one unit of analysis) or an embedded design (multiple units of analysis). A single case study is often used to analyze an extreme or unique case. A multiple case study can be used to establish whether the findings in one case, also seem to occur in another one (Saunders et al., 2009).

For this study the researcher wants to discover whether there is consensus between the two groups of participants, about what factors play an important role during the commercialization phase of the MedTech start-up. Thus, to discover whether such a consensus actually seems to exist, multiple cases are analyzed. Regarding the second dimension, this study deals with one specific unit of analysis, namely those MedTech start-ups that try to commercialize medical devices. Within each case the MedTech start-up is analyzed in its entirety and no sub-units (e.g. departments) are subject to analysis. Therefore, the chosen research design is that of a holistic multiple case study.

3.2. Selection

As mentioned in the previous section one would focus on two groups, namely; professionals that represent the investor perspective and professionals that represent the healthcare perspective. Therefore, one must select organizations that are a good representation of the population as a whole and have the highest probability to come up with meaningful insights. First, to get a complete view on the investor perspective, one would select governmental investment funds, private investment funds and venture capital funds. Second, to get a complete view on the hospital perspective, one would select professionals that play an important role in the procurement, introduction and implementation of new medical technology in the hospital setting. As mentioned earlier, the researcher will only discuss these MedTech start-ups that specifically commercialize relatively new and innovative medical devices and not simply all MedTech start-ups in general.

Investment professionals
Participant 1 • Investment professional • Almost 2 decades of experience in listed, fund in fund, private equity and venture capital. • For 7 years focus on healthcare innovations • Managing partner of a VC-fund that has been initiated by a Dutch insurance company • The fund invests in early stage highly innovative medical- and healthcare start-ups that are looking for an investment for product development and market introduction.
Participant 2 • Investment professional with broad experience in pharmaceutical & biotech industry. • Functioned as consultant for several small biotech and pharmaceutical start-up companies.

- Authored many peer reviewed scientific papers and book chapters on pharmacology and drug development.
- Currently managing partner at a venture capital fund that invests in early-stage private companies that aim to develop and commercialize innovative medical products for diagnosis, cure, care or prevention.

Participant 3

- Seasoned investment manager that has over 15 years of experience within the field of Venture Capital and for the past 10 years has been focusing specifically on the healthcare industry.
- Currently managing partner of an early stage fund for Dutch healthcare innovations.

Participant 4

- Investment manager with 15 years of international experience of which the past 10 years he has been devoting himself to the fields of life sciences, medical technology and healthcare.
- Currently active as an investment director for a Dutch private equity group that is specifically focused on healthcare and medical technology innovations.

Participant 5

- Senior investment manager with almost 13 years of experience in the field of healthcare & life sciences.
- Before this, he operated in the oil & gas industry and banking environment.

Healthcare(-related) professionals

Participant 6

- Senior purchase officer of a Dutch academic hospital.
- 30+ years' experience in buying medical technology & devices

Participant 7

- For the past years this person has been working as innovation manager for a hospital that provides specialized healthcare in several medical domains.
- Has a deep understanding of how insurance companies affect the purchase decision of hospitals, as he was responsible for doing the contract negotiations with them in the name of the hospital.

Participant 8

- For the past three years, this person has been the CEO of a medical university spin-off company that helps other MedTech start-ups/scale-ups regarding their medical innovations and technologies.

- The company assists medical-based companies in all stages of development with the analyses of patient needs, healthcare gains, and possible market opportunities regarding their medical solutions.

- Due to her previous work experience within the hospital itself on many board positions, she has a great understanding of the different stakeholders within a hospital, how they function and what moves them.

Participant 9 • Senior engineer who has extensive experience at a very large international strategist in the sector of medical devices.
Participant 10 • Head of commercial operations for a specific department of a large multinational strategist in the sector of medical devices.

Table 1: Description of participants

3.3. Data collection

To see whether the formulated propositions in section 2.1.4. indeed, play a role in the commercialization phase and to see whether there are any discrepancies between the literature and the practical experience of the groups, but also individually between the two groups (entrepreneurs & hospital professionals) one must collect more in-depth data. A highly sufficient method to collect this data, is by conducting interviews. One can conduct several different forms of interviews, namely: structured interviews, semi-structured interviews and unstructured in-depth interviews.

The most suitable form for this specific research is to conduct data via *audio-recorded* **semi-structured interviews**. This data is quantitively analyzed and can be used to understand the 'what' the 'how', but also the explorative aspect, namely the 'why' (Saunders et al., 2009). "In semi-structured interviews the researcher will have a list of themes and questions to be covered, although these may vary from interview to interview" (Saunders et al., 2009, p. 320). This flexibility is extremely useful as on the one hand one wants to explore whether the factors that are derived from the existing literature indeed seem to play a role in the phase at issue, but on the other hand one also wants to see whether the investors and entrepreneurs perceive factors that are not mentioned in the existing literature yet. To get more in-depth insight it is also useful to make adjustments from case to case in order to link with the organizational context and to build on previous interviews.

3.3.1. Preparing the semi-structured interview

Wilson (2014) describes the following steps to prepare a semi-structured interview:

Step 1	Determine the goals or research focus of your semi-structured interview.
Step 2	Develop a list of general questions that you want to ask during the interview.
Step 3	Develop your interview guide with the general questions and basic script for the interview.
Step 4	Recruit participants who meet your screening criteria.
Step 5	Create and assemble any forms or documents that you need.
Step 6	Prepare a briefing memo that describes the company.

Table 2: Preperation of semi-structured interview (Wilson, 2014)

Due to the window of opportunity, there is no time available to conduct pilot interviews, therefore step 7 & 8 as described by Wilson (2014) have no value for this research.

3.3.2. Conducting the semi-structured interview

Wilson (2014) describes the following steps that are important when conducting a semi-structured interview:

Step 1	If possible meet with the participant(s) prior to the interview and provide an overview of the general plan.
Step 2	When you meet each respondent, ask where you should sit.
Step 3	Review the interview process briefly with each participant. Mention the following things: a) A brief description of the interview topic and goals, the stages of the interview process, recording and ethical issues, cutting short some discussions and prompting. b) The amount of time that is used for the interview. c) Determine what to do if the participant has to answer the phone or leave momentarily. d) What you will be doing with the data and if and how they will get a summary of the results.
Step 4	Begin the interview with some warm-up or introductory questions that are easy, nonthreatening, and relevant.
Step 5	During the main part of the interview, you will begin with questions on the interview schedule that you want everyone to answer and then ask the remaining questions.
Step 6	Signal a clear end to the conversation by thanking the participant, putting away note-taking materials, and turning off any recording devices.

Table 3: Conducting semi-structured interview (Wilson, 2014)

3.3.3. Reliability & validity

Due to the fact that semi-structured interviews are non-standardized, concerns in relation to reliability may occur (Saunders et al., 2009). Nevertheless, as a semi-structured interview is highly suitable for this specific research design (for arguments, see section 3.3.), the challenge is to reduce these potential threats as much as possible. One of the ways how this can be done is to make other researchers very clear why certain decision are made, e.g. why a specific research design is chosen and why certain methods are used for collecting and analyzing the data. Although it is impossible to replicate the exact same data, it will at least give other researchers the ability to reanalyze the data that has been collected in this research (Saunders et al., 2009). Furthermore, a very structured literature review is performed to make sure that one has enough knowledge about the issue at hand, which allows to really collect in-depth data. Next to that, "credibility may also be promoted through the supply of relevant information to participants before the interview" (Saunders et al., 2009, p. 328). Thus, to enhance the

quality of the interviews the participants will receive a list of themes that will play a role during the interview.

Another concern when using semi-structured interviews is the potential threat to validity. Or in other words, "if the findings are really about what they appear to be about" (Saunders et al., 2009, p. 157). As this research is of a qualitative nature, it is mainly important to improve internal validity. Which means that one must make sure that there are no flaws in the research design. External validity refers to the generalizability of the study. As the research question is of an explorative nature and as the purpose of this study is to build a conceptual model, generalizability is of less relevance. Generalizability would be of importance in an additional study if one would want to statistically test the conceptual model.

3.4. Data analysis

The first step that must be taken if one wants to analyze qualitative audio-recorded data is to transcribe it, reproduce it in written language. This will be done by listening to the conversation and literally type down what is being said. Not only will this reduce any potential bias, but it will also help one to deeply understand not only what is being said, but also how it is being said and in what context.

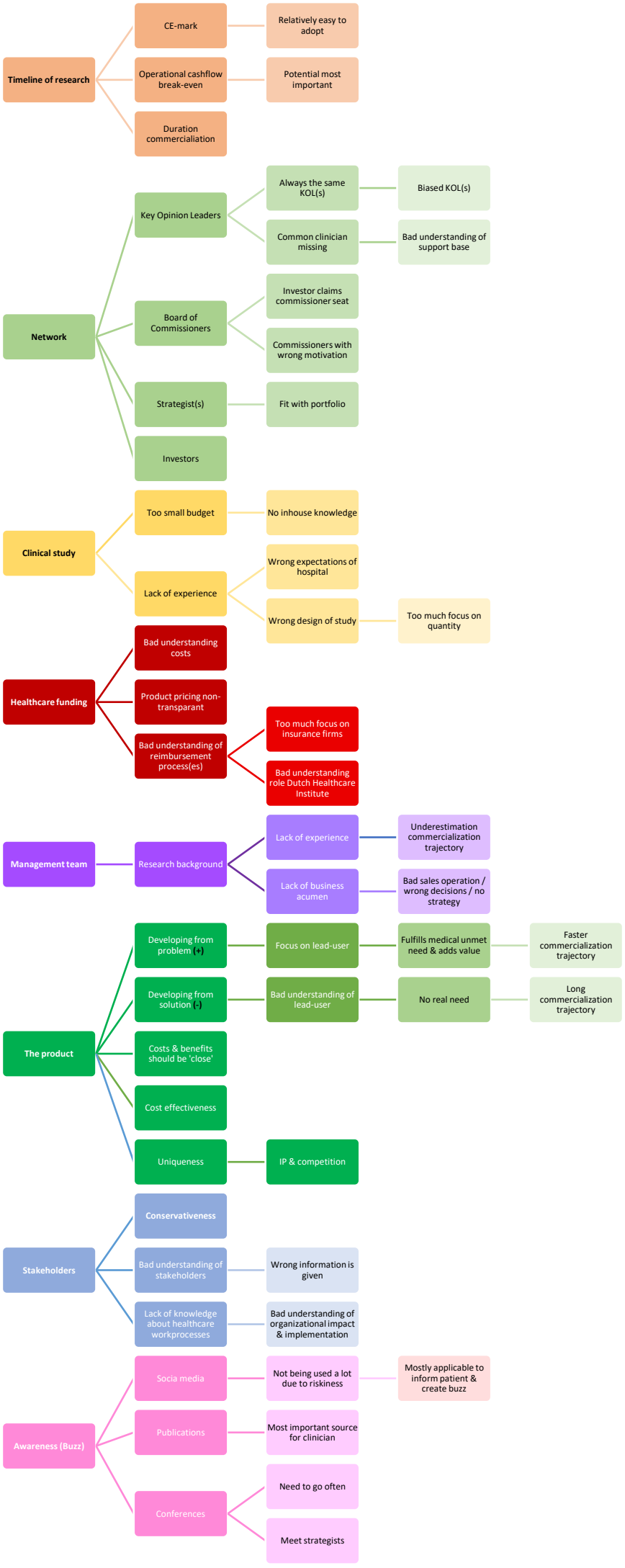
Next, the actual analysis of the data can follow either a deductive or an inductive approach. A deductive approach means that the researcher has made use of existing theoretical frameworks to determine the research question and its objectives. The upside from using a deductive approach is that "it will link your research into the existing body of knowledge in your subject area, help you to get started and provide you with an initial analytical framework" (Saunders et al., 2009, p. 490). An inductive approach means that you will start to collect data right away and analyze it whilst collecting. This approach is completely explorative in its nature and is mainly used to develop hypothesis that can be tested in additional research. Nevertheless, although the researcher may commend to one of the two approaches, it is most likely that in practice a research is most likely to combine elements of both (Saunders et al., 2009).

For this research one could indeed say that both approaches are relevant and will be used. On the hand, a deductive approach will be used to see whether the propositions developed in section 2.1.4. are also perceived as relevant by investors and hospital professionals in relation to the phase 'from CE-adoption to operational cashflow break-even'. On the other hand, this research also uses an indicative approach to see whether there are also other relevant factors that are not mentioned in the literature yet, but according to the investors and hospital professionals seem to play a role in the phase 'from CE-adoption to operational cashflow break-even'. Next to that, it is also inductive as it tries to explore whether there are differences between the perspectives of investors and medical professionals and how they value certain factors in importance from practical experience.

In general, (Saunders et al., 2009) describes three common qualitative analysis processes, namely: summarizing of meanings, categorizing of meanings and structure of meanings using narrative. Boeije (2005) describes this process of organizing and sorting data as the *coding* of the data. During the coding process the researcher defines different theme's or categories from the batch of data and gives each theme or category a specific code. The coding process has three stages that built on each other, namely: *open coding, axial coding and selective coding*.

The first step of open coding is used to examine, compare, conceptualize and categorize data. Thus, for starters, all the interviews were scanned, and the most logical and best self-explanatory 'code' was given to the data that seemed to be of interest. These codes were imported into an Excel file. For a visual representation of this process, see *appendix F*. In the second step, axial coding is used to make connections between the categories that have been distinguished during the first step. The goal of axial coding is to discover which categories are most important for the research question and are relevant for the purpose of the study. The axial coding process has been done in three phases. By coding the dataset in different phases, one tried to narrow down the total amount of codes used and to get a better understanding of the core- and sub-categories. Whereas phase I & II are closely related to axial coding, phase III already gives a clearer look on the relationships between the categories and can be used as a start for the selective coding process. For a visual representation of this process, see *appendix G, H and I*. Finally, selective coding focuses on the integration and the relations between the different categories and will give insight in which categories can be qualified as core categories. This final step will help to write the results and to visualize them. In the last step all the data is structured and visually represented in a so-called 'code tree' to give an idea of the most important information, observations and themes. See next page for the visual representation.

Figure 3: Selective coding: code tree



4. Results

In this section the most important results of the interviews are presented and discussed. The goal of the interviews, again, is 1) to see whether the factors mentioned in the propositions of section 2.1.4. also play a role in this specific phase of the commercialization process and 2) to explore whether there are more factors that have not been adopted in the existing literature, but according to the participants could possibly play a role in the commercialization phase from CE-mark (regulatory approval) up until operational cashflow break-even (commercial success). To not steer the interview in favour of the propositions and to leave room for an open discussion, which has a positive effect on the explorative nature of this research, a semi-structured interview approach has been used.

In the following section the results will be presented. The results are based on the themes (*the product ; management team ; awareness ; clinical study ; healthcare funding ; stakeholders ; network*) that according to the coding-process play the most important role in the overall context of this research. Therefore, the propositions as mentioned in section 2.1.4. will be discussed alongside these themes. By doing this the researcher tries to really reason from what is being said and meant and not by what is being expected upfront from its own point of view. The goal is thus to not only present an overview of the participants their perspectives, but also to give a better understanding of the coherence between the different topics and an impression on the bigger picture. If applicable the propositions from section 2.1.4. will be refined, extended or discarded. Due to the explorative nature of this research, there is also a possibility that new propositions are formulated in this section. If the participant does not really address the question/topic, his or her response is left out of the results.

4.1. Timeline of commercialization

Before moving on to the different themes and the proposition, this section briefly reflects on the timeline of the research to see whether the troublesome commercialization formulated in the introduction of this research is perceived the same by professionals from everyday experience. As the timeline of the research is something that directly impacts the investors and because they probably will have the most interesting insight in this topic, this section will focus on their reactions only.

The researcher started the interviews by asking how the participants felt about the proposed timeline of the research (from CE-marking up until operational break-even) and if they also perceived this timeline as one that deserves more attention.

Participant 1 reflects:
"In the past year we did 15 investments, which takes me to your second question 'do you recognize this?' Yes, I recognize it. […]. I have learned that the technological development itself, it can take a while, but eventually that will work out. The biggest challenge is to get it into the market, and uhm, that is very difficult."
Participant 2 confirms that indeed adopting CE is not enough to realize sales and points out that from that moment on, there is still a long way to go:
"*.. and that is the big crux, that, especially in the past, the point of adopting CE and actually having enough evidence to sell your product, those are two different moments. […]. Because why would an insurance firm or hospital put money on the table? They want to see that the business case is proven. And that takes an awful lot of time and that aspect is extremely underestimated by most companies. They all think that once they adopt CE that the party time has begun and 'then we will be able to make money'. And that last part always disappoints, because that is not how it works."*

When asked a bit more in detail if the point of CE-adoption is being valued as an important milestone, this same participant mentions the following:
"Look, getting approval is important, because then at least you showed that you have addressed a couple of risks which will make the authorities say 'hey, we don't see any reason why this can't be allowed on the market'. But really… the biggest hurdle in my opinion is not there, but in the next phase which you also show, that it adds value."
When asked the same question **participant 3** mentions the following:
"No, absolutely not. I know that some may think that it is important. But uhm, let me put it like this. I never witnessed a company going broke, because they weren't able to get a CE-mark for their product. It takes some effort and then you will get it. I have never seen that somebody wasn't able to get it."

The reactions from the participants seem to confirm that although CE is important, it is not really seen as a hurdle that brings a lot of challenges. The biggest challenge as perceived by the participants is the phase after CE-adoption, in which the start-up must start to generate sales and become a commercially stable company. These reactions seem to imply that 'the second valley of death' as described in the literature is also perceived by the professionals in the field.

The researcher also asked how the participants feel about the chosen point of operational cashflow break-even and if this holds any importance to them.

Participant 1 mentions the following:
"Yes, that is an important milestone for sure. Or, milestone… Look there are different milestones. […]. If you mean is it a milestone, like a happening, then yes... cashflow... without a doubt! Because, up until that point you are constantly looking at your runway, what is our burnrate per month? How far can we get with our money? So, once you achieve cashflow break-even then it is a very big relief."
Participant 2 mentions that his focus is not on becoming cashflow break-even, but that he puts emphasis on creating value. He elaborates:
"[…]. No, no, no. […] Look, if you are going to steer on becoming cashflow break-even then you are quite possibly not investing on value creation to its fullest potential. You are focusing on cashflow break-even where you keep costs low and try to sell as much as possible to achieve that cashflow break-even. But that does really match well with value maximization. There you possibly want to invest upfront, to perhaps, get active in more countries or do more studies."
Participant 3 seems to have a somewhat similar view on the topic by stating that cashflow break-even is sometimes also a choice and that the potency of being cashflow break-even is more important than actually being it:
"What occurs at a certain moment in time is that one can potentially become break-even. That moment is way more important than the fact of actually being it. Because sometimes if it is very successful, then you just want to invest more money to penetrate the market even more."
When asked about the overall timeline of the study, **participant 4** organically emphasizes the importance of the operational cashflow break-even point, saying:

"Achieving the point of operational cashflow break-even is the hardest aspect of a company. So yes, that's right! Yes, I recognize it and I also recognize the challenge that comes with it."

The reactions of the participants seem to confirm that also the point of operational cashflow break-even is one that bears importance to them. In fact, the reaction of participant 1 is quite similar to the situation that is formulated in the introduction of this study. Namely that up until the point of operational cashflow break-even, capital injections from the investors are a necessity to keep the business running. Here it is interesting to see that participant 2 and 3 put some nuance on the operational cashflow break-even point. What they seem to mean is that the operational cashflow break-even is not a goal on its own, but that utilizing on its potency is, which could eventually result in operational cashflow break-even. Participant 3 perhaps formulates this the clearest by saying that the moment of potentially being break-even is more important than actually being it.

Finally, the participants were asked if they recognized the variaton between start-ups regarding the speed of commercialization.

When asked if a strong variation is perceived when it comes to achieving the point of commercial success, **participant 2** reacts:
"Yes, definitely. Especially the point of commercial success… So, the point that one can potentially 'become' break-even."
Participant 5 adds to this by saying:
"Yes, I recognize the issue and the fact that it is very hard to make comparisons. Some go fast, and others go slower."
Nevertheless, the investors also critically reflect that although they recognize variation within their own portfolios, that they can't make any significant statement about this for the whole population of MedTech start-ups.
Participant 1 replies:
"Well, we don't have... We don't have an extraordinariy large portfolio, but yes they differ."
Participant 2 mentions:
"It simply takes very long... it takes long to make all the necessary steps which we just discussed. But to do it right you have to look at a very long period of time."

4.2. The product

The first recurring theme that seems to play a role in the commercialization phase from CE-adoption (regulatory approval) up until operational cashflow break-even (commercial success) is 'the product'. *Alongside this theme, the first proposition as formulated in section 2.1.4. will be discussed.* To repeat, the researcher argued that MedTech start-ups are mainly focused to provide the perfect clinical solution to an existing problem or need, solely from the perspective of the patient. By doing that it could be that they forget the importance of cost on an organizational level. Thus, eventually one ends up with an excellent product that is too costly for hospitals to adopt. This mismatch could explain why the path towards a successful and timely commercialization is for some start-ups very long and difficult. In this rationale, the following proposition was formulated:

- **Proposition 1**: It could be that there is a mismatch between the a) rationale on which the product is developed by the start-up and b) the rationale on which new technology is adopted by the hospitals.

For this proposition the goal of the interviews was to find out which aspects/characteristics of the product are being valued the most by both groups; investment professionals and medical professionals. Furthermore, the researcher wanted to know how the participants perceive the trade-off between added value and costs and how this affects the adoption decision by hospitals. Altogether this information could indicate whether there is a possible mismatch.

The researcher asked the participants if there are certain aspects that they ideally see occur in the business case of the product and what they personally value as extremely important.

Participant 1 reflects:
"From the moment that the proposition is brought in, I immediately want to know 'who is the end-customer and how can you make sure that the sales are already secured from the start.' It could be that the customer is already involved in the development process, it also could be that there are already some contracts (…). […]. If you would ask the market then a lot of times they will say 'yes, that's something that I want, and this is my turnover and such and such', but if they will actually buy it, that's second thing. There can be a difference between those two things."
When asked if there are more things that he values as important he elaborates:
"Well, the difference between a need-to-have and a nice-to-have. There are a lot of products, a lot of innovations, of which I think 'yes, they have some important benefits, but uhm... What its really about is 'is the user is dissatisfied?' What matters is that the user thinks that the current situation is unacceptable. When the user is still comfortable with the old situation, then he will not be motivated to use something new."
The reaction from participant 1 seems to suggest that, indeed, there are products being developed by start-ups that do not really match with the needs from the user. Or in his own words, that are more a nice-to-have then a need-to-have.
Participant 2 shares his view:
"We focus really strong on the added value of the product. Will the product add value in a market five years from now? So, the competitive position. Does it have added value for patients, but also for clinicans?" […]. But I also think that it is extremely important to know happens with your product in

practice. How is it perceived by clinicians, nurses, by whoever works with it? You really should stay in touch with them, because you can learn a lot in the sense of like 'does your product perform good or not, are there any improvements to be made, what are the issues, irritiations etcetera."

Here it is interesting to see that participant 2 stresses the importance of understanding both, the perception of the patient but also of the clinician.

Participant 3 mentions that it is very important to reason from the problem and not from the technology itself**:**

"Well at least they must reason from the healthcare and not from the technique. I think that that is the most important thing. So, if they reason like 'this is how it works right now in healthcare, this is were it always goes wrong and we can improve that by doing this', to me that is a much more trustworthy story then 'we are from the University of Twente and we developed a new technology which we think fits best here. First, we thought that we had to be in aerospace, but now we have pivoted towards healthcare.' I get really nervous, really fast, when I hear stories like that."

Later in the conversation he again mentions multiple times that good products are created by those who really understand their user. He also mentions that this is something that goes wrong quite often:

"Look, the biggest problem arises if you develop the wrong product. It is so often, that they develop something and then later reflect 'yeah we thought that it would work, and we went to the market, but apparently they want this or that'. If that happens, you can start over again."

Here it is interesting to see that participant 1 and 3 seem to touch on a similar issue. Namely, that in some cases products are developed that are not really created from an urgent need, but more from what the entrepreneur expects that the market needs. This implicates some sort of disconnect between the supplier and the buyer.

Participant 4 stresses the importance of creating a product that is also easy to implement.

"I think that... yes well, if it replaces an existing product. If it is an alternative for an existing device, then its easier to commercialize it. In other words, it should be as close as possible to the existing situation. That will make the transition, the implementation and acceptation smaller. On the other hand, the disadvantage about that. Is it unique enough? Does it really improve something? So, the ideal proposition is one that really brings a significant improvement opposed to the existing situation, but that fits really well in the market qua acceptance, qua sales trajectories, qua reimbursement, etc."

Participant 5 also feels that the product should address an unmet need:

"What problem is this device going to solve? Because, the bigger the problem, or the unmet medical need, the higher the chance is to succeed. Because then it will be easier to get people to support you. So, clinicians that will adopt it and you will also have faster regulatory trajectories when there is a big unmet medical need then when this is not the case. So, everything starts with 'how big is the unmet medical need?"

To summarize the above, the product characteristic that is valued the most by the investors, is the way that it addresses an unmet medical need and thus if it adds value. The investors also seem to suggest that successful technologies are those that are developed from a clear problem definition and not from the technology itself. In line with this, they all seem to agree that it is very important to keep in touch with the user, not only during the development phase, but also after the product is adopted to

successfully implement it. The reactions from participant 1 and 3 seem to suggest that in some occassions, indeed, there are products being developed that do not fit with the needs from the user and thus are having a hard time to commercialize. Nevertheless, to get a better understanding about whether there is a mismatch or not, it is important to get a better understanding of 'the user' in the hospital setting as the user seems to play a key role in the adoption decision. Futhermore, from the information above it is not yet completely clear whether the participants refer to the clinician or the patient by mentioning 'the user'.

Considering this, the researcher also asked the participants affiliated to the medical sector what aspects they value when they look at a new MedTech product. Furthermore, the researcher tried to discover what is meant by 'the user'.

Participant 6, the senior purchaser says the following:
"Let's start with saying that it really should have an added value for the patient. People talk way too less about that, but it should really have added value."
When asked how the purchase-department decides what technology is interesting to look at, participant 6 mentions the following:
"The ones that play a prominent role in that process are the clinicans."
Participant 7, the innovation manager says:
"I think that the most important factor if something will succeed or not, is the acceptance by the healthcare professional. If that person thinks that it is an improvement, then things can go really fast. If that person does not really see it that way, then you can push as hard as you want, but then it really won't happen."
When asked a bit more in detail how entrepreneurs can prevent this from happening, the innovation manager replies:
"Well it is sometimes said that you must involve the patient in the development phase. Well, that's a beautiful story and in some way it is true, but perhaps it is even more important to make sure that you involve the healthcare professional very well..."
Participant 8, the CEO that focuses on health technology assessments replies:
"What we see quite often is that a lot of MedTech start-ups arise from the technology and say, 'we can make something'. Great. 'We can measure something and that we can measure something, that has an effect'. That's a great start, but then what. Then you have developed something reasoning from the solution, while you should have reasoned from the problem. So, what is the problem and what is the solution for that problem? If you are first going to develop the solution and then look for a problem that fits, then for sure you will get into trouble. And that is something that we see MedTech companies do very often."
Later she adds to this:
"So, if you ask me, what are reasons that innovations have stranded somewhere along the process. First of all, they don't really know the problem at hand. So, who is really looking for this and how big is the problem really? They are too focused on the solution that they are developing themselves.

Often, they have no clue how complex the medical sector really is and which factors they should take into account. They have almost no contact with the medical community."
Participant 9, the strategists shows that for them other aspects are valued as well:
"What is also very important for us as (…) is our mission, that gives a lot of guidance in what we do and what we don't do. […] Then we have the other considerations, such as do we already have it? Or does it fill a gap in the things we do not offer yet?"
When asked if a strategist also collaborates with hospitals during the development phase, he replies:
"Oh yes, hospitals and clinicians are very important partners for us. Because that is were the real treatment takes place and therefore the clinicians can really see 'what do we need'. And we also collaborate in a sense that we also have advisory boards that are filled with clinicans. They advise us on where the possible medical unmet needs are."

To summarize the above, the reactions clearly reflect that although the patient is certainly important, it is the clinician that is the decisive factor in whether a product will be used in the hospital setting. Or in other words, the lead-user (clinician) seems to play a more important role when it comes to hospital adoption than the end-user (patient). As with the group of investors, here we also see that, indeed, in some occasions start-ups develop products that do not match with the needs of the hospital and therefore are having a hard time to commercialize. Nevertheless, this mismatch does not seem to stem from being too focused on the needs of the patient, but from developing from the view of the solution instead of the problem. This results in products that do not truly fulfill a medical unmet need.

As mentioned earlier, the researcher argued that start-ups are perhaps too focused on developing the perfect clinical solution which leads to products that are too expensive for hospitals to adopt. Therefore, the researcher also wanted to get a better understanding about the trade-off between costs and added value.

The researcher thus asked the participants what happens with the duration of the commercialization phase, if the product on the one has a lot of added value for the patient and clinician, but on the other hand is relatively expensive.

Participant 1 replies:
"Yes, that will make it harder. But I also think that that is an answer you would expect."
The researcher asked the participant, if a product that is more expensive then the current solution, still has a chance to be adopted. He replies:
"Oh yes, yes for sure. […]. If reimbursement is established, then a device can be used by a lot of people, per patient we then talk about relatively a small amount of money. And then I am pretty sure that it will lead to a reduction in costs per patient."
Participant 2:
"I think that when it costs too much money for the tenable value that it adds, then you will have a problem. […]. You should already have an idea about that in your first analyses, about for how much you will be able to make it, the costs of goods. So, the price in the market versus what it adds in value

and what you think that the society in a broad sense, would be willing to pay. If that balance isn't right, then you should not even start."

Participant 3 argues that high costs are not always a problem:

"Well what you see is that if you have some sort of lifesaving thing, then things can go relatively quick. Even if its expensive and very good. […]. So, what you see is that the obvious things, they fit relatively fast within the system."

Participant 4 that expensive products are always harder to commercialize, even if they're better:

"*Well it is not immediately a no-go, but it is definitely a strong disadvantage. Look if its more expensive, that can only happen if it is also better. But that it is better, that is also something that you have to substantiate. But what you then see, is that the sales trajectory becomes very laborious, because you always have to explain why it is better. That makes it simply a bit more difficult."*

Participant 6, the purchasher explains how this affects his work:

"Then you will get a game between the supplier, the hospital and the insurance firm, because when will an insurance firm provide reimbursement for a product? That can take multiple years. That is what I know from my everyday experience. It can take three to four years."

This sparked the interest of the researcher and thus the participant was asked whether the decision of the insurance firm is a decisive factor on whether or not the hospital will adopt the product.

"No, you will get in the medical ethical. Am I going to deprive a product with clear added value from the patient, because we don't have the resources? In that trajectory I am not the decision maker though."

To get a better understanding of this, the researcher asked if it thus could be that a hospital decides to buy something, even when the product is not eligible for reimbursement.

"Oh yes, that could happen. And after a certain time, you could still involve the marktparties and tell them 'what you ask of us, that is not something we can pay, so you should give in'."

Participant 7:

"Managing a hospital is the hardest thing there is. So, in that light, you probably understand that the space for innovation... You cannot justify a lot of failures."

Participant 7 also explained quite a lot about how the cost structure works for a hospital and how everything is financed. Nevertheless, this will be discussed in section 4.6.

Participant 8, responsible for conducting Health Technology Assesments mentions:

"Cost-effective is something that 'adds value to the health of patients against lower costs. Or it adds value to the health of patients against acceptable additional costs. Then you also have the option 'it can save costs and result in small health loss', but that option isn't attractive. So, it is important for an innovation that it makes healthcare less expensive, cheaper, but also better. And 'better' is the most important aspect and the costs should be kept between boundaries. If you can save costs, then that is fantastic… It is important, but it is not… You see that a lot of innovations get on the market

that are not cost effective at all, but that still make it. So, that is not the thing that determines whether something will get on the market or not, but it surely is an important factor."

To summarize the above, one can see that the costs are definitely taken into consideration, but it is not the factor that determines whether a product will be adopted in the hospital setting. Furthermore, as was mentioned earlier, also here the decisive factor on whether something will be adopted seems to be if and how the product addresses a medical unmet need. If a medical unmet need is addressed, then the product can even be (a bit) more expensive then the existing solution. Therefore, it does not seem to be the case that products that are more expensive directly result in a no-go.

To conclude all of this, one can see that a couple factors are extremely important if the start-up wants to create synergy with the hospital. First, both groups of participants stress the importance that a product should address an unmet medical need and thus add value for both patient and clinician. If a product is developed from a clear problem definition and not from the solution, then in most cases the product will correspond with the wishes and needs of the hospital and thus add value. Regarding the costs, it has been made clear that although high costs are not desirable, they do not straight away result in a no-go as long as they are justifiable. Second, to realize added value it is very important that the start-up engages with the clinician, as the clinician plays a key role in whether a technology will be used in the hospital setting. Although this wasn't the goal of this section, this seems to go against the literature of Shah & Robinson (2009) who mention that in order for medical device to succeed, the acceptance of the patient (end-user) is key. These results suggest otherwise, namely that although patients are certainly important, the real power is on the side of the clinician (lead-user) that must use the device. Regarding the proposition, we have seen that in some occasions indeed there seems to be a mismatch between the rationale on which the product is developed by the start-up and the rationale on which the product is adopted by the hospital. Nevertheless, this does not stem from a sole focus on the need of the patient, but more from developing from the perspective of the solution (technology) instead of from a clear problem definition. All of this gives the researcher enough motive to *revise the first proposition*, into the following:

- **Revised proposition 1**: If the start-up reasons from the perspective of the solution instead of the problem, then (a) the developed product does not add any value, which (b) creates a mismatch with the rationale on which new technology is adopted by the hospitals.

Due to this, the researcher argues that **the added value of the product** could be another factor that affects the duration of the commercialization phase (from CE-marking up until operational cashflow break-even). As in line with the initial expectations of the researcher, this factor seems to mainly have an influence on the **hospital level.**

1. The added value of the product

4.3. Awareness

The second recurring theme that seems to play a role in the commercialization phase from CE-adoption (regulatory approval) up until operational cashflow break-even (commercial success) is 'awareness'. Specifically, how entrepreneurs can create awareness for their product and how this awareness can affect the course of the commercialization phase. *Alongside this theme, the second, third and fourth proposition as formulated in section 2.1.4. will be discussed.*

To repeat, *regarding the second proposition*, the researcher argued that medical technology start-ups are not yet making a lot of use of social media to engage with both, lead-users and end-users. If that is the case, then they might also not benefit from the possible positive side effects such as engagement with key opinion leaders and early adopters, whom can increase their chances of diffusion & market adoption and thus a timely commercialization. This rationale led to the following proposition:

- **Proposition 2**: It could be that MedTech start-ups do a) not make enough use of social media and thus are b) not sufficiently engaged with both end- & lead-users.

To get a better understanding of this, the researcher asked the participants to what extent social media plays a role in the commercialization phase.

Participant 1 reflects:
"Well if I look at my investments, barely. While I do think that sometimes it could be used. I know one specific case. Look it depends is it B2B or B2C, but if the product really ends up with the patient… Then I think that you could target that patient via Facebook. For instance, we invested in a way to make mammography less painful for women. […]. If you create buzz for something like that via social media, then you could effectuate that women are actually going to look for it. We did that very limited here (…) and then women called us with the question 'where this could be done'. And at that time, it could only be done at (…)."
When asked if he thinks that this is something that could be used more often, he replied:
"Yes, I think so, but I personally would not exactly know how. I don't know how you for instance could target clinicans at Facebook or Instagram. But it is definitely interesting!"
Participant 2 reflects:
*"I think that it really depends if it is a product of which patients can have an opinion or if it is something that is only used by clinicians. […]. But for instance, if it is a product of which you know that you would like to target patient associations and that you know that they would be happy with the product… Via social media you could intelligently anticipate on that and provide information… […]. *Gives example of a company they invested in* Well in that case it is extremely convenient to communicate via social media, via a lot of different channels actually and to make patients aware of the fact that there is a reimbursed treatment."*
When asked if this is something that preferably is used for products that are focused on the patient, he replies:

"It can be one of the channels you must use to create awareness. It is mainly to create consciousness, so that people know that the option exists and that they will ask their doctor about it, because that is what you would want. But it is very tricky, advertising medical products. That is very regulated, so only providing information is okay."

Participant 3 reflects:

"Yes, that can be very fun. With (…) we did a crowdfunding. We also did that a bit to show how big the problem was. There we gave people the chance to buy the product, but not by buying it themselves, but by setting up a sort of mini crowdfunding in which they could mobilize people in their surroundings to fund that product for their child. That became an enormous success. We sold like 120 of them via that crowdfunding, and not completely via social media like Facebook, Twitter, but also via movies on the internet and that created buzz. Then we saw that the reaction of a lot of insurance firms was like 'oh yes, apparently that is really a big problem'. That's something else than just a couple of numbers like 'so many people in the Netherlands…'. The fact that people mobilized their families, friends to do such things, it really helped. It really helps for the public perception."

To ge a better understanding, the participant was asked if social media is used often by MedTech start-ups, he replies:

"No, way to less. […] But that is also how our sector works. We as investors think it is very scary. I think that… there are a lot of introvert technicians that work at those start-ups. And the investors, they also think like, publicity can turn against you very quick. A small press release that you have invested in something is fun, but not too much you know."

When asked if he thinks that social media could also influence the duration of the commercialization phase, he replies:

"I wish that patients would pressure their clinicians a bit more to try some new technologies. […]. Me personally, I am not against telling the people what is out there, even if it is not proven yet. That does not mean that it doesn't work, it has just not been proven yet."

Participant 4 replies:

"Well it depends on the product. If it's a product like (…) then it could work via social media. Next to addressing the clinician. The other way is to approach the patient and to make the patient go to the clinician and say, 'hey heard about this and that, isn't that something fo me?' So yeah, you could approach both and specifically for those more consumer kind of products it could be very useful to use social media and similar campagnes to reach your target group. But if it is really a device that is used in the hospital, for patients that are to be treated there, then social media is not very effective I think."

Participant 5 adresses the question from a different perspective:

[…]. Maybe also to attract good quality people, so employees. Because, on a daily basis talent signs up like 'I want to work for you guys'. That is also extremely important, to get good quality people on board that are eager to work. Students are ofcourse a lot on social media, so they see that stuff. They get triggered by things like that. Also, the patient groups. Ofcourse you have to be careful with that, but if the patient groups ask for something and you have the solution, then things can come together beautifully. That could speed things up! Ofcourse you must be careful, because a clinician would never like to be passed upon."

When asked how the clinician should be treated in such a situation, he replies:
"You should have your clinical evidence. A lot of publications, KOL's, conferences, to also give the scientific community a solid place. […]. Because then, the patient also has a solid argument to pressure the clinician."
Participant 6, the purchaser says that he is not affected by social media:
"No that reaches us barely. Ofcourse it is true that due to the internet, patients are getting more empowered and that they also could suggest how they would like to be treated. But normally we don't notice that, we are too far from the patient. We can make a guess, but the patient is anonymous to us."
When asked if patients nowadays are more empowered by social media, **participant 7** replies:
"I immediately want to say 'yes, absolutely true'. A patient 'could…'. […]. But it also could be a very dangerous weapon, it can turn into public anger, where the facts… a Donald Trump kind of thing. Where the facts don't really matter, but where it's more about the setting you create. So, I would also get why entrepreneurs that spend 10 years of time and money into building a meniscus protheses think 'hmm, maybe we should be careful about that, because if somebody starts to scream that it is bullshit, then I have to do a whole lot of talking to set the facts straight.' Damage is done very quick."
Participant 8 does not really believe in the power of social media:
"Hmm, well, making a name for yourself is important for every business, no matter what you do. Only the more of a specialist you are, the less impact social media will have. Or at least, that is what my gut feeling says."
When asked if patients could use it to provide more feedback, she replies:
"Patients are not very influential when it comes to treatment within the hospital setting. It is only recently that patients are able to choose by who they get treated. […]. Ten years ago, that was certainly not the case. But the patient still has no influence on how they get treated."

To conclude, the reactions above show that, indeed, there seems to be some undiscovered potential when it comes to the use of social media in the healthcare sector. This potential seems to be mainly there for devices that can be used in the home setting of the patient. Some participants gave good examples of how social media can be used to create awareness for a problem and to mobilize and activate patients to take matters into their own hands. Most participants suggest that social media could be used a lot more, but that there is still some conservativeness under entrepreneurs and investors that withholds them from using it. For that matter, one could definitely argue that social media is not yet used to its fullest potential and could be used as a tool to enhance the commercialization of the device. Nevertheless, the reactions also show that social media is less effective when it comes to enhancing the adoption of devices that are used by the clinician in the hospital setting. In the hospital setting we, again, see that the clinician has the most power on whether a device will be adopted and also here we see that the existence of clinical evidence is decisive. Again, this seems to go against the literature of Shah & Robinson (2009) who mention that in order for a

medical device to succeed, the acceptance of the patient (end-user) is key. Nevertheless, the results do give the researcher enough motivation to *revise the second proposition* into the following:

- **Proposition 2**: MedTech start-ups do a) not make enough use of social media and thus b) could be better engaged with end-users than they currently are.

Due to this, the researcher argues that the **active use of social media** could be another factor that affects the duration of the commercialization phase (from CE-marking up until operational cashflow break-even). Nevertheless, the researcher also believes that *active use of social media* only plays a role for those devices that can be used by the patient in the home setting and not for devices that are used in the hospital setting by clinicians. Opposed to the initial expectations of the researcher, this factor thus does not seem to be as influential on both, the end- & lead-user level, but mainly on the **end-user level** (patient).

2. Active use of social media

Regarding the third the proposition, the researcher argued that a publication could give a medical technology start-up the chance to prove clinical validity. When clinical validity is proved, this could make the device more eligible for reimbursement which could spark the interest of clinicians and motivate them to recommend the device to the hospital they work for. Altoghether, this could enhance the chance of being adopted by hospitals. This led to the following proposition:

- **Proposition 3**: It could be that a publication in a journal a) is seen as a measure of validation that could lead to b) a better chance of being adopted by clinicians.

The researcher thus asked the participants about the role of publications in relation to duration of the commercialization phase:

Participant 1 replies:
"Well as I told you, I am not very aware of the scientific insights on this matter."
The researcher explained the participant that he is talking about the clinical evidence that is being publicated. The participant replies:
"Oh, now I get it. Yes, publications are very important. So first you have CE and then you have to do the clinical studies to prove that it really works and that is being done via those publications. […]. Yes, and eventually those publications also will make it easier to realize reimbursement."

The situation above made the researcher realize that when participants talk about clinical studies, that they inherently talk about publications. Publications seem to be a logical result of doing clinical studies

and not something that can be seen separately from the gathering of the clinical evidence. Thus, the researcher additionally asked the participants if they could tell a bit more about the importance of the clinical studies.

Participant 1 continues:
"One can have CE meaning that it is safe, but with the clinical studies you really have to show that it 'works'. Most of the times, a lot of effort has to be put into that still. So, one of the factors that makes these trajectories very long is due to the duration of the clinical studies."
Participant 2 confirms the importance of the clinical studies regarding the adoption of the product:
".. you must do a clinical study and eventually, based on that data, you have to convince clinicians, users and the payer that your product has added value."
Participant 3 acknowledges the importance of the studies, but also their troublesome trajectory:
"Those studies always cost way too much time and then when they are finally done, it still takes ages for somebody to perform some analyses on them. And after that it will, again, take ages for somebody to write an article and to get it published. So, it strikes me that this always takes a lot of time, but it is very important. Eventually the whole healthcare sector is evidence-based, so people really want to see proven results."
Participant 4 acknowledges both, the importance and its duration:
"Clinical validation is even more important. So, support that the device is effective or that it adds value in comparison to the existing solutions." […]. The clinical validation in relation to the reimbursement, can take way more time than expected."
Participant 5 explains the importance of the clinical studies a bit more in detail.
"You need the clinical evidence for the regulatory 'story'. CE and safety are one thing, but in order to sell it, independently of the class of device, you need permission of the EMEA or the FDA in America. They have certain demands when it comes to the quality of the evidence, with tests, randomized multicenter clinical trails. So that is the hardest thing, so to say."
Participant 9 stresses the importance of the clinical evidence in relation to the adaption of the product:
"...eventually you will get better evidence and the better your evidence is, the higher the probability will be that the medical sector will accept your product."

First, the reactions above, and especially those of participant 2 and 3, clearly reflect that the healthcare sector is very evidence-based and that thus it is very important to prove clinical effectiveness. This clinical effectiveness is showed in studies which are subsequently published. Without convincing clinical evidence, it is highly unlikely that a clinician will decide to adopt a certain device. In other words, these publications are indeed an important, if not the most important, source of information for the clinicians and thus it seems that the literature of Escarce (1996) still holds value to this day.

Thus, one could conclude that indeed a publication in a journal is seen as a measure of validity, which confirms the first part (a) of proposition 3. Second, participant 1 also acknowledges that those publications will also help to realize reimbursement, which could be a trigger for hospitals to use a certain product. The quote of participant 9 is also very striking by mentioning that 'the better your evidence is, the higher the the probability will be that the medical sector will accept your product'. Therefore, also the second part (b) of proposition 3 also seems to be confirmed. Altogether, one could thus state that proposition 3 is confirmed.

✓ **Proposition 3**: It could be that a publication in a journal a) is seen as a measure of validation that could lead to b) a better chance of being adopted by clinicians.

Nevertheless, during the interviewing process it also became clear that the publication by itself is simply a result of these clinical studies. In fact, if you even want your product to be seriously considered by a clinician or hospital for adoption, having a publication with clinical evidence is a standard requirement. This is also clearly reflected in the reactions above. When asked about the publications, most participants immediately mention that conducting the study to gather the clinical data is the most troublesome aspect. Thus, after a while it became clear that perhaps the real influential factor on the duration of the commercialization phase is not the publication, but the set-up of the clinical study itself and how the data is gathered before it gets published. Therefore, and in line with the explorative nature of this study, the researcher wanted to go a step further by trying to see why conducting these clinical studies take so much valuable time. *This part is discussed alongside the theme 'Clinical study' in section 4.5 on page 42.*

Regarding the fourth proposition, the researcher argued that attending conferences could not only give the start-up the opportunity to create awareness for the product, but also to extend their network and team-up with credible partners. Being present in those surroundings could therefore also be perceived as a measure of validation for clinicians. This led to the following proposition:

- **Proposition 4**: It could be that making an appearance at a conference a) is seen as a measure of validation that could lead to b) a better chance of being adopted by clinicians.

To get a better understanding of this, the researcher asked the participants about the role of those conferences in relation to the commercialization phase.

Participant 1 replies:
"Well theoretically, those conferences are a place were Key Opinion Leaders speak to inspire other people. So that is the theory, but I think it would be interesting to see what really the effects are of those conferences. I don't know that. So, it looks quite important. It probably is, but it is very hard to measure. It cost a lot of money, so yeah."
When asked if participant 1 values the attendance of such conferences when it comes to his own portfolio companies, he replies:

"Well, it is not on the top of my prioritylist. Maybe also, because it is really hard to measure the effects."

When asked if he thinks that the time that start-ups put into attending these conferences is justifiable, he says:

"Look, I really don't know. On the one side, it probably is, but I also have an example of a company that attends these conferences quite often and still we are having a hard time to get that one going. In that case […] maybe its more a nice-to-have […]. And then you could be at those conferences, but if everyone there thinks 'well I don't really need it, I'm fine', then well you know."

Participant 2 replies:

"If you do your clinical studies, then it could take a couple of years. What you see then, is that on those conferences, they will do a small talk about what the study will look like, who designed it, etc. And then you will have like a short update in which they already raise the corner of the vail about how it goes. And most of the times, right before they publish the clinical evidence, they have another talk about the most important results. And if you got something that makes an impact, then that is the ideal platform to share it with a lot of people and most of the times it will create buzz. So, conferences are simply very important part of the awareness and to let the medical community know like 'hey, something new is coming!'"

When asked if participant 2 thinks that the time that start-ups put into attending these conferences is justifiable, he says:

"Yes, absolutely. These conferences are a great way to also communicate with the 'common' specialist. […]. To look what has interest and what are the questions. It's a very early form of marketing of which you can get a lot. I always notice that companies learn a lot about which questions are relevant. If you really get that, then you will be able to translate that into the development. That you also make sure that you tackle those questions, because apparently those questions are relevant and needed to be answered."

Participant 3 replies:

"Look, those conferences, that is were the most clinicians are and those are very important. You have to be there, and you must make sure that people know you. Also, here, just attending one time will not help. You must make sure that you have been there multiple times. […]. They only take you serious after like three times. And again, first just go without presenting anything, just to taste a little bit of the atmosphere. Then to show some of your ideas and your research. You must invest in that."

Participant 5 replies:

"Well on the one hand it's to stay in contact with your surroundings, like 'what is going on?'. On the other hand, it's also to let the community know what you are up to. So, it's a kind of marketing. […]. If you are doing something that could solve a large problem, then people would like to know about it. Let's say you only get into the picture at the moment that you have something. Then people will be like 'What company is that? I never heard from them. That's out of the blue.' Whilst if you have already been telling for the past 5 years what you have been up to, who your partners are and build some credibility… Then people are interested and willing to invite you to come over."

The participants, for the most part, seem to have a uniform opinion on the matter. A conference is seen as the ideal platform to share clinical results and to connect with clinicians. Thus, also here, the literature of Escarce (1996) still seems to hold value. Furthermore, it is also valued as the perfect place to not only connect with prominent clinicians but also with 'common' clinicians and thus to get a better understanding of the problems that clinicians experience on a daily basis. If a start-up is able to translate these problems into answers and is able to tackle this in the development phase, then they have a better chance of creating a product with added value. And as one knows by now, a product with convincingly added value will be easier to commercialize. Furthermore, from the above one could also conclude that if a start-up wants to successfully diffuse their product, they must attend these conferences on a regular basis to build their credibility among the clinicians. If a start-up is able to build this credibility and to show interesting results, then indeed, it could be that they are invited at hospitals sooner, then if they would have not attended these conferences. Altogether, the fourth proposition seems to be confirmed.

✓ **Proposition 4**: It could be that attending conferences a) is seen as a measure of validation that could lead to b) a better chance of being adopted by clinicians.

Due to this, the researcher argues that **attending conferences** could be another factor that affects the duration of the commercialization phase (from CE-marking up until operational cashflow break-even). In line with the initial expectations of the researcher, this factor seems to be mainly influential on the **lead-user level** (clinician).

3. Attending conferences

4.4. Management Team

The third recurring theme that seems to play a role in the commercialization phase from CE-marking (regulatory approval) up until operational cashflow break-even (commercial success) is 'the management team'. *Alongside this theme, the fifth proposition as formulated in section 2.1.4. will be discussed.* To repeat, the researcher argued that, due to the fact that medical technology is often developed by researchers and/or clinicians, it could be that their main focus is on doing research and the development of the technology itself and that there is a lack of attention for the commercial aspect of the business. Therefore, it could be that they are not sufficiently informed on the market, its competitors and are not able to set up a good sales operation. This lack of business acumen could possibly explain why the path towards successful commercialization is for some start-ups very long and difficult. This rationale led to the following proposition:

- **Proposition 5**: It could be that most of the entrepreneurs behind the MedTech start-ups have a) a strong research background which leads to b) a lack of business acumen and subsequently c) a bad sales operation

To get a better understanding of this, the researcher asked the participants how they would value the business acumen of the entrepreneurs behind the start-ups. Furthermore, he also asked if the entrepreneurs have a clear sales strategy in mind to commercialize their product.

Participant 1 replies:
"Way too less attention for sales. They are all focused on the product and why it could be interesting for the market. But not on how they are goin to sell the product in reality. For some reason, the mind-set is not on sales. The development, its pure at the development of the technology."
When asked if the entrepreneurs have a certain strategy in mind, he replies:
"No, not always."
When asked about the level of business acumen, **participant 2** replies:
"In general, not very high. I think that they have a very flattened perception of the reality. They have a plan for the Netherlands and they have a plan for the CE-mark and that's it. They have no understanding of how hard it is… because most people… they have never done this before. Most of them have a background in the medical sector or in science, with an innovation, an idea."
When asked how the investor tackles this problem, he mentions:
"Well, we try to give feedback on which they can build. […]. Really, we want to think together with them once we are on board and help them to refine things. But the foundation must be done. They should also be able to do that. If they are not able to do that and are not able to translate the feedback and take it to a higher level… Yes, that stays a problem, also later when the company should evolve, because then you take the risk that the entrepreneurs are too limited in their background and capabilities."
When asked if entrepreneurs have a certain strategy in mind, he replies:
"Well it happens, but not very often. […]. That's because we do early-stage and because most of the people do this for the first time, they are scientists or clinicians. So yeah, that aspect lacks."
When asked about the level of business acumen, **participant 3** replies:
"Wel it varies. Look, I don't have people on my table that don't have any sense of business. So that they do have. The reasoning of a techie in general, is the following… I always have one big check to see whether somebody is a techie. That is the answer on the following question 'a good product, sells itself'. If you answer 'yes' then you are for sure a big techie and what I see is that most people that come here, they answer this question with a heartfelt 'yes'. They think 'if we just make the product, if we just get CE and if we just do that study', then they would not know what should happen more. Then it's like 'but then everybody will buy it, right. Then it's better, it's proven, and we have CE.' Well, they couldn't be more wrong! […]. Things should be sold, or actually even implemented! Often, I see with techies that on a certain moment they think "Allright commercialization phase, that doesn't happen by itself. So, we should get somebody that could sell for us.' And then they get like a type of car salesman. Yeah right, like that person will sell. No, you need somebody that talks with the clinicians with an ER-manager, a purchaser, a floormanager etc."
When asked about the level of business acumen, **participant 4** replies:

"Well, with a few exceptions, but most entrepreneurs in this sector are very technologically oriented. I think that often it is extremely underestimated how much time and money it costs to build a successful sales organization."
Participant 8 mentions:
"Team, very important! You can have the best innovation in the world, but with a bad team you will never get it on the market."
When asked about what he thinks is the biggest cause of a long commercialization trajectory, **participant 10** replies:
"It could be what you see most of the times with start-ups and what I have also witnessed on multiple instances. That you have to deal with a couple of people that are very proud of their own technology and think that it is amazing. But on the other hand, also really seem to struggle to bring it to the market. That's a whole other ball game, you know. Then you must deal with marketing, with sales and those are a couple of characteristics that do not immediately correspond with an inventor and often that is why those start-ups come to an end. And they are very enthusiastic, and they can certainly invent things, but by god have no clue to whom they should sell it and how they should do that. So, that is the first pitfall."
He immediately continues:
"The second pitfall is that they look insufficiently to their competitors and that they have build an insufficient IP position. In that case they have thought of something very smart, but then it already appears to be on the market by somebody who covered it better. That also happens a lot."

From the above, one could conclude that, indeed, most of the entrepreneurs behind the MedTech start-ups have a very strong research background and they tend to feel comfortable in the development of the technology, but no so much in the commercialization of that technology. Furthermore, due to a lack of previous experience and know-how, the entrepreneurs seem to underestimate what it takes to set up a good sales organization. Due to these reasons, the participants value the overall level of business acumen of the entrepreneurs rather low. Especially participant 3 and 10 give two striking examples of how this lack of business acumen can result in setting up a bad sales operation (e.g. attracting a type of car salesmen) or even worse, developing a product that is already on the market and better covered by IP. Altogether, these reactions seem to correspond with the rationale of the researcher and thus one could say that proposition 5 is hereby confirmed. Therefore, even after a decade, the literature of Scanlon & Lieberman (2007) still seems to hold and indicates that there is still not an optimal synergy between science and business.

✓ **Proposition 4**: It could be that most of the entrepreneurs behind the MedTech start-ups have a) a strong research background which leads to b) a lack of business acumen and subsequently c) a bad sales operation

Due to this, the researcher argues that **the business acumen of the management team** could be another factor that affects the duration of the commercialization phase (from CE-marking up until operational cashflow break-even). In line with the initial expectations of the researcher, the business acumen of the management team seems to be mainly influential on the performance of the start-up and thus on the **start-up level** itself.

4. The business acumen of the management team

4.5. Clinical study

The fourth recurring theme that seems to play a role in the commercialization phase from CE-adoption up until operational cashflow break-even is 'the clinical study'. *As mentioned earlier in section 4.3., the researcher believes that perhaps the real influential factor on the duration of the commercialization phase is not the publication, but the set-up of the clinical study itself and how the data is gathered before it gets published.* Therefore, and in line with the explorative nature of this study, the researcher wanted to go a step further by trying to see why conducting these clinical studies takes so much valuable time.

The researcher thus asked the participants what it takes to successfully conduct a clinical study and if, in general, the entrepreneurs know how to conduct those studies in a successful manner.

Participant 5 replies:
"Ofcourse they have no experience at all and naturally then you have to make sure to get people on board that do have experience and also have a medical background. Having a Chief Medical Officer with the necessary clinical experience is a must."
Participant 10 acknowledges the fact that some entrepreneurs seem to underestimate how hard it is to conduct a successful clinical study:
"[…] the amount of work that it takes to conduct these clinical studies in a proper way, that is being underestimated most of the times. It costs a lot of time, it costs a lot of organizing, it costs a lot of money. The time… it depends on the hospitals or other institutes you collaborate with. It also takes a lot of time to bargain the contracts and to negotiate. And most of the times, what is also being extremely underestimated, is how easy it is to enroll patients."
Participant 8 stresses the importance of experience:
"Somewhere along the way you need to get your expertise. You must find somebody and say 'look, we are going to conduct a clinical study and you are going to find out for us what it is we exactly need to do'. And that person cannot be the technician who made the device."
Later she elaborates a bit more:
"I think one must realize that the medical world is so specific that you can't escape the fact that at a certain point of time you need employ somebody that really gets it. Who knows how it works. And that person is or a clinician or somebody that has experience in conducting such clinical studies."

In some cases, a lack of experience seems to result in the entrepreneur having wrong expectations about what the hospital is willing to arrange for them and overall poor study designs that give unsatisfactory results.

Participant 8 reflects on her personal experience:
"Sometimes I hear MedTech start-ups say, 'I will go to the hospital and then we are going to conduct a research'. Then I'll ask them 'what kind of research are you going to do?' And then they say 'uhm... yeah…'. They don't know what to do, because 'that is what the clinician is going to tell them'. No, the clinician is not going to tell them, at all. You must know what your targetgroup is, how your research will look and how you are going to do the data analysis. The hospital is not going to decide that for you. I see that wrong expectations are developed."
When asked if there is also certain path that seems to lead towards a successful clinical study, she continues her story:
"A large pitfall of the entrepreneurs that I see is that they immediately want to start as broad as possible. But the trick is to start small and then to go broad. Conducting clinical studies is extremely expensive. And what you see is that often they pick a targetgroup that is way too broad. That is a) way too expensive, and b) it tremendously decreases the rate of success. […] The only thing they seem to think about is 'numbers, numbers, numbers'. But all those results are going to decrease weaken your effect. Start measuring in only one group and if you have shown that it works in that group, then move to other groups."
When asked the same question, **participant 4** also stresses the importance of the study design.
"The most important thing is that you think really carefully about the design of the study. What is it you are going to measure? Does that provide an answer to your most important questions? Does that provide an answer to the most important questions that potential buyers might have? And there is a difference. […]. A researcher might want to measure all kinds of exotic things, while a company simply wants to know if it is better than the alternative and wants to see if you can prove that. So, think carefully about your study design and how that fits within your marketing and sales strategy. That is very important."
Participant 5 adds:
"… the design of the study, that is something that should have been really carefully thought about. With a lead-investigator that helps to set-up such a study in a hospital. Also, with the permission of the medical ethical committees and with clear end-goals. What are the end-points that you want to see? What is it you are going to measure? You do not want to leave any room for fuzyness there."

From the reactions above one could indeed argue that the real influence on the duration is perhaps not caused by the publication itself, but by the process prior to that, namely the design of the clinical study and the way how the data is gathered to prove clinical effectiveness. A couple of things could definitely be concluded. First, most medical technology start-ups seem to underestimate how difficult it is to set-up a qualitative clinical study. They seem to underestimate the costs, in-depth knowledge and organizing skills that go with conducting such a clinical study. Second, they also seem to lack the necessary in-house experience and skills that are needed to set-up such a qualitative clinical study. In some cases, this lack of experience seems to result in the entrepreneur having wrong expectations

about what the hospital is willing to arrange for them and overall poor study designs that give unsatisfactory results and regarding the commercialization phase, cause a lot of unnecessary delay. Finally, it could also be argued that the quality of the clinical study is an important measure for both clinicians, but also for the hospital overall, to validate the level of professionalism of the start-up and to make a judgement on its reliability. If the start-up is constantly relying on the expertise of the clinician, then this could implicate a lack of necessary medical knowledge. In the worst case this could lead to the belief of the clinician that the start-up is unqualified to successfully develop a medical device, which could have negative implications on whether he/she will recommend the hospital to adopt the device. Furthermore, even if the end-product is up to par, if the clinical trajectory has been very long and difficult, then the hospital could establish serious doubts about the reliability of the start-up. As hospitals most often work with large multinational MedTech companies that are known to be reliable, it is of the upmost importance that the start-up shows an acceptable level of reliability.

Altogether, this gives the researcher the motivation to believe that **the quality of the clinical study design** is a factor that affects the duration of the commercialization phase (from CE-marking up until operational cashflow break-even). Due to the above-mentioned reasons, the researcher strongly believes that this factor mainly has an influence on both the **lead-user** (clinician) and **hospital level.**

5. The quality of the clinical study design

4.6. Healthcare funding

The fifth recurring theme that seems to play a role in the commercialization phase from CE-adoption up until operational cashflow break-even is 'healthcare funding'. Although there was no initial proposition that was linked to this theme, the way how healthcare is funded, and the understanding of the funding system were brought up quite often when the researcher asked the participants what they value as other important factors that could affect the duration of the commercialization phase. In this section, two topics will be discussed, namely: *the understanding of the cost structure and the understanding of reimbursement process(es).*

During the conversation with participant 7, the innovation manager, it became clear that it is very hard to get a good understanding of the cost structure in the healthcare sector. When the researcher asked about the influence of costs and the role of insurance firms, he metioned that to get a good understanding of both, one should first have a clear understanding of how costs are structured and what this means for a hospital.

Thus, **participant 7** explained:
"Okay so what I notice. Picture this. A hospital makes deals with these insurance firms and in general that's something like a budget-agreement. It has another name, but actually, it is just a budget-agreement where the hospital takes all the risk. So, in other words, I make an agreement with (…) that I can run production for the insured, for an amount of €50 million. If I run €49 million, then I will get payed €49 million. […]. If I run €51 million, then they will say 'wow, we agreed on €50 million, so that last million you have to pay for yourself. That agreement is made in November and I don't know who, in the next year, will come walking through the gates between January and December. I can look back historically, but I also have to deal with fluctuations. So, you get that, one million is 2% of €50 million. So, if I am 2% off, then I go under for one million and with 4% I go under for two. Congratulations, that is how healthcare works. […]. We find it very difficult to say on November 1st, 'So, you are insuranced by (…), that's a pity. Come back in January, because we don't have any more

money to spend.' That doesn't feel very friendly. The patient also thinks 'what now?' Then we have to go to (…), because our agreement with (…) doesn't hold. […] So, in that light you probably understand that, when it comes to new innovations, we cannot afford ourselves a lot of mistakes."

When asked if in his opinion start-ups are aware of this, he replies:

"No, most of the times they have no idea at all or a very gullible perception. So, that is my experience."

He gives an example of the above:

"They are fixated on their own inventions and then they come up with a crazy cost saving on a social level. But really, the society 'can get it'. Because it can save the society perhaps €1 billion, yes, we talk about such crazy numbers. But that will mean that I have to spend €1 million now, by myself. If you Bram, should spend privately €10.000 of you own money, so that the society can save a ton, then I am pretty sure that you would not do it. And that is exactly what those entrepreneurs ask of us."

Thus, the researcher asked if he understood correctly that it would be easier if both, the costs & benefits, are aimed at the same organization. He replied:

"Yes, why would I care about society? It is about the hospital, and well, if you really want to save costs. That's fine with me, let's say we can run the hospital for €10 million less. Really less costs. Then you could say, on a social level, this is within our goal. Because if we can offer the same quality of healthcare for €10 million less. […]. Then I think we should do it, because then society really gains €10 million. It is not that our wallet makes society better. Everything together should correspond."

The researcher remembered that something similar was mentioned in an earlier conversation. **Participant 1**, the investor of which the fund has strong ties to an insurance firm mentioned the following:

"…you know what is also very important. Who has the benefits when the price goes down and who pays for it? Often, there is a discrepancy between those two things. So, the benefits are not… We as an insurance firm for instance could invest in a product, but that doesn't mean that we will have lower costs due to that. It could be that the hospital ends up with lower costs. So that makes it difficult."

Participant 3 mentions the same:

"The closer the costs & benefits are, the easier everything is. ****Gives an example of a start-up where the costs & benefits are not close**** *[…]. In that situation you see that the costs and benefits are miles away from eachother. And it is also in a different reimbursement system. Because nursery homes are (…) and this is health insurance. Well, then it's almost impossible and that is also what we saw.* ****Gives an example start-up of which the product belongs to a Diagnose Behandel Combinatie**** *[…] so in that case the hospital is the one that must pay. That makes it already a lot easier, because in that situation you only have to prove your business case in the hospital setting."*

The above gives some very interesting insight in how healthcare in the Netherlands is funded. Furthermore, it is also very useful information for a MedTech start-up. From the above, one could namely argue that it is not per se the pricing of the product itself, and whether it is expensive or not, that has an influence on the adoption decision, but maybe that it is more about how the product is positioned within the cost structure. If the costs and benefits of a certain product are shown to advantage one single organization, then this could make the decision whether to buy/adopt easier. In that case, the start-up only must convince one single party of the business case and does not have to take into consideration all the other parties that are possibly affected by the procurement. If a start-up has a good understanding of this, then this could already be taken into consideration during the development of the product, which subsequently could result in less slack during the commercialization phase and could make the adoption decision by the hospital a lot easier.

Altogether, the researcher believes that **the understanding of the cost structure** is a factor that affects the duration of the commercialization phase from (CE-marking up until operational cashflow break-even). Due to the above-mentioned reasons, the researcher strongly believes that this factor mainly has an influence on the **hospital level.**

6. The understanding of the cost structure

Another factor that is also mentioned above and kept coming back during the interviews was the importance of reimbursement in relation to the commercialization phase and the role of the insurance firms. After a couple of interviews, the researcher noticed that it is not very easy to understand all the different routes.

Participant 2 explains:
"In the Netherlands we work with insurance firms, if it's a product that is categorized under… what is directly funded by the insurance firms, then ofcourse you must deal with them directly. In that case, it would be good as a start-up to go and talk to them to see what their perception is. But if it is something that is being used in the hospital setting, then often it is part of a 'dot', then it is wrapped up somewhere. In that case you are dealing with purchasers and not so much with insurance firms. Look, if it's part of a procedure, for instance a kidney transplantation, well in that case you do not have to talk with an insurance firm, because they have no opinion about that. In that case they only say 'yes, we reimburse that procedure and if that procedure is getting better and cheaper by this, then that is something for the purchasers to have an opinion about."
When asked about the role of the insurance firms in relation to the commercialization phase, **participant 3** mentions:
"Well, that role is way less then people might think. We have three insurance firms in our fund. That is actually quite funny, because sometimes we have people over and they seem to think 'oh you have insurance companies on your side, so if you invest in us, then you will make sure that we get reimbursement'. The gag is that, insurance firms have no role there. They can help, they have opinions and they have budgets for temporary reimbursement… So, sure, they absolutely have some sort of role, but they are definitely not the only party. For instance, the National Healthcare Institute is at least as important. Everything that is connected to the basic health insurance should be arranged together with the National Healthcare Institute. And sometimes via the NZA (Nederlandse Zorg Autoriteit) if it becomes a new activity within DBC (Diagnose Behandel Combinatie). And

sometimes you need to get in the protocols of the NHG (Nederlandse Huisartsen Genootschap). So, it really depends where it is positioned, and insurance firms have a lot less to say about everything then you might expect."

Participant 6 put some strong questionmarks at the role of the insurance firms. He says:

"So, what is the actual role of the insurance firm? What value does an insurance firm add? Or are they just an administration office? […]. Me personally, I value them more as an administration office then something that adds in-depth medical added value. They exist, but I think they could be made better use of.

When asked about the role of the insurance firms, **participant 7** says:

"Well, you know. Actually, they don't have a role at all and everyone seems to think that."

The researcher mentioned that he is still not completely sure whether insurance firms have an important role or not. Fortunately, participant 7 was willing to explain it a bit more:

"What is their role? Well I will try to explain it to you. I also get the confusion and I will also explain that. Insurance firms sometimes have the tendency to outrageously interfere with hospital management. […]. They seem to succeed in that, mainly in the first line of care. So, fysiotherapy and the general practicioner. But in hospitals, it is simple, the hospital management is the ruler. Not the insurance firm. […]. So, everything what we buy, that's what 'we' buy. Only the choice in artificial knee A or B will not change the reimbursement that I get for the total procedure. The insurance firm also has no say in that decision. […]. The question is, is it eligible for reimbursement? Will it get into the basic health insurance, yes or no? The insurance firms don't make that decision. The government decides, and they made certain investments. Subsequently, it is the role of the National Healthcare Institute to form an opinion on that and they have a special procedure for that."

Participant 8 seems to perceive the same misunderstanding:

"Look, insurance firms have no say in the basic health insurance. And what you see is that hospital care, that's all affiliated to the basic health insurance. And those are the big technical innovations, for instance, things on the ER, surgery robots, things like that. That is all basic health insurance. Insurance firms are more focused on additional healthcare, such as 'being able to live longer in your own home, specifically for elderly, etc.' So, that is not about the healthcare in the hospital, but all the healthcare around it. So, the real big chances and important things in healthcare are in the hospitals. That is basic health insurance, so the insurance firms have no say in that. And that is were a lot of parties seem to make a bad judgement call. You don't need the insurance firms to get into the basic health insurance. Everybody always immediately goes to the insurance firms, because 'yeah, they reimburse the healthcare'. Yes, they reimburse healthcare, but mainly additional healthcare. So, I also see that a lot of people have a very bad understanding of the reimbursement landscape. And that is not only the companies to blame, but also how things are set-up here in the Netherlands. It is extremely untransparant, unclear and there is nobody that can clearly explain how you should tackle that and that is very difficult for companies."

When asked which party is responsible for the basic health insurance, she replies:

"The National Healthcare Institute. Or your product simply fits within an existing reimbursement and the clinician now buys your product instead of that of another party. In that case you just need to visit hospitals and try to sell it there. But everybody seems to think 'yeah, I'm not going to do

that, I'll let the insurance firm handle that.' But the question is where that will bring you. And most of the times it will bring you nowhere."
Later in the conversation, she touches the topic of the insurance firms again.
"I see people that take very strange routes, of which I think 'why are you doing that?' And I also don't get the focus on the insurance firms. Because insurance firms are not going to fund your innovation. It depends on the innovation if reimbursement plays a role. But everyone seems to look at the insurance firms."

Again, the above gives some interesting insight in how reimbursement is organized in the Netherlands. It not only shows that all the different reimbursement routes are quite complex, but the participants also seem to suggest that a lot of start-ups are struggling to deal with this complexity and lack a good understanding of the different reimbursement routes. Multiple participants seem to notice that a lot of start-ups focus on the insurance firms, while they only reimburse a specific niche of the total healthcare market, namely the additional healthcare. As this research is focused on MedTech in relation to medical devices, which is mostly used in the hospital setting, this focus is quite alarming and confirms that the start-ups have no clear view of the reimbursement landscape. The real focus of the start-ups should go to the National Healthcare Institute, as they are the decisive institute about hospital care and whether something will get covered in the basic health insurance. If start-ups focus on the wrong institute for reimbursement, then adopting reimbursement could become a very difficult task. As reimbursement is a way to make new medical technology less expensive for hospitals to use, it is important for the start-up to know how and where to become eligible for reimbursement. If the start-up is not able to adopt reimbursement for its device, then this could affect the adoption decision of the hospital in a negative way, which as a result could slow down the commercialization of the device.

Altogether, the researcher believes that **the understanding of the reimbursement landscape** is a factor that affects the duration of the commercialization phase (from CE-marking up until operational cashflow break-even). Although the start-up is the entity that must make sure that it has a good understanding of the reimbursement landscape, the researcher strongly believes that this level of understanding will eventually unfold in the adoption decision of the hospital. Thus, this factor mainly seems to be influential on the **hospital level.**

7. The understanding of the reimbursement landscape

4.7. Stakeholders

The sixth recurring theme that seems to play a role in the commercialization phase from CE-adoption up until operational cashflow break-even are the stakeholders. Although there was no initial proposition that was linked to this theme, the importance of understanding all the different stakeholders was brought up quite often when the researcher asked the participants what they value as other important factors that could affect the duration of the commercialization phase. During the conversations it became clear that understanding the stakeholders is twofold, namely: *understanding who they are, but also what they do and how their workprocesses look.*

First, the participants stress the importance of knowing who your stakeholders are.

Participant 2 says:
"You must, and that is a very difficult and you must start with that immediately from day one, think really carefully about: how is this product going to be used and by whom? Who do I have to convince and what do I need to do to convince a person like that? Understanding that, also in different systems, that costs an awul lot of time."
When asked if participant 2 has seen a specific strategy that seems to work very well, he again touches the importance of stakeholders.
"No, there is never one plan or one answer. The bottom line of the story is 'the business that we are in is very difficult' and that is because of all the different stakeholders. It is not a one-on-one transaction with a buyer, but there is a whole network around it and they all have interest that you must deal with. Medical standards, purchasers, insurance firms, you name it. They have specific wishes, surgeons and doctors are conservative. Changing people is also extremely difficult."
Participant 3 adds:
"Clinicans are important as an initiator, but other roles, and especially if you talk about 'MedTech in the hospital setting', are becoming more important. In the past a clinician could simply say 'I want to use this product' and then it was arranged, but there are a lot of people nowadays that can block that. So, these people you really have to bring in on it."
When asked what he means with 'these people', he replies:
"Well, purchasers, materialmanagers, ER managers, floormanagers, CSA is also important. All these peoples have an opinion about it and all of them can say 'no, we are not doing that'."
Participant 7:
"Who is the decision-making unit? Who decides what and who makes the purchasing decision? You really need to know who your customer is. And simply the question, 'who is my customer?' That question you must ask about 5 times to the people that you are helping. Who is really my customer? 'Yeah, the hospital'. Okay but who in the hospital? Is that the Board? Are they the ones that do the purchasing? Is it the clinician that tells the purchaser, buy this for me? Is it the fysiotherapist that eventually must work with it? Who is your customer? Do you really know them? Do you understand them? Do you know what they want?"
Participant 8 adds:
"Also, very important. Are you a discussionpartner for the clinician? Do you show that you know what you are talking about? […]. How well can you speak the same language as the clinician and have a feeling for what they value as important? Because if you come with a cost-savings story to a clinician… hmm, there is no need for that. He will not be impressed by that, but an insurance firm is. So, you should really know which story to tell, to which stakeholder, you should separate them. And that is also something of which we see that a lot of companies are not doing that well."

The reactions above show that, when it comes to medical technology, one must deal with a rather complex stakeholder situation. It is not just about the view of the clinician, but also about all the other parties that are affected by the adoption of the technology. It is not as with 'regular' technology that you have a supplying and a buying party, but also a lot of other parties that can influence the adoption. In order for the start-up to 'tell the right story', one should know all the roles in the ecosystem and what is being valued as important to them. If a start-up knows which story to tell, to which stakeholder, then this might enable them to save unnecessary slack during the commercialization phase.

In relation to this, the participants explain the importance of understanding all the different organizational healthcare (work)processes of these stakeholders.

Participant 3:
"Honestly, I think that sales is a wrong word in healthcare. We feel that it is more about implementationprocesses. […]. It is not like you must convince a specific person to buy it. You must convince people that this will make the healthcare system better, that they should use this and fit it within their procedures."
Participant 5 stresses that it is about changing procedures:
"What you should not forget, because that is also often the case… You must change procedures. You need to look at the whole methodology and see how every aspect is positioned in the procedure. (…). For example, a molecular diagnostics test. A microbiologist has a variety of different devices, from a large company. He doesn't want to put another small device next to it. So how should that fit? He will say 'I want that test, but I only want it if it will fit on my mainframe. I don't want a separate device."
Participant 7 gives an example of what could happen if you don't have a good understanding of the workprocesses:
"Okay, for example. If, with for instance fysiotherapy or other medical rehabilitation trajectories, you are being payed for the minutes you spend on treatment. Then somebody comes over with an innovation, of which he claims that the patient now only needs half of the time to rehabilitate. It costs €10.000. Then, I as a fysiotherapist, must invest €10.000 to see that from now on, I spend less time on treatment. Well, that's not a very strong business case, because I am getting payed by the minutes of treatment. In that way you are never going to make it. That is something you should understand, if you don't understand that, wel…"
Participant 8 gives another example:
"We have seen a company that developed a sticker which could measure how the contractions during labour. With that you could make a better estimate, whether somebody would need a c-section. […]. C-sections cost a lot of money, it is not pleasant for the women and not good for the baby. So, preventing c-sections is a good thing! But every sticker can only be used once, and they cost €60. Plus, the hospital will now do less c-sections, so that means that they also make less money on them. So, is this something that a doctor would want? Yes, because it is the best choice for the patient. Is this something that the management or the hospital would want? Well no, they do not per se want less c-sections. So, there are also powers that do not per se prevent innovations from succeeding, but you must definitely understand those powers when you are developing your innovation. You must understand the resistance that you could come across during the implementation. […]. Changing something in healthcare is very hard. Also, because one must deal with standardized processes,

which is important for the quality. I think that a lot of companies underestimate how hard it is to implement something in healthcare."

Here, one can see clearly that it is not only important to know who all the different stakeholders are, but also how they work and what their professional incentives are. It is crucial to understand how all of the workprocesses are organized and how they influence each other. All the examples above show that at first sight something might look like a great invention that will make things better, faster or easier, but in time might appear to be not attractive at all, because it has a negative outcome on the incentive of one of the stakeholders. It is also interesting that the participants seem to suggest that the success of MedTech commercialization is not per se in making a lot of sales, but more in the ability to successfully implement your technology or device into those workprocesses. If a start-up has a good understanding of this, then it could prevent that it must deal with unnecessary conservativeness or resistance from the stakeholders. Taking all this into consideration enhances the existence of harmony and synergy between all the different stakeholders, which will make it easier for a hospital to implement a certain device. Altogether this could thus smoothen up the adoption decision of the hospital.

To conclude, one could say that the understanding of stakeholders is twofold, namely: understanding who they are, but also what they do and how their workprocesses look. If a start-up has a good understanding of this, then it will be easier for them to implement their technology, which can have a positive influence on the commercialization phase. Therefore, the researcher believes that **the understanding of stakeholders** is a factor that affects the duration of the commercialization phase from CE-mark up until operational cashflow break-even. In line with the argumention, the researcher strongly believes that this factor will mainly have an influence on the **hospital level.**

8. The understanding of stakeholders

4.8. Network

The final recurring theme that seems to play a role in the commercialization phase from CE-adoption up until operational cashflow break-even is the 'network'. Although there was no initial proposition formed to discuss alongside this theme, it became clear that the network of the start-up plays an important role during the commercialization phase. During the interview one learned that the average network of a MedTech start-up consists of: investors, strategists, key opinion leaders and the board of commissioners. From all these parties, one deserves some more in-depth attention, namely the key opinion leaders. Thus, in this section, one will discuss the role and functioning of the key opinion leaders in relation to the course of the commercialization phase.

The researcher asked the participants about the role of the key opinion leaders in relation to the commercialization phase.

Participant 1 explains:

"Yes, they are very important. We also try to… we rather call them ambassadors, but actually… I have a couple of chirurgical tools and then you look around like, which surgeons could function as a key opinion leader or ambassador, for instance by using the device and show like 'hey, it works!' You could use that in the sales trajectory towards others."

When asked if they could affect the duration of the commercialization phase, he says:
"Yes, yes absolutely."
He continues his story and introduces the topic of biased KOL's:
"So, you are going to look, which people could say something interesting about this and ofcourse you would need people that are being put forward by the company, but you would also want to find a couple yourself, to see whether there is a discrepancy between the two. Because that first group could be biased."
When asked about the importance of the network, **participant 2** immediately emphasizes the importance of the Key Opinion Leaders:
"I expect that when a company (start-up) comes over, that they at least have thought very carefully, for about a half year to a year and that they also associated themselves with all kinds of people, experts, key opinion leaders, just pick a word for them. That know a lot about it and that have thought along with them, shared knowledge, which makes it a way more believable story. And not only from the side of the clinician, but also from the side of manufacturers, parties that think about quality, that think about regulations. So, that they have clear perception of what is needed. […]. So when you are ready, then they are fantastic advocates for your product. Because they can plug it at companies (strategic parties) and talk enthusiastic about it. Which subsequently creates enthusiasm at those companies to potentially buy the company. So they are very important."
Participant 2 also stresses the importance of involving the 'common' clinician:
"But beware, most of the times it are people (KOL's) that are very strategic and think in a different way as the common clinician that works in the hospital in for instance Zeeland. You must talk with both, because you also want to involve people that have experience in practice, that work with patients and know the system of a hospital. It should resonate on both sides."
When asked if they could potentially also affect the duration of the commercialization phase, he replies:
"Yes, there they could. Because in the medical sector, and that is important for drugs, but also for devices, is that they get into the guidelines. To realize that you need those people, because they are in those committees. And on congresses you need to tell 'the story', you should do that via those people. Often, they are also involved with the clinical studies, because then they can publish. So they are lubricate for the whole process. They are key in that."
Participant 3 also stresses the importance of involving the 'common' clinician:
"[…] it is important to have good contacts and not only with Key Opinion Leaders. That always sounds very academic to me. We as a fund aim at the whole spectrum of healthcare. […] those things are often at local hospitals, nurseries or other clinics. So then it is not always logic to assume that a Key Opinion Leader has the best perspective on that."
Participant 4 mentions that Key Opinion Leaders are also important to realize reimbursement:
"In order to realize reimbursement, it is very important to collaborate with Key Opinion Leaders that support your product."

Participant 5 also values the Key Opinion Leader as an important partner:
"[…]. Yes, and you need to involve good KOL's. Because, well they can bring you in connection with important parties. In Amerika, in hospitals, they are an entrance for FDA. Those people can realize those things."
When asked about the role of the KOL and its task, he says:
"Well, they can establish extra credibility, for the validation, that you have a good solution for a problem. Because a KOL is somebody with authority in a certain domain and if he/she says 'I see the added value of this', then that will help."
The researcher also asked what motivates a KOL to collaborate with a start-up.
"Well, the intrinsic driver to help his domain. […]. But it can also be that there is some financial gain. That you give such a person options, a small gift. […]. But you must keep that in the back of your mind, because you must keep watch on the objectivity. […]. You should make sure that there is not a sort of blindness, also not for KOL's that are already longer on board."

From the reaction of the investors, one can conclude a couple of things. First, due to their expertise in specific domains, key opinion leaders are valued as important ambassadors for your product. Due to this, hospitals and strategic companies value the presence of KOL's as an important indicator of reliability and validity. Therefore, KOL's seem to function as a catalyst for adoption and diffusion. Second, the KOL's are represented in all kinds of entities that are important to realize reimbursement or to get adopted into the medical guidelines. Thus, the presence of KOL's could also mean that these processes can be completed faster than without their presence. Nevertheless, there is also a critical note. The participants seem to question the objectivity and quality of some of the KOL's. Furthermore, they stress that it is important to also involve the 'common' clinician and not only the most prominent KOL's.

The other group of participants seem to share these concerns and also stress the importance of having unbiased KOL's.

Participant 7 reflects:
"[…]. Maybe it is even more important to involve the healthcare professional and not only that nice guy who has been on your side for the past 20 years. That is your highschool friend and he will never be able to say something critical anymore. No, I rather see somebody on your side that you also don't know. Somebody of which you say 'here you have my product, what do you think about it, tell me?!' And if that person says what an awful thing, then you really know 'I should take some more necessary steps'."
Participant 8 says:
"They (the start-ups) have way too less contact with the medical sector. Most of the times you will see that companies only have one clinician on board and that clinician is a 'fan'. But most of the times, it is limited to this one clinician. And that clinician goes to all kinds of places with the device to show and then the company think 'hey, there is a support-base'. But one clinician that believes in your product, that is not the same as a support-base. That is really something else. So it can be that

you have one clinician that thinks that your product is amazing, but that all the others really don't want it at all. So you should look broader then that one clinician."

From the above one could argue that the presence of biased key opinion leaders is also something that is being noticed by the everyday experience of the participants closely affiliated with the medical sector. Here we see that biased key opinion leaders are not taking seriously by the medical professionals and thus could have a negative outcome on the adoption and diffusion of the technology.

To conclude, it is without a doubt that key opinion leaders fulfil an important role as ambassador, intermediar, and advisor during the commercialization phase. Nevertheless, the above also confirms that they are only perceived as valuable when they are unbiased and when the pool of key opinion leaders does not only constist of prominent figures, but also those people that represent the more 'common' clinician. Altogether, this gives the researcher motive to believe that another important factor during the commercialization phase (from CE-marking up until operational cashflow break-even) is **the quality and diversity of the key opinion leaders.** In line with the argumentation above, the researcher strongly believes that qualitative and diverse key opinion leaders could be influential on a multitude of levels, namely on the **start-up level, lead-user level** and **hospital level.**

9. The quality and diversity of the key opinion leaders

4.9. Overview of factors & levels

	Levels			
Factors	Start-up	End-user level (patient)	Lead-user level (clinician)	Hospital level
The added value of the product				√
Active use of social media		√		
Attending conferences			√	
The business acumen of the management team	√			
The quality of the clinical study design			√	√
The understanding of the cost structure				√
The understanding of the reimbursement landscape				√
The understanding of stakeholders				√
The quality and diversity of key opinion leaders	√		√	√

Table 4: Overview of the factors and the levels on which they presumably have an influence

4.10. Medical Device Roadmap (conceptual model)

As mentioned in section 1.2. the purpose of this study was to build a conceptual model that could be used by investors and entrepreneurs as a guide during the commercialization phase. This conceptual model is presented on the next page.

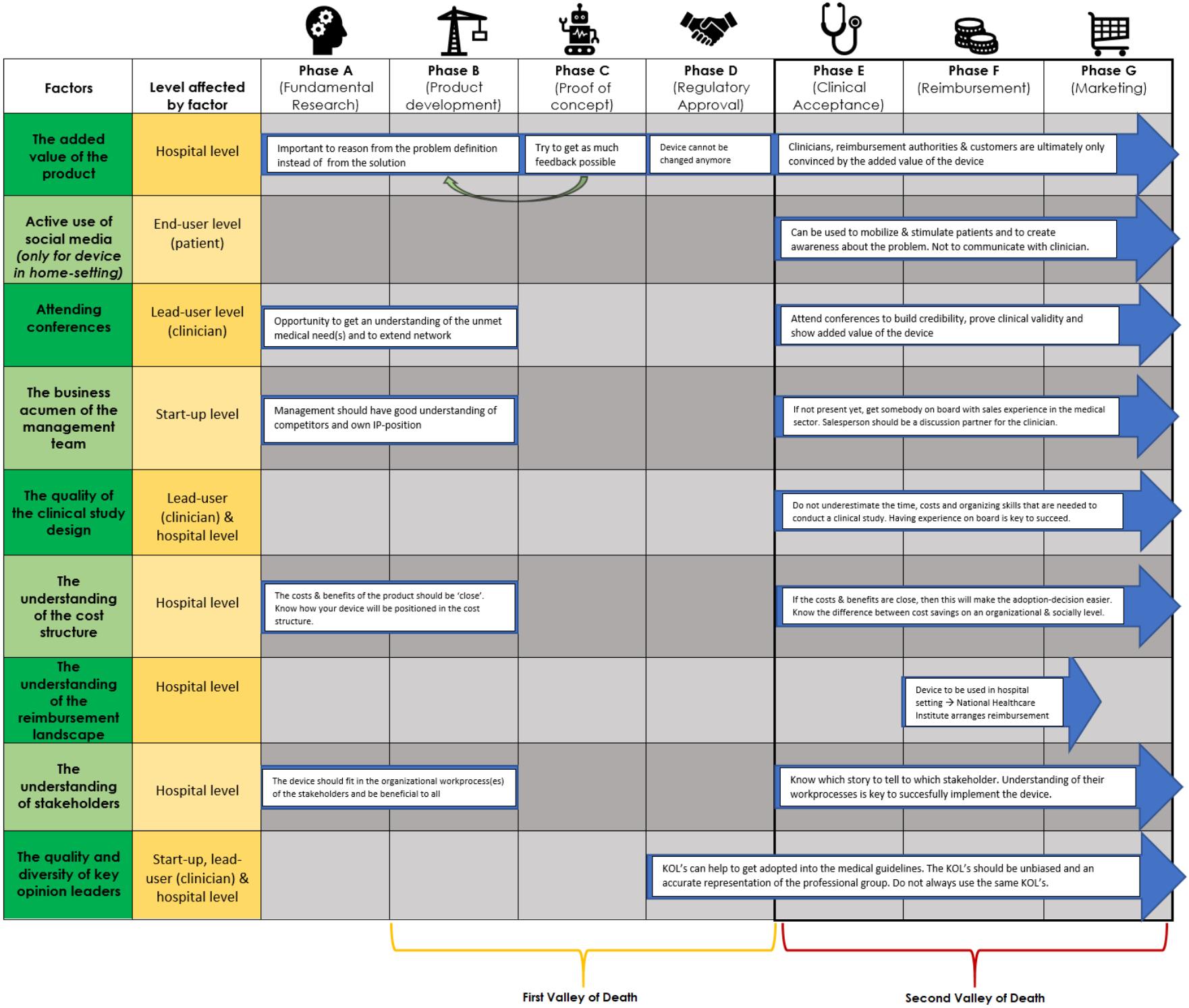


Figure 4: Medical Device Roadmap, inspired by 'Development of medical devices' by (Wijk, van. M., 2014)

5. Conclusion and discussion

5.6. Key findings

To summarize, the researcher wanted to find out what factors could possibly affect the duration of the commercialization phase (from the point of adopting CE-marking up until the point of operational cashflow break-even) of MedTech start-ups. To discover these factors, a total of 10 semi-structured interviews were conducted, of which 5 interviews with healthcare-focused investment professionals and 5 interviews with professionals that are closely related to the hospital setting/medical field. These 10 interviews gave an extensive set of data (142 pages), which the researcher coded in three separate steps. After this coding process, it became clear that 7 themes seemed to play a crucial role during the interviews, namely: *the product, awareness, management team, clinical study, healthcare funding, stakeholders and network.* Alongside these themes, the five propositions as formulated in section 2.1.4. were discussed.

The first recurring theme was the product. Alongside this theme the *first proposition* as formulated in section 2.1.4. was discussed, which was the following: It could be that there is a mismatch between the a) rationale on which the product is developed by the start-up and b) the rationale on which new technology is adopted by the hospitals.

First, both groups of participants stressed the importance of adressing an unmet medical need and thus the added value of the product for both patient and clinician. If a product is developed from a clear problem definition and not from the solution, then in most cases the product will correspond with the wishes and needs of the hospital and thus add value. Regarding the costs, it has been made clear that although high costs are not desirable, they do not straight away result in a no-go, as long as they are justifiable for the value they add. Second, to realize added value it appeared to be very important that the start-up engages with the clinician, as the clinician plays a key role in whether a technology will be used in the hospital setting. Although this wasn't the goal of this section, this seems to go against the literature of Shah & Robinson (2009) who mention that in order for medical device to succeed, the acceptance of the patient (end-user) is key. These results suggest otherwise, namely that although patients are certainly important, the real power is on the side of the clinician (lead-user) that actually has to use the device. Regarding the proposition, one saw that in some occasions, indeed, there seemed to be a mismatch between the rationale on which the product was developed by the start-up and the rationale on which the product was adopted by the hospital. Nevertheless, this does not seem to stem from a sole focus on the need of the patient, but more from developing from the perspective of the solution (technology) instead of from a clear problem definition.

Due to this the first proposition was revised into the following: If the start-up reasons from the perspective of the solution instead of the problem, then a) the developed product does not add any value, which b) creates a mismatch with the rationale on which new technology is adopted by the hospitals.

The above gave the researcher enough motive to believe that **(1) the added value of the product** is one of the factors that affects the duration of the commercialization phase (from the point of CE-marking up until operational cashflow break-even) and that this factor will mainly have an influence on the **hospital level.**

The second recurring theme was awareness. Alongside this theme the second, third and fourth proposition as formulated in section 2.1.4. were discussed.

The *second proposition* was the following: It could be that MedTech start-ups do a) not make enough use of social media and thus are b) not sufficiently engaged with both end- & lead-users.

First, the reactions of the participants showed that, indeed, there seems to be some undiscovered potential when it comes to the use of social media in the healthcare sector. Some participants gave clear examples of how social media can be used to create awareness for a problem and to mobilize and activate patients to take matters into their own hands. Most participants suggest that social media could be used a lot more, but that there is still some conservativeness under entrepreneurs and investors that withholds them from using it. For that matter, one could definitely argue that social media is not yet used to its fullest potential and could be used as a tool to enhance the commercialization phase of devices that are used in the home setting. Second, the reactions also showed that social media is less effective when it comes to enhancing the adoption of devices that are used by the clinician in the hospital setting. For these devices the presence of clinical evidence is key and here social media does not seem to be effective. As in the previous section, these results seem to question the belief of Shah & Robinson (2009).

Due to this, the second proposition was revised into the following: MedTech start-ups do a) not make enough use of social media and thus b) could be better engaged with end-users than they currently are.

The above gave the researcher enough motive to believe that **(2) the active use of social media** is another factor that could affect the duration of the commercialization phase (from the point of CE-marking up until operational cashflow break-even). Opposed to the initial expectations of the researcher, this factor does not seem to be as influential on both, the end- & lead-user level, but mainly on the **end-user level** (patient).

The *third proposition* was the following: It could be that a publication in a journal a) is seen as a measure of validation that could lead to b) a better chance of being adopted by clinicians.

First, the researcher realized that when the participants talked about clinical studies, that they inherently referred to the publications. Publications seem to be a logical result of doing clinical studies and are not something that can be seen separately from the gathering of the clinical evidence. Second, the reactions clearly reflected that the healthcare sector is very evidence-based and that thus it is crucial to prove clinical effectiveness. Without convincing clinical evidence, it is highly unlikely that a clinician will decide to adopt a certain device. In other words, these publications are indeed an important, if not the most important, source of information for the clinicians and thus it seems that the literature of Escarce (1996) still holds value to this day. Furthermore, it was also acknowledged that publications will help to realize reimbursement, which subsequently could be a trigger for hospitals to start using a certain device. Altogether the researcher concluded that, indeed, publications in journals are seen as a measure of validation that could lead to a better chance of being adopted by hospitals.

Due to this, the third proposition was confirmed. Nevertheless, during the interviewing process it also became clear that the publication by itself is simply a result of these clinical studies. In fact, if you even want your product to be seriously considered by a hospital for adoption, having a publication with clinical evidence is a standard requirement. Thus, after a while it became clear that perhaps the real influential factor on the duration of the commercialization phase is not the publication, but the set-up

of the clinical study itself and how the data is gathered before it gets published. This train of thought was discussed alongside the theme clinical study.

The *fourth proposition* was the following: It could be that making an appearance at a conference a) is seen as a measure of validation that could lead to b) a better chance of being adopted by clinicians.

The reactions of the participants reflected that a conference is seen as the ideal platform to share clinical results and to connect with clinicians. Thus, also here, the literature of Escarce (1996) still seems to hold value. Furthermore, it is also valued as the perfect place to not only connect with prominent clinicians but also with 'common' clinicians and thus to get a better understanding of the problems that clinicians experience on a daily basis. If a start-up is able to translate these problems into answers and is able to tackle this in the development phase, then they have a better chance of creating a product with added value. And as one knows, a product with convincingly added value will be easier to commercialize. Furthermore, it was also emphasized that it is important to attend these conferences to build credibility. If a start-up is able to build this credibility and to show interesting results, then indeed, it could be that they are invited at hospitals sooner, then if they would have not attended these conferences.

Due to this, the fourth proposition was confirmed and led to the belief that **(3) attending conferences** is another factor that could affect the duration of the commercialization phase (from the point of CE-marking up until operational cashflow break-even). In line with the initial expectations of the researcher, this factor seems to be mainly influential on the **lead-user level** (clinician).

The third recurring theme was the management team. Alongside this theme the fifth proposition as formulated in section 2.1.4. was discussed, which was the following: It could be that most of the entrepreneurs behind the MedTech start-ups have a) a strong research background which leads to b) a lack of business acumen and subsequently c) a bad sales operation.

First, the reactions of the participants showed that, indeed, most of the entrepreneurs behind the MedTech start-ups have a very strong background in research and tend to feel comfortable in the development of the technology, but no so much in the commercialization of that same technology. They also explained that most techies do not posses the necessary capabilities to successfully commercialize a product and to effectively realize sales. Second, due to a lack of previous experience and know-how, a lot of entrepreneneurs seem to underestimate what it takes to set up a good sales organization. During the interviews, numerous examples were given of how all this can negatively affect the commercialization. The participants strongly advised to get external sales experience on board, when this is not yet present in the management team of the start-up. Altogether, these reactions seemed to correspond with the rationale of the researcher. Therefore, even after a decade, the literature of Scanlon & Lieberman (2007) still seems to hold and indicates that there is still not an optimal synergy between science and business.

Due to this, the fifth proposition was confirmed and led to the belief that **(4) the business acumen of the management team** is another factor that could affect the duration of the commercialization phase (from the point of CE-marking up until operational cashflow break-even). In line with the initial expectations of the researcher, the business acumen of the management team seems to be mainly influential on the **start-up level.**

The fourth recurring theme was the clinical study. As mentioned in the last part of proposition 3, the researcher came to understand that perhaps the real influential factor on the duration of the commercialization phase was not the publication, but the set-up of the clinical study itself and how the data is gathered before it gets published. Therefore, and in line with the explorative nature of this study, the researcher wanted to go a step further by trying to see why conducting these clinical studies takes so much valuable time.

A couple of things could be concluded. First, most medical technology start-ups seem to underestimate the costs, in-depth knowledge and organizing skills that are needed to conduct a good qualitative study. Second, most of the start-ups lack the necessary in-house expertise that is needed to set-up and conduct a qualitative clinical study. Furthermore, and as a result of the above, some entrepreneurs seem to have a rather naive view about what the hospital is willing to arrange for them and what they should do themselves. In the worst case, this all could lead to overall poor study designs that give unsatisfactory results. These unsatisfactory results can cause a lot of delay and have a negative influence on the adoption decision of hospitals and thus the commercialization phase. Furthermore, it could also mean that the partner with whom the study is conducted, is not willing to participate anymore and that the commercialization comes to a fateful ending.

Altogether, this gave the researcher the motivation to believe that **(5) the quality of the clinical study design** is another factor that affects the duration of the commercialization phase (from CE-marking up until operational cashflow break-even). Furthermore, the researcher strongly believes that this factor mainly has an influence on both the **lead-user** (clinician) and **hospital level.**

The fifth recurring theme was healthcare funding. Although there was no initial proposition linked to this theme, the way how healthcare is funded, and the understanding of the funding system were brought up quite often when the researcher asked the participants what they value as other important factors that could affect the duration of the commercialization phase.

First, the results showed that the cost structure of the healthcare sector is a rather complex one, that is not easy to understand. Furthermore, it can be argued that it is not per se about the pricing of the product itself and whether it is expensive or not, that has an influence on the adoption decision, but maybe it is more about how the product is positioned within the cost structure.If the costs and benefits of a certain product are shown to advantage one single entity, then this could make the decision whether to buy/adopt easier. In that case, the start-up only must convince one single party of the business case and does not have to take into consideration all the other parties that are possibly affected by the procurement. If a start-up has a good understanding of this, then this could already be taken into consideration during the development of the product, which subsequently could result in less slack during the commercialization phase.

Altogether, this gave the researcher the motivation to believe that **(6) the understanding of the cost structure** is another factor that affects the duration of the commercialization phase (from the point of CE-marking up until operational cashflow break-even). Furthermore, the researcher strongly believes that this factor mainly has an influence on the **hospital level.**

Second, the results not only showed that all the different reimbursement routes are quite complex, but the participants also mentioned that a lot of start-ups are struggling to deal with this complexity and lack a good understanding of the different reimbursement routes. Multiple participants noticed that a lot of start-ups focus on the insurance firms, while they only reimburse a specific niche of the total healthcare market, namely the additional healthcare. As this research is focused on MedTech in relation to medical devices, which is mostly used in the hospital setting, this focus is quite alarming and confirms that the start-ups have no clear view of the reimbursement landscape. The real focus of the start-ups should go to the National Healthcare Institute, as they are the decisive institute about hospital care and whether something will get covered in the basic health insurance. If start-ups focus on the wrong institute for reimbursement, then adopting reimbursement could become a very difficult task. As reimbursement is a way to make new medical technology less expensive for hospitals to use, it is important for the start-up to know how and where to become eligible for reimbursement. If the start-up is not able to adopt reimbursement for its device, then this could affect the adoption decision of the hospital in a negative way, which as a result could slow down the commercialization of the device.

Altogether, this gave the researcher the motivation to believe that **(7) the understanding of the reimbursement landscape** is another factor that affects the duration of the commercialization phase (from the point CE-marking up until operational cashflow break-even). Although the start-up is the entity that must make sure that it has a good understanding of the reimbursement landscape, the researcher strongly believes that this level of understanding will eventually unfold in the adoption decision of the hospital. Thus, this factor mainly seems to be influential on the **hospital level.**

The sixth recurring theme were the stakeholders. Although there was no initial proposition that was linked to this theme, the importance of understanding all the different stakeholders was brought up quite often when the researcher asked the participants what they value as other important factors that could affect the duration of the commercialization phase.

First, the results showed that one must deal with a rather complex stakeholder situation. It is not just about the view of the clinician, but also about all the other entities that are affected by the adoption of the technology, externally, but also within the organization itself. Furthermore, in order for the start-up to 'tell the right story', one should know all the different roles in the ecosystem and what is being valued as important to them. If a start-up knows which story to tell, to which stakeholder, then this might enable them to save unnecessary slack during the commercialization phase.

Second, the results showed that it is not only important to know who all the different stakeholders are, but also how they work and what their professional incentives are. It is crucial to understand how all of the workprocesses are organized and how they influence each other. The results showed that at first sight something might look like a great invention that will make things better, faster or easier, but in time might appear to be not attractive at all, because it has a negative outcome on the incentives of the stakeholder. It was also interesting to see that the participants suggested that the success of MedTech commercialization is not in making a lot of sales, but in being able to successfully implement your technology or device into those workprocesses. If a start-up has a good understanding of this, then it could prevent that it must deal with unnecessary conservativeness or resistance from the stakeholders. Taking all this into consideration enhances the existence of harmony and synergy between all the different stakeholders, which could make it easier for a hospital to implement a certain device.

Finally, one could say that the understanding of stakeholders is twofold, namely: understanding who they are, but also what they do and how their workprocesses look. If a start-up has a good understanding of this, then it will be easier for them to implement their technology, which can have a positive influence on the commercialization phase. Therefore, the researcher believes that **(8) the understanding of stakeholders** is another factor that affects the duration of the commercialization phase (from the point of CE-marking up until operational cashflow break-even). In line with the argumention, the researcher strongly believes that this factor will mainly have an influence on the **hospital level.**

The seventh and final recurring theme was the network. Although there was no initial proposition formed to discuss alongside this theme, it became clear that the network of the start-up plays an important role during the commercialization phase. During the interview one learned that the average network of a MedTech start-up consists of: investors, strategists, key opinion leaders and the board of commissioners. From all these parties, specifically the key opinion leaders seemed to play a role in relation to the commercialization phase.

First, the results showed that due to their expertise in specific domains, key opinion leaders are valued as important ambassadors for the product. Due to this, hospitals and strategic companies see the presence of KOL's in the network as an important indicator of validation. As a result of this, KOL's seem to enhance the process of adoption. Second, the KOL's appear to be represented in all kinds of entities that are important to realize reimbursement or to get adopted into the medical guidelines. Thus, the presence of KOL's could also mean that these processes can be completed faster than without their presence. Furthermore, the participants stress the importance of having ubiased KOL's and also to involve 'common' clinicians and not only the most prominent KOL's.

Altogether, this gave the researcher the motivation to believe that another important factor during the commercialization phase (from the point of CE-marking up until operational cashflow break-even) is **(9) the quality and diversity of the key opinion leaders.** In line with the argumentation above, the researcher strongly believes that qualitative and diverse key opinion leaders could be influential on a multitude of levels, namely on the **start-up level, lead-user level** (clinician) and **hospital level.**

In order to get a better understanding of the commercialization phase, the researcher formulated the following research question: "What factors affect the duration of the commercialization phase (from the point of adopting CE-certification up until the point of operational cash flow break-even) of MedTech start-ups that focus on exploiting new, innovative medical devices?"

In total, 9 factors were found that could possibly affect the duration of the commercialization phase (from the point of CE-marking up until operational cashflow break-even), namely: *the added value ; the active use of social media ; attending conferences ; the business acumen of the management team ; the quality of the clinical study design ; the understanding of the cost structure ; the understanding of the reimbursement landscape ; the understanding of stakeholders ; the quality and diversity of the key opinion leaders.*

An overview of these factors and the levels on which they presumably are the most influential can be found in section 4.9. Furthermore, in line with the purpose of this study, these factors were integrated in a conceptual model, which can be found in section 4.10.

5.7. Practical implications

First, this study can be used as an informative guide for entrepreneurs that are thinking about setting up a medical technology start-up. The study contains numerous examples of do's and dont's from everyday practice as experienced by professionals that have build credibility in the medical field. A quick read through the results can already be very insightful and prevent those start-ups from making the same unnecessary mistakes as their predecessors. Second, the factors that have been found in this study can be used by these start-ups as a checklist to see whether they have thought about the most important aspects as perceived by investors and healthcare-related professionals. Next to that the conceptual roadmap model as presented in section 4.10. can be used to see what aspects of the business deserve (more) attention in each specific phase of the lifecycle. Altogether this could help entrepreneurs to take all the necessary hurdles that are needed to succesfully commercialize their medical device. In that same light, this conceptual model could also be used by investors as an easy handhold for their own portfolio companies. Moreover, the reactions of the participants also clearly showed that the reimbursement landscape in the Netherlands is rather complex and unclear to both, experienced professionals and up-and-coming entrepreneurs, which is quite alarming. Thus, in that light, this study also points out a systematical weakness for Dutch policymakers and (hopefully) challenges them to do something about this.

5.8. Academical implications

As mentioned earlier, a lot of the current literature is focusing on how MedTech start-ups could overcome the 'first valley of death', which is the phase in which a start-up must attract enough financial resources to move from a proof-of-concept into a marketable product. Therefore, a lot of focus is put on how these start-ups can adopt CE and thus receive regulatory approval. Nevertheless, not a lot of the current literature focuses on the 'second valley of death' that occurs for a lot of MedTech start-ups, which is the phase in which they must prove that the business case is attractive to the market, establish recurring sales and subquently upscale their business. Therefore, this study wanted to specifically focus on this phase of the company lifecycle and to see what factors can influence the duration of this phase. Eventually 9 factors were found that could possibly affect the duration of the commercialization phase from the point of CE-marking up until operational cashflow break-even. Furthermore, the researcher concluded that after a very extensive literature review, no useful academically reviewed models or frameworks were found that specifically focus on the commercialization of medical technology. Thus, the conceptual roadmap model in this study is a first attempt at developing such a model and to give a better insight in this troublesome phase of the company lifecycle. Finally, there are also several contributions to the existing literature. Perhaps the most interesting is that the results of this study challenge the literature of (Shah & Robinson, 2009) who mention that in order for a medical device to succeed, the acceptance of the patient (end-user) is key. The results in this study suggest otherwise, namely that although patients (end-users) are certainly important, the real decisive power on whether a medical device will be accepted and used is on the side of the clinician (lead-user). Furthermore, the results of this study showed that the literature of Escarce (1996) still seems to hold value as conferences and publications in journals are indeed pointed out as the most important sources of information to a clinician. Finally, the results in this study also clearly show that, even after a decade, the study of Scanlon & Lieberman (2007) still seems to hold truth. This study clearly shows that the academic community hasn't been able (yet) to change the culture of the scientist in a way that they are able to successfully commercialize their technology. The synergy between science & business still seems to be rather sub-optimal.

5.9. Discussion, limitations & future research

This study tried to give more insight in the commercialization phase from regulatory approval up until commercial success. To make both of these points more measurable, the researcher linked the point of CE-marking to regulatory approval and operational cashflow-break even to commercial success. The initial idea of this study was to take a large sample of MedTech start-ups that have been through the whole phase of adopting CE-marking and becoming operational cashflow break-even and to find these factors by conducting a quantative study. Nevertheless, after a while it became clear that the MedTech industry in the Netherlands is relatively small and that such a study would not give any significant results. Then, the researcher decided to follow a qualitative approach in which he wanted to, again, interview three groups, namely: investment professionals, healthcare(-related) professionals and entrepreneurs of MedTech start-ups that been through the whole phase of CE-marking up until operational cashflow break-even. Nevertheless, also here the relatively small MedTech industry of the Netherlands formed a problem as the researcher could not find enough MedTech start-ups that matched the qualifications above and that were willing to participate in the study. Thus, the researcher shifted from this idea and decided to conduct semi-structured interviews with only two groups, namely: investment professionals with a healthcare focus and healthcare(-related) professionals. In total 5 participants per group were found, which gave a total of 10 semi structured interviews. Now that the origin of this study is clear, in this section the researcher will briefly reflect on the possible limitations of this study and about future research.

The first thing that perhaps comes to mind when reading this study is that not all the 9 factors look like they specifically focus on the commercialization phase from the point of CE-adoption up until operational cashflow break-even. For instance, in section 4.10. one can clearly see that some of the factors are also related to the fundamental research and development phase. Although some of these factors indeed already play a role in the earlier phases of the start-up, the way how these factors are tackled during those earlier phases manifest themselves during the commercialization phase. For this reason, the researcher decided to also take into consideration these factors. *The second thing* that perhaps comes to mind when reading this study, is that it does not seem to build on one consistent theoretical framework, but that it uses multiple sources of literature as its foundation. Again, this is true, but as mentioned earlier, after an extensive literature review, the researcher came to the understanding that there was no suitable model that appropriately explained the commercialization of medical technology. For the consistency of the thesis, it would have been better to use one single framework, but in practice this appeared not workable to eventually achieve the goal of this study. Therefore, several pieces of literature were used on which the initial propositions were formed that were used as the backbone of this thesis. *The third thing* that can be seen as a limitation, is that this study only focused on MedTech in the sense of medical devices. This was done to put a bit more focus to the research and thus, for example, E-Health products were not discussed. It is very possible that a study with a focus on E-health products would give other factors then the ones that came to the surface during this research. For future research it would be interesting to see if there are differences between the commercialization of medical devices and E-health or other MedTech solutions. *Finally,* it is important to notice that the 9 factors were derived from a qualitative study design, meaning that none of these factors have been statistically tested yet and thus are not proven to be significant. For that same reason it always states that a factor could possibly *affect* the duration of the commercialization phase and not that it has an *effect* on the duration. For future research it would be interesting to statistically test the 9 factors as proposed in this study and to see whether the model as proposed in section 4.10. is perceived as useful in practice.

6. Bibliography

Amyx, S. (2015, August 25). For Medical Technology Startups, FDA Approval is crucial. Retrieved from: https://readwrite.com/2015/08/25/medical-technology-fda-approval/

Boeije, H. (2005). *Analyseren in kwalitatief onderzoek*. Boom Lemma Uitgevers.

Cain, M., & Mittman, R. (2002). Diffusion of innovation in health care.
Chatterji, A. K., Fabrizio, K. R., Mitchell, W., & Schulman, K. A. (2008). Physician-industry cooperation in the medical device industry. *Health affairs*, *27*(6), 1532-1543.

Chi, C. (2012, February 2). Which Way to Go: CE Mark or FDA Approval? Retrieved from: https://www.mdtmag.com/article/2012/02/which-way-go-ce-mark-or-fda-approval

Chiesa, V., & Frattini, F. (2011). Commercializing Technological Innovation: Learning from Failures in High-Tech Markets. *Journal of Product Innovation Management*, *28*(4), 437-454.

Cosh, E., Girling, A., Lilford, R., McAteer, H., Young, T. (2007). Investing in new medical technologies: A decision framework Journal of Commercial Biotechnology, 13 (4), pp. 263-271.

del Campo, A. A., Sparks, A., Hill, R. C., & Keller, R. T. (1999). The transfer and commercialization of university-developed medical imaging technology: Opportunities and problems. *IEEE Transactions on Engineering Management*, *46*(3), 289-298.

Egeland, R. D., Rapp, Z., & David, F. S. (2017). From innovation to market adoption in the operating room: The “CFO as customer”. *Surgery*, *162*(3), 477-482.

Escarce, J. (1996). Externalities in hospitals and physician adoption of a new surgical technology: an exploratory analysis. *Journal of Health Economics*, *15*(6), 715-734.

Gans, J. S., & Stern, S. (2003). The product market and the market for “ideas”: commercialization strategies for technology entrepreneurs. *Research policy*, *32*(2), 333-350.

Glaser, B. G., & Strauss, A. L. (1967). *The discovery of grounded theory: Strategies for qualitative research*.

Greer, A. L. (1985). Adoption of medical technology: the hospital's three decision systems. *International Journal of Technology Assessment in Health Care*, *1*(3), 669-680.

Hsu, D. H. (2006). Venture capitalists and cooperative start-up commercialization strategy. *Management Science*, *52*(2), 204-219

Jull, T. (2016, September 7). New Regulations for CE: The Changing Landscape for Medical Devices in Europe. Retrieved from: https://www.ecnmag.com/blog/2016/09/new-regulations-ce-changing-landscape-medical-devices-europe

Kirsh, D. (2018, February 26). Regulatory changes a top concern for medtech companies in 2018. Retrieved from: https://www.medicaldesignandoutsourcing.com/regulatory-changes-top-concern-medtech-companies-2018/

Kramer, D. B., Xu, S., & Kesselheim, A. S. (2012). How does medical device regulation perform in the United States and the European union? A systematic review. *PLoS medicine*, *9*(7), e1001276.

Lettl, C., Hienerth, C., & Gemuenden, H. G. (2008). Exploring how lead users develop radical innovation: opportunity recognition and exploitation in the field of medical equipment technology. *IEEE Transactions on Engineering Management*, *55*(2), 219-233.

Mitchell, W., & Singh, K. (1996). Survival of businesses using collaborative relationships to commercialize complex goods. *Strategic management journal*, 169-195.

Mot, E., Aalbers, R., Stuut, K., Douven, R. (2017). De introductie van dure technologie in de zorg. *CPB Policy Brief.* Retrieved from: https://www.cpb.nl/sites/default/files/omnidownload/CPB-Policy-Brief-2017-06-De-introductie-van-dure-technologie-in-de-zorg.pdf

Pellikka, J., Lauronen, J. Fostering commercialisation of innovation in small high technology firms (2007) International Journal of Technoentrepreneurship, 1 (1), pp. 92-108.

Greenberg, D., Pliskin, J.S., Peterburg, Y. Decision making in acquiring medical technologies in Israeli medical centers: A preliminary study (2003) International Journal of Technology Assessment in Health Care, 19 (1), pp. 194-201.

Pietzsch, J. B., & Paté-Cornell, M. E. (2008). Early technology assessment of new medical devices. *International Journal of Technology Assessment in Health Care*, *24*(1), 36-44.

Robson, C. (2002). *Real world research*. 2nd Edition. Oxford: Blackwell Publishing.

Rogers, E. (2004). Diffusion of Innovations, 5th (fifth) edition.

Saunders, M. Lewis, P., Thornhill, A. (2009). *Research Methods for Business Students*. Fifth edition. Pearson Education Limited.

Scanlon, K. J., & Lieberman, M. A. (2007). Commercializing medical technology. *Cytotechnology*, *53*(1-3), 107-112.

Shah, S.G.S., Robinson, I. (2007). Benefits of and barriers to involving users in medical device technology development and evaluation International Journal of Technology Assessment in Health Care, 23 (1), pp. 131-137.

Shah, Syed & Robinson, Ian & Alshawi, Sarmad. (2009). Developing medical device technologies from users' perspectives: A theoretical framework for involving users in the development process. International journal of technology assessment in health care. 25. 514-21.

Teece, D. J. (1988). Capturing value from technological innovation: Integration, strategic partnering, and licensing decisions. *Interfaces*, *18*(3), 46-61.

Teplensky, J. D., Pauly, M. V., Kimberly, J. R., Hillman, A. L., & Schwartz, J. S. (1995). Hospital adoption of medical technology: an empirical test of alternative models. *Health services research*, *30*(3), 437.

The European Medical Technology Industry – in figures 2018. (2017). Retrieved from: http://www.medtecheurope.org/sites/default/files/resource_items/files/2018_MTE_MedTech_FactsFigures.pdf

Wijk, van. M. (2014, May 30). The occurrence of a second valley of death during medical device development. Retrieved from: https://www.ttopstart.com/news/the-occurrence-of-a-second-valley-of-death-during-medical-device-developmen

Wilson, C. (2014). *Interview techniques for UX practitioners: A user-centered design method*. Waltham, MA: Morgan Kaufmann.

Wilson, N., Wright, M., Kacer, M. (2018). The equity gap and knowledge-based firms. *Journal of Corporate Finance*, *50*, 626-649.

Wolfswinkel, J., Furtmueller-Ettinger, E., & Wilderom, C. P. M. (2013). Using grounded theory as a method for rigorously reviewing literature. *European journal of information systems*, *22*, 45-55.

Yin, R.K. (2003). *Case Study Research: Design and Methods* (3rd edn). Beverly Hills, CA: Sage.

7. Appendices

A. Search stage – Systematic Literature Review

Keyword	Database	Direct or for-backward citation	Article name	Year	Field of research	Central theme	Times cited	Useful? √/x
Medical technology	Scopus	Direct	Moloney, T. W., & Rogers, D. E. (1979). Medical technology—a different view of the contentious debate over costs. *New England Journal of Medicine*, *301*(26), 1413-1419.	1979	Medicine	Costs	322	X
Medical technology	Google scholar	Direct	Timmermans, S., & Berg, M. (2003). The practice of medical technology. *Sociology of health & illness*, *25*(3), 97-114.	2003	Sociology	Medical technology	319	X
Medical technology	Google scholar	Direct	Greenland, S., & Neutra, R. (1980). Control of confounding in the assessment of medical technology. *International Journal of Epidemiology*, *9*(4), 361-367.	1980	Medicine	Technology assessment	187	X
Medical technology	Google scholar	Direct	McClellan, M., & Newhouse, J. P. (1997). The marginal cost-effectiveness of medical technology: a panel instrumental-variables approach. *Journal of Econometrics*, *77*(1), 39-64.	1997	Business	Cost-effectiveness	120	X
Medical technology	Scopus	Direct	Tymstra, T. (1989). The imperative character of medical technology and the meaning of "anticipated decision regret". *International journal of technology assessment in health care*, *5*(2), 207-213.	1989	Business	Technology assessment	130	X
Medical technology	Google Scholar	Direct	Phelps, C. E., & Parente, S. T. (1990). Priority setting in medical technology and medical practice assessment. *Medical care*, *28*(8), 703-723.	1990	Healthcare	Assessment	145	X

Medical technology	Google Scholar	Direct	Chernew, M. E., Hirth, R. A., Sonnad, S. S., Ermann, R., & Fendrick, A. M. (1998). Managed care, medical technology, and health care cost growth: a review of the evidence. *Medical Care Research and Review*, *55*(3), 259-288.	1998	Healthcare	Costs	138	√
Medical technology	Google Scholar	Direct	Rublee, D. A. (1989). Medical technology in Canada, Germany, and the United States. *Health Affairs*, *8*(3), 178-181.	1989	Healthcare	MedTech industry	78	X
Medical technology	Google Scholar	Direct	Teplensky, J. D., Pauly, M. V., Kimberly, J. R., Hillman, A. L., & Schwartz, J. S. (1995). Hospital adoption of medical technology: an empirical test of alternative models. *Health services research*, *30*(3), 437.	1995	Healthcare	Technology adoption	121	√
	Google Scholar	Backward citation via Teplensky (1995)	Greer, A. L. (1985). Adoption of medical technology: the hospital's three decision systems. *International Journal of Technology Assessment in Health Care*, *1*(3), 669-680.	1985	Healthcare	Decision system	87	√
	Scopus	Backward citation via Teplensky (1995)	Balcer, Y., & Lippman, S. A. (1984). Technological expectations and adoption of improved technology. *Journal of Economic Theory*, *34*(2), 292-318.	1984	Business	Technology adoption	289	√
Medical technology	Scopus	Direct	Shah, Syed & Robinson, Ian & Alshawi, Sarmad. (2009). Developing medical device technologies from users' perspectives: A theoretical framework for involving users in the development process. International journal of technology assessment in health care. 25. 514-21.	2009	Healthcare	Technology assessment	59	√
Medical technology	Scopus	Direct	O'Malley, S., & Jordan, E. (2009). Horizon scanning of new and	2009	Healthcare	Technology assessment	18	X

			emerging medical technology in Australia: Its relevance to Medical Services Advisory Committee health technology assessments and public funding. *International Journal of Technology Assessment in Health Care, 25*(3), 374-382.					
Medical technology	Scopus	Direct	Bunker, J.P., Fowles, J., Schaffarzick, R. Evaluation of Medical-Technology Strategies: Effects of Coverage and Reimbursement (1982) New England Journal of Medicine, 306 (10), pp. 620-624.	1982	Medicine	Strategy	26	X
Medical technology	Scopus	Direct	Montague, E.N.H., Kleiner, B.M., Winchester III, W.W. Empirically understanding trust in medical technology (2009) International Journal of Industrial Ergonomics, 39 (4), pp. 628-634.	2009	Business	Trust	27	X
Medical technology	Scopus	Direct	Wilkowska, W., Gaul, S., Ziefle, M. A small but significant difference - The role of gender on acceptance of medical assistive technologies (2010) Lecture Notes in Computer Science (including subseries Lecture Notes in Artificial Intelligence and Lecture Notes in Bioinformatics), 6389 LNCS, pp. 82-100.	2010	Computer science	Gender	18	X
Medical technology	Scopus	Direct	Bryce, C.L., Cline, K.E. The Supply and Use of Selected Medical Technologies (1998) Health Affairs, 17 (1), pp. 213-224.	1998	Healthcare	Technology assessment	20	X
Medical technology	Scopus	Direct	Gallego, G., Casey, R., Norman, R., Goodall, S. Introduction and uptake of new medical technologies in the Australian health care	2011	Health Policy	Technology adoption	5	X

			system: A qualitative study (2011) Health Policy, 102 (2-3), pp. 152-158.					
Medical technology	Scopus	Direct	Greenberg, D., Pliskin, J.S., Peterburg, Y. Decision making in acquiring medical technologies in Israeli medical centers: A preliminary study (2003) International Journal of Technology Assessment in Health Care, 19 (1), pp. 194-201.	2003	Healthcare	Technology assessment	9	√
Medical technology	Scopus	Direct	Mahal, A., Karan, A.K. Diffusion of medical technology: Medical devices in India (2009) Expert Review of Medical Devices, 6 (2), pp. 197-205.	2009	Medicine	Technology diffusion	5	X
Medical technology	Scopus	Direct	Bonair, A., Rosenfield, P., Tengvald, K. Medical technologies in developing countries: Issues of technology development, transfer, diffusion and use (1989) Social Science and Medicine, 28 (8), pp. 769-781.	1989	Medicine	Technology diffusion	32	X
Medical technology	Scopus	Direct	Shah, S.G.S., Robinson, I. Benefits of and barriers to involving users in medical device technology development and evaluation (2007) International Journal of Technology Assessment in Health Care, 23 (1), pp. 131-137.	2007	Healthcare	Technology assessment	94	√
Medical technology	Scopus	Direct	Cosh, E., Girling, A., Lilford, R., McAteer, H., Young, T. Investing in new medical technologies: A decision framework (2007) Journal of Commercial Biotechnology, 13 (4), pp. 263-271.	2007	Biotechnology	Investment criteria	40	√

Medical Technology	Scopus	Direct	Kouris, K., Abdel-Dayem, H.M. Transfer of medical technology from a developed to a developing country (1988) Journal of Biomedical Engineering, 10 (4), pp. 326-330.	1988	Biomedical	Technology transfer	3	X
Medical technology	Scopus	Direct	Rabinovich, M., Greenberg, D., Shemer, J. Threshold values for cost-effectiveness ratio and public funding of medical technologies (2007) Harefuah, 146 (6), pp. 453-458.	2007	Medicine	Costs		X
Medical technology	Scopus	Direct	Glasser, J.H., Chrzanowski, R.S. Medical technology assessment: adequate questions, appropriate methods, valuable answers (1988) Health policy, 9 (3), pp. 267-276.	1988	Health Policy	Technology assessment	11	√
Medical technology	Scopus	Direct	Brown, I.T., Smale, A., Verma, A., Momandwall, S. Medical technology horizon scanning (2005) Australasian Physical and Engineering Sciences in Medicine, 28 (3), pp. 200-203.	2005	Medicine	Technology assessment	8	X
Medical technology	Scopus	Direct	Greenberg, D., Peterburg, Y., Vekstein, D., Pliskin, J.S. Decisions to adopt new technologies at the hospital level: Insights from Israeli medical centers (2005) International Journal of Technology Assessment in Health Care, 21 (2), pp. 219-227.	2005	Healthcare	Technology assessment	61	√
Medical technology	Scopus	Direct	Doyle, Y.G., McNeilly, R.H.M. The diffusion of new medical technologies in	1999	Healthcare	Technology diffusion	3	√

			the private sector of the U.K. Health Care System (1999) International Journal of Technology Assessment in Health Care, 15 (4), pp. 619-628.					
Medical technology	Scopus	Direct	Hutton, J. Assessment of medical technology: The role of engineers (1993) Medical & Biological Engineering & Computing, 31 (1), pp. HTA11-HTA15.	1993	Medicine/ Biotechnology	Technology assessment	1	√
Medical technology	Scopus	Direct	Retèl, V.P., Grutters, J.P.C., Van Harten, W.H., Joore, M.A. Value of research and value of development in early assessments of new medical technologies (2013) Value in Health, 16 (5), pp. 720-728.	2013	Healthcare	Technology assessment	5	√
Medical technology	Web of Science	Direct	Ciani O, Wilcher B, van Giessen A, Taylor RS. 2017. Linking the regulatory and reimbursement processes for medical Devices: the need for integrated assessments. Health Economics 26(Suppl.1): 13–29.	2017	Healthcare	Technology assessment	4	√
Medical technology AND commercialization	Google Scholar	Direct	Gans, J. S., & Stern, S. (2003). The product market and the market for “ideas”: commercialization strategies for technology entrepreneurs. *Research policy*, *32*(2), 333-350.	2003	Policy	Commercialization	1136	√
Medical technology AND commercialization	Scopus	Direct	del Campo, A. A., Sparks, A., Hill, R. C., & Keller, R. T. (1999). The transfer and commercialization of university-developed medical imaging technology: Opportunities and problems. *IEEE Transactions on Engineering Management*, *46*(3), 289-298.	1999	Business	Commercialization	32	√

Medical technology AND commercialization	Scopus	Direct	Volpatti, L.R., Yetisen, A.K. Commercialization of microfluidic devices (2014) Trends in Biotechnology, 32 (7), pp. 347-350.	2014	Biotechnology	Commercialization	81	√
Medical technology AND commercialization	Scopus	Direct	Lettl, C., Hienerth, C., Gemuenden, H.G. Exploring how lead users develop radical Innovation: Opportunity recognition and exploitation in the field of medical equipment technology (2008) IEEE Transactions on Engineering Management, 55 (2), pp. 219-233.	2008	Business/ Technology	Lead users, Opportunity Recognition and exploitation	49	√
Medical technology AND commercialization	Scopus	Direct	Pietzsch, J.B., Paté-Cornell, M.E. Early technology assessment of new medical devices (2008) International Journal of Technology Assessment in Health Care, 24 (1), pp. 36-44.	2008	Healthcare	Technology assessment	39	X
Medical technology AND commercialization	Scopus	Direct	Pietzsch, J.B., Shluzas, L.A., Paté-Cornell, M.E., Yock, P.G., Linehan, J.H. Stage-gate process for the development of medical devices (2009) Journal of Medical Devices, Transactions of the ASME, 3 (2), art. no. 021004, .	2009	Medicine Business	Stage-gate process	36	√
Medical technology AND commercialization	Scopus	Direct	Bertram, T.A., Tentoff, E., Johnson, P.C., Tawil, B., Van Dyke, M., Hellman, K.B. Hurdles in tissue engineering/regenerative medicine product commercialization: A pilot survey of governmental funding agencies and the financial industry	2012	Medicine	Commercialization	20	√

			(2012) Tissue Engineering - Part A, 18 (21-22), pp. 2187-2194.					
Medical technology AND commercialization	Scopus	Direct	Del Campo, A.A., Sparks, A., Hill, R.C., Keller, R.T. The transfer and commercialization of university-developed medical imaging technology: Opportunities and problems (1999) IEEE Transactions on Engineering Management, 46 (3), pp. 289-298.	1999	Medicine & Business	Commercialization	20	**Double**
Medical technology AND acceptance	Google Scholar	Direct	Hu, P. J., Chau, P. Y., Sheng, O. R. L., & Tam, K. Y. (1999). Examining the technology acceptance model using physician acceptance of telemedicine technology. *Journal of management information systems*, *16*(2), 91-112.	1999	Management	Technology acceptance model	1989	√
Medical technology AND acceptance	Google Scholar	Direct	Chismar, W. G., & Wiley-Patton, S. (2003, January). Does the extended technology acceptance model apply to physicians. In *System Sciences, 2003. Proceedings of the 36th Annual Hawaii International Conference on* (pp. 8-pp). IEEE.	2003	Business	Technology acceptance model	329	√
Medical technology AND acceptance	Google Scholar	Direct	Yarbrough, A. K., & Smith, T. B. (2007). Technology acceptance among physicians: a new take on TAM. *Medical Care Research and Review*, *64*(6), 650-672.	2007	Healthcare	Technology acceptance model	354	√
Medical technology AND acceptance	Google Scholar	Direct	Holden, R. J., & Karsh, B. T. (2010). The technology acceptance model: its past and its future in health care. *Journal of biomedical informatics*, *43*(1), 159-172.	2010	Healthcare	Technology acceptance model	974	√
								√

Medical technology AND acceptance	Scopus	Direct	Aggelidis, V. P., & Chatzoglou, P. D. (2009). Using a modified technology acceptance model in hospitals. *International journal of medical informatics*, *78*(2), 115-126.	2009	Medicine Healthcare	Technology acceptance model	334	
Technology acceptance model	Google Scholar	Direct	Venkatesh, V., & Davis, F. D. (2000). A theoretical extension of the technology acceptance model: Four longitudinal field studies. *Management science*, *46*(2), 186-204.	2000	Management	Technology acceptance model	13789	X
Technology acceptance model	Google Scholar	Direct	Legris, P., Ingham, J., & Collerette, P. (2003). Why do people use information technology? A critical review of the technology acceptance model. *Information & management*, *40*(3), 191-204.	2003	Management	Technology acceptance model	3703	X
Medical technology AND adoption	Google Scholar	Direct	Poon, E. G., Jha, A. K., Christino, M., Honour, M. M., Fernandopulle, R., Middleton, B., ... & Kaushal, R. (2006). Assessing the level of healthcare information technology adoption in the United States: a snapshot. *BMC Medical Informatics and Decision Making*, *6*(1), 1.	2006	Medicine	Technology adoption	280	X
Medical technology AND diffusion of innovation	Google Scholar	Direct	Cain, M., & Mittman, R. (2002). Diffusion of innovation in health care.	2002	Healthcare	Diffusion of innovation	181	√
Medical technology AND diffusion of innovation	Scopus	Direct	Greer, A. L. (1988). The state of the art versus the state of the science: the diffusion of new medical technologies into practice. *International journal of technology assessment in health care*, *4*(1), 5-26.	1988	Healthcare	Diffusion of innovation	440	√
Medical technology AND diffusion of innovation	Scopus	Direct	Baker, S. R. (1979). The diffusion of high technology medical innovation: The computed tomography scanner example. *Social Science & Medicine. Part*	1979	Medicine	Diffusion of innovation	120	√

			D: Medical Geography, *13*(3), 155-162.					
Medical technology AND diffusion of innovation	Scopus	Direct	Escarce, J. (1996). Externalities in hospitals and physician adoption of a new surgical technology: an exploratory analysis. *Journal of Health Economics*, *15*(6), 715-734.	1996	Healthcare	Technology adoption	120	√
Medical technology AND diffusion of innovation	Scopus	Direct	Lee, T. T. (2004). Nurses' adoption of technology: application of Rogers' innovation-diffusion model. *Applied Nursing Research*, *17*(4), 231-238.	2004	Healthcare	Innovation diffusion	156	X
	Google Scholar	Backward citation from article of Lee → 4th edition of Rogers	Rogers, E. (2004). Diffusion of Innovations, 5th (fifth) edition.	2004	Business & Innovation	Diffusion of Innovations	247	√
Medical technology AND diffusion of innovation	Google scholar	Direct	Wilson, C. B. (2006). Adoption of new surgical technology. *Bmj*, *332*(7533), 112-114.	2006	Business & Healthcare	Adoption of technology	126	√
Medical technology AND diffusion of innovation	Scopus	Direct	Battista, R. N. (1989). Innovation and diffusion of health-related technologies: a conceptual framework. *International journal of technology assessment in health care*, *5*(2), 227-248.	1989	Technology & Healthcare	Innovation & diffusion	107	√
Medical technology AND diffusion of innovation	Google Scholar	Direct	Greer, A. L. (1981). Medical technology: assessment, adoption, and utilization. In *Use and Impact of Computers in Clinical Medicine* (pp. 15-35). Springer New York.	1981	Medicine	Assessment, adoption and utilization	59	√
Medical technology AND commercialization strategy	Google Scholar	Direct	Slater, S. F., & Mohr, J. J. (2006). Successful development and commercialization of technological innovation: insights based on strategy type. *Journal of Product Innovation Management*, *23*(1), 26-33.	2006	Innovation	Commercial lization	327	√

Medical technology AND commercialization strategy	Scopus	Direct	Eldred, E. W., & McGrath, M. E. (1997). Commercializing new technology—II. *Research-Technology Management*, *40*(2), 29-33.	1997	Technology	Commercial lization	98	√
Medical technology AND commercialization strategy	Google Scholar	Direct	Hsu, D. H. (2006). Venture capitalists and cooperative start-up commercialization strategy. *Management Science*, *52*(2), 204-219.	2006	Management	Commercia lization strategy	372	√
Medical technology AND commercialization strategy	Google Scholar	Direct	Mitchell, W., & Singh, K. (1996). Survival of businesses using collaborative relationships to commercialize complex goods. *Strategic management journal*, 169-195.	1996	Management	Commercia Lization strategy	609	√
Medical technology AND commercialization strategy	Google Scholar	Direct	Nevens, T. M. (1990). Commercializing technology: what the best companies do. *Planning review*, *18*(6), 20-24.	1990	Business & Management	Commercia lization	328	X
Medical technology AND commercialization strategy	Google Scholar	Direct	Teece, D. J. (1988). Capturing value from technological innovation: Integration, strategic partnering, and licensing decisions. *Interfaces*, *18*(3), 46-61.	1988	Innovation & Management	Technological Innovation & Licensing	606	√
Medical technology AND commercialization strategy	Google Scholar	Direct	Chiesa, V., & Frattini, F. (2011). Commercializing Technological Innovation: Learning from Failures in High-Tech Markets. *Journal of Product Innovation Management*, *28*(4), 437-454.	2011	Innovation & Management	Commercia lization	147	√
Medical technology AND strategy	Scopus	Direct	Wonglimpiyarat, J. (2010). Commercialization strategies of technology: lessons from Silicon Valley. *The Journal of Technology Transfer*, *35*(2), 225-236.	2010	Technology & Business	Commercia lization & Strategy	56	√
Medical technology AND strategy	Scopus	Direct	Frishammar, J., Lichtenthaler, U., & Rundquist, J. (2012). Identifying technology commercialization opportunities: the importance of integrating product development	2012	Innovation & Management	Identifying technology commercia lization	68	√

			knowledge. *Journal of Product Innovation Management*, *29*(4), 573-589.					
Medical technology AND strategy	Google Scholar	Direct	Chatterji, A. K., Fabrizio, K. R., Mitchell, W., & Schulman, K. A. (2008). Physician-industry cooperation in the medical device industry. *Health affairs*, *27*(6), 1532-1543.	2008	Healthcare	Physician-industry cooperation	112	√
Medical technology AND commercialization strategy	Scopus	Direct	Pietzsch, J.B., Shluzas, L.A., Paté-Cornell, M.E., Yock, P.G., Linehan, J.H. Stage-gate process for the development of medical devices (2009) Journal of Medical Devices, Transactions of the ASME, 3 (2), art. no. 021004, .	2009	Healthcare	State-gate process	36	Double
High-tech AND commercialization phase	Scopus	Direct	Athaide, G.A., Meyers, P.W., Wilemon, D.L. Seller-buyer interactions during the commercialization of technological process innovations (1996) Journal of Product Innovation Management, 13 (5), pp. 406-421.	1996	Innovation Management	Seller-buyer interactions	83	√
High-tech AND commercialization phase	Scopus	Direct	Pellikka, J., Lauronen, J. Fostering commercialisation of innovation in small high technology firms (2007) International Journal of Technoentrepreneurship, 1 (1), pp. 92-108.	2007	Business	Fostering commercial lisation	8	√
Medical technology AND investor	Scopus	Direct	Cappellaro, G., Ghislandi, S., & Anessi-Pessina, E. (2011). Diffusion of medical technology: the role of financing. *Health Policy*, *100*(1), 51-59.	2011	Policy	Diffusion of technology	38	X
Medical technology AND investor	Google Scholar	Direct	Cosh, E., Girling, A., Lilford, R., McAteer, H., & Young, T. (2007). Investing in new medical technologies: a decision	2007	Biotechnology	Investment decision	66	Double

			framework. *Journal of Commercial Biotechnology*, *13*(4), 263-271.					
Medical technology AND product-market strategy	Google Scholar	Direct	Hellmann, T., & Puri, M. (2000). The interaction between product market and financing strategy: The role of venture capital. *The Review of Financial Studies*, *13*(4), 959-984.	2000	Business	Product-market strategy & financing	1445	√
Medical technology AND competitive strategy	Google Scholar	Direct	Grant, R. M. (1999). The resource-based theory of competitive advantage: implications for strategy formulation. In *Knowledge and strategy* (pp. 3-23).	1999	Business	Resource-based theory & strategy	13166	√
	Google Scholar	Backward citation from Grant (1999)	Porter, M. E., & Porter, M. E. (1979). How competitive forces shape strategy.	1979	Business	Competitive advantage & strategy	4765	√
Porter AND strategy	Google Scholar	Direct	Porter, M. E. (2008). The five competitive forces that shape strategy. *Harvard business review*, *86*(1), 25-40.	2008	Business	Competitive forces	3788	√
Medical technology AND network	Scopus	Direct	Anderson, J. G., & Jay, S. J. (1985). The diffusion of medical technology: Social network analysis and policy research. *The Sociological Quarterly*, *26*(1), 49-64.	1985	Sociology	Network	53	√
Medical technology AND alliances	Google Scholar	Direct	Yeheskel, O., Shenkar, O., Fiegenbaum, A., & Cohen, E. (2001). Cooperative wealth creation: Strategic alliances in Israeli medical-technology ventures. *The Academy of Management Executive*, *15*(1), 16-24.	2001	Management	Alliances	39	√
Medical technology AND alliances	Google Scholar	Direct	Gulati, R. (1998). Alliances and networks. *Strategic management journal*, *19*(4), 293-317.	1998	Management	Alliances & Networks	6353	X
Capabilities AND commercialization	Google Scholar	Direct	Zahra, S. A., & Nielsen, A. P. (2002). Sources of capabilities, integration and technology commercialization.	2002	Management	Capabilities & commercial lization	773	X

			Strategic Management Journal, *23*(5), 377-398.					
Capabilities AND commercialization	Google Scholar	Direct	van Hemert, P., Nijkamp, P., & Masurel, E. (2013). From innovation to commercialization through networks and agglomerations: analysis of sources of innovation, innovation capabilities and performance of Dutch SMEs. *The Annals of Regional Science*, *50*(2), 425-452.	2013	Innovation	Networks & capabilities	93	√
Capabilities and commercialization	Google Scholar	Direct	Lockett, A., & Wright, M. (2005). Resources, capabilities, risk capital and the creation of university spin-out companies. *Research policy*, *34*(7), 1043-1057.	2005	Policy	Resources & capabilities	758	X
Time to break even AND startup	Scopus	Direct	Oe, A., & Mitsuhashi, H. (2013). Founders' experiences for startups' fast break-even. *Journal of Business Research*, *66*(11), 2193-2201.	2013	Business	Experience	26	√
How to commercialize medical technology	Google	Found by incident (direct)	Scanlon, K. J., & Lieberman, M. A. (2007). Commercializing medical technology. *Cytotechnology*, *53*(1-3), 107-112.	2007	Technology	Commercialization	6	√
MedTech AND market adoption	Google Scholar	Direct	Egeland, R. D., Rapp, Z., & David, F. S. (2017). From innovation to market adoption in the operating room: The "CFO as customer". *Surgery*, *162*(3), 477-482.	2017	Medicine & Healthcare	Market adoption	-	√

B. Analyze stage – Systematic Literature Review

	Articles			**Concepts**			
No.		*Network/ alliances*	*Product-market strategy*	*Lead-user involvement*	*Technology acceptance/ diffusion*	Venture capital & accelerator	Capabilities
1	Chernew et al. (1998)						
2	Teplensky et al. (1995)		√				
3	Greer (1985)		√		√		
4	Balcer et al. (1984)				√		
5	Shah & Robinson (2009)			√			
6	Greenberg et al. (2003)		√		√		
7	Shah & Robinson (2007)			√			
8	Cosh et al. (2007)		√				
9	Glasser & Chrzanowski (1988)				√		
10	Greenberg et al. (2005)	√			√		
11	Doyle & McNeilly (1995)						
12	Hutton (1993)						
13	Retèl et al. (2013)						
14	Ciani et al. (2017)						
15	Gans & Stern et al. (2003)						√
16	Del Campo et al. (1999)			√			√
17	Volpatti & Yetisen (2004)				√		
18	Lettl et al. (2008)	√		√	√		√
19	Pietzsch et al. (2009)						
20	Bertram et al. (2012)						
21	Hu et al. (1999)				√		
22	Chismar & Wiley-Patton (2003)				√		
23	Yarbrough & Smith (2007)				√		
24	Holden & Karsh (2010)				√		
25	Aggelidis & Chatzoglou (2009)				√		
26	Cain & Mittman (2002)	√		√	√		√
27	Greer (1988)	√		√			
28	Baker (1979)						
29	Escarce (1996)			√			
30	Rogers (2004)	√			√		
31	Wilson (2006)		√				√
32	Battista (1989)				√		
33	Greer (1981)				√		
34	Slater & Mohr (2006)						
35	Eldred & McGrath (1997)						
36	Hsu (2006)	√				√	

37	Mitchell & Sing (1996)	√					
38	Teece (1988)		√				√
39	Chiesa & Frattini (2011)	√					
40	Wonglimpiyarat (2010)					√	
41	Frishammar et al. (2012)						
42	Chatterij et al. (2008)			√			
43	Athaide et al. (1996)			√			
44	Pellikka & Lauronen (2007)	√		√			
45	Hellmann & Puri (2000)					√	
46	Grant (1999)						√
47	Porter (1979)		√				
48	Porter (2008)		√				
49	Anderson & Jay (1985)						
50	Yeheskel (2001)	√					
51	Van Hemert et al. (2013)	√					
52	Oe & Mitsuhashi (2013)						√
53	Scanlon & Lieberman (2007)					√	
54	Engeland et al. (2017)		√				

C. Personal Interview guide – Participant 1,2,3,4,5

Personal interview guide *Investor perspective*		
Origin of research		
"This research focuses specifically on the phase between the MedTech start-up adopting CE-marking (regulatory approval) up until operational cashflow break-even (commercial success). Apparently, it seems that MedTech start-ups move through this phase at different speeds. Next to that it seems that the duration/length of this specific phase can vary between start-ups by a couple of years."		
Question	**Follow-up question (depending on answer)**	**Links to proposition " "**
1. Do you recognize the situation above from your own working experience?		Origin of research
2. Is 'the MedTech start-up adopting a CE-certificate' valued as an important milestone within your organization? Why?		Origin of research
3. Is 'the MedTech start-up achieving the point of operational cashflow break-even' valued as an important milestone within your organization? If yes, why? If no, why?		Origin of research
4. Could you describe your role as investor during the commercialization phase from CE-mark up until operational cashflow break-even?		

5. From the perspective of an investor. What factors would you value as most important for a timely commercialization when you observe the business case of the MedTech start-up?	*What factors are critical for you when you invest in a MedTech start-up?*	**Proposition 1**
6. How does the cost-efficiency of the product affects the duration of the commercialization trajectory from CE up until operational cashflow break-even?	*How are a product its characteristics related to the duration of the commercialization phase?*	**Proposition 1**
7. What role does the healthcare system play during the commercialization phase from CE up until operational cashflow break-even?	*In what way does the healthcare system influence the duration of the commercialization phase?*	**Proposition 1**
8. What role does reimbursement play in relation to the duration of the commercialization phase from CE up until operational cashflow break-even?		**Proposition 1**
9. If a product on the one hand provides a lot of added value for the patient/clinician, but on the other hand is relatively expensive. How would this affect the duration of the commercialization phase for such a product?		**Proposition 1**

10. Let's say a MedTech start-up comes to you for an investment. What role does the network of the start-up play in the decision-making process of whether you would invest in the start-up?	*How would you value the role of key opinion leaders during the commercialization phase?* *Are key opinion leaders able to influence the duration of the commercialization phase (from CE up until operational cashflow break-even? If yes, how?*	**Proposition 2**
11. How do MedTech start-ups connect with clinicians/patients during the commercialization phase?		**Proposition 2/3/4**
12. In that same light, what role does social media play during the commercialization phase?	*How would you describe the role of social media in relation to the duration of the commercialization process?*	**Proposition 2**
13. Do MedTech start-ups actively make use of social media?	Answer **'yes'** then: *In what way? For what purpose do they use social media?* Answer **'no'** then: *Should/could MedTech start-ups make more use of social media? Could you think of any reasons of how being active on social media could be beneficial to MedTech start-ups during the commercialization phase?*	**Proposition 2**

14. Could you describe the role/importance of scientific publications in relation to the duration of the commercialization phase of MedTech products?	*What role do scientific publications play for you as an investor?* *Do you know how much time on average MedTech start-ups dedicate to being published?* *Do you think that MedTech start-ups are dedicating too much attention to this, or is it about right?*	**Proposition 3**
15. Could you describe the role/importance of conferences in relation to the duration of the commercialization phase of MedTech products?	*What role do conferences play to you as an investor?* *Do you think that MedTech start-ups are dedicating too much attention to this, or is it about right?*	**Proposition 4**
16. If you look at the entrepreneurs behind the MedTech start-ups you have seen during your career. How would you value their business skills? From your own experience, how would you value the commercialization strategies that are being used?	*What do you do if a start-up has a great product or technology, but not enough business acumen? How do you help them?*	**Proposition 5**
17. From your personal experience, do you feel that these companies also consciously start their business with a specific strategy in mind?	Answer **'yes'** then: *What strategy do they use? How does this strategy help them to shorten the duration of the commercialization phase?*	**Proposition 5**

	Answer **'no'** then: *Would it be useful if entrepreneurs directly from the beginning would start operating with a specific strategy in mind? Why?*	
18. From your personal experience. Is there a certain strategy of which you have seen that it enables the start-up to move through the phase from CE up until operational cashflow break-even at a faster speed?	Answer **'yes'** then: *Which strategy, could you tell a bit more about it?*	**Proposition 5**
19. Are there in your opinion some necessary steps that you must take to realize a timely (< 5 years) and successful commercial exit?	*How does your ideal exit look?* *What is your ideal partner for an exit?* *Have you experienced that certain partnerships lead to earlier exits? Do you have an explanation for this?*	**Proposition 5**
20. Which advice would you have for MedTech start-ups that are at the beginning of the commercialization phase?		

D. Personal interview guide – Participant 6

Personal interview guide *Purchaser perspective*		
Origin of research		
"This research focuses specifically on the phase between the MedTech start-up adopting CE-marking (regulatory approval) up until operational cashflow break-even (commercial success). Apparently, it seems that MedTech start-ups move through this phase at different speeds. Next to that it seems that the duration/length of this specific phase can vary between start-ups by a couple of years."		
Question	**Follow-up question (depending on answer)**	**Links to proposition " "**
1. Could you tell me something about your professional background and the position you currently fulfill within your organization?		Origin of research
2. Do you recognize the timeline as described above from your own working experience?	Why do you think that the commercialization of MedTech is taking that long?	Origin of research
3. Could you describe the purchasing-process within your organization?	Which steps are taking during this process? Who are the decisionmaking units within your organization? What are the important stakeholders?	Origin of research
4. Did this purchasing process change in the last couple of years? If yes, how?	What has been the reason for this change? And why?	
5. How do you get into contact with the MedTech start-ups? Could you tell a bit more	• What is the role of clinicians? • Wat is the role of patients?	

about this exploration process for new start-ups?	• What is the role of social media? • What role do conferences play?	
6. From what type of suppliers do you buy your technology? Could you give a description/example?	• Strategists? • MedTech start-ups? • Directly or indirectly?	
7. In what phase are the companies of which you buy your medical devices? How would you value the expertise/level of these companies?		
8. Do you think that there is a difference between the purchasingprocess of academic and circumferential hospitals?		
9. When does a certain MedTech product/innovation become interesting for your department? What aspects are you looking for?		
10. Which of these aspects are critical in deciding whether you purchase a certain product?	• Costefficiency • Availability of reimbursement	
11. Which of these aspects can be a dealbreaker during the purchasing process?		

12. Is there a certain aspect that you have perceived as being a dealbreaker a lot?	• Why do you think that is? • How could this problem be tackled?	
13. Could you tell me something about the role of the insurance firms during the commercialization trajectory?	What is the influence of those insurance firms on the duration of the commercialization trajectory?	
14. If MedTech start-ups knock on your door to sell you their product. How do they approach you?	Do they know which factors are most important to you? Do they know what you are looking for? Are they aware of the decision tree within your organization?	
15. Are there also certain partnerships a MedTech start-up can engage (with a hospital) to increase the change of being procured?		
16. If a product on the one hand provides a lot of added value for the patient/clinician, but on the other hand is relatively expensive. How would this affect the duration of the commercialization phase for such a product? Does this affect the duration of the purchasing process? If yes, how?		

17. To what extend do you look at the purchasing behaviour of other hospitals? Does this affect your own purchasing behaviour? How?	Are hospitals able to influence one another?	
18. From your perspective. Could you describe the role of scientific publications and clinical evidence?		
19. Do you also partner up with MedTech start-ups to gather clinical evidence during the commercialization phase?	Does this also affect the purchasing process? Does this influence the duration of the purchasing process? Does this shorten the duration of the purchasing process?	
20. Some people say that 'innovative technology makes healthcare more expensive'. What do you think about such a statement?		
21. If you look at the Dutch Healthcare system. What do you think could be done better?		
22. Which advice would you have for MedTech start-ups that are at the beginning of the commercialization phase?		

E. Personal interview guide – Participant 8

Personal interview guide *Specialist perspective*		
Origin of research		
"This research focuses specifically on the phase between the MedTech start-up adopting CE-marking (regulatory approval) up until operational cashflow break-even (commercial success). Apparently, it seems that MedTech start-ups move through this phase at different speeds. Next to that it seems that the duration/length of this specific phase can vary between start-ups by a couple of years."		
Question	**Follow-up question (depending on answer)**	**Links to proposition " "**
1. Could you tell me something about your professional background and the position you currently fulfill within your organization?	In what phase are the companies you work with?	Origin of research
2. Do you recognize the timeline as described above from your own working experience?		Origin of research
3. Why do you think that the commercialization of MedTech is taking as long as it does?		
4. What do you think, is the nature of this variation between start-ups?	Is the overall quality that different between start-ups?	
5. Why does it take longer for MedTech start-ups to generate a steady source of income opposed to 'regular' start-ups?		

6. If you look at the entrepreneurs behind the MedTech start-ups you have seen during your career. How would you value their business skills?	Are these entrepreneurs sufficiently aware of the course of the commercialization trajectory and what steps they need to take to succeed?	
7. What do you think, is the most common mistakes that is being made by MedTech start-ups during the commercialization trajectory?		
8. From your perspective and experience. What aspects are ideally present in the business case of a MedTech start-up?		
9. What role do insurance firms play in the commercialization phase of MedTech start-ups? Do they influence the duration of the trajectory?	What requirements do they have and how should you cope with this as an entrepreneur?	
10. What role do Key Opinion Leaders play in the commercialization phase?		
11. What is the best way to create awareness of clinicians for you product?	- Conferences? - Publications? - KOL's?	
12. To what extent are patients directly targeted by MedTech start-ups to create awareness?	How do you for instance look at the role of social media during the commercialization phase?	

13. If a product on the one hand provides a lot of added value for the patient/clinician, but on the other hand is relatively expensive. How would this affect the duration of the commercialization phase for such a product?		
14. In your opinion. What is the best way to set-up a clinical study without losing precious time?	Do you also partner up with MedTech start-ups during the trajectory of clinical studies?	
15. What do you think MedTech start-ups could do to shorten the commercialization phase?	Have you seen some effective strategies, regarding this?	
16. Some people say that 'innovative technology makes healthcare more expensive'. What do you think about such a statement?		
17. If you look at the Dutch Healthcare system. What do you think could be done better?		
18. Which advice would you have for MedTech start-ups that are at the beginning of the commercialization phase?		

F. Open Coding

	A	B	C	D	E	F	G	H
1			**Investor perspective - Open Coding process**					
2			**Participant 1**	**Participant 2**	**Participant 3**	**Participant 4**	**Participant 5**	
3	**Code**		Role insurance firm	CE-mark differs from saleable product	Possibility of being break-even	Operational cashflow break-even difficult	Recognition of troublesome commercialization	
4			Recognition timeline	Clinical evidence important	Class of device influential for CE	Operational cashflow break-even result from milesto	Importance of medical unmet need	
5			Market entry hard	Commercialization underestimated	Try to start early with sales	Clinical validation most important	Oligopolistic market	
6			Variety in duration	Showing added value is biggest hurdle	Variety potential cashflow break-even	Disposable important	Influence of conservativeness	
7			Recognition cashflow break-even	Doing multiple things at once	Getting CE is relatively easy	IP is important	Importance of medical need	
8			Recognition cashflow break-even	Focus on value creation	Recurring sales important for investor	Management team is important	Clinician as source of innovation	
9			Role investor	Description commercial success	Not sales, but implementation processes	Technological development can take long	Academic hospitals on forefront innovation	
10			Business acumen entrepreneur	Role investor	Improvement of healthcare system	Getting reimbursement takes long	Clear design clinical study	
11			Investors claim BoC position	Added value important	Role insurance firms overrated	Sales trajectory is being underestimated	Pick right patient populatoin for clinical study	
12			Investor & BoC overlap	Need & willingness to pay	Conservative attitude National Healthcare Inst	High cost has negative effect on duration	Experience is key for clinical studies	
13			Involve end-user development	Management team important	Unique value proposition important	Entrepreneurs are technically oriented	Get in-house knowledge for clinical study	
14			Contracts	Influence of cost on adaption	Explanation reimbursement system	Sales trajectory is being underestimated	Strong IP-position important	
15			Need-to-have	Clear added value	Developing out of need	Key Opinion Leader important for reimbursement	Experience important	
16			Added value	Knowledge about reimbursement sytem	Relation with customer important	Getting adopted by medical guidelines	Solid investor-base	
17			Influence of cost	Market strategy takes time	Not only contact with Key Opinion Leader	Clinical evidence to prove cost effectiveness	Key Opinion Leaders to extend network	
18			Reimbursement	Lowest resistance	Buyer important	Lack of experience	Multinational approach important	
19			Lack of knowledge reimbursement	Difference purchasers & insurance firms	Network influential on duration	Attracting experience is key	Motivation of Key Opinion Leader	
20			Long trajectory clinical study	Influence of cost on adaption	Making the wrong product	Network is important	Objective Key Opinion Leader important	
21			Taking lead in clinical study	Stakeholder analysis important	Contact potential customers necessary	Lead-user should be main focus	Critical feedback is key	
22			Cost clinical study	Lack of business acumen entrepreneur	Social media to mobilize patients	Convincing clinician	Link-up with strategists	
23			Network validation	Investor does not pull	Social media barely used	Social media to reach patient	Naive view on exit	
24			Importance Key Opinion Leader	Importance of team	Technicians introvert	Important to create the 'right' product	No relevant role insurance firms	
25			Type of Key Opinion Leader	Inexperienced people	Negative view on MedTech innovation	Set-up clinical study important	Lack of knowledge reimbursement	
26			Minimal role social media	Stakeholder situation complex	Difference between entrepreneur & technician	Attract experts to make right decision	Lack of sales strategy due to technical background	
27			Social media interesting	Key opinion leaders realiability	Too much focus on end-product		Attract experienced sales persons	
28			Publications important	Key opinion leader influence commercialization	Commercial CEO important		Educative role investor	
29			Publications to validate	Type of key opinion leader	Long research trajectories		Presence of experienced Medtech engineer	
30			Publications to realize reimbursement	Key opinion leaders influence regulatory adaptic	Giving away products is wrong		Role of Board of Commissionaires	
31			Conferences inspire	Stay in touch with clinician	Congres to create awareness		Board of Commissionaires suboptimal	
32			Conferences no high priority	Distributors are not the answer	Know your stakeholders		Conferences to build credibility	
33			Observed discrepancy cost & benefits	View of common clinician important	Description stakeholders		Indirect credibility	
34			Reimbursement to make cost acceptable	Possible role social media	Naive commercialization strategy		Possibilities of Social Media	
35			Getting reimbursement difficult	Social media impact on patient population	Important to keep cost & benefit close		Participation clinician social media	
36			Insurance firms cannot influence clinician	Social media to create awareness under patient	Different reimbursement routes		Participation clinician social media	
37			Using scientist to communicate with clinician	Social media to activate patients	Reimbursement hard to understand		Timing of social media	
38			Not enough attention for sales	Social media not main channel	Fulfill first need		Difference clinical evidence and publications	
39			Co-creation with customer	Publication highest form of evidence	Bad contact with lead-user		Indirect sales not effective	
40			No clear strategy	Publication in relation to CE	Contact strategist ASAP		Negative experience OEM	
41			Need to anticipate	End-result important	Know your stakeholders		Negative experience OEM	
42			Insufficient budget	Congress to create buzz	Description role BoC		Product available for try	
43			Underestimating needed funding	Congress to communicate with common clinican			Consservative clinicians & hospitals	
44			Develop with buyer	Money for parallel processes			Costs & Benefits should be close	
45			Agile	Share information with strategists			Knowledge about hospital value chain	
46			Direct feedback	Congresses to link-up with strategists			Being acceptive of feedback	
47				Strategists are passive				
48				validate with potential customers				
49				Cost structure is hard to understand				
50				Context too narrow				
51				Validation in own ecosystem bad				

	A	C	D	E	F	G
1		**Medical perspective - Open coding process**				
2		**Participant 6**	**Participant 7**	**Participant 8**	**Participant 9**	**Participant 10**
3	**Code**	Position hospital during commercialization	Market mechanism healthcare unclear	Commercialization troublesome	Acknowledgement of trajectory	Researcher is not a sales person
4		Role purchasing department	Knowledge about financing important	Cost-effectiveness important factor	Importance reimbursement	Inadequate view of competition & IP position
5		Approach of MedTech companies	Classification of technology	Important factors for insurance firms	Clinical evidence results in acceptance	Unique product makes acceptance hard
6		Regulatory constrictions	Acceptance of clinical professional	Understanding impact on healthcare process	Guidelines important for adoption	Right timing is essential
7		Strategists have prominent role	Involvement lead-user development	Understanding impact of innovation	Strategists does not want risk	Clinical study trajectory underestimated
8		Importance of added value	Unbiased Key Opinion Leaders important	Developing from 'solution' is wrong	Mission strategist	Key Opinion Leaders needed for medical guidelines
9		cost efficiency & savings important	Importance of free samples	Understanding impact on healthcare process	Fit with portfolio	Start-ups acquired if they add value to portfolio
10		Influence of high cost on purchasing	Description adaption process	Multiple surgeries not bad	Clinicians advise strategists on unmet nee	Reimbursement takes long
11		Role of reimbursement on purchasing	Improvement of: quality, service or cost	Influence of DBC	Influence on competition	Hard to understand reimbursement trajectory per country
12		Purchase decisionmaking process	Description cost structure hospital	Healthcare conservative		Entrepreneurs have to realize how hard it is
13		Co-creation with clinician	Narrow budgets	Changing standardized processes		Lot of regulatory hurdles to sell international
14		Clinical studies opportunity PhD.	Bad understanding cost structure	Bad understanding of problem		
15		Importance of lead-user	Bad understanding cost savings	Bad understanding of complexity		
16		Influence of high cost on purchasing	In-depth knowledge essential to succeed	Ingnorant view suppport base		
17		Doubts about role insurance company	Patients overall not influential	Discussionpartner clinician		
18		Insurance firm no added value	Riskiness Social Media	Know your stakeholder		
19		No contact between patient & purchaser	Role of insurance firms	Clinician in team essential for insurance firm		
20		Clinician decides treatment	Description reimbursement process	Insurance firms & health coverage		
21		Influence of narrow budget department	Understanding of decision-making unit	Bad understanding reimbursement		
22		Effect of high costs	Negotiation with insurance firm	Role National Healthcare Institute		
23		Monopolistic market	Social media can create 'feel good'	Insurance firms will not sell product		
24		MedTech pricing not transparant	Social media can persuade insurance firms	Patients no power in hospital		
25		Difference circumferential/academic hospitals	Product pricing is important	Too much focus on insurance firms		
26		Function of publications	MedTech pricing is not transparant	Role insurance firms unclear		
27		No IP for hospital	Importance of reputation	Insurance firms false hope		
28		Duration of purchasing process		Keep clinical study small		
29		Overlap with existing product		Wrong expectations of hospital		
30		Complex processes are causing trouble		Expertise needed to succeed clinical study		
31				Implementation is crucial		
32				Team is important		
33				Conservative view towards innovation		
34				Hypocrisy of healthcare system		

G. Axial Coding (Phase I)

	B	C	D	E	F	G	H
1		**Investor perspective - Axial coding phase I**					
2		**Participant 1**	**Participant 2**	**Participant 3**	**Participant 4**	**Participant 5**	
3		Agile	Added value important	Commercial CEO important	Operational cashflow break-even difficult	Conservative clinicians & hospitals	
4		Business acumen entrepreneur	CE-mark differs from saleable product	Bad contact with lead-user	Attract experts to make right decision	Academic hospitals on forefront innovation	
5		Co-creation with customer	Clear added value	Buyer important	Attracting experience is key	Attract experienced sales persons	
6		Conferences inspire	Clinical evidence important	Class of device influential for CE	Clinical evidence to prove cost effectiveness	Being acceptive of feedback	
7		Conferences no high priority	Commercialization underestimated	Congres to create awareness	Clinical validation most important	Board of Commissioners suboptimal	
8		Contracts	Congress to communicate with common clinicar	Conservative attitude National Healthcare Institut	Convincing clinician	Clear design clinical study	
9		Cost clinical study	Congress to create buzz	Contact potential customers necessary	Disposable important	Clinician as source of innovation	
10		Develop with buyer	Congresses to link-up with strategists	Contact strategist ASAP	Entrepreneurs are technically oriented	Conferences to build credibility	
11		Direct feedback	Context too narrow	Description role BoC	Getting adopted by medical guidelines	Costs & benefits should be close	
12		Long trajectory clinical study	Cost structure is hard to understand	Description stakeholders	Getting reimbursement takes long	Critical feedback is key	
13		Getting reimbursement difficult	Difference purchasers & insurance firms	Developing out of need	High cost has negative effect on duration	Difference clinical evidence and publications	
14		Importance Key Opinion Leader	Distributors are not the answer	Difference between entrepreneur & technician	Important to create the 'right' product	Educative role investor	
15		Insufficient budget	Doing multiple things at once	Different reimbursement routes	IP is important	Experience important	
16		Insurance firms cannot influence clinician	End-result important	Explanation reimbursement system	Key Opinion Leader important for reimbursement	Experience is key for clinical studies	
17		Investor & BoC overlap	Focus on value creation	Fulfill first need	Lack of experience	Get in-house knowledge for clinical study	
18		Investors claim BoC position	Importance of team	Getting CE is relatively easy	Lead-user should be main focus	Importance of medical need	
19		Involve end-user development	Importance of team	Giving away products is wrong	Management team is important	Importance of medical unmet need	
20		Market entry hard	Inexperienced people	Important to keep cost & benefit close	Network is important	Indirect credibility	
21		Minimal role social media	Influence of cost on adaption	Improvement of healthcare system	Operational cashflow break-even result from milesto	Indirect sales not effective	
22		Need to anticipate	Influence of cost on trajectory	Know your stakeholders	Sales trajectory is being underestimated	Influence of conservativeness	
23		Need-to-have	Investor does not pull	Know your stakeholders	Sales trajectory is being underestimated	Key Opinion Leaders to extend network	
24		Network validation	Key opinion leader influence commercialization	Long research trajectories	Set-up clinical study important	Knowledge about hospital value chain	
25		No clear strategy	Key opinion leaders influence regulatory adapti	Making the wrong product	Social media to reach patient	Lack of knowledge reimbursement	
26		Not enough attention for sales	Key opinion leaders reliability	Naive commercialization strategy	Technological development can take long	Lack of sales strategy due to technical background	
27		Observed discrepancy cost & benefits	Knowledge about reimbursement sytem	Negative view on MedTech innovation		Link-up with strategists	
28		Publications important	Lack of business acumen entrepreneur	Network influential on duration		Motivation of Key Opinion Leader	
29		Publications to realize reimbursement	Lowest resistance	Not only contact with Key Opinion Leader		Multinational approach important	
30		Publications to validate	Management team important	Not sales, but implementation processes		Naive view on exit	
31		Recognition cashflow break-even	Market strategy takes time	Possibility of being break-even		Negative experience OEM	
32		Recognition cashflow break-even	Money for parallel processes	Recurring sales important for investor		Negative experience OEM	
33		Recognition timeline	Possible role Social Media	Reimbursement hard to understand		No relevant role insurance firms	
34		Reimbursement	Publication highest form of evidence	Relation with customer important		Objective Key Opinion Leader important	
35		Lack of knowledge reimbursement	Publication in relation to CE	Role insurance firms overrated		Oligopolistic market	
36		Reimbursement to make cost acceptable	Role investor	Social media barely used		Participation clinician social media	
37		Role insurance firm	Share information with strategists	Social media to mobilize patients		Participation clinician social media	
38		Role investor	Showing added value is biggest hurdle	Technicians introvert		Pick right patient population for clinical study	
39		Social media interesting	Social media impact on patient population	Too much focus on end-product		Possibilities of Social Media	
40		Taking lead in clinical study	Social media not main channel	Try to start early with sales		Presence of experienced Medtech engineer	
41		Type of Key Opinion Leader	Social media to activate patients	Unique value proposition important		Product available for try	
42		Underestimating needed funding	Social media to create awareness under patient	Variety potential cashflow break-even		Recognition of troublesome commercialization	
43		Using scientist to communicate with clinician	Stakeholder analysis important			Role of Board of Commissioners	
44		Variety in duration	Stakeholder situation complex			Solid investor-base	
45		Added value	Stay in touch with clinician			Strong IP-position important	
46		Influence of cost	Strategists are passive			Timing of social media	
47			Type of key opinion leader				
48			Validate with potential customers				
49			Validation in own ecosystem bad				
50			View of common clinician important				
51			Willingness to pay				

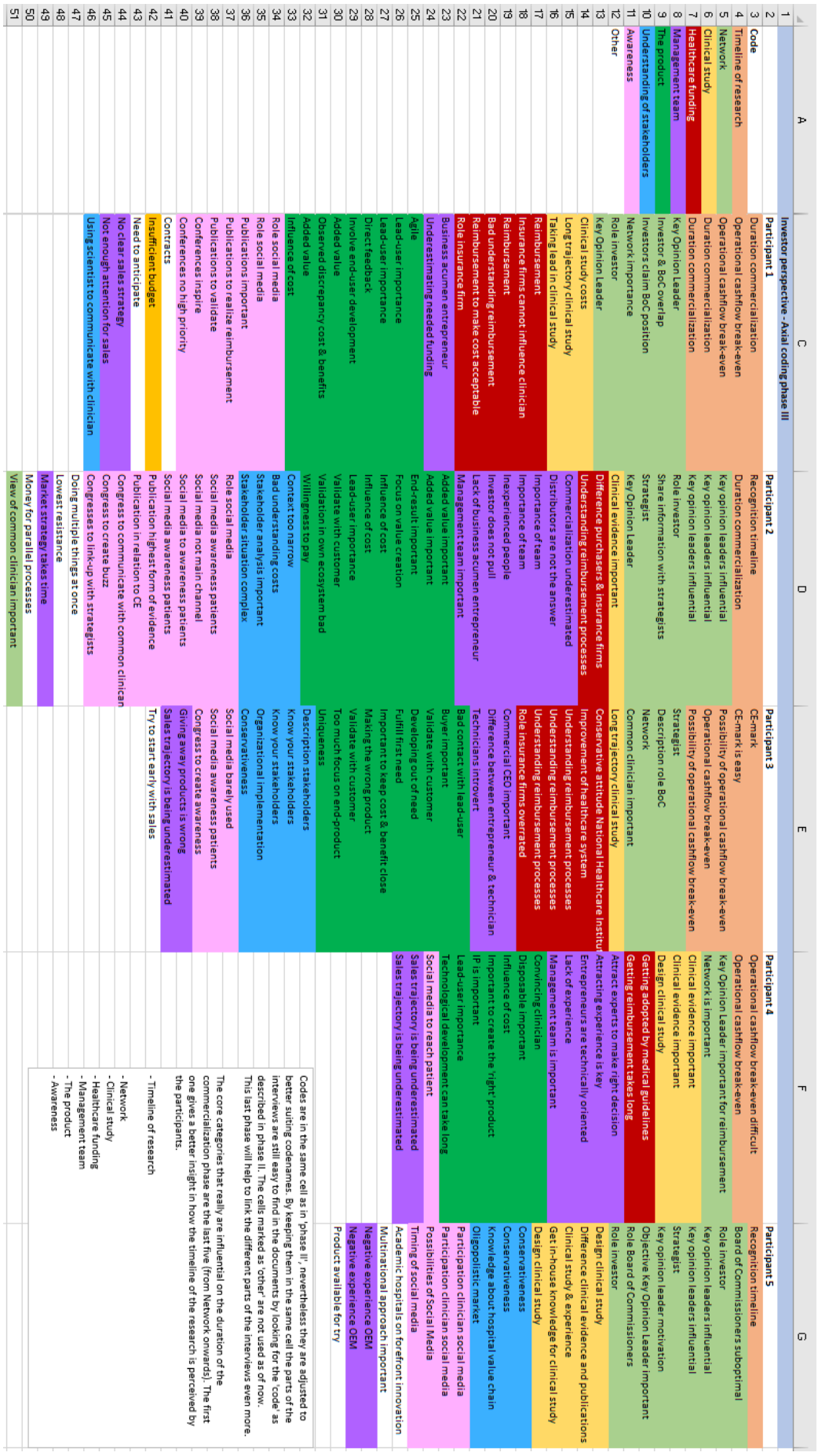
	A	B	C	D	E	F	G
1			**Medical perspective - Axial coding phase I**				
2			**Participant 6**	**Participant 7**	**Participant 8**	**Participant 9**	**Participant 10**
3	**Code**		Approach of MedTech companies	Acceptance of clinical professional	Bad understanding of complexity	Acknowledgement trajectory	Researcher is not a sales person
4	Timeline of research		Clinical studies opportunity PhD.	Bad understanding cost savings	Bad understanding of problem	Clinical evidence results in acceptance	Inadequate view of competition & IP position
5	Network		Clinician decides treatment	Bad understanding cost structure	Bad understanding reimbursement	Clinicians advise strategists on unmet needs	Unique product makes acceptance hard
6	Clinical study		Co-creation with clinician	Classification of technology	Changing standardized processes	Fit with portfolio	Right timing is essential
7	Reimbursement		Complex processes are causing trouble	Description adaption process	Clinician in team essential for insurance firm	Guidelines important for adoption	Clinical study trajectory underestimated
8	Management team		cost efficiency & savings important	Description cost structure hospital	Commercialization troublesome	Importance reimbursement	Key Opinion Leaders needed for medical guidelines
9	Development of the 'right' product		Difference circumferential/academic hospitals	Description reimbursement process	Conservative view towards innovation	Influence of competition	Start-ups acquired if they add value to portfolio
10	Stakeholder impact		Doubts about role insurance company	Importance of free samples	Cost-effectiveness important factor	Mission strategist	Reimbursement takes long
11	Social media		Duration of purchasing process	Importance of reputation	Developing from 'solution' is wrong	Strategist does not want risk	Hard to understand reimbursement trajectory per country
12	Publications		Effect of high costs	Improvement of: quality, service or cost	Discussionpartner clinician		Entrepreneurs have to realize how hard it is
13	Conferences		Function of publications	In-depth knowledge essential to succeed	Expertise needed to succeed clinical study		Lot of regulatory hurdles to sell international
14	Commercialization strategy		Importance of added value	Involvement lead-user development	Healthcare conservative		
15	Irrelevant		Importance of lead-user	Knowledge about financing important	Hypocrisy of healthcare system		
16			Influence of high cost on purchasing	Market mechanism healthcare unclear	Implementation is crucial		
17			Influence of high cost on purchasing	MedTech pricing is not transparant	Important factors for insurance firms		
18			Influence of narrow budget department	Narrow budgets	Influence of DBC		
19			Insurance firm no added value	Negotiation with insurance firm	Ingnorant view suppport base		
20			MedTech pricing not transparant	Patients overall not influential	Insurance firms & health coverage		
21			Monopolistic market	Product pricing is important	Insurance firms false hope		
22			No contact between patient & purchaser	Riskiness Social Media	Insurance firms will not sell product		
23			No IP for hospital	Role of insurance firms	Keep clinical study small		
24			Overlap with existing product	Social media can create 'feel good'	Know your stakeholder		
25			Position hospital during commercialization	Social media can persuade insurance firms	Multiple surgeries not bad		
26			Purchase decisionmaking process	Unbiased Key Opinion Leaders important	Patients no power in hospital		
27			Regulatory constrictions	Understanding of decision-making unit	Role insurance firms unclear		
28			Role of reimbursement on purchasing		Role National Healthcare Institute		
29			Role purchasing department		Team is important		
30			Strategists have prominent role		Too much focus on insurance firms		
31					Understanding impact of innovation		
32					Understanding impact on healthcare process		
33					Understanding impact on healthcare process		
34					Wrong expectations of hospital		

H. Axial Coding (Phase II)

	A	C	D	E	F	G
1		Investor perspective - Axial coding phase II				
2		Participant 1	Participant 2	Participant 3	Participant 4	Participant 5
3	Code	Market entry hard	CE-mark differs from saleable product	Class of device influential for CE	Operational cashflow break-even difficult	Recognition of troublesome commercialization
4	Timeline of research	Recognition cashflow break-even	Showing added value is biggest hurdle	Getting CE is relatively easy	Operational cashflow break-even result from milestone	Board of Commissioners suboptimal
5	Network	Recognition cashflow break-even	Key opinion leader influence commercialization	Possibility of being break-even	Key Opinion Leader important for reimbursement	Educative role investor
6	Clinical study	Recognition timeline	Key opinion leaders influence regulatory adapti	Recurring sales important for investor	Network is important	Indirect credibility
7	Reimbursement	Variety in duration	Key opinion leaders reliability	Variety potential cashflow break-even	Clinical evidence to prove cost effectiveness	Key Opinion Leaders to extend network
8	Management team	Importance Key Opinion Leader	Role investor	Contact strategist ASAP	Clinical validation most important	Link-up with strategists
9	Development of the 'right' product	Investor & BoC overlap	Share information with strategists	Description role BoC	Set-up clinical study important	Motivation of Key Opinion Leader
10	Stakeholder impact	Investors claim BoC position	Strategists are passive	Network influential on duration	Getting adopted by medical guidelines	Objective Key Opinion Leader important
11	Social media	Network validation	Type of key opinion leader	Not only contact with Key Opinion Leader	Getting reimbursement takes long	Role of Board of Commissioners
12	Publications	Role investor	Clinical evidence important	Long research trajectories	Attract experts to make right decision	Solid investor-base
13	Conferences	Type of Key Opinion Leader	Difference purchasers & insurance firms	Conservative attitude National Healthcare Institut	Attracting experience is key	Clear design clinical study
14	Commercialization strategy	Cost clinical study	Knowledge about reimbursement sytem	Improvement of healthcare system	Entrepreneurs are technically oriented	Difference clinical evidence and publications
15		Long trajectory clinical study	Commercialization underestimated	Different reimbursement routes	Lack of experience	Experience is key for clinical studies
16		Taking lead in clinical study	Distributors are not the answer	Explanation reimbursement system	Management team is important	Get in-house knowledge for clinical study
17		Getting reimbursement difficult	Importance of team	Reimbursement hard to understand	Convincing clinician	Pick right patient population for clinical study
18		Insurance firms cannot influence clinician	Importance of team	Role insurance firms overrated	Disposable important	Conservative clinicians & hospitals
19		Reimbursement	Inexperienced people	Commercial CEO important	High cost has negative effect on duration	Influence of conservativeness
20		Lack of knowledge reimbursement	Investor does not pull	Difference between entrepreneur & technician	Important to create the 'right' product	Knowledge about hospital value chain
21		Reimbursement to make cost acceptable	Lack of business acumen entrepreneur	Technicians introvert	IP is important	Oligopolistic market
22		Role insurance firm	Management team important	Bad contact with lead-user	Lead-user should be main focus	Participation clinician social media
23		Business acumen entrepreneur	Added value important	Buyer important	Technological development can take long	Participation clinician social media
24		Underestimating needed funding	Clear added value	Contact potential customers necessary	Social media to reach patient	Possibilities of Social Media
25		Agile	End-result important	Developing out of need	Sales trajectory is being underestimated	Timing of social media
26		Co-creation with customer	Focus on value creation	Fulfill first need	Sales trajectory is being underestimated	Academic hospitals on forefront innovation
27		Develop with buyer	Influence of cost on adaption	Important to keep cost & benefit close		Multinational approach important
28		Direct feedback	Influence of cost on trajectory	Making the wrong product		Negative experience OEM
29		Involve end-user development	Stay in touch with clinician	Relation with customer important		Negative experience OEM
30		Need-to-have	Validate with potential customers	Too much focus on end-product		Product available for try
31		Observed discrepancy cost & benefits	Validation in own ecosystem bad	Unique value proposition important		
32		Added value	Willingness to pay	Description stakeholders		
33		Influence of cost	Context too narrow	Know your stakeholders		
34		Minimal role social media	Cost structure is hard to understand	Know your stakeholders		
35		Social media interesting	Stakeholder analysis important	Not sales, but implementation processes		
36		Publications important	Stakeholder situation complex	Negative view on MedTech innovation		
37		Publications to realize reimbursement	Possible role Social Media	Social media barely used		
38		Publications to validate	Social media impact on patient population	Social media to mobilize patients		
39		Conferences inspire	Social media not main channel	Congres to create awareness		
40		Conferences no high priority	Social media to activate patients	Giving away products is wrong		
41		Contracts	Social media to create awareness under patient	Naive commercialization strategy		
42		Insufficient budget	Publication highest form of evidence	Try to start early with sales		
43		Need to anticipate	Publication in relation to CE			
44		No clear strategy	Congress to communicate with common clinican			
45		Not enough attention for sales	Congress to create buzz			
46		Using scientist to communicate with clinician	Congresses to link-up with strategists			
47			Doing multiple things at once			
48			Lowest resistance			
49			Market strategy takes time			
50			Money for parallel processes			
51			View of common clinician important			

	A	B	C	D	E	F	G
1			**Medical perspective - Axial coding phase II**				
2			**Participant 6**	**Participant 7**	**Participant 8**	**Participant 9**	**Participant 10**
3	**Code**		Clinical studies opportunity PhD.	Market mechanism healthcare unclear	Commercialization troublesome	Acknowledgement trajectory	Key Opinion Leaders needed for medical guidelines
4	Timeline of research		Doubts about role insurance company	Unbiased Key Opinion Leaders important	Ingnorant view suppport base	Clinical evidence results in acceptance	Clinical study trajectory underestimated
5	Network		Insurance firm no added value	Bad understanding cost savings	Expertise needed to succeed clinical study	Importance reimbursement	Reimbursement takes long
6	Clinical study		Regulatory constrictions	Bad understanding cost structure	Keep clinical study small	Clinicians advise strategists on unmet needs	Hard to understand reimbursement trajectory per country
7	Reimbursement		Role of reimbursement on purchasing	Description cost structure hospital	Wrong expectations of hospital	Fit with portfolio	Researcher is not a sales person
8	Management team		Co-creation with clinician	Description reimbursement process	Bad understanding reimbursement	Guidelines important for adoption	Entrepreneurs have to realize how hard it is
9	Development of the 'right' product		cost efficiency & savings important	Narrow budgets	Important factors for insurance firms		Unique product makes acceptance hard
10	Stakeholder impact		Effect of high costs	Negotiation with insurance firm	Influence of DBC		Inadequate view of competition & IP position
11	Social media		Importance of added value	Role of insurance firms	Insurance firms & health coverage		Right timing is essential
12	Publications		Overlap with existing product	Acceptance of clinical professional	Insurance firms false hope		Start-ups acquired if they add value to portfolio
13	Conferences		Clinician decides treatment	Improvement of: quality, service or cost	Insurance firms will not sell product		Lot of regulatory hurdles to sell international
14	Commercialization strategy		Complex processes are causing trouble	Involvement lead-user development	Role insurance firms unclear		
15	Irrelevant		Duration of purchasing process	Description adaption process	Role National Healthcare Institute		
16			Influence of high cost on purchasing	Knowledge about financing important	Too much focus on insurance firms		
17			Influence of high cost on purchasing	Understanding of decision-making unit	Clinician in team essential for insurance firm		
18			Influence of narrow budget department	Patients overall not influential	Team is important		
19			MedTech pricing not transparant	Riskiness Social Media	Bad understanding of complexity		
20			Monopolistic market	Social media can create 'feel good'	Bad understanding of problem		
21			Position hospital during commercialization	Social media can persuade insurance firms	Cost-effectiveness important factor		
22			Purchase decisionmaking process	Importance of free samples	Developing from 'solution' is wrong		
23			Role purchasing department	Importance of reputation	Changing standardized processes		
24			Strategists have prominent role	In-depth knowledge essential to succeed	Conservative view towards innovation		
25			No contact between patient & purchaser	MedTech pricing is not transparant	Healthcare conservative		
26			Function of publications	Product pricing is important	Hypocrisy of healthcare system		
27			Difference circumferential/academic hospitals		Implementation is crucial		
28					Know your stakeholder		
29					Multiple surgeries not bad		
30					Understanding impact of innovation		
31					Understanding impact on healthcare process		
32					Understanding impact on healthcare process		
33					Patients no power in hospital		
34					Discussionpartner clinician		

I. Axial Coding (Phase III)



	Investor perspective - Axial coding phase III					
	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5	
Code	Duration commercialization	Recognition timeline	CE-mark	Operational cashflow break-even difficult	Recognition timeline	
Timeline of research	Operational cashflow break-even	Duration commercialization	CE-mark is easy	Operational cashflow break-even	Board of Commissioners suboptimal	
Network	Operational cashflow break-even	Key opinion leaders influential	Possibility of operational cashflow break-even	Key Opinion Leader important for reimbursement	Role investor	
Clinical study	Duration commercialization	Key opinion leaders influential	Operational cashflow break-even	Network is important	Key opinion leaders influential	
Healthcare funding	Duration commercialization	Key opinion leaders influential	Possibility of operational cashflow break-even	Clinical evidence important	Key opinion leaders influential	
Management team	Key Opinion Leader	Role investor	Strategist	Clinical evidence important	Strategist	
The product	Investor & BoC overlap	Share information with strategists	Description role BoC	Design clinical study	Key opinion leader motivation	
Understanding of stakeholders	Investors claim BoC position	Strategist	Network	Getting adopted by medical guidelines	Objective Key Opinion Leader important	
Awareness	Network importance	Key Opinion Leader	Common clinician important	Getting reimbursement takes long	Role Board of Commissioners	
Other	Role investor	Clinical evidence important	Long trajectory clinical study	Attract experts to make right decision	Role investor	
	Key Opinion Leader	Difference purchasers & insurance firms	Conservative attitude National Healthcare Institu	Attracting experience is key	Design clinical study	
	Clinical study costs	Understanding reimbursement processes	Improvement of healthcare system	Entrepreneurs are technically oriented	Difference clinical evidence and publications	
	Long trajectory clinical study	Commercialization underestimated	Understanding reimbursement processes	Lack of experience	Clinical study & experience	
	Taking lead in clinical study	Distributors are not the answer	Understanding reimbursement processes	Management team is important	Get in-house knowledge for clinical study	
	Reimbursement	Importance of team	Role insurance firms overrated	Convincing clinician	Design clinical study	
	Insurance firms cannot influence clinician	Importance of team	Commercial CEO important	Disposable important	Conservativeness	
	Reimbursement	Inexperienced people	Difference between entrepreneur & technician	Influence of cost	Conservativeness	
	Bad understanding reimbursement	Investor does not pull	Technicians introvert	Important to create the 'right product	Knowledge about hospital value chain	
	Reimbursement to make cost acceptable	Lack of business acumen entrepreneur	Bad contact with lead-user	IP is important	Oligopolistic market	
	Role insurance firm	Management team important	Buyer important	Lead-user importance	Participation clinician social media	
	Business acumen entrepreneur	Added value important	Validate with customer	Technological development can take long	Participation Clinician social media	
	Underestimating needed funding	Added value important	Developing out of need	Social media to reach patient	Possibilities of Social Media	
	Agile	End-result important	Fulfill first need	Sales trajectory is being underestimated	Timing of social media	
	Lead-user importance	Focus on value creation	Important to keep cost & benefit close	Sales trajectory is being underestimated	Academic hospitals on forefront innovation	
	Lead-user importance	Influence of cost	Making the wrong product		Multinational approach important	
	Direct feedback	Influence of cost	Validate with customer		Negative experience OEM	
	Involve end-user development	Lead-user importance	Too much focus on end-product		Negative experience OEM	
	Added value	Validate with customer	Uniqueness		Product available for try	
	Observed discrepancy cost & benefits	Validation in own ecosystem bad	Description stakeholders			
	Added value	Willingness to pay	Know your stakeholders			
	Influence of cost	Context too narrow	Know your stakeholders			
	Role social media	Bad understanding costs	Organizational implementation			
	Role social media	Stakeholder analysis important	Conservativeness			
	Publications important	Stakeholder situation complex	Social media barely used			
	Publications to realize reimbursement	Role social media	Social media awareness patients			
	Publications to validate	Social media awareness patients	Congress to create awareness			
	Conferences inspire	Social media not main channel	Try to start early with sales			
	Conferences no high priority	Social media to awareness patients				
	Contracts	Social media awareness patients				
	Insufficient budget	Publication highest form of evidence				
	Need to anticipate	Publication in relation to CE				
	No clear sales strategy	Congress to communicate with common clinican				
	Not enough attention for sales	Congress to create buzz				
	Using scientist to communicate with clinician	Congresses to link-up with strategists				
		Doing multiple things at once				
		Lowest resistance				
		Market strategy takes time				
		Money for parallel processes				
		View of common clinician important				

Codes are in the same cell as in 'phase II', nevertheless they are adjusted to better suiting codenames. By keeping them in the same cell the parts of the interviews are still easy to find in the documents by looking for the 'code' as described in phase II. The cells marked as 'other' are not used as of now. This last phase will help to link the different parts of the interviews even more.

The core categories that really are influential on the duration of the commercialization phase are the last five (from Network onwards). The first one gives a better insight in how the timeline of the research is perceived by the participants.

- Timeline of research
- Network
- Clinical study
- Healthcare funding
- Management team
- The product
- Awareness

	A	B	C	D	E	F	G
1			**Medical perspective - Axial coding phase III**				
2			**Participant 6**	**Participant 7**	**Participant 8**	**Participant 9**	**Participant 10**
3	**Code**		Clinical study	Pricing non-transparant	Duration commercialization	Duration commercialization	KOL medical guidelines
4	Timeline of research		Insurance firm	Biased KOL(s)	Bad understanding support base	Clinical study	Clinical study
5	Network		Insurance firm	Understanding cost structure	Clinical study & experience	Reimbursement processes	Reimbursement processes
6	Clinical study		Regulatory constrictions	Understanding cost structure	Wrong design of study	Lead-user	Reimbursement processes
7	Healthcare funding		Effect reimbursement purchasing	Understanding cost structure	Wrong expectations of hospital	Fit with portfolio	Research background
8	Management team		Co-creation lead-user	Reimbursement process	Bad understanding reimbursement	Guidelines important for adoption	Experience
9	The product		Cost efficiency	Understanding cost structure	Understanding reimbursement processes		Uniqueness
10	Understanding of stakeholders		Costs	Insurance firm	Understanding reimbursement processes		Competition & IP
11	Awareness		Added value	Understanding reimbursement processes	Insurance firm & Healthcare Institute		Right timing is essential
12	Other		Uniqueness	Lead-user	Too much focus insurance firm		Fit with portfolio
13			Understanding of stakeholders	Added value	Too much focus insurance firm		Lot of regulatory hurdles to sell international
14			Understanding of healthcare workprocesses	Lead-user	Too much focus insurance firm		
15			Understanding of healthcare workprocesses	Understanding healthcare workprocesses	National Healthcare Institute		
16			Understanding of healthcare workprocesses	Understanding of stakeholders	Insurance firm		
17			Understanding of healthcare workprocesses	Understanding of stakeholders	Experience		
18			Understanding of healthcare workprocesses	Patient	Management team		
19			Product pricing not transparant	Social media risky	Bad understanding lead-user		
20			Product pricing not transparant	Social media buzz	Bad understanding problem		
21			Understanding of stakeholders	Social media buzz	Cost-effectiveness		
22			Understanding of healthcare workprocesses	Importance of free samples	Developing from solution		
23			Understanding of stakeholders	Importance of reputation	Understanding healthcare workprocceses		
24			Understanding of stakeholders	Understanding of stakeholders	Conservativeness		
25			Social media	Product pricing not transparant	Conservativeness		
26			Publications	Product pricing	Understanding stakeholders		
27			Difference circumferential/academic hospitals		Organizational implementation		
28					Understanding of stakeholders		
29					Understanding of healthcare workprocesses		
30					Understanding of impact		
31					Understanding of impact		
32					Understanding of impact		
33					Patient		
34					Understanding stakeholders		
35							
36							

Codes are in the same cell as in 'phase II', nevertheless they are adjusted to better suiting codenames. By keeping them in the same cell the parts of the interviews are still easy to find in the documents by looking for the 'code' as described in phase II. The cells marked as 'other' are not used as of now. This last phase will help to link the different parts of the interviews even more.

The core categories that really are influential on the duration of the commercialization phase are the last five (from Network onwards). The first one gives a better insight in how the timeline of the research is perceived by the participants.

- Timeline of research

- Network
- Clinical study
- Healthcare funding
- Management team
- The product
- Awareness