LUNDS UNIVERSITET
Lunds Tekniska Högskola

# IDENTIFYING FACTORS BEHIND SUCCESSFUL MARKET ESTABLISHMENT OF ICT-BASED MEDICAL SELF-CARE SOLUTIONS

- a multiple-case study

**Division of Production Management**
**Lund University, Faculty of Engineering, LTH**
**2018**

**Authors:** Marcus Carlson
Josefine Nyberg

**Supervisors:** Ola Alexanderson, Lund University
Per-Anders Hedin, Sigma Connectivity

# Acknowledgements

This Master Thesis was written during the spring of 2018 by Marcus Carlson and Josefine Nyberg, as the final part of the M.Sc. program Industrial Engineering and Management at the Faculty of Engineering, Lund University.

The thesis has given the authors a deep understanding of what factors are needed for a successful market penetration and establishment of Information and Communication Technology based Monitoring and Preventive Medical Self-Care Solutions.

We would like to express our greatest gratitude towards Sigma Connectivity which has provided us with the possibility to carry out this project, and especially to our supervisor Per-Anders Hedin who has enlightened us with insights to the MedTech industry. Thank you for always challenging us with analytical discussions, and for constantly meeting us with a smile and a joke close at hand.

We would also like to thank our supervisor at the Faculty of Engineering, Ola Alexanderson. Thank you for guiding us through this process and for all your time and feedback, it has been a pleasure to work with you throughout this final project.

Last but not least, we would like to give our warmest thank you to our families and friends, who have not only supported us throughout this thesis, but also through these last five years. Thank you.

Lund, June 2018

# Abstract

**Title**
Identifying Factors Behind Successful Market Establishment of ICT-based Medical Self-Care Solutions

**Authors**
Marcus Carlson, marcuscarlson@live.se
Josefine Nyberg, josefine.nyberg94@gmail.com

**Supervisors**
Ola Alexanderson, Lund University, Faculty of Engineering
Per-Anders Hedin, Sigma Connectivity

**Background**
Today's healthcare faces a transformation, driven by an ageing population and an over encumbered care and welfare sector. Self-care solutions based on emerging information and communication technologies make it possible for patients to monitor their medical conditions from home, without the direct assistance of healthcare professionals. Thereby time and resources within the healthcare sector are liberated. Monitoring and preventive self-care solutions can proactively impede deteriorating health and injuries. However, the healthcare sector is a complex system, with several stakeholders such as county councils, municipalities, private operators, physicians and patients. Who bears the responsibility of financing medical devices may vary. The healthcare system is given an opportunity to handle the changing and aggravating landscape dynamics through a new set of care solutions, but the road to markets which fully adopt such self-care solutions has not yet presented itself clearly. This is why the market penetration and establishment of Information and Communication Technology based Monitoring and Preventive Medical Self-Care Solutions are the targets of this study.

**Purpose**
The purpose of this study was to identify what enables market penetration and establishment of Information and Communication Technology based Monitoring and Preventive Medical Self-Care Solutions (ICTMPMSCS) to succeed. The final

objective of this study was to present factors, preconditions and dynamics that characterise successful market penetration and establishment of ICTMPMSCS.

**Methodology**
To best fulfil the purpose, a qualitative exploratory approach was used. A literature review was conducted as well as a multiple case study, where each case was selected through selective sampling. In each case, interviews were conducted along with archival research. Additionally, an extensive literature review was performed during the entire study. Data triangulation was used to analyse the studied cases and existing literature.

**Conclusions**
This study identifies 12 factors which can impact the success of an ICTMPMSCS's market penetration and establishment. These factors differ depending on what phase of market entry the company happens to find itself in. The 12 factors consist of factors based on industry & environmental indications, company internal factors, and factors based on the market network, i.e. the interplay between patients, physicians, administrators and the MedTech company itself. The study identifies the roles physicians and patients have in the adoption of self-care solutions, where it is likely that patients will drive the adoption of ICTMPMSCS but physicians will bring legitimacy to the product. Companies should initially focus solely on a few value-creating activities and insource necessary aid, but gradually integrate more activities in-house as the company expands. Similarly, companies should also at first focus on one customer segment, and one sales channel. Companies will also need to pursue multiple business models simultaneously. The study also finds that adoption of ICTMPMSCS meets resistance from the healthcare sector, and these issues need to be dealt with by demonstrating possible cost savings, in a clear manner.

**Keywords**

Healthcare, ICT, Market establishment, Market penetration, Medical Self-care, MedTech, Monitoring care, Preventive care.

# Abbreviations and Vocabulary

## Abbreviations

**CE** - Conformité Européene or, European Conformity
**CGM** - Continuous Glucose Monitoring
**CSF** - Critical success factors
**ECG** - Electrocardiography
**FDA** - U.S. Food and Drug Administration
**HCP** - Healthcare Professional
**ICT** - Information and Communication Technology
**ICTMPMSCS** - Information and Communication Technology based Monitoring and Preventive Medical Self-Care Solutions
**OECD** – The Organisation for Economic Co-operation and Development
**PMA** - Premarket Approval
**PMN** - Premarket Notification
**ROI** - Return on Investment
**SKL** - Sveriges Kommuner och Landsting. The Swedish Association of Local Authorities and Regions
**TLV** - Tand och Läkemedelsförmånsverket. A Swedish central government agency

## Vocabulary

**Healthcare sector** - The healthcare sector consists of all entities involved in providing care. Such as hospitals, physicians and other healthcare professionals, primary care, specialised care, emergency treatment, elderly care, disability care and family support services.
**MedTech** - Medical technology products are 'medical devices' which cover any instrument, apparatus, appliance, materials or other article to be used for people with the purpose to provide healthcare.
**Self-care** - A healthcare solution which a registered HCP has decided that a person can use or perform by oneself or with the assistance of someone else.

**CE-marking** - A declaration which insures that a product being sold within the European Economic Area meets all legal requirements, such as: high safety, health and environmental protection requirements.

# Table of Content

**ACKNOWLEDGEMENTS** ..... **III**

**ABSTRACT** ..... **V**

**ABBREVIATIONS AND VOCABULARY** ..... **VII**

ABBREVIATIONS ..... VII

VOCABULARY ..... VII

**TABLE OF CONTENT** ..... **IX**

**LIST OF FIGURES** ..... **XI**

**LIST OF TABLES** ..... **XI**

**1. INTRODUCTION** ..... **1**

1.1 BACKGROUND ..... 1

1.2 PURPOSE ..... 6

1.3 OBJECTIVE ..... 6

1.4 RESEARCH QUESTIONS ..... 6

1.5 DELIMITATIONS ..... 7

1.6 DISPOSITION ..... 7

**2. METHODOLOGY** ..... **9**

2.1 RESEARCH STRATEGY ..... 9

2.2 RESEARCH METHODS ..... 10

2.3 RIGOR ..... 15

2.4 SUMMARY OF METHODOLOGY ..... 16

**3. THEORY** ..... **19**

3.1 IDENTIFYING INDUSTRY COMPETITIVENESS ..... 20

3.2 BUSINESS MODEL CANVAS ..... 23

3.3 PESTEL ..... 27

3.4 STAKEHOLDER THEORY ..... 32

3.5 DIFFUSION OF INNOVATION ..... 34

3.6 CROSSING THE CHASM ..... 37

3.7 PRODUCT LIFE CYCLE ..... 39

3.8 THEORETICAL FRAMEWORK ..... 42

**4. EMPIRICS - INDUSTRY INSIGHTS ..... 45**

**5. EMPIRICS - CASE STUDIES ..... 49**

5.1 COALA LIFE ..... 50

5.2 DEXCOM ..... 56

5.3 DIASEND ..... 61

**6. CASE ANALYSIS ..... 69**

6.1 COALA LIFE ..... 69

6.2 DEXCOM ..... 74

6.3 DIASEND ..... 78

6.4 AGGREGATED ANALYSIS ..... 83

**7. DISCUSSION AND CONCLUSIONS ..... 87**

7.1 IDENTIFIED INDUSTRY SPECIFIC AND MACRO-ENVIRONMENTAL FACTORS ..... 88

7.2 IDENTIFIED INTERNAL FACTORS ..... 89

7.3 IDENTIFIED MARKET NETWORK FACTORS ..... 92

7.4 FULFILMENT OF PURPOSE ..... 93

7.5 RELIABILITY AND VALIDITY ..... 93

7.6 CONTRIBUTIONS TO THEORY ..... 95

7.7 SUGGESTIONS FOR FURTHER RESEARCH ..... 95

**REFERENCE LIST ..... 97**

# List of Figures

**Figure 1.1** Disposition of study.
**Figure 2.1** Work process.
**Figure 2.2** Methodology.
**Figure 3.1** Business Model Canvas.
**Figure 3.2** PESTEL.
**Figure 3.3** Stakeholder mapping.
**Figure 3.4** Diffusion of Innovation.
**Figure 3.5** Crossing the Chasm.
**Figure 3.6** The Product Life Cycle.
**Figure 3.7** The Product Development Lifecycle for Medical Devices.
**Figure 3.8** The three phases for market penetration and establishment of medical devices.
**Figure 3.9** Theoretical framework.
**Figure 5.1** Disposition of case studies.
**Figure 6.1** Theoretical framework.

# List of Tables

**Table 4.1** Industry experts.
**Table 5.1** Interviewees of case studies.

# 1. Introduction

*The following chapter depicts a background over the use and need of medical self-care solutions. The purpose of the study is then presented along with the specific research questions. Finally, a disposition of the entire study is laid out.*

## 1.1 Background

### 1.1.1 The Healthcare Sector

The Swedish healthcare sector is facing major changes. The government has issued health related goals where all Swedish citizens are to be offered individual service and interactive e-solutions in order to obtain self-determination by their own ability (Regeringen 2016). Together with the Swedish Association of Local Authorities and Regions (Sveriges Kommuner & Landsting, SKL), the government is working on the project "Vision e-hälsa 2025" which aims to achieve equal health and welfare with the help of digitalization. The aim is to make healthcare and good health equally accessible to all socio-economic groups in Sweden by the year 2025. SKL together with the government suggest that digital solutions will achieve these goals (E-hälsa 2025 2017).

The healthcare sector in Sweden consists of county councils, municipalities and private operators. County councils' responsibilities include specialised care, emergency treatment and primary care. It is funded by county tax, which on average is 11,36% of gross income, depending on what county one belongs to (SCB 2017). Primary care includes local health centers, youth guidance centers, child healthcare centers and maternity clinics to name a few (Region Skåne 2017). The social responsibilities of the municipalities include care of the elderly, disability care and family support services (Regeringen 2015). Municipal activities are funded by municipal tax, which in 2017 on average was 20,75% of gross income (SCB 2017). In 2014, 84% of the total healthcare expenditures were public expenditures and the remaining 16% were private (EMERGO 2016).

The structure and the means of financing the healthcare sector is not the same in all countries. In 2016, 74,52% of the U.S. healthcare expenditures per payer came from health insurance, and 10,56% was out of pocket expenditures (Center for Medicare & Medicaid Services 2018). In addition, the U.S. care providers are in most cases privately owned with little involvement from federal agencies (AICGS 2012). In Germany, healthcare is financed quite differently from the U.S. In 2014, 77% of the German healthcare expenditures were public expenditures and 23% private expenditures. Private expenditures consist of out-of-pocket spending and private insurance (EMERGO 2016). The same year, 84% of the Danish healthcare expenditures were public and 16% private (EMERGO 2016). All Danish citizens are entitled to public healthcare and the responsibility to finance the healthcare lies upon the state and the municipalities. The regions have responsibility for general practitioners, public hospitals and specialists in private practices. Additionally, municipalities are responsible for elderly care and primary care (The Ministry of Health 2017, p. 49). Given these examples, it is obvious that healthcare is both financed and structured in different ways and that some countries show more resemblance to Swedish healthcare than others.

As the Swedish population ages, the need for care will increase. Meanwhile, Per Trossmark[1] describes that, as people grow older, the size of the Swedish workforce diminishes, leaving the system with fewer taxpayers to finance the welfare. A report published by the consultancy firm PwC in 2016 shows that 24% of the Swedish population is older than 60 years old. Further, it is stated that 20% of the population suffer from obesity and 44% suffer from at least one chronic disease (PwC 2016, p. 6). In addition, the report presents that 3-4% of the healthcare patients account for approximately 50% of the total cost of healthcare, and patients suffering from one or more chronic diseases are responsible for 85% of the total healthcare costs (Ibid, p. 12). Given that the cost per patient is constant, total healthcare costs will increase from 9,6% of GDP 2012 to 16% of GDP 2050 (Ibid, p. 6).

According to OECD, it is not only the Swedish population that is ageing. Populations within the OECD are ageing as well. The share of the population above the age of 65 years across all OECD countries in 2015 was approximately 17%. In 2050, this figure is expected to have risen to 28%. This has already resulted in more people in need of

[1] Per Trossmark, CEO at Respiheart, phone call the 16th of February 2018

long-term care. Spending by governments and compulsory insurance schemes on long-term care grew at an annual rate of 4,6% from 2005 to 2015 across all OECD countries. At the same time, despite a growth in long term-care costs, the number of hospital beds have decreased. In 2000, OECD countries had 5,6 beds on average per 1000 inhabitants. Fifteen years later, the figure has fallen to 4,7, that is a decrease by 16%. (OECD 2017)

### 1.1.2 Medical Devices

This development implies increased pressure on the healthcare sector in Sweden, as well as in other OECD countries. Industry experts highlight the importance to utilise the opportunities enabled by MedTech solutions (Swedish Medtech 2018). Ghodeswar & Vaidyanathan (2007) give a definition to MedTech. ”*Medical technology products are ‘medical devices’ which cover any instrument, apparatus, appliance, materials or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease or an injury or a physiological process*” (Ibid, p. 57). The Swedish Medical Products Agency add to this definition by stating that if the effect of the solution is achieved through pharmacological, immunological or metabolic means it is not considered to be a medical device, but rather a pharmaceutical (Läkemedelsverket 2014). Solutions that prevent diseases or injuries, decrease pain and aid healthcare professionals (HCPs) to streamline their daily work will lead to savings in both healthcare and society as a whole (Swedish Medtech 2018).

MedTech will likely change healthcare in four different areas according to the consultancy firm Deloitte. First, a shift will likely be seen from acute to preventive care and from specialised to self-care, giving patients the opportunity to remotely access their own data and take action. It is anticipated that healthcare will take place in less traditional settings, for example by moving patients from hospitals to the comfort of their own home. Second, by using artificial intelligence (AI) multiple biometric indicators can be monitored instead of single ones. Third, precision based healthcare with roots in the patient’s individual characteristics might be used instead of intuitive approaches. Fourth, the healthcare sector will move from specialised silos to centralised knowledge centers. (Deloitte Center for Health Solutions 2015a, p. 1)

As medical self-care solutions are developing, the patients are becoming more independent. The Swedish National Board of Health and Welfare defines the concept of self-care as: *A healthcare solution which a registered HCP has decided that a person can use or perform by oneself or with the assistance of someone else* (Socialstyrelsen 2013). Commonly, self-care solutions take their form in telecare, or telehealth as it is sometimes referred to as. Telecare utilises information and communication technologies (ICT) to provide health and care services from a distance (Brownsell 2009).

There is not one specific definition of ICT, however according to Rouse & Pratt (2017) there is a general consensus on the meaning of the term. Rouse and Pratt (2017) choose to define ICT as: "*[...] all devices, networking components, applications and systems that combined allow people and organizations (i.e., businesses, nonprofit agencies, governments and criminal enterprises) to interact in the digital world*". The incorporation of ICT into healthcare adds value to both healthcare services and the skills of the professionals using these services (World Health Organization 2016).

With the assistance of monitoring and preventive MedTech solutions it is possible to develop self-care and as a result also decrease the pressure on today's primary and specialised care (Eklind 2017). There are a few different types of self-care solutions on the market, for example: Holter monitors, portable Electrocardiographies (ECGs); Self-Monitoring of Blood Glucose, so called SMBGs; and Pedometers, movement trackers (Technavio 2016). However, the healthcare sector is a complex system, with several stakeholders such as county councils, municipalities, private operators, HCPs and patients. But who bears the responsibility of financing medical devices may vary. Per Trossmark, points out that within the market of self-care solutions, the customer is not necessarily the same entity as the user of the device.

Connected MedTech solutions have the potential to reduce costs in healthcare, liberate time for the HCPs and ultimately save lives. However, one requirement for this to work is that the patient must be monitored in real time. Bansal & Gandhi (2017) examine the benefits of Holter monitors. By identifying irregularities in the patient's heartbeat, a diagnosis can be made prior to the patient's arrival at the care unit, subsequently leading to treatment being commenced immediately. In an article written by Eklind (2017) it is shown that a project involving a digital self-care center in Liverpool has been successful with cost reductions for emergency room and

specialised care. Jeroen Tas, CEO of Philips' Connected Care and Informatics, says emergency care and readmissions of patients with chronic diseases may be reduced due to an increase in the use of connected care (Wicklund, 2017). By involving patients in their own caretaking and allowing them to learn about their own condition, with the help of MedTech, cost reductions can be made since patients can decide when they actually need to seek help (Eklind 2017).

The introduction of ICT-based self-care solutions, will allow direct communication of care data between the healthcare devices and patient, and will also give HCPs and the patient's family access to said data. In this way, it will become easier for the patient to lead an independent life but also easier for relatives to stay informed on the patient's condition. The quality of the self-care can increase by involving relatives, since the patient might become motivated to embrace healthy behaviours (Shih-Jung et al. 2017). Early signs of worsened patient health make proactive solutions possible and health consultations more efficient and targeted (Eklind 2017). Further, the data gathered by ICT solutions will most likely be of interest to other stakeholders than HCPs, patients and the patient's relatives. In an article in The Economist, the author identifies the value of collected patient data. "*At a time when health-care budgets around the world are stretched, payers are desperate for insights that might enable them to cut costs*." (The Economist 2018, p. 52). These data sets can be used to give more precise predictions. Alphabet, the parent company of Google, claim they have developed an AI capable of predicting the deaths of hospitalised patients two days earlier than any existing method. This gives HCPs more time to intervene, and target efforts towards specific patients (The Economist 2018). Large data sets also provide basis for future research and development (Telia IBD Home 2017).

The potential of the digital technology is understood, however healthcare sectors are struggling to act on this potential. Even though the technology is available, companies offering MedTech solutions are yet to produce the proof that their solutions contribute to long-term improvement in the patient's health as well as they lead to cost reductions (Aue, Biesdorf & Henke 2016). Chiesa & Frattini (2011) discuss the complexity of commercialising new technology in high tech markets. "*Empirical studies have in fact shown that fully commercialised new products have a remarkable failure rate of 40–50%, and this performance has not changed much over the past 20 years*" (Chiesa & Frattini 2011, p. 437). Therefore, from the perspective of MedTech companies, it is

important to understand what factors drive successful market penetration and establishment of medical devices.

Sweden along with other OECD countries face demographic and organisational issues in the healthcare sector, with ageing populations, over-encumbered care and welfare sectors, rising costs in long-term care and large shares of chronically ill patients. Self-care solutions based on emerging ICT make it possible for patients to monitor their medical conditions from home, without the direct assistance of HCPs. Thereby time and resources within the healthcare sector are liberated. Monitoring and preventive self-care solutions can proactively impede deteriorating health and injuries. In conclusion, the healthcare system is given an opportunity to handle the changing and aggravating landscape dynamics through a new set of care solutions. This is why Information and Communication Technology based Monitoring and Preventive Medical Self-Care Solutions are the targets of this study.

## 1.2 Purpose

The purpose of this study is to identify what enables market penetration and establishment of Information and Communication Technology based Monitoring and Preventive Medical Self-Care Solutions (ICTMPMSCS) to succeed.

## 1.3 Objective

The final objective with this study is to present factors, preconditions and dynamics that characterise successful market penetration and establishment of ICTMPMSCS.

## 1.4 Research Questions

**Research question 1:** What macro-environmental factors have an impact on the success of ICTMPMSCS, and how do these change over time as the company grows?

**Research question 2:** What company internal factors play a vital role for the company offering the ICTMPMSCS, and how do these change over time as the company grows?

**Research question 3:** Who are the stakeholders of the ICTMPMSCS, what roles do they play and what incentives do different stakeholders have to promote adoption of the medical self-care solution?

# 1.5 Delimitations

**What to study**
This study will look at what characterises successful market penetration and establishment of ICTMPMSCS. This will be done by examining company internal as well as macro-environmental factors, preconditions and dynamics over the course of time that the product is developed and then brought to market. The studied care setting is primarily the Swedish healthcare sector. The case studies in the report are all operational in Sweden and have thus penetrated the Swedish market. However, as the success of an ICTMPMSCS may depend on its ability to spread to new geographical markets, care settings in other countries will be briefly investigated when deemed necessary.

**What not to study**
The study will not investigate the relative change in the quality of care due to the adoption of ICTMPMSCS. Nor does the study directly deal with how these ICTMPMSCS facilitate the work of HCPs. On a company internal level, the study does not focus on operational excellence and how the company can maximise profits. Rather, focus is aimed towards entering and establishing an ICTMPMSCS on a market.

# 1.6 Disposition

The disposition of the report is presented below in (see fig. 1.1). The case studies and analysis are divided into the studied cases respectively. These are then aggregated in the discussion and the report's final conclusions are presented. In a final statement, the authors present reflections on the study.

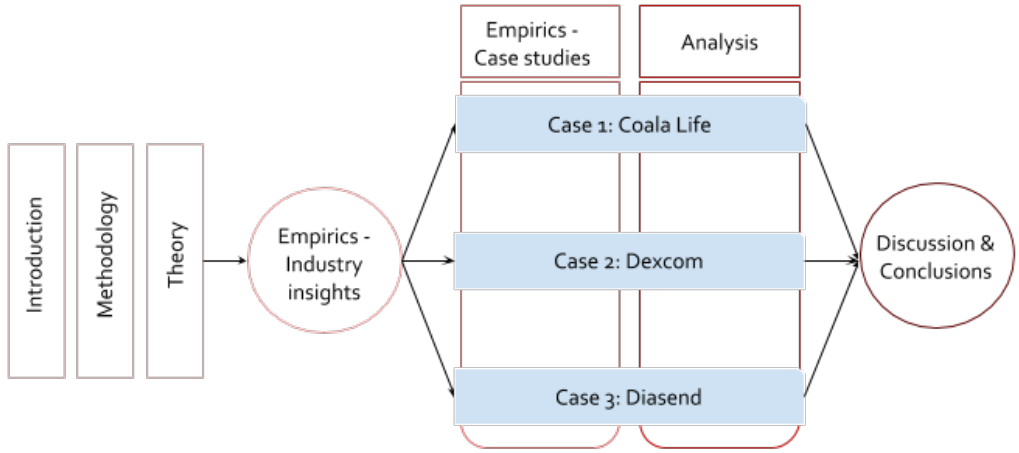


*Figure 1.1. Disposition of study. A visual representation of the study's disposition and its chapters.*

# 2. Methodology

*This chapter presents the research strategy and research methods of this study. The quality of the chosen research approach is discussed in terms of its reliability and validity. Finally, the chapter ends with a short and brief summary of the chosen research approach.*

## 2.1 Research Strategy

The research strategy is the general plan of the study. It defines how the research questions ought to be answered in the most correct way. The chosen strategy should be feasible, suitable for the study at hand, and ethical (Denscombe 2010). This subchapter selects an appropriate strategy according to these three aspects.

The chosen methodology depends on the purpose, goal and character of the study. There are four general types of purposes for a Master's Thesis:

- *Descriptive studies* aim to describe the phenomenon at hand, how it works and what parts play an active role.
- *Exploratory studies* delve deep in the matter and aim to define and create an understanding to how something works. It is often used to define research questions and hypotheses for coming studies.
- *Explanatory studies* commit to finding reasons behind the phenomenon and causal relationships.
- *Problem solving studies* aim to find a solution to a previously identified issue.

(Höst, Regnell & Runeson 2006; Yin 2003).

The purpose of this study builds upon the observed phenomenon that ICT-based medical self-care solutions are becoming an increasingly common part of healthcare. However, factors determining which MedTech solutions end up being successful in the market are yet to be defined. Therefore an inductive approach is chosen for this thesis, with the purpose to make observations, find patterns and finally form a hypothesis regarding what factors have an impact on the market penetration and establishment of these MedTech solutions.

Because this phenomenon has not yet been fully mapped out, and the involved stakeholders form a complex network of exchanged health services, the study will adopt the approach of an exploratory study. When the phenomenon to be studied is new, dynamic or complex, it is more difficult to identify relevant research variables and there may be a lack of existing theories on the subject (Creswell 1998), which is the case in this study. In order to fully explore the phenomenon, a qualitative research methodology is preferred, where primary data is collected out in the field (Golicic, Davis & McCarthy 2005). This is confirmed by Höst, Regnell & Runeson (2006, p. 43) who point out that when the purpose of the study is exploratory in nature, primary data should be qualitative. Further, due to the study's exploratory nature, the initial scope is rather broad but will eventually be used to give suggestions on future topics to be studied.

The collected data may either be quantitative or qualitative. Depending on whether the purpose of the study is based on inductive or deductive reasoning, a qualitative or quantitative approach is chosen (Golicic et al. 2005). Qualitative data is analysed by inductively assembling a theoretical model through observations. Quantitative data on the other hand is used to confirm the validity of an existing theoretical model through deductive reasoning. In the case of an inductive approach to the study, qualitative research methods ought to be selected (Golicic et al. 2005), which further reinforces the choice of methodology for this study.

However, Golicic, Davis & McCarthy (2005, p. 16) mention that there is a need for a combination of inductive (qualitative) and deductive (quantitative) research methods in order to fully be able to contribute to the development of knowledge. Therefore a deductive approach will be used to create a theoretical framework through existing secondary data, as well as used in answering the research questions of this study. The deductive approach takes shape through a literature review.

## 2.2 Research Methods

The following subchapter describes the research methods that will be used in this study to collect data.

## 2.2.1 Literature Review

The literature review has two main purposes. First of all, it facilitates the process of generating new ideas for research and summarises existing research by identifying patterns in previous findings (Seuring, Müller, Westhaus & Morana 2005). Second, the literature is used to assess and compare the new contributory knowledge with existing theories and models (Ibid).

Höst, Regnell & Runeson (2006, p. 60) add two complementing purposes on top of those recently proposed by Seuring, Müller, Westhaus & Morana (2005). In the beginning of the thesis, literature helps compile a solid informative background, giving the reader an insight into the topic to be discussed. The second purpose, as suggested by Höst, Regnell & Runeson (2006), is to give a clearer focus on the research questions, and the literature can by that be used to answer part of the thesis' purpose and research questions.

This study gathers its literature from sources such as library catalogues, search engines, and online databases. Rowley & Slack (2004) present four search strategies for literature reviews:

- *Citation pearl growing.* Starts from one or a few relevant documents and uses suitable search terms in those documents to find new sources of information.
- *Briefsearch*. A quick superficial search that retrieves a few documents. It can be useful to start with a briefsearch before adopting another search strategy.
- *Building blocks*. This search strategy builds on current search terms by adding, and attempting to use synonyms in order to find relevant documents.
- *Successive fractions*. A search within an already retrieved set of documents. This is a suitable strategy when posed to large sets and amounts of data.

(Rowley & Slack 2004)

The literature review of this study adopted the search strategies citation pearl growing, briefsearch and building blocks. Terms that were used included, but were not limited to the following: *"ambient intelligence medtech", "ICT", "medical devices", "medical tech", "medical technology", "medicon valley", "Medtech", "medtech cluster", "medtech healthcare", "self-care solutions", "telecare", "telecare systems"*.

## 2.2.2 Case Studies

A case study studies one or several cases in-depth, without significantly affecting or altering the studied object (Höst et al. 2006). Denscombe (2010, p. 30) acknowledges the fact that a case study is a way to illustrate the general by studying the specific. The method is used to empirically examine a present phenomenon, when the phenomenon and delimitations of its context is not fully apparent (Yin 2003).

A multiple-case study covers three important aspects:

1. Each case can be studied in-depth, improving triangulation in the analysis.
2. There is a possibility to discover contradictory situations.
3. Several studied cases enable the links between studied objects to be explored, when looking at their integrated activities.

(Van Donk & Van der Vaart 2005).

The following techniques for collecting data are usually utilised in case studies:

- *Archival research*
- *Interviews*
- *Observations*

(Höst et al. 2006).

### Archival Research

As part of the archival research, documentation relevant to the object of the case study is examined. The documentation is existent and was created for another purpose than the specific purpose of this study (Höst et al. 2006). For this study, the archival research will consist of investigating the case study objects' ICTMPMSCS as well as the organisational structure of the company.

### Interviews

Interviews, as a method for collecting data, are most suitable when studying subtle and complex phenomenon (Denscombe 2010), which seems to correspond to previous definitions with the inductive and exploratory approach of this study (*see chapter 2.1 'Research Strategy')*.

The interviews can be structured in one of three different ways:

- *Structured interviews* give the interviewer significant control. The questions asked by the interviewer are predetermined and the answers are often pre-coded, facilitating the analysis. High resemblance to a survey, however the questions are given orally.
- *Semi-structured interviews* are similar to structured interviews in the sense that the interviewer has a clear list of questions to be addressed, but the interviewee is left room to elaborate on his/her ideas and to discuss freely from the administered questions.
- *Unstructured interviews* means the interviewee himself/herself leads the interview by freely expressing his/her thoughts. The objective of the interviewer is to remain unobtrusive, but assists the interviewee in setting the ball in motion by addressing the topic at hand to be discussed.

(Denscombe 2010)

Since the studied phenomenon is still relatively unexplored, and this study adopts an exploratory approach, the semi-structured interview technique is chosen. By choosing the semi-structured interviewing technique, interviewees are not restricted to elaborate on their answers.

## Selection of Case Companies

Sampling is a technique that aims to obtain a representative and accurate result from the collected data, without having to examine the entire survey population of the study (Denscombe 2010). The concept of 'survey population' includes all stakeholders and individuals who are of interest to the study in order to be able to come to some sort of conclusion (Lekvall & Wahlbin 2007). The sampled population is a subset to the larger survey population. There are primarily two groups of sampling methods:

- *Probability sampling* enables the researcher to quantitatively calculate the risk for inference errors (the risk for systematic measurement errors). High demands are made on the sampling methods in order to ensure inference.
- *Non-probability sampling* is used when the researcher needs to select a specific or certain unit of study. An additional reason to choosing a non-probability sampling method is a lack of sufficient information regarding who the survey population consists of. Because inference errors cannot be calculated when using non-probability sampling methods, the researcher must instead resort to using qualitative judgment of measurement error, rather than quantitative.

(Lekvall & Wahlbin 2007)

When the goal of the sample is to obtain a particular composition of respondents in order to illuminate the answers to a certain set of research questions, selective sampling can be a possible sampling technique (Lekvall & Wahlbin 2007). Selective sampling is suggested to be used during exploratory studies (Ibid). Owing to the thesis exploratory nature, selective sampling is chosen as the technique to select case study objects.

The following criteria for case study objects are set:

- The company offers an ICTMPMSCS.
- The company has a commercially available product on the Swedish market.
- The self-care solution is used by the patient outside the walls of the care facility, without the direct assistance from a HCP.
- The solution collects and stores data regarding the patient's health.
- The solution involves some sort of hardware, worn or carried by the patient or exists in the vicinity of the patient's surroundings.

## 2.2.3 Industry Experts

As a complement to the literature review and case studies, insights from industry experts will be used to create an understanding of the industry and market dynamics. Unstructured interviews offer the industry experts to freely express their minds and highlight what they consider to be the most crucial factors of success in the industry. Insights from these experts strengthen the data triangulation in the analysis phase.

### Selection of Industry Experts

This study identified its industry experts through the technique of snowball sampling. Each interviewee is asked to nominate other people who would be relevant for the authors to interview for the purpose of the study. The size of the sample typically snowballs in size as each of the interviewees is asked to further nominate. By utilising the means of nomination, credibility is enhanced compared to if the study every time approached a completely new interviewee. (Denscombe 2010)

## 2.3 Rigor

The credibility of the study lies in a lack of measurement errors. One way to prevent these types of errors is to examine the methodology's reliability and validity. The notion of these concepts and their role in this study is described below.

### 2.3.1 Reliability

Reliability, much as the word suggests, is concerned with the reliability of the collected data and the analysis that has been conducted of this data. The sample selection of case study objects is one factor contributing to a high level of reliability (Höst et al. 2006).

To guarantee a high level of reliability in the collected primary data, it is of great importance that the interview guide is structured in a clear manner to ensure all interviewees are given the exact same questions and thereby given equal opportunities to answer. The choice of a semi-structured interview form therefore endorses the study's reliability.

Other aspects to be taken into account during the data collection phase are for example more situational bound factors affecting the reliability of the data. E.g. distractions in the surrounding during the interviews or variations in the way questions are posed (Lekvall & Wahlbin 2007).

### 2.3.2 Validity

Validity poses the question: Are we measuring what we should be measuring? Ensuring validity focuses on avoiding systematic errors (Höst et al. 2006).

In this study, actions are taken proactively to confirm the report is achieving a high level of validity.

- A spreadsheet is used to track what literature answers what research question.
- Regular contact with the supervisors who review the working process. As an example, input from the supervisors help form the interview guides. This acts as an extra precaution to ensure validity.

- The use of data triangulation. By researching different sources of information, validity is enforced (Denscombe 2010). The choice of a multi-case study plays a vital role in this aspect. Triangulation utilises information gathered from secondary as well as primary sources.

Stuart, McCutcheon, Handfield, McLachlin & Samson (2002) point out that there are shortcomings in the use of case studies. The authors mean that the choice of conducting a case study is based on mere assumptions that there are no current established and applied theories to the phenomenon. Therefore, to further ensure the validity it is highly important that a thorough literature review is included in the study to map out what areas academia has already covered.

# 2.4 Summary of Methodology

The process for this study consists of six phases. Each phase lays the foundation and understanding for the next. It should also be noted that the entire process contains several iterative steps. As new insights emerge, previous phases may need to be revisited in order to make adjustments and improvements. An illustration of the work process is presented below (see fig. 2.1) along with a summarising visual representation (see fig. 2.2) of the chosen methodology of the study.

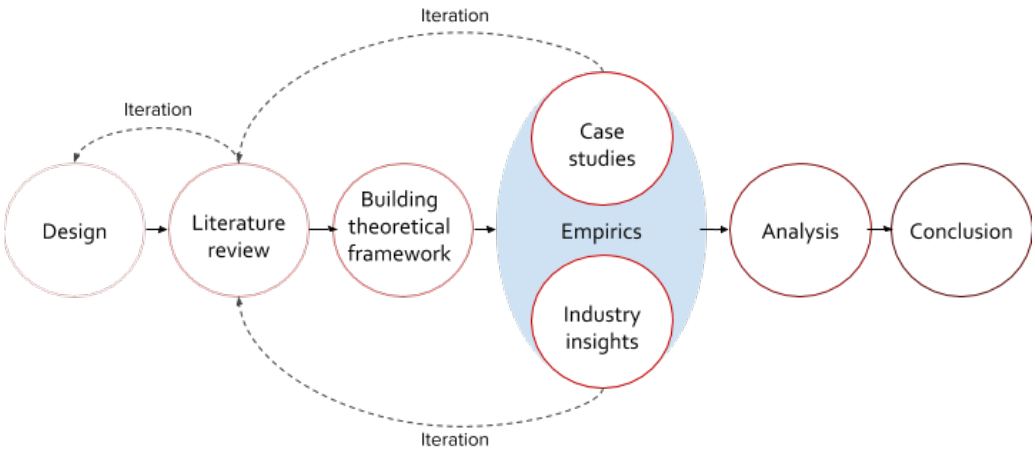


*Figure 2.1 Work process. The iterative work process of the study, presented in chronological order from left to right.*

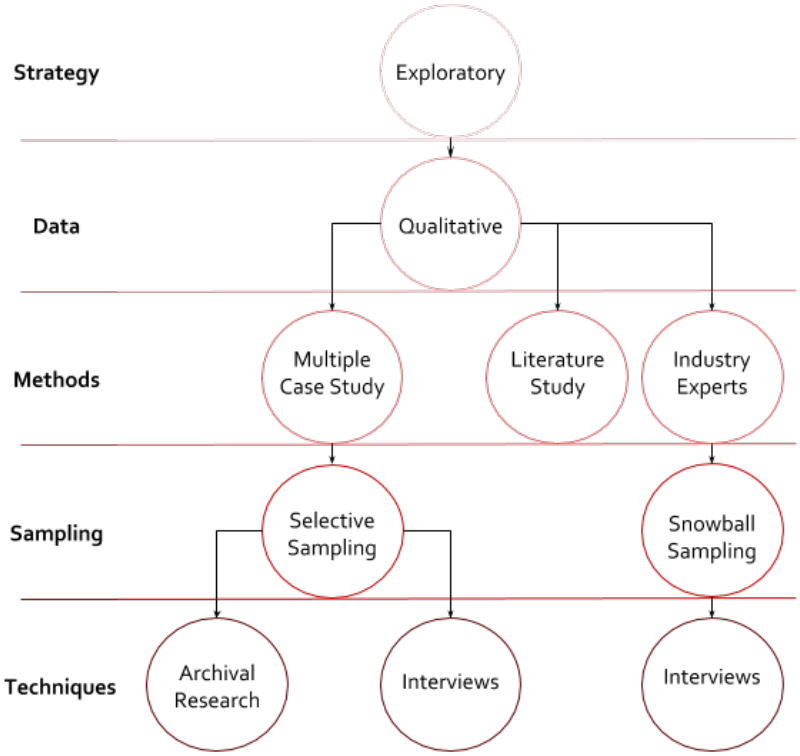


*Figure 2.2. Methodology. A summarising illustration over the chosen methodology for this study.*

# 3. Theory

*The following chapter will describe what theoretical and academical observations form the foundation of this study. Each subchapter contains an explanation and description of a certain theoretical model, and then outlines what parts of that specific model can and will be applied to build upon the theoretical framework of this study. At the end of the chapter, the theoretical framework specifically designed for this study is presented. Because of the exploratory nature of this study, a broad selection of theoretical models is presented. However, some models are altered to fit in with the purpose of the study.*

In order to fulfil the purpose of the study as proposed in chapter 1.2 and to answer the proposed research questions in chapter 1.4, there is a need for a theoretical framework which facilitates the analysis of the collected data.

As described in the background of this study (*see chapter 1.1 'Background'*), the Swedish population is rapidly ageing. As a result, healthcare costs are expected to increase all the while the number of taxpayers are declining. New technologies are emerging, one example being ICT. The trends in emerging technologies and the shift in healthcare, indicate a need to understand macro-environmental factors that have an impact on MedTech companies.

The healthcare sector is a complex one, with multiple stakeholders. Different stakeholders may have different incentives for the adoption of certain medical devices. Although several stakeholders may have an interest in the product, it is likely only a few of them have any actual influence on the adoption. The product will incrementally be either adopted or rejected by the market. To gain an understanding of this adoption, it is vital to understand how stakeholders' roles change and how MedTech companies can make strategic decisions that lead to market establishment. These strategic decisions make up the business model of the company. There is a need to understand what activities and decisions MedTech companies pursue, in order to produce successful ICTMPMSCS. Additionally, there needs to be an understanding on how to create viable business solutions in a macro environment constantly undergoing change.

Therefore, this study requires a theoretical framework that addresses the following aspects:

- *Macro-environmental factors*
- *Industry specific factors*
- *Stakeholders influencing the adoption of medical devices*
- *The market's susceptibility to a medical device*
- *A suitable definition of success*
- *Factors determining whether medical devices remain on the market or not*
- *Possible business models a company offering ICTMPMSCS may adopt*
- *Activities and decisions of companies which play the most vital role in the market establishment of medical devices*

# 3.1 Identifying Industry Competitiveness

*The theories regarding industry competitiveness aim to give an understanding of what activities and decisions companies make that play the most vital role in the market establishment of medical devices. The theories illustrate the interplay between company internal activities and macro-environmental dynamic within the industry they operate. A suitable definition of success for this study is presented.*

Industry conditions are dynamic and exposed to change. Thompson, Strickland & Gamble (2010) mean industry conditions change because industry participants and stakeholders alter their actions and behaviours. The authors refer to the behaviours and actions as *driving forces*, able to influence and reshape the industry landscape. Some driving forces can be found in the organisation's larger macro environment whereas most driving forces derive from more local industry activity. Driving forces generally fall into one of 14 categories:

1. *Changes in long-term industry growth rate*
2. *Globalization*
3. *Emerging new internet capabilities and applications*
4. *New customer segments and new areas of application*
5. *Product innovation*
6. *Technological and manufacturing process change & innovation*
7. *Marketing innovation*
8. *Large major firms enter or leave industry*
9. *Diffusion of know-how across companies and geographical borders*

10. *Changes in cost and efficiency*
11. *Shift in customer preferences (e.g. from standardised products to more differentiated)*
12. *Reduction in industry uncertainty and business risk*
13. *Regulatory and government policy changes*
14. *New social attitudes, lifestyles and concerns*

(Thompson et al. 2010)

The driving forces impact on what factors turn out to be the industry specific success factors. All industries have their own sets of success factors, which are determined by the characteristics of each industry (Bullen & Rockart 1981). Managers and organisations need to evaluate which of these driving forces will have the greatest impact on the organisation, and adapt their strategy in accordance with these changes. The factors that have the largest positive impact on the organisation's performance are labelled Critical Success Factors (CSF) (Thompson et al. 2010). Knowing the CSFs of the organisation is crucial. It makes it possible to focus limited time and resources to those activities that create the most value (Bullen & Rockart 1981). There is no need for managers to compile a complete list of all factors that play a role on the organisation's performance, instead efforts ought to be concentrated on those truly crucial to the organisation's long-term competitive success (Thompson et al. 2010).

Bullen & Rockart (1981) give a summarised definition of CSFs as being the limited number of activities where satisfactory results will lead to successful competitive performance for the individual, department or organisation. However, Bullen & Rockart (1981) also acknowledge that macro-environmental factors, i.e. factors the organisation cannot directly affect, also influence the success of the organisation. The notion of success is usually based on the success of an organisation. However, for this study, focus is aimed towards the self-care solution itself rather than the company or organisation as a whole. Despite this, there is still a need to define the concept of success. Drucker (2002) defines success as the organisation's ability to develop in the long run. Di Benedetto (1999) suggests the following three measures of success in the pursuit of identifying critical success factors for new product launches:

- *Perceived profitability.*
- *Sales.*
- *Relative market share of product in comparison to competing products.*

(Di Benedetto 1999, p. 534)

Cooper & Kleinschmidt (2007) offer a slightly more detailed approach by addressing a total of ten performance metrics associated to the critical success factors that underlie excellent new product performance:

- *Success rate*. The proportion of projects that reach commercialisation from a development phase.
- *Percentage of sales by new products*. Percentage of sales that are accounted for by those products released within the last three years.
- *Profitability relative to spending*. The profit generated by the new product in relation to the development and commercialisation costs.
- *Technical success rating*. From a technical/technological perspective how successful was the development?
- *Profit impact*. How large was the profit generated by the new product in relation to the organisation's profit as a whole?
- *Meeting sales objectives*. To what extent were previously set sales objectives met?
- *Meeting profit objectives*. To what extent were previously profit objectives met?
- *Profitability versus competitors*. How does the organisation's profitability generated by the new product stack against the profitability of competitors?
- *Overall success*. All metrics taken into account, how successful was the new product effort in comparison to competitors?

(Cooper & Kleinschmidt 2007, p. 55)

A merger of Drucker's (2002), Di Benedettos's (1999), and Cooper & Kleinschmidt's (2007) definition leaves us with the definition of success used for this study. Namely, an ICTMPMSCS that reaches commercialisation, and is able to maintain a market position in a long-term perspective with steady or growing sales is considered successful.

Because ICTMPMSCS are a fairly new phenomenon, identifying cases of solutions who have had long term success may prove to be an issue. This issue was also identified by Igor Ansoff during the 80's, who stated that strategic planning required strong signals, i.e. detailed information that is available early on. However, at some times, strong signals are not available. Instead one may look at so called weak signals, not with the purpose to understand future state of affairs, but rather to identify what

processes are likely to initiate changes. Weak signals can be seen as early symptoms of possible future changes. When these weak signals first become apparent, the information they consist of is very vague, and there is only a slight sense of a possible threat or opportunity (Holopainen & Toivonen 2012).

Thompson, Strickland & Gamble (2010) mention industry conditions are fluid and subject to change, and Bullen & Rockart (1981) state that the success factors depend on the characteristics of the industry which would mean that CSFs too are exposed to change as the industry goes through change. Bullen & Rockart (1981) add that some factors do have an impact on the organisation's success but are only in question during shorter periods of time due to unforeseen events. The aspect of time and industry life cycle apparently plays a role on the CSFs. This study will focus on the success of initial market penetration and then the prospected promise of a strong future market presence. This is done by looking at the weak signals as suggested by Holopainen & Toivonen (2012), which indicate what processes are likely to shape future market dynamics.

# 3.2 Business Model Canvas

*In order to analyse the business model (internal activities and internal decisions of the companies offering medical devices), the theoretical framework Business Model Canvas is applied. It highlights nine building blocks that make up a company's business model. The Business Model Canvas is slightly altered to fit the purpose of this study.*

## 3.2.1 The Model

A business model describes how an organisation creates, delivers and captures value. The business model should be simple, relevant and intuitive all the while it should not simplify the complexity of the organisation's functions and activities (Osterwalder & Pigneur 2010). Casadesus-Masanell & Tarziján (2012) mention that attempting to operate more than one business model at a time is frequently considered to lead to strategic failure. Yet there might be situations which demand the company to address several customer segments simultaneously. Reasons for this could be to crowd out competition, expand into new markets, make more efficient use of resources and assets or simply to find new sources of revenue (Casadesus-Masanell & Tarziján 2012).

Osterwalder & Pigneur (2010) refer to their developed model, the *Business Model Canvas,* as a tool used to create an understanding and analysis of an organisation's business model (see fig. 3.1).

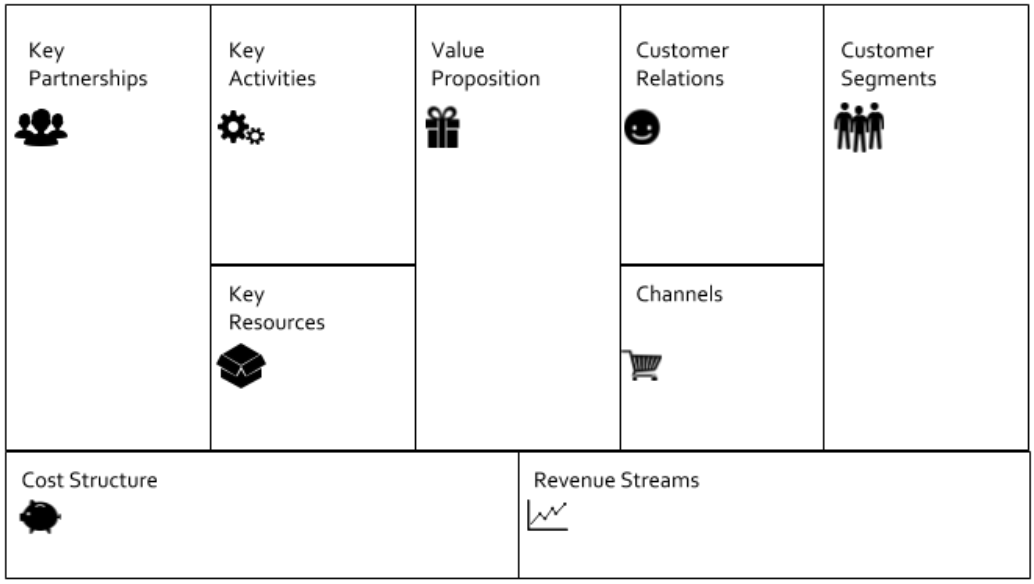


*Figure 3.1. Business Model Canvas. The illustration is based on the proposed model in "Business Model Generation: A Handbook for Visionaries, Game Changers and Challengers", p.44 (Osterwalder & Pigneur 2010).*

## 3.2.2 Applying the Model

Key Partnerships, Customer Segments, Customer Relations, Channels, Value Proposition, Key Resources and Key Activities are identified as the most vital building blocks of the Business Model Canvas for this study. The building blocks 'Customer Segments', 'Customer Relations' and 'Channels' are fused together and referred to as 'Market Network', because of the complexity within the MedTech industry to distinguish the customer from the user of the medical device. The building blocks 'Revenue Streams' and 'Cost Structure' are excluded as the purpose of this study focuses on initial market penetration and establishment, rather than on achieving long-term operational profits.

## Key Partnerships

Larsson, Bill, Ingridsdotter & Olsson (2011) discuss the need for MedTech companies to move away from working solely on a sales-purchasing relationship with the public healthcare sector and instead highlight the need to work more collaboratively and cocreatively with external partners in order to achieve healthcare innovation. The importance of partnering up with other stakeholders is also noted by the consulting firm Deloitte. In order to acquire the capabilities needed to develop future MedTech solutions, companies ought to identify partners and alliances with whom they should collaborate (Deloitte Center for Health Solutions 2015a).

## Market Network

Apart from identifying partnerships, MedTech companies also need to identify specific customer segments. The consulting firm Boston Consulting Group point out that: "*In the medtech industry, the top 10% of customers can represent as much as 50% of the business in a given product category*" (Boston Consulting Group 2018). The consulting firm McKinsey & Company identify a rise of "value customers" in the MedTech industry, that is, customers who are more drawn to competitively priced products. Previously, the MedTech industry has been dominated by premium-segment products (Llewellyn, Podpolny & Zerbi 2015). These insights indicate the need to understand, and strategically target certain customer segments within the MedTech industry.

However, as previously mentioned when looking at MedTech, the customer and user are not necessarily the same entity. An example of this is the organisational adoption of MedTech in the healthcare sector. An organisation, in this case a hospital, makes the decision to acquire a technology even though the user is the HCP, who may or may not have a saying in what is to be purchased (Ghodeswar & Vaidyanathan 2007).

Aside from customers and users, there may be other parties with a commercial interest in the ICTMPMSCS. As The Economist (2018) indicates in its article 'Surgical Intervention', tech companies are interested in analysing big data sets, generated from patients using certain medical self-care solutions. There is a commercial potential in the data providers of ICTMPMSCS collect.

## Value Proposition

The importance of a clearly defined value proposition for MedTech companies is essential to succeed according to Vaishali Kamat, Commercial Director and Head of Digital Health at Cambridge Consultants (Greener 2016). The Boston Consulting Group have also identified the need for well-defined value propositions. The consulting firm points out that MedTech companies are still focusing on the technical features of their products, when they should be putting emphasis on the delivered value of the medical device, such as: reduced cost of care, shorter hospital stays or lower rate of recurring surgeries (Boston Consulting Group 2018). Healthcare companies should expand on their existing value proposition by adding new services to their offered products and solutions to keep the attention of patients (Biesdorf & Niedermann 2014).

## Key Resources and Key Activities

Key resources and key activities are the assets a company has and the actions it must take to be able to deliver on its value proposition (Osterwalder & Pigneur 2010). Resources and activities are closely linked together. Resources are physical, intellectual or human assets the company has, and activities deal with how well the company manages these resources. A resource could be the company's brand, and a key activity would therefore deal with how well the brand is maintained, e.g. through the activity of marketing (Osterwalder & Pigneur 2010). Key resources and activities are what set an organisation apart from its competitors and can leverage competitive advantage and aid in achieving superior performance (Johnson, Whittington & Scholes 2012).

Buzzell (1983) mentions some observers claim vertical integration of activities to be crucial for survival, whereas others mean it causes corporate failure. Vertical integration means integrating more than one stage of a supply chain or process into the same company. Vertical integration can lead to lower transaction costs, supply assurance, improved coordination and synergies in technological capabilities. However, downsides include higher capital requirements, reduced flexibility and loss of specialisation in core competencies (Buzzell 1983).

The concept of analysing the organisation's resources and activities is known as the resource-based view (RBV) (Wernerfelt 1984). According to Johnson, Whittington & Scholes (2012) strategic capabilities, which is comprised of the organisation's

resources and competences, are "*the capabilities of an organisation that contribute to its long-term survival or competitive advantage*" (Johnson et al. 2012, p. 51). The definition of strategic capabilities given by Johnson, Whittington & Scholes is similar to Drucker's definition of success (*see chapter 3.1 'Identifying success'*). Therefore, in order to understand the importance of the MedTech companies' value proposition, it is imperative to understand the fundamental resources and activities.

# 3.3 PESTEL

*To identify and evaluate the success factors of an organisation it is crucial to understand the macro-environmental driving forces of industry change as proposed by Thompson, Strickland & Gamble (2010). The driving forces exerted by the industry's participants and stakeholders shape the industry specific success factors. The PESTEL-model contributes to the analysis of the organisation's external macro environment in this study.*

## 3.3.1 The Model

The PESTEL-model is a tool for analysing the broad macro environment of an organisation by looking at six key influences, or key drivers, to environmental changes (see fig. 3.2). PESTEL is an abbreviation for these six key drivers:

- *Political*. Refers to the role of government and public authorities.
- *Economic.* Refers to macro-economic phenomenons such as exchange rates, business cycles and business growth in different countries.
- *Social*. Social influences are of a cultural and demographic character.
- *Technological*. Refers to the rise of new technological innovations, available to entire industries and countries, not just specific companies or other entities.
- *Environmental.* The environmental aspect refers to "green" factors, such as levels of pollution and waste.
- *Legal*. Embraces legislative restrictions, such as health and safety legislation.

(Johnson et al. 2012)

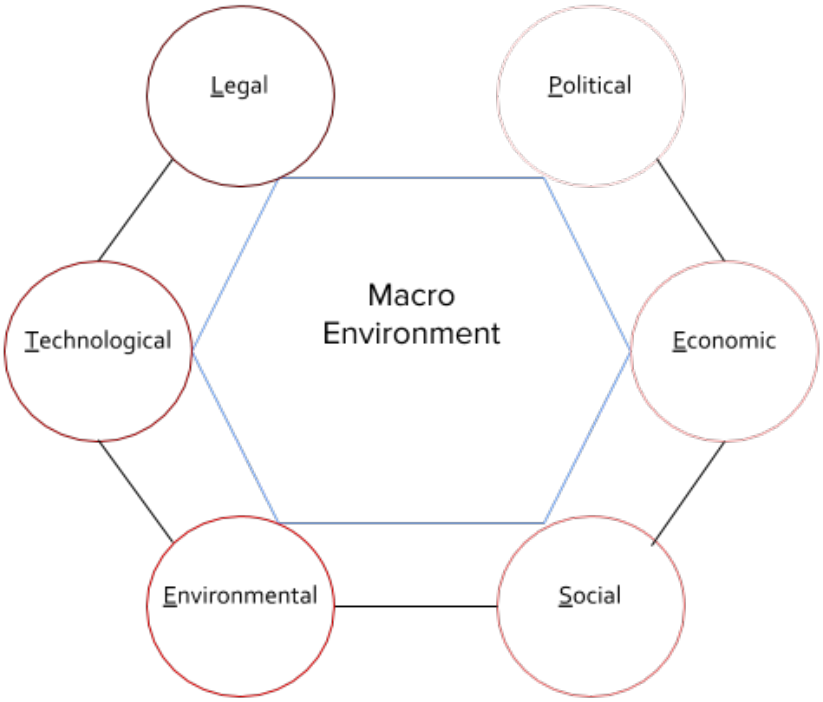


*Figure 3.2 PESTEL. The PESTEL model is used for analysing the broad macro environment of an organisation. Adapted from Johnson, Whittington & Scholes (2012, p. 22).*

Johnson, Whittington & Scholes (2012) talk about the necessity for organisations to identify these key drivers for change which they define as: "*Key drivers for change are the environmental factors likely to have a high impact on the success or failure of strategy*" (Johnson et al. 2012, p. 22). The statement here presented by Johnson et al. (2012) matches the reasoning and arguments brought forth by Thompson, Strickland & Gamble (2010) in their discussion regarding driving forces (*see chapter 3.1 'Identifying success'*). This implies it is essential to understand these macro-environmental drivers in order to identify the CSFs of an organisation.

## 3.3.2 Applying the Model

Four of the six key drivers in PESTEL are selected for this study to be used as research tools. These drivers were Political, Social, Technological and Legal. The Economical aspect is disregarded, as it is considered that economical volatilities do not only affect

the MedTech industry, but affect global markets. Macro-economic uncertainties impact entire countries and not just a selection of industries. It is therefore considered to be out of scope for this study. The Environmental aspect too is discarded. The environmental impacts derived from the MedTech industry are not seen as significant in comparison to those of other industries, such as food & agriculture, transportation and energy.

## Political

The political driver highlights macro-environmental influences from governments and public entities (Johnson et al. 2012). Medical devices are often met by well-articulated criteria and demands from authorities. Agencies such as the Food and Drug Administration (FDA) in the U.S., as well as National Health Services (NHS) in the UK have developed criteria for health apps. Criteria include the need to review the device, where the reviewing process is performed by a technical team as well as a clinical team (Deloitte Center for Health Solutions 2015b).

Other political issues revolving the trade of medical devices are those regarding public procurement. In Sweden, all public procurement must abide by the law of public procurement[2] (LOU). The purpose of LOU is to promote competition to stimulate an efficient use of the public's resources. Procurement is done at both county and municipal levels. A specification document for the medical device needs to be established prior to the procurement process. The specification document should include, among other things: a demand for the device to have a CE-marking (European Conformity marking); a list of demands the buyer has on the device; demands on a certain minimum performance, demands for specific features and functionalities (Fjärstedt 2017). However, there are situations when procurements do not need to go through a rigorous process. According to LOU, when the total sum of the public entity's procurement expenditure is below 586 907 SEK during a fiscal year, the entity can purchase its equipment and supplies directly from a supplier of choice (Swedish Competition Authority 2018).

[2] Lagen om Offentlig Upphandling, SFS 2016: 1145

## Social

The social driver of the PESTEL-model aids in analysing the demographic and cultural situations and changes in society (Johnson et al. 2012). Deloitte identifies four challenges for the future of healthcare, if healthcare is to function sustainably and in the long-run:

- Constrained budgets and the rising costs of advanced medical treatments
- Increasing patient expectations and demand for better quality, patient-centered healthcare
- Increasing complexity and costs of delivering care to an ageing comorbid population
- Reduced availability and increased costs of HCPs, in-patient beds and residential care places

(Deloitte Center for Health Solutions 2015b)

## Technological

Deloitte identifies five building blocks behind the technological progress of medical devices:

- Increased computing power
- Large data storage capacity
- Hardware miniaturisation
- Network connectivity
- Advance software capability

(Deloitte Center for Health Solutions 2015a)

ICT-based monitoring and preventive medical self-care solutions are dependent on connectivity. They therefore rely on factors such as, but not excluded to, broadband speed (Deloitte Center for Health Solutions 2015b).

## Legal

The legal driver for medical devices deals with aspects such as how collected patient data is managed, and what factors constitute legal approval of said devices, e.g. CE-marking and approval of public agencies. CE-marking, or CE-certification, is a declaration that the product being sold meets all legal requirements, such as: high safety, health and environmental protection requirements (European Commission

2018a). There is however no requirement for clinical studies to have been conducted. For medium and high-risk products, an external notified body needs to carry out a conformity assessment, before the CE-marking can be affixed to the product. CE-markings do not only apply to medical devices, but also to other product categories such as televisions, toys and construction products (European Commission 2018b).

In the U.S., medical devices must be approved by the Food and Drug Administration (FDA) before they can be marketed. Low and medium-risk products require a Pre-Market Notification (PMN) approval, also known as a 510(k) clearance (FDA 2018a). High-risk products require a stricter approval known as a Pre-Market Approval (PMA) (FDA 2018b). Both 510(k) clearances and PMAs require clinical studies to be conducted. These legal aspects have proven to delay market entry for MedTech companies on the U.S. market. New products are obtaining clearance at a faster rate in Europe through the CE-marking than FDA-approval in the U.S. according to an industry survey conducted by the Northwestern University (PR Newswire 2011).

When a medical device has received a PMA-approval, any changes to the device require applicants to submit a so-called PMA supplement. Without an approval of the PMA supplement, changes are not permitted to be made. Changes or alterations to the device that require submissions of PMA supplements include, but is not excluded to: new intended use of device, labelling changes, changes in packaging and changes in manufacturing processes just to name a few. (FDA 2018c)

The healthcare sector in the U.S. is heavily financed by insurers. Insurers finance 75% of total national healthcare expenditure (Center for Medicare & Medicaid Services 2018). Creating reimbursement strategies is vital in the U.S. for MedTech companies if they wish to get paid for their products and solutions. A solid reimbursement plan includes three building blocks:

1. *Coding*. Coding is the ”language” used to identify what, where and how a medical device will be used in the care setting.
2. *Coverage*. The coverage refers to a payer’s decision to include the medical device in a benefit program or not. Public insurers, such as Medicare, and private insurers set up criteria that need to be met for coverage to apply.
3. *Payment*. Transfer of money from insurers to care providers, such as hospitals. Hospitals are always looking to cut costs while still improving care. Reimbursements must cover the hospital’s cost of use of the device.

(Diage 2013; The Atticus Group 2017)

In the EU, an approaching concern for companies who amass vast amounts of data is that of the new EU-directive General Data Protection Regulation (GDPR). The enforcement day for GDPR is the 25th of May 2018. The new regulation replaces the previous directive on data and privacy from 1995. Companies who do not comply with the regulation, are charged with a penalty of 4% of yearly revenue, or €20 million (whichever is larger). The most significant changes in the new directive are that people are given stronger rights in deciding how companies manage their personal data. As an individual, you have the right to access the data a company might store about you. You also have the right to demand that this data is forgotten, or erased. Additionally, in the case of a data breach, companies are obligated to inform individuals of this breach within the first 72 hours. (EUGDPR N/A)

Although not necessarily a legal requirement, companies can apply to be certified in ISO 13485. The standard specifies the requirements for a quality management system for organisations who need to demonstrate that their medical devices satisfy customer and regulatory expectations.

Understanding the dynamics of these legal key drivers and their effect on medical devices is proven to be crucial in the pursuit of identifying success factors behind market penetration and establishment of ICTMPMSCS.

## 3.4 Stakeholder Theory

*Stakeholder Theory is applied in order to gain an understanding on which stakeholders influence the adoption of medical devices, and how this is done.*

The World Health Organization (WHO) states the importance of identifying stakeholders. "*All potential consumers and contributors of health information need to be identified to improve the way health and social care will be delivered"* (World Health Organization 2016, p. 85).

### 3.4.1 The Model

Mendelow (1983) says stakeholders are "*judges of organizational effectiveness*" (Mendelow 1983, p. 70). Following this claim, organisations need to determine who its stakeholders are. Managers need to understand what stakeholders have the greatest influence over their operations, since this understanding will suggest to managers how they ought to allocate time and resources to different activities. At a high-level approach, Johnson, Whittington & Scholes (2012) suggest stakeholders can be divided into four overarching categories depending on the nature of their relationship with the organisation:

- *Economic stakeholders*. These include suppliers, distributors, shareholders and competitors.
- *Social and political stakeholders.* Stakeholders such as regulatory and government agencies impact the dynamics and context the organisation operates within.
- *Technological stakeholders*. These are stakeholders who influence diffusion of innovation and adoption of industry standards. Examples include standard agencies, owners of competitive technology and key technology adopters.
- *Community stakeholders.* Community stakeholders do not necessarily have a direct formal relationship with the organisation, but may in a wider sense be indirectly affected by the organisation's actions.

(Johnson et al. 2012)

Mendelow presents a two by two matrix explaining how organisations should manage different stakeholders (Mendelow 1986, see Johnson et al. 2012, p. 91). The two dimensions of the matrix are:

- The *interest* a stakeholder has in influencing the organisation's actions and behaviours.
- The *power* a stakeholder has over the organisation and the ability it has to influence the organisation to do certain things.

(Mendelow 1986, see Johnson et al. 2012, p. 91)
Each box in the matrix highlights a different strategy in regard to how much time and effort is to be focused on a specific stakeholder (see fig. 3.3).

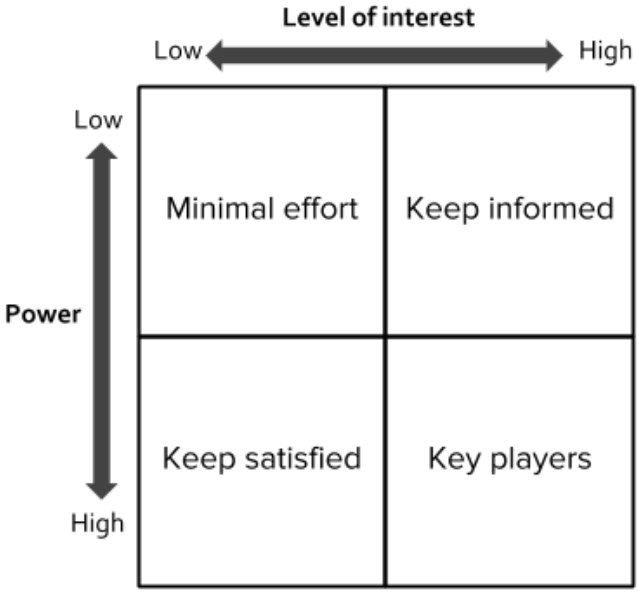


*Figure 3.3. Stakeholder mapping. Power/interest matrix as suggested by Aubrey Mendelow (1986, see Johnson et al. 2012, p. 91).*

### 3.4.2 Applying the Model

Understanding the roles and incentives of stakeholders within the MedTech industry is critical when identifying the success behind market penetration and establishment of ICTMPMSCS. Healthcare is from a stakeholder perspective, extremely complex with a range of service providers, care-recipients and financiers. As an example, Deloitte Center for Health Solutions (2015b) identify HCPs as a stakeholder who may prove to be reluctant to adopting new digital and ICT-based self-care solutions. There are also a few indirectly engaged stakeholders. Biopharma, researchers and educators may not necessarily have a stake in the ICTMPMSCS itself, but have an interest in the data generated by patients using their self-care solutions (Lupton 2014).

## 3.5 Diffusion of Innovation

*In accordance with the notion of success, the market's susceptibility of a medical device is fundamental in whether the device should be viewed as successful or not.*

*Roger's Diffusion of Innovation will be used to gain an understanding how products are received on a market.*

## 3.5.1 The Model

The theory of Diffusion of Innovation is used to describe how a new innovation is spread through a social system and at what rate different groups adopt innovations (Rogers 1983). Rogers defines the rate of adoption as *"the relative speed with which an innovation is adopted by members of a social system"* (Rogers 1983, p. 240).

Individuals in a social system adopt an innovation at different rates. There are five attributes which influence the perception of the innovation and determines the rate of adoption. These attributes are the innovation's:

1. *Relative advantage.* The degree to which an innovation is perceived as better than the idea it supersedes. The relative advantage of an innovation, as perceived by members of a social system, is positively related to its rate of adoption.
2. *Compatibility.* The degree to which an innovation is perceived as consistent with the existing values, past experiences, and needs of potential adopters. The compatibility of an innovation, as perceived by members of a social system, is positively related to its rate of adoption.
3. *Complexity.* The degree to which an innovation is perceived as relatively difficult to understand and use. The complexity of an innovation, as perceived by members of a social system, is negatively related to its rate of adoption.
4. *Trialability.* The degree to which an innovation may be experimented with on a limited basis. The trialability of an innovation, as perceived by members of a social system, is positively related to its rate of adoption.
5. *Observability.* The degree to which the results of an innovation are visible to others. The observability of an innovation, as perceived by members of a social system, is positively related to its rate of adoption.

(Rogers 1983, pp. 238-240)

In order to describe how an innovation can be expected to be adopted, individuals are divided into five different groups, where individuals in the same group can be considered to possess the same degree of innovativeness (see fig. 3.4). The adopter categories, in the order they adopt new innovations, are:

- *Innovators* are the individuals who are the most eager to adopt new innovations. They represent 2.5% of the total market.
- *Early adopters* represent 13.5% of the total market. They are looking to decrease uncertainty of the innovation and are doing so by adopting it.
- *Early majority* adopt innovation before an average individual in the social system and represents 34% of the market.
- *Late majority*. The individuals within this category are sceptical and adopt new ideas just after the average individual, the reasons for adopting the new idea is often economical or pressure from surrounding network. Late majority represents 34% of the total market.
- *Laggards* are suspicious of new ideas and prefer the old ways of doing things. This category represents 16% of the market.

(Rogers 1983)

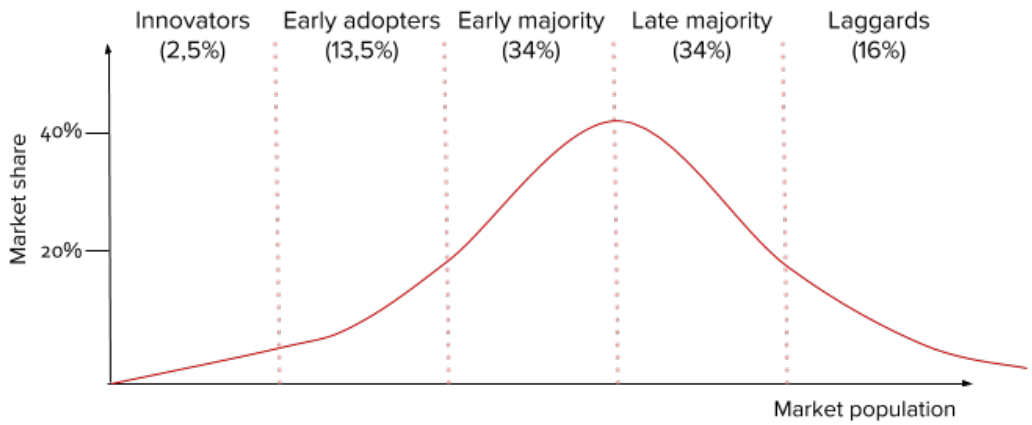


*Figure 3.4. Diffusion of Innovation, as suggested by Rogers (1983).*

## 3.5.2 Applying the Model

At this time, there is no evidence to verify the effectiveness of some of the emerged technologies. A report from the consulting firm McKinsey & Company suggests that more than 75% of the respondents from their survey are positive to the usage of digital service aid within the healthcare sector, given the services meet their need and expectation of quality service level (Biesdorf & Niedermann 2014). Additionally, by applying the Diffusion of Innovation theory those not yet willing to accept digital services might change their minds as the adoption gradually takes place.

Since ICTMPMSCS will in some cases be used by HCPs it is important to study their adoption rate. As previously mentioned, HCPs are often reluctant to adopting new technology. According to Deloitte Center for Health Solutions (2015b) this is due to development pace and scale, but also because of lack of training and education in how to deploy these new technologies in a clinical setting. HCPs also find concerns with new technologies' quality, privacy, security, and data overload (Deloitte Center for Health Solutions 2015b), which might cause the Diffusion of Innovations to slow down. The concerns raised by HCPs might all be reasons as to why diffusion of new technologies stagnates. However, the adoption of technological innovation is a considerable dimension in the healthcare industry as it affects the cost, care, quality and competitive position (Ghodeswar & Vaidyanathan 2007).

# 3.6 Crossing the Chasm

*As a new technology enters the market it is crucial that it not only enters the market but is also further adopted. The theoretical framework of Crossing the Chasm will be used in order to analyse how companies overcome market barriers and what methods are used in order to facilitate the market susceptibility of a medical device.*

## 3.6.1 The Model

The theory of Crossing the Chasm originates from Diffusion of Innovations described in 3.5.1. The bell curve in figure 3.4 offers a fairly good representation of how customers adopt new innovations. However, in reality the bell curve contains cracks, and more importantly a chasm between early adopters and early majority (see fig. 3.5). This chasm has emerged because early adopters and early majority are adopting innovations for different reasons. Early adopters are hoping to gain a competitive advantage while the early majority want productivity improvements for already existing operations. The differences result in the fact that an early adopter is not a good reference for the early majority, when considering the innovation. There is a need for organisations to bridge the two categories in order for the innovation to survive. This is known as crossing the chasm. There are four steps in crossing the chasm:

1. *Target the point of attack*: Select a specific market niche and focus all resources on becoming the dominant leader in this segment.

2. *Assemble an invasion force*: Create one whole product and involve customer's problems and how the product will solve these problems. Create a product that is compelling to buy.
3. *Define the battle*: Create strategies of how to manage and beat competition.
4. *Launch the invasion*: Establish strategies regarding pricing and distribution.

(Moore 2001)

Moore (2001) explains that in order to fully cross the chasm, companies must expand into nearby niche-markets once they have become the dominant leader in their initial market. From there, new niche-markets eventually help the company reach the entire mass-market.

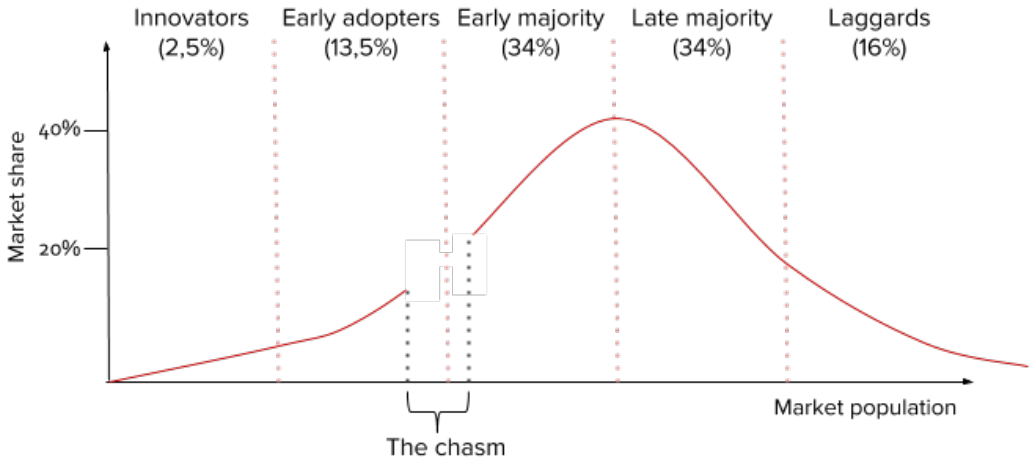


*Figure 3.5. Crossing the chasm. The chasm represents the difficulty companies experience in reaching the early majority.*

## 3.6.2 Applying the Model

In addition to what has previously been mentioned in section 3.3.2, political and regulatory decisions can act as barriers and stop the new technology to spread between customer segments.

Deloitte Center for Health Solutions (2015b) suggests the importance of including variables characterised by trust and legitimacy when trying to overcome barriers. Companies providing technology enabled care should for example: establish trust of data privacy and security; let patients control their own data; develop solutions and

design together with HCPs, patients and carers. A reference case published by consultancy firm Tieto (2011) presents the successful implementation of an integrated digital care and self-care system focused on chronically ill patients. The focus on a niche group, in this case patients with chronic conditions, is in line with the strategy of how to cross the chasm defined by Moore (2001). An article by PR Newswire (2011) suggests that American MedTech companies enter the European market prior to the U.S. market because of the hard regulations set by FDA in addition to long U.S. review. This essentially means many U.S. based companies seek regulatory clearance outside the U.S. border as a way to cross the chasm faster.

A strategy to mitigate risk concluded by Llewellyn, Podpolny & Zerbi (2015) is to pilot new products and business models in one specific market as a way to gain customer and competitive insights which can help to refine new strategies. These new strategies can later be used on other markets where the product or business model can spread. Further, consultancy firm Boston Consulting Group point out six steps in order to describe how to transform a MedTech commercial model. The six steps show a resemblance to the theory of Crossing the Chasm, both in selecting a target group, creating a business case around the product and differentiating the product to gain competitive advantages (Boston Consulting Group 2018).

# 3.7 Product Life Cycle

*In addition to understanding the market's susceptibility to new products, there is also a need to identify factors determining whether medical devices stay competitive on the market or not. The Product Life Cycle will be used to analyse the medical devices throughout different period of times through its life cycle.*

## 3.7.1 The Model

The concept known as Product Life Cycles (PLCs) is not a new phenomenon. It has been described by several different authors, each presenting the model in a slightly different manner based on who the targeted audience has been. The model identifies four market stages a successful product goes through (see fig. 3.6):

- *Market development.* Initial launch of the product. Sales are generally low.
- *Market growth*. Demand for the product increases.
- *Market maturity*. Demands stabilise.

- *Market decline.* Market sales start diminishing. Consumer-appeal grows weaker, potentially due to rise in popularity of a substitute product.

(Levitt 1965)

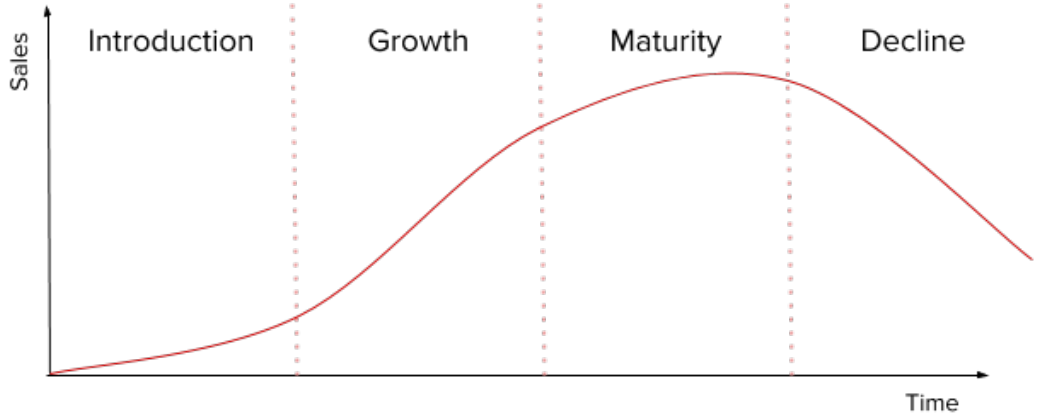


*Figure 3.6. The Product Life Cycle. Illustrates how sales of a product typically change over time.*

## 3.7.2 Applying the Model

The PLC-model describes how a successful product's market demand increases and decreases during a period of time, starting with the initial date of the product launch. The British Standards Institution (BSI) suggests a product development lifecycle (see fig. 3.7), which focuses on the stages of bringing a medical device to the market rather than looking at the product's rise and fall in market demand as the more traditional model does (BSI 2018). The product development lifecycle consists of six phases:

- *Phase 1: Concept.* Is it possible to develop this product and would it be commercially viable?
- *Phase 2: Planning.* Defines the needed input for development and commercialisation, such as customer needs and technological requirements.
- *Phase 3: Design.* The design of the product starts to take shape. User feedback facilitates the process. Manufacturing process is designed and verified.
- *Phase 4: Validation.* The manufacturing process is in a final instance completely validated, and preparations are made for product launch. Regulatory submissions are made, e.g. to obtain the CE-marking.
- *Phase 5: Launch.* Products are approved in accordance to FDA and CE-markings. Sales-personnel and clinicians are given proper training.

- *Phase 6: Post-market.* Follow-up on the product's establishment on the market. User complaints are dealt with. Product improvements are made. External third-party bodies conduct audits. Products are launched on new markets.

(BSI 2018)

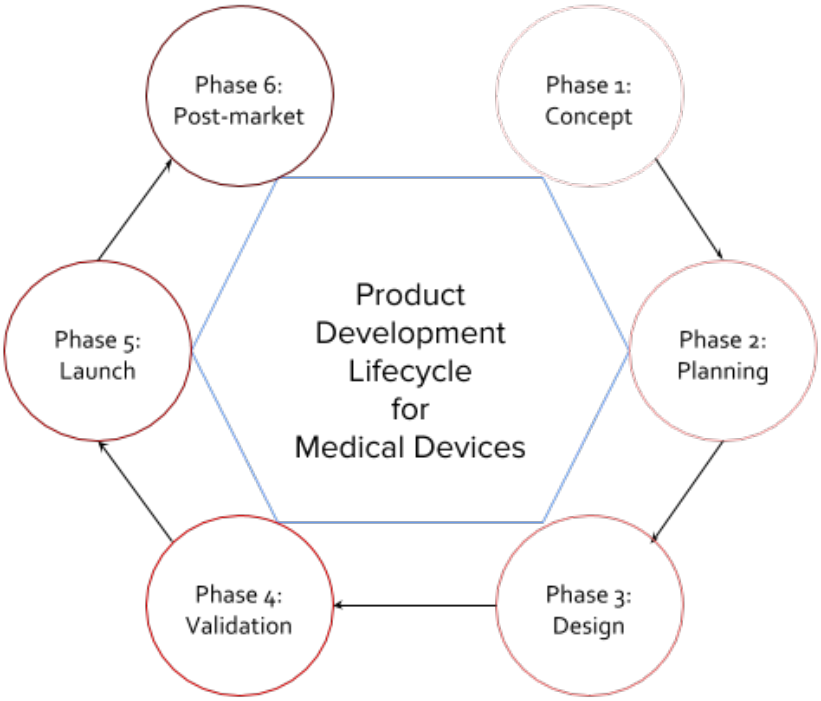


*Figure 3.7. The Product Development Lifecycle for Medical Devices. Adapted from BSI (2018).*

For this study, the product development lifecycle as presented by BSI, is further simplified by narrowing the six phases down to three (see fig. 3.8): Development phase, To-market phase and finally the Post-launch phase. Phase one to three in the BSI product development lifecycle are all considered to be part of the 'Development' phase in this simplification. Phase four and five of the BSI model are represented by the 'To-market' phase, and Phase six in the BSI model is represented by the 'Post-launch' phase. The 'Development' phase will focus on how the idea behind the product was born, and what parties were involved in the development of the physical self-care solution. The 'To-market' phase focuses on those internal activities and macro-environmental conditions that determine how the self-care solution is brought to market. This includes, but is not excluded to, the choice of customer, choice of

channel, potential partnerships and regulatory market barriers such as CE-markings. The final phase, 'Post-launch', focuses on entering new geographical markets, expanding to new customer segments as well as maintaining and increasing current market shares.

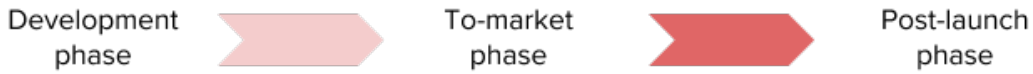


*Figure 3.8. The three phases for market penetration and establishment of medical devices.*

# 3.8 Theoretical Framework

*The theories and models presented in chapter 3 are here aggregated to form the theoretical framework specifically designed for this study. The theoretical framework is used to analyse the collected empirics.*

The ICTMPMSCS' path to market penetration and establishment is divided into the three suggested phases in chapter 3.7.2 'Product Life Cycle: Applying the model': Development phase, To-market phase and Post-launch phase. Each phase is analysed by looking at three pillars: the specific industry dynamics & macro environment, the company internal aspects, and finally the market network.

- *Industry dynamics and macro-environmental analysis.* Analyses what macro-environmental forces shape the industry the studied case operates within. These forces include those that are regulatory, social, technological and political as described through chapter 3.1 'Identifying Success' and chapter 3.3 'PESTEL', and affect all companies within the industry. Industry dynamics may differ depending on what geographical market the product is marketed on.
- *Internal analysis.* The internal analysis focuses on what activities each company has pursued and what decisions it has had to make. The internal analysis builds upon the Business Model Canvas discussed in chapter 3.2.
- *Market network analysis.* The market network analysis seeks to gain an understanding of the interplay between those stakeholders who have an active commercial interest in the ICTMPMSCS studied for each case, and how this interplay controls the adoption of the studied self-care solutions. These stakeholders are generally the patients, HCPs and any additional channels who

may be involved in the sales of the ICTMPMSCS. Finally, it also seeks to understand the interplay between these stakeholders and the company offering the ICTMPMSCS. The market network analysis builds upon Stakeholder Theory described in chapter 3.4 along with chapter 3.5 ‘Diffusion of Innovation’ and 3.6 ‘Crossing the Chasm’. Utilising these three models simultaneously gives an understanding as to how patients, HCPs and channels influence the adoption of studied ICTMPMSCS. The stakeholders and their roles may differ depending on what geographical market they operate on. As the market network analysis is used to understand how involved stakeholders drive the adoption of the ICTMPMSCS, it is not included during the Development phase.

It should be noted that the three pillars of the analysis are highly interconnected, not necessarily mutually exclusive. As an example, changes in industry dynamics can have a direct effect on company internal decisions. Similarly, stakeholders within the market network can exert their collective strength to alter both industry dynamics as well as company internal activities. What constitutes as vital factors for market establishment may change over the passing of time. In conclusion, it is important to see these pillars as a whole and not as isolated phenomena, along with the incorporated aspect of time. A visualisation of the theoretical framework is presented below (see fig. 3.9).

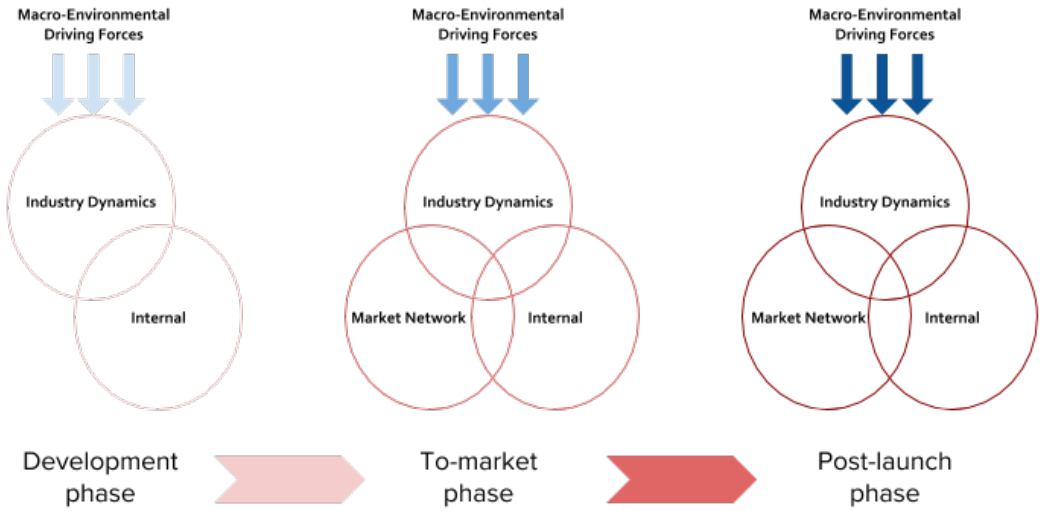


*Figure 3.9. Theoretical framework used for this study. The collected empirical data will be analysed using this theoretical framework along with its fundamental models and theories described in chapter 3.*

# 4. Empirics - Industry Insights

*This chapter presents insights offered by industry experts (see table 4.1). The promises, barriers and trends of the ICTMPMSCS industry are given in the words of these industry experts.*

| Name | Title | Company | Background |
|---|---|---|---|
| Per Trossmark | CEO | Respiheart | Respiheart is a medical device for the measuring and monitoring of several vital parameters, such as breathing. |
| Niklas Sundler | Business Unit Manager Cloud Services | Axians | Vast experience from the healthcare sector and industry. First as CIO at Region Skåne and then as Business Developer Executive Healthcare at Telia Company. |
| Johan Feltner | Project Manager - Service Development | SCA | Currently working with TENA Identifi, a medical device that aids elderly care professionals by providing fact-based investigations on patient's incontinence troubles. |

*Table 4.1. Industry experts. The industry experts who contributed with their insights to this study.*

According to Per Trossmark[3], the possibility for patients to care for themselves through the use of ICTMPMSCS could imply great reductions in cost for the healthcare sector. Trossmark has seen how monitoring self-care solutions can lead to fewer visits to primary care. Additionally, he predicts ICTMPMSCS will be able to achieve a high

[3] Per Trossmark, CEO at Respiheart, phone call the 16th of February 2018

level of diagnostic quality. For the patient, this would mean that he or she would not have to come back for recurring visits. Trossmark also believes that monitoring self-care solutions can help patients take better care of themselves. When patients see how their health improves, or impairs, it can create incentives to lead a healthier lifestyle.

Although the upsides of ICTMPMSCS are apparent, the market for the solutions is not there quite yet. Trossmark means processes in today's healthcare are slow and conservative. Decision making and purchasing mechanisms are lengthy processes. Niklas Sundler[4] contributes with his thoughts on this. His assessment is that at least Swedish healthcare is highly proficient when it comes to acute care, but not when it comes to preventive care. Trossmark reckons in order for preventive solutions (such as ICTMPMSCS) to be adopted, companies developing these solutions need to work closely with HCPs. It is often the physician who first has to make a diagnosis before referring the patient to a certain medical device, Sundler adds.

Sundler, Trossmark and Johan Feltner[5] all highlight the issue of who should pay for the ICTMPMSCS. Trossmark means the issue derives from the fact that patients themselves expect to receive beneficial self-care solutions as part of the healthcare system. For Sundler it is a question about compensation models. Stakeholders within healthcare all want to experience the reduction in cost induced by the implementation of ICTMPMSCS, but few are willing to finance it to start off with. Feltner believes it may be necessary for MedTech companies offering ICTMPMSCS to manage several business models for the same product, simultaneously. As an example, he says one cannot solely rely on sales through municipal public procurements, one may have to go through the county's procurement processes as well. He also adds that the same product may need to go through different channels depending on what geographical market you target. In Sweden, Feltner reckons going through primary care units is a wise choice because patients are highly dependent on their physicians, whereas in parts of southern Europe patients are more frequent visitors to pharmacies. In these countries, direct sales through pharmacies may prove more successful than promoting the product via primary care units. Sundler adds to this reasoning by pointing out the situation in the U.S. Insurance companies are willing to keep their customers healthy

[4] Niklas Sundler, Business Unit Manager Cloud Services at Axians, phone call 2nd of March 2018
[5] Johan Feltner, Project Manager - Service Development at SCA, phone call 7th of March 2018

through the use of monitoring and preventive solutions, in order to avoid paying for more urgent treatments as these often are significantly more expensive.

Sundler also speculates that depending on who the solution is designated for, incentives to pay for it may differ. He believes parents are willing to pay out-of-pocket for ICTMPMSCS which aid their children. However, if the solution is designated for themselves, they will expect the healthcare system, or insurers, to provide and finance the solution for them.

# 5. Empirics - Case Studies

*In this chapter, each case study is presented individually as its own subchapter. Each subchapter begins with a short background of the studied case company in order to create an understanding and give context to the ICTMPMSCS and situation. The disposition is then divided into three phases as suggested by the Product Life Cycle in chapter 3.7.2: Development phase, To-market phase and finally the Post-launch phase. Further, each phase is divided into the external and internal aspects that have shaped the company and its ICTMPMSCS. External aspects highlight what has happened outside the company, whereas the internal aspects focus on what activities the company has pursued and the decisions it has had to make. The disposition of each case is visualised in figure 5.1.*

The case studies were conducted through interviews and secondary data from relevant sources. The selection of case companies was based on the sampling criteria set up in chapter 2.2.2, under *Sampling*. The interviewees from each company were individually selected based on their background within the company (see table 5.1). Empirical data collected through these case studies will be analysed in the next chapter by applying the theories discussed in chapter 3.

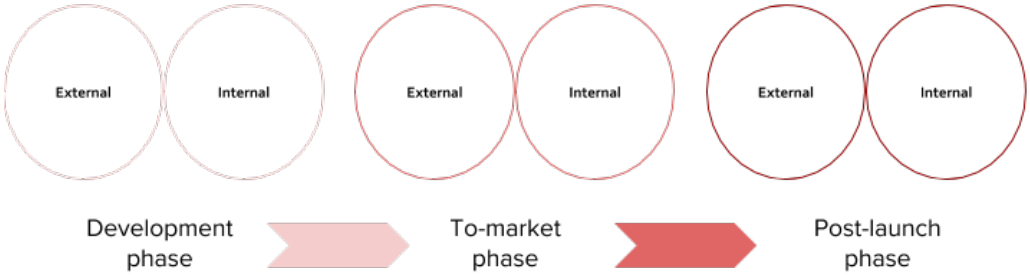


*Figure 5.1. Disposition of case studies. The disposition of each case in chapter 5.*

| Company | Name | Title | ICTMPMSCS |
|---|---|---|---|
| Coala Life | Philip Siberg | CEO | Coala Heart Monitor.<br><br>A portable ECG used by the patient. |
| Dexcom | Peter Gerhardsson | Vice President - International Business Development | Dexcom G5 CGM System.<br><br>A continuous glucose monitor for diabetics, connected to a smart phone. |
| Diasend | Anders Sonesson | VP EMEA at Glooko (Diasend merged with Glooko in 2016) | diasend® Personal and diasend® Clinic.<br><br>An analysis tool, managing data of diabetics' glucose levels. |

*Table 5.1. Interviewees of case studies. The interviewees of this study and their respective company and ICTMPMSCS.*

# 5.1 Coala Life

## 5.1.1 Background

In 2001, a group of IT specialists and medical students discussed problems related to heart monitoring and the difficulties of listening to heart sounds. Heart problems are some of the most common causes of death. In spite of this, physicians continue to use a tool which has not been updated since the 1930s, namely the stethoscope (Coala Life 2018). Since diagnosis through a stethoscope are subjective, the physician's professional experience will be vital. In addition, it is difficult to compare heart sounds that have been observed at different times and by different physicians. An idea of creating a digital stethoscope, with the possibility to gather data was born and so was the journey of what in 2004 became Coala Life (Coala Life 2018).

Today, in 2018, Coala Life offers two products: Coala Heart Monitor and Coala Heart Monitor Pro. Coala Heart Monitor uses digital technology to register and digitalise heart sounds along with sensors to measure ECG (Coala Life N/Aa). The Coala Heart Monitor is used by patients who want to regularly monitor their own heart, as a means to feel secure about their health. Coala Heart Monitor Pro is developed specifically for the healthcare sector and uses both chest and thumb ECG for more accurate measurements in addition to the digital heart sound surveillance (Coala Life N/Ab). Both devices are connected to an external healthcare operator, MedHelp, which provides advice to the patient if needed. Coala Heart Monitor is distributed through Coala Life's webshop as well as LloydsApotek and can be combined with several different subscriptions (Coala Life N/Aa).

## 5.1.2 Development Phase

### External

In 2015, Swedish studies presented results of preventive EGC screenings. The studies showed that preventive ECG screening resulted in both more and earlier detection of atrial fibrillation. (Coala life 2018)

During the development phase, Coala Life was dependent on external operators. The company had developed partnerships with Stockholm Heart Centre, Microsoft, Sigma Connectivity and Ericsson. Philip Siberg[6] describes that Coala Life provided the ideas and concepts, however the technical consultancy firm Sigma Connectivity would be the one to develop a physical product along with the required sensors. In addition to the dependency on Sigma Connectivity, there were technical necessities which made Coala Life depend on a manufacturing license from Apple, which took approximately three months to obtain. Further, Coala Life's app needed to be approved by Apple in order to be sold in The App Store, this took an additional three weeks. There were also other external tests such as electrical safety tests which needed to be conducted. These tests were both expensive and complex. Out of all barriers Coala Life needed to overcome, Philip Siberg implies the regulatory activities were the most time consuming.

[6] Philip Siberg, CEO at Coala Life AB, phone interview 26th of March 2018

### Internal

None of the founders of Coala Life had any personal history with cardiovascular diseases. However, one of those involved in the foundation was a cardiologist who had expressed a need for better equipment. In an early stage, focus lay on developing sensors. In order to do so, several people were involved such as scientists from both Linköping and Lund who experimented with different methods. The first generation of Coala was developed in 2007 and the same year, Coala Life had its first patents approved. Some years later, in 2013, the fourth generation's technology platform was developed, making it possible for Coala to concurrently digitalise heart sounds, perform ECG on the chest and conduct cloud based analysis (Coala Life 2018). One year later, the fourth-generation technology platform was verified and the company got a new patent. Further, Coala has developed into a MedTech system, representing an innovative e-health service working together with caregivers (Ibid).

Philip Siberg describes how Coala Life raised venture capital in different rounds and worked towards specific goals in each round. First when a goal had been achieved, they set up new goals and raised more capital. Time to market was an important metric which Coala Life had set up together with the investors.

## 5.1.3 To-Market Phase

### External

Coala Heart Monitor obtained a CE-marking in 2016. The same year, Coala Life received an ISO 13485 certificate.

Philip Siberg identifies four key stakeholders to the Coala Heart Monitor, and their different incentives for adoption of the product.

1. *The customer*. The customer uses the heart monitor to calm his or her worry, gain an understanding of the heart and to amass data. Should anything happen to the customer, having historical monitored data of the heart facilitates continued treatment.
2. *The healthcare sector*. The healthcare sector benefits from Coala Heart Monitor by attaining faster and smarter digital cardiac investigations. The alternative for the Swedish healthcare sector to using the Coala Heart Monitor

is a lengthy process. The process starts with the patient visiting his or her primary care physician. All patients who state they have experienced heart irregularities are sent on referral to a specialist, a cardiologist. This can take up to three months. The cardiologist then performs a traditional ECG, a method and equipment that according to Siberg has not changed since the 1960s. In 50% of the cases, a second ECG needs to be performed at a later instance. The patient then receives an answer about one month later. All in all, it could add up to six months from the time of the first visit in primary care until the answer has been received. With the Coala Heart Monitor, the cardiac investigation can be done from home. The analysis usually takes two weeks to process. If the results indicate any severities, the patient can then be sent to a specialist on referral from the primary care unit. Not everyone experiencing heart irregularities is actually in need of a specialist. The Coala Heart Monitor can pinpoint who as a matter of fact needs to visit a specialist for treatment. This leads to fewer people being sent to specialists, freeing up time and shortening waiting times for those who truly require specialist assistance.

3. *Insurance companies*. Insurance companies have incentives to provide their clients with the Coala Heart Monitor, in particular clients with e.g. high blood pressure. The insurance companies may have to conduct investigations on clients with health insurance. The Coala Heart Monitor is in this case a faster and cheaper alternative than making the client go through the tedious process described above. Should something happen to the client, the data collected by the heart monitor can be analysed to see what has happened. The more data collected, and the more clients who use the Coala Heart Monitor, the easier it becomes for insurance companies to analyse and make predictions. Siberg does not rule out the possibility that insurance companies might even be interested in paying for the Coala Heart Monitor themselves.
4. *Research institutes.* Coala Life has built up the largest database of ECG and heart sound data. Researchers who want to crack the code behind cardiovascular diseases have an interest in the data Coala Heart Monitor generates. Coala Life has already been in touch with a few institutes.

## Internal

When Coala Life first launched their product Coala Heart Monitor in 2017, they chose to do so by directly targeting the consumer. Coala Life partnered up with LloydsApotek, a Swedish chain of pharmacies. There had been no doubts that targeting

consumers directly was the appropriate action. It was reckoned physicians and HCPs already had all their processes in place, and because of the conservative mindset in healthcare, Coala Life made the active decision to avoid HCPs as customers. Selling its product through solely one channel, the pharmacies, allowed Coala Life to quickly gain market traction given their available resources. Philip Siberg means it was more rewarding for the company to only pursue one strategy during market entry. Internal resources to pursue more than one strategy simply were not available at the time.

After the development phase came to an end and Coala Life went to market with their heart monitor, the team grew significantly in size. Siberg believes the greatest factor behind their successful market entry was the collective strength of the team. Coala Life had managed to assemble a multi-disciplinary team of dedicated workers specialising on product development, overcoming regulatory barriers and marketing.

## 5.1.4 Post-Launch Phase

### External

Users of Coala Heart Monitor are proving to be an important player when it comes to the spread and rate of adoption of the product. What they have done is brought the product to their physicians. After this, physicians started directly contacting Coala Life saying they too were interested in the product. Siberg speculates that patients have a need to check in with their physicians on most matters regarding healthcare, and therefore they sought their physicians' opinion after having purchased a Coala Heart Monitor.

Philip Siberg is of the opinion that processes in the healthcare sector are still conservative and not too likely to change rapidly. The healthcare sector has become used to being the center of attention, and Siberg means processes are not patient-centric. He predicts patients will in time convince their physicians to change their current methods. The patients can have a strong influence and bargaining power. Innovation does not take place within the healthcare sector, but rather in small companies and startups. The entire MedTech market is seeing an increase in venture capital investments. As patients adopt these company-innovated solutions, they exercise their influence and bargaining power on the healthcare sector to incrementally adopt the solutions. Siberg believes that if structural changes are to be made in the

adoption of preventive MedTech solutions, such as ICTMPMSCS, it has to begin with the patients acting as customers and influencers. It would take too long to rely on politics to realise necessary changes. Additionally, patients have incentives for the healthcare sector to adopt ICTMPMSCS, since they ultimately are the ones who finance the healthcare sector through taxes.

## Internal

As Coala Life has gained market traction, the company has moved from product development and refinement to activities revolving around commercialisation. Six months after initial market launch through direct customer sales at pharmacies, Coala Life has now started targeting physicians and hospitals. Their biggest client is Lund University Hospital, but several smaller clinics have also joined in. In contrast to the strategy during initial market entry, Coala Life is now pursuing sales through two channels simultaneously: selling directly to the customer and selling to hospitals & clinics. The heart monitors sold by Coala Life are still considered relatively cheap, and they have therefore been able to sell directly to hospitals and clinics without going through public procurement processes. Siberg says the two parallel channel strategies help build one another. The Coala Heart Monitors purchased by clinics and hospitals are lended to patients who suspect they're having heart irregularities. Depending on the result from the test, the patient is either sent on referral to a specialist or no action is necessary to take.

Focus now is on further commercialisation and efforts are made to encourage customers to adopt the Coala Heart Monitor. As the team has gradually mobilised, activities that previously had been conducted by external parties have now been integrated in the company's internal operations. Coala Life is working on new product bundling options together with external partners. Including the heart monitor in health insurance is one such bundling option that has been up for discussion.

But expansion is no easy task. In order for Coala Heart Monitor to succeed with its expansion, Philip Siberg singles out six important aspects:

- There needs to be a solid scientific foundation supporting the product.
- The product must be easy to use and practically useful.
- It must be able to demonstrate economical benefits, such as cost reductions in the healthcare sector.
- It should keep its promise of intended use.

- It needs to be adapted to entire teams of physicians, nurses and administrators. It has to work for all parties involved within healthcare.
- The company needs to be backed up by competent, dedicated investors who are in it for the long run.

Coala Life has provided proof of concept of the product on the Swedish market for both private use as well within the healthcare sector. The next step is to expand internationally to new geographical markets. Coala Life is currently pursuing expansions within Europe as well as overseas in the U.S. For the U.S. market, Coala Life has hired an external reimbursement expert, i.e. a party specialised on developing appropriate reimbursement strategies for the Coala Heart Monitor. Philip Siberg points out that as soon as they receive the FDA approval, they will be ready to launch the heart monitor in the U.S. with an appropriate reimbursement plan.

Philip Siberg sees possibilities to further develop the product by adding additional sensors, more advanced algorithms and by incorporating machine learning.

# 5.2 Dexcom

## 5.2.1 Background

In 1967, American researchers successfully managed to measure the level of blood glucose by measuring the electric current caused by the reaction of glucose and an enzyme, helping diabetics to keep track of their glucose levels. However, it was not until 1999 researchers realised it was possible to continuously monitor blood glucose levels, and the first Continuous Glucose Monitor, MiniMed, was born. Dexcom was founded the same year. The following years, Dexcom worked dedicated with product development and commercialisation. The company launched its first CGM-solution in 2005. A few years later, in 2008, Dexcom started its internationalisation. As of 2018, Dexcom has developed several global partnerships and as a result Dexcom's solutions are now represented all around the world, with headquarters situated in San Diego.

In 2015, Dexcom launched its fifth generation of CGM, the Dexcom G5 CGM System. It became the first and only fully mobile CGM system at the time to monitor the patient's own glucose levels from a compatible smart device, such as a smartphones or

tablet (Dexcom 2018a). Unlike a blood glucose meter (BGM) or Self-Monitoring of Blood Glucose solutions (SMBGs), CGM offers the patient real-time monitoring of glucose information, with updates every five minutes. The Dexcom G5 CGM System consists of three parts: A small sensor, placed under the skin; a transmitter, able to wirelessly send information on glucose levels to a display; a receiver or smart device that displays real-time blood glucose levels. The patient can set individual alerts, warning the patient when glucose levels reach critical highs or lows (Dexcom 2018b). Dexcom G5 makes it possible to share the real-time data of blood glucose levels with up to five other devices, thereby enabling family members to continually track and monitor the patient's wellbeing (Dexcom 2018c).

After Dexcom's launch of the G5 CGM System in 2015, the company has ranked as one of the top 50 health care equipment and services companies based on profit growth in the world. In 2016/2017 the company reached an impressive 11.9% profit growth (European Commission 2017a), along with a 42.6% growth in total sales during the same period of time, ranking the company as one of the top 10 health care equipment and services companies based on sales growth (European Commission 2017b).

## 5.2.2 Development Phase

### External

In order for the G5 to exist there was a need for the developed mobile telephone technology of today. Peter Gerhardsson[7] has noticed a shift in the industry. Earlier, focus lay on biochemical development, particularly revolving the membrane. Now focus has shifted to the development of electronics and digitalisation. Data generated by the medical device can first be of use for the doctor after the patient has agreed to share it. Gerhardsson implies the underlying reason is the Swedish law regarding patient data[8] (Patientdatalagen). Gerhardsson further describes that some physicians have been unwilling to use the product in fear of being overloaded with data. As a result, Dexcom added a feature to give physicians the opportunity to download the data when necessary, given the fact that patient has given consent.

[7] Peter Gerhardsson, Vice President International Business Development, Interview 5th of March 2018
[8] Patientdatalagen, SFS 2008:355

### Internal

Gerhardsson implies some of Dexcom's success originates from the company's talented developers who have carried out most of the product development inhouse. Dexcom has patented the membrane attached to the sensor of the product. This membrane, which determines the accuracy of the measurement, has historically always been better than those of competitors, Gerhardsson claims. Gerhardsson argues the introduction of CGM in 1999 was a disruptive technology, but since then development has been incremental. However, he believes Dexcom's most recent product, the Dexcom G5 is a disruptive innovation. It feeds information directly to a smartphone, making it possible to monitor glucose levels in real-time and in addition share this information with close ones.

## 5.2.3 To-Market Phase

### External

Gerhardsson spontaneously refers to Rogers' model, implying that the adoption of Dexcom's products follow the Diffusion of Innovation with the explanation that early majority want evidence that the product actually works. This evidence is not only needed in theory. According to Gerhardsson the majority wants to know why they should pay more money for something they do not know will help the patient, or why this new concept is better than the old one.

Gerhardsson has noticed a rapid development of MedTech companies but slow processes among the notified bodies and certifying organisations. As a result, the time between product development and a certified product will be long. Applying for a CE-marking is the first step in order to obtain an approved MedTech device in the EU, and is often followed by national regulations. If a product is not approved in the targeted market, market penetration will be slow and the financial situation will become extremely vulnerable, at least when dealing with CGM according to Gerhardsson.

In Sweden, CGM is procured by county councils and since the procurement takes place at a regional level, several regions must be targeted in order to gain national market coverage.

Gerhardsson states that it is somewhat less time-consuming to obtain a CE-marking than an FDA approval which makes it possible to enter the European market before the U.S. market. Further Gerhardsson argues that companies can learn a lot from the preparations of the CE-marking process which later can be used when applying for FDA approval.

In addition to the differences in national regulations, market penetration depends on the financiers in each market. In England, Dexcom's product is used in clinics but the patients have to finance it themselves. Gerhardsson further describes how national conditions differ. Sometimes the healthcare sector finances it, and sometimes the patient has to pay for it. In the U.S. market, insurance companies often finance the CGM devices since they substantially reduce cost of treatment. It might be less expensive to finance a CGM than to treat the same patient for hypoglycaemia. In spite of this fact, CGM has not attained full market penetration. Approximately 10-20% of all type 1 diabetes patients in the U.S. use a CGM according to Gerhardsson.

CGM gained a foothold on the Swedish market after patient groups in the southern region, Skåne, pushed the county councils to fund CGM for their children. As a result of the patient groups' action, physicians started realising the benefit of CGM, Gerhardsson describes. When aiming to attract families and children, Gerhardsson implies the importance of addressing emotional aspects, specifically focusing on how CGM can facilitate the daily life of families who have children suffering from diabetes.

## Internal

In order to prepare for regulatory barriers, Dexcom has a *Market Access* team specialised in entering new markets. Further, Gerhardsson argues the importance of upholding a good relationship to the notified bodies, since this might make it easier to get the products approved. Dexcom first launched CGM in the U.S. and managed all sales in this market by itself. When Dexcom later decided to expand globally, the company built the sales upon partnerships and distributors, a result of a relatively limited budget. In 2016, Dexcom started setting up their own sales organisation in Germany, England, Ireland, Switzerland and Austria, similar to the already existing one in the US. In Sweden, Dexcom has a partnership with Infucare, who manages all sales for the Swedish market. When Dexcom's product entered the Swedish market Infucare decided to focus directly on the patient instead of the healthcare who considered the product to be too expensive, Gerhardsson adds.

## 5.2.4 Post-Launch Phase

### External

Gerhardsson believes it is vital to join the technological development. One example is how Dexcom developed their newest product G5 and incorporated technology which made it compatible with smartphones. Further technological development is possible as a result of Dexcom's open data platform. Dexcom's sales of sensors are increasing as new businesses are invited to develop monitoring software from the data provided by Dexcom.

CGM leads to fewer hypoglycaemias which cost a lot for the healthcare sector. A decreased number of hypoglycaemias will lower emergency and ambulance care costs. Gerhardsson argues CGM will implicate cost savings in healthcare. Cost savings which are easily proven. However, long term effects of hyperglycaemia might not emerge until 20 years later. Since no one has knowledge of such distant budgets, no one is willing to take responsibility for this, Gerhardsson continues.

### Internal

The launch of CGM has taught Dexcom that physicians can put pressure on county councils if they like a specific product. This facilitates public procurement processes for MedTech companies.

Dexcom is according to Gerhardsson focused on continuous development of the products. At this moment Dexcom is developing a product together with Google which is aimed to attract the large mass-market. It will be based on similar technology as the one used today, but at a cheaper price and lower production cost.

Dexcom has started to develop the concept of how to make use of all the anonymous data generated by the devices. The data is gathered in an open data platform and cannot be traced back to a single individual, and the data is always older than three hours. Some companies have signed agreements with Dexcom and can access the open data platform. According to Gerhardsson, there is a lot of work and science put into understanding how to make use of all gathered data, and the open data platform is one idea of how to make use of it. Dexcom's developers are also working with machine

learning algorithms. Gerhardsson believes that the massive increase of data generated by the new devices, can be used to build these algorithms. By connecting CGM with insulin pumps and algorithms generated by the patients' glucose data it might be possible generate an "artificial pancreas", Gerhardsson means that it will not be long until the first "artificial pancreas" exists.

In the future, Gerhardsson reckons CGM might be used by non-diabetics as well. One possible area of usage could be to track sugar consumption with the intention to lose weight. CGM can also be used in cases where HCPs otherwise need to use frequent SMBG, such as keeping track of glucose levels of a patient who has had a heart attack.

Over all, Gerhardsson believes the most important aspect in order for MedTech solutions to become successful is that the solution actually fulfills the requirements it is intended for.

# 5.3 Diasend

## 5.3.1 Background

Diasend manages monitored data from patients' diabetes equipment. It presents patient information in an easy-to-understand manner to both HCPs and patients themselves, with a focus on type 1 diabetes. They offer *diasend® Clinic* to HCPs, and *diasend® Personal* to patients. What's unique for Diasend is their product's compatibility. It is compatible with glucose monitors from most suppliers, such as Roche, Bayer and Dexcom just to name a few. HCPs thereby only need to rely on one data monitoring system, *diasend® Clinic*, for all their patients, even though the patients may have different glucose monitoring devices. Patients can simultaneously monitor their own diabetes on *diasend® Personal*.

The company was founded by Anders Sonesson, now VP EMEA at Glooko, and his two co-founders in 2005. It all started at Chalmers University, where Anders and his two co-founders studied a two year program dedicated to entrepreneurship. The aim of this program was for all the students to eventually start their own company. They began working together with a company focusing on electrical boxes. Their initial idea dealt with the data connectivity of these electrical boxes, i.e. how to analyse the flow

of current through these electrical boxes. Soon however, they switched path. They came in contact with HCPs working with diabetes, and realised the same technique they had been working on for electrical boxes could be used to give detailed analysis of patients' state of diabetes. None of the founders had any prior personal experience with diabetes.

Since 2005 the company has expanded. At first, business grew at a slow pace. But today, Diasend is a well established solution in Sweden, as well as abroad, and has managed to succeed where other companies have failed and completely disappeared from the market. In 2016, Diasend merged with American Glooko, a merger which has led to a larger customer base and a larger pool of staff.

## 5.3.2 Development Phase

### External

Before Diasend went to market with their product, the landscape was dominated by the suppliers (Roche and Bayer among other), who all had their own data analysis tools. Although these companies seemingly were competitors to Diasend, it was partly thanks to them Diasend could develop a product. These suppliers developed sensors that continually monitored the patient's glucose levels, which generated large amounts of data, which in turn needed to be managed and analysed. In 2005, the existing monitors did not generate those vast amounts of data, rendering the need to analyse it less useful. However, these new sensors increased the traffic of data, and the need for HCPs and patients to manage this data arose.

### Internal

From day one, Diasend has worked in close cooperation with HCPs. The product was designed and created in-house, but continuous valuable input was offered from physicians and nurses during the entire development phase. The product was created to function technologically well, with smooth data transfers rather than putting emphasis on product design. Even though HCPs liked the idea and concept of Diasend, they saw it more as a "good-to-have" device, rather than a "need-to-have" device. Incentives to pay for the product were not sufficient. They were met by similar reasoning from The Dental and Pharmaceutical Benefits Agency (Tand och Läkemedelsförmånsverket,

TLV), a Swedish central government agency who determine whether a pharmaceutical product, a medical device or any form of dental procedure qualifies for a state subsidy, making it more affordable for the patient. TLV argued Diasend was a suitable tool for clinicians and HCPs, rather than it being a tool for patients, thereby not making it eligible as a subsidy through the agency. The patients themselves were not interested in paying for a system such as Diasend, as they meant that it was the clinics who benefitted from that kind of solution. All parties involved considered the product to be beneficial to the healthcare sector, but no one had strong enough incentives to finance it. Anders Sonnesson[9] believes this is one of the healthcare sector's greatest obstacles: Deciding who should pay for it.

The first years were quite tough for Diasend. They had a product which stakeholders saw a use for, but the will to pay for it was non-existent. Additionally, Diasend never received any larger financial contributions from investors. Although it may sound contradictory, in hindsight Sonesson thinks this might actually have been one reason behind Diasend's success. If venture capital firms had invested they had likely asserted tougher criteria and demand on faster ROI, something Diasend never needed to abide by.

## 5.3.3 To-Market Phase

### External

Diasend's competitors adopted a fundamentally different to-market approach to that of Diasend. They decided to wholeheartedly turn their attention to the patients, rather than the HCPs. As it turns out, these competitors have all disappeared and do no longer exist. The rest of the competitive landscape also changed during this time. The analysis tools offered by Roche, Bayer and the other suppliers of glucose monitors became redundant as Diasend consolidated the different needs for analysis. The demand for the suppliers' own analysis tools ceased.

According to Sonesson, patients can strongly influence HCPs on what self-care solutions the healthcare sector ought to adopt. Yet, most patients are not interested in spending a lot of time caring for themselves, as it constantly reminds them of their

[9] Ander Sonesson, VP EMEA at Glooko. Interview 22nd of March, Gothenburg.

chronic disease. Therefore, Sonesson argues you should not rely on patients to get fully involved in the adoption of the self-care solution. Patients want to be assured that someone else is taking responsibility for their disease if they are to adopt the solution.

Medical software solutions in Sweden, such as *diasend® Clinic* and *diasend® Personal*, are subject to CE-marking just like any hardware medical devices in the EU. Sonesson acknowledges that a CE-marking can serve as a barrier towards less devoted competitors.

Sonesson believes the general mindset towards big data evolved, something that facilitated the adoption of data management tools and consequently Diasend's solutions. The amount of data gathered kept growing, making the need to manage it even more apparent.

## Internal

Diasend chose to target Swedish primary care clinics directly as their main customer. Because of low incentives to pay for the product, the initial to-market strategy was to offer clinics a free trial period as part of a pilot study. Diasend took advantage of the pilot study, and were able to further develop their product with user feedback from the HCPs using it. At the time, Diasend was a small company, and because of its small size with little to no bureaucracy, they could quickly make adjustments and augmentations to their product after receiving feedback from the HCPs. The clinics were not used to interacting with MedTech companies who were so responsive to their feedback. Diasend gradually gained trust from several clinics. As an entrepreneur, Sonesson points out the need to be persistent. You cannot simply dismiss customers who are sceptical to your product. Instead, listen to them, and make the improvements they demand if you expect them to adopt your product. Diasend even offered a few clinics prolonged trial periods, free of charge, who stated that they saw a use of Diasend's solution but could not afford it. The philosophy behind the decision to prolong, was that eventually the clinics would become highly dependent on Diasend, and would at that point prioritise including Diasend in their budget. Diasend was convinced their product, and its compatibility with several glucose monitors made it superior to the other existing analysis tools. Clinics who started using Diasend's product would be reluctant to end their subscription once they had tried it out. Sonesson means that companies at an early stage sometimes need to act before they have a fully functional business model.

The beginning of Diasend's commercialisation was characterised by high levels of service minded hard work, focused on a selected few clinics who would later on be used as references. It was of great importance to Diasend that they broke through with these clinics. Anders Sonesson[10] suggests that patients usually do what their physicians recommend, and adopt the solutions physicians hand them. If Diasend were to gain a foothold of the patient market, they needed to go through the physicians. At first Diasend had reached out to whoever was willing and had time to talk to them. These HCPs had not necessarily been the ones in charge of purchasing. After an initial proof of concept, Diasend strategically targeted physicians who were also part of different counties' medical public procurement processes, to build awareness around Diasend and to make sure that these physicians in particular were pleased with Diasend's product.

When Diasend had started gaining market traction, new partnerships started taking form. Johnson & Johnson wanted to include Diasend's solution in their diabetes product offering. Even though Diasend had conducted several pilot studies prior, Johnson & Johnson also wanted to start off with a pilot study of Diasend's product to see the actual demand for it. At first Diasend were quite reluctant to conducting further pilot studies, as they did not see any need to yet again prove there was a need for their product. However, the pilot study Johnson & Johnson suggested was significantly larger than Diasend had anticipated, including a total of 200 clinics. To put this figure in perspective, at this point in time, Diasend had after five years a total of 100 clinics in their current customer base.

## 5.3.4 Post-Launch Phase

### External

According to Sonesson, clinics have become heavily reliant on *diasend® Clinic*. The brand of the glucose monitors and sensors are no longer as essential as they once were. Generic brands often have sensors just as accurate and reliable as the more well-known brands. What's important is that there is one system, or solution, to manage the collected data. This has proven to be quite true. A requirement in a few Swedish

[10] Anders Sonesson, VP EMEA at Glooko. Interview 22nd of March, Gothenburg.

counties' public procurement specifications for glucose sensors and monitors, is that they are compatible with Diasend.

Communication between the HCP and patient needs to function properly. The patient might otherwise think their physician monitors their data as soon as they choose to upload it. Should anything happen to the patient, the clinic can be reported according to Lex Maria[11], for not preventing injury or worsened state of the patient. HCPs therefore need to communicate that Diasend's tools are used to monitor, but not necessarily to identify cases of emergency. The patient still holds a responsibility for his or her own health. Sonesson even says some clinics encourage their patients to not upload their data from at home, with the purpose that patients should not feel like they are constantly under surveillance. In May 2018, GDPR was implemented in the EU. This will most definitely affect Diasend, primarily it will require new processes and increasingly structured documentation. However, the collected diabetes data is not owned by Diasend, but rather by the patient, which would imply that the changes induced by GDPR may after all not alter the situation too much from what it is now.

Sonesson predicts the competitive landscape will change. He says larger tech companies, such as Apple and Google are starting to pose a threat. The supplier Roche has also started entering the same business area as Diasend has started dominating. Still, he adds that the world's MedTech market is growing. He believes Diasend's technology could likely be used in other areas of application, but for now, diabetes is a large enough area.

## Internal

After an initial proof of concept on the Swedish market, Diasend expanded to new countries and is still under an internationalisation process. The collaboration with Johnson & Johnson is just one way Diasend has begun its journey in reaching new geographical markets. Sonesson recognises the need to develop new business models for every new country the company enters. There are significant dissimilarities in the different geographical markets, and the business model that progressively has been refined in Sweden is not certain to be applicable elsewhere. One aspect is that of financing the solution. In the U.S., solutions regarding type 2 diabetes is often financed

[11] Lex Maria, the name of the compulsory notification following the Swedish law on patient safety (patientsäkerhetslagen), chapter 3 §5

by insurers, whereas clinics usually pay for those solutions dedicated to type 1 diabetes. There are also a few manufacturers of insulin pumps who, as part of the product offering, sponsor with a subscription to Diasend. Aside from the aspect of who pays for the solution, there might be disparities in products used by the patients. In 2015, roughly 40% of Swedish type 1 diabetes patients had an insulin pump. In the UK, the same figure was at a mere 4%. Other dissimilarities regard e.g. data privacy. Some countries do not allow patients to upload their monitored data from their own computer.

An increased focus on market expansion and new market penetration has initiated a need for efficiently dealing with regulatory entry barriers. Diasend now has three employees working full time on regulatory matters, such as applying for FDA approvals and preparing submission to local national approval agencies. The more complex the products become, the more likely they are to fall within a higher medical device classification and approvals will become harsher.

As the company has grown, so has its workforce. As a company dedicated to making life easier for patients with diabetes, it has also attracted new employees who they themselves have diabetes and therefore an emotional bond to the business.

# 6. Case Analysis

*In this chapter, the case studies are individually analysed in order to determine what enabled these cases to penetrate the market and establish the product. Each case study is analysed in its own subchapter by applying the theoretical framework (see fig. 6.1) as described in chapter 3.8 'Theoretical framework'.*

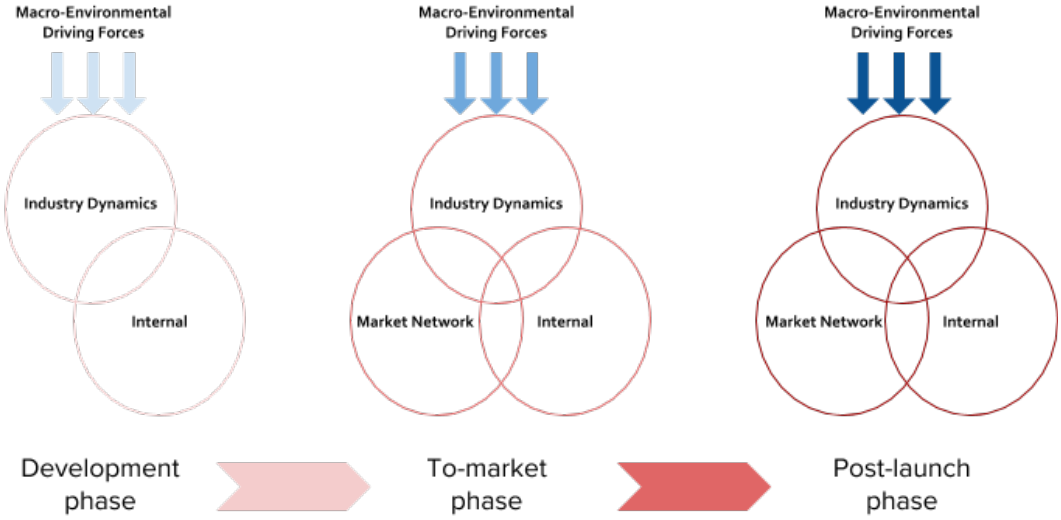


*Figure 6.1. Theoretical framework used for this study. The collected empirical data is analysed using this theoretical framework along with its fundamental models and theories described in chapter 3.*

## 6.1 Coala Life

### 6.1.1 Development Phase

#### Industry Dynamics and Macro-Environmental Analysis

Thompson et al. (2010) describe how new social attitudes to products can shape industries. When Swedish studies presented the positive effects of preventive ECG screenings, the fundamental value of Coala Heart Monitor was made apparent. The results of these studies led to increased market susceptibility to devices such as the Coala Heart Monitor.

## Internal Analysis

Coala Life has, as mentioned in chapter 5.1.2, with its product developed an extensive MedTech system. Their value proposition goes beyond their Coala Heart Monitor. It is the combination of the physical device and the aid of HCPs through Medhelp which makes the solution trustworthy.

The funding strategy (chapter 5.1.2) during the development phase might be one of the underlying reasons as to why the company succeeded in reaching the to-market phase. Coala Life only received new funding once they had met certain objectives. Had they received a larger investment from day one, chances are investors would have set up harsher criteria. As the Coala Heart Monitor development phase was long, it was important to find investors who were interested in the long-term commitment to Coala Life.

During the development phase of Coala Heart Monitor, Coala Life depended to a great extent on external parties. From a strategic perspective, it is truly important to develop strong partnerships based on trust, which Coala Life did. Without these strong relationships, Coala Life might not have obtained the same qualitative device or managed to launch the product in time.
The partnerships were essential as a result of limited resources, which made it impossible to manage all activities in-house. The importance of developing sensors was mentioned in chapter 5.1.2 and the importance of consultancy firm Sigma Connectivity can be visualised by the Stakeholder Power/Interest Matrix suggested by Aubrey Mendelow (1986, see Johnson et al. 2012, p. 91). Sigma Connectivity held high power over the product development, since they were the ones developing it. Further, by controlling product features, Sigma Connectivity indirectly affected Coala Life's business model which to a great extend depended on the product. By applying the theory of the Stakeholder Power/Interest Matrix suggested by Aubrey Mendelow (1986, see Johnson et al. 2012, p. 91), Sigma Connectivity is a 'Key Player'. In this case Sigma Connectivity has been Coala Life's partner during the development phase. Keeping the partnership alive can become an advantage, for example if Coala Life wishes to modify the Coala Heart Monitor in the future.

## 6.1.2 To-Market Phase

### Industry Dynamics and Macro-Environmental Analysis

Philip Siberg[12] has identified insurance companies and research institutes to be some of the stakeholders which are affected by the adoption of Coala Heart Monitor. By receiving data regarding the customers health insurance companies can calculate risk which will affect their business. Further, research institutes can continue to research on heart diseases. In conclusion, both insurance companies and research institutes have incentives to pay for the data generated by the Coala Heart Monitor.

### Internal Analysis

Coala Life´s to-market strategy shows similarities with Moore's Crossing the Chasm (2001). When Coala Life chose to launch Coala Heart Monitor through one channel and gained market traction, they followed the first step of how to cross the chasm. In addition, the choice of channel was supported by the fact that it is difficult to pursue multiple activities when having limited resources, which was the situation for Coala Life at the time.

### Market Network Analysis

According to Siberg there are four stakeholders who have incentives to adopt the product, these are presented in chapter 5.1.3 as: patients, the healthcare sector, insurance companies and research institutes. The effects these stakeholders have on each other will implicate how Coala Life should design its value proposition when launching the product. Siberg has noticed that involving the patient in the process creates a higher level of engagement, which in turn forges incentives for the patient to care for their own health and not solely rely on a physician to treat them. With this insight in mind, one can imagine that products that allow for patients to aid the HCPs in their care taking will have a better chance of success during market launch. In addition, there are incentives for the healthcare sector to use ICTMPMSCS because they aid HCPs to save time, making the daily work more efficient.

[12] Philip Siberg, CEO at Coala Life AB, phone interview 26th of March 2018

## 6.1.3 Post-Launch Phase

### Industry Dynamics and Macro-Environmental Analysis

It has been noticed that innovation takes place in small companies and start-ups rather than within the healthcare sector. As the patients become more involved with their own care plans, Siberg described that he believes patients will in time convince physicians to change their current and traditional methods. The shift of these methods will mean that the patients are going to change the industry dynamics by adopting new solutions.

Another reason to why patients want change in the healthcare sector is because of the increasing technological adoption in society. Technology is changing patients' lifestyles, routines and expectations on service accessibility. Thompson et al. (2010) describe how new social attitudes, lifestyles and concerns (*see chapter 3.1 'Identifying success')* are driving forces that can change industry dynamics. It could be that patients get tired of the healthcare sector's inertness in adopting technology, when other sectors are adopting technology more rapidly. If the healthcare sector cannot meet the patients' expectations on technology, patients might go looking for solutions and pursue technology adoption on their own.

In Sweden, the healthcare system is partly financed through taxpayers' money which means patients have incentives for the healthcare sector to invest in solutions, such as ICTMPMSCS, that increase efficiency and lower costs. This is coherent with what Thompson et al. (2010) mention, when they suggest that changes in cost and efficiency are driving forces that shape industry dynamics. Cost and efficiency are parameters which will become more important considering the Swedish population is ageing. This is also identified by Siberg who highlights the importance of Coala Life's product to demonstrate economic benefits in order for it to succeed.

### Internal Analysis

In the post-launch phase, Coala Life started to gradually mobilise the team and activities. As an example, market regulatory issues became more and more prominent, and frankly more complex. Because of the increased complexity of the issues, regulatory matters became intertwined with the commercialisation process to a greater extent. Having regulatory matters being dealt with externally just was not good

enough, it needed to be incorporated in the company's internal daily work. Specialised teams were therefore vertically integrated into the company. In a strategic perspective, this action seems accurate since it is desirable to not be overly dependent on an external party. Additionally, one should also consider the cost of adding such a team. Johnson, Whittington & Scholes (2012) mean key activities are activities which can be used to gain competitive advantages. At this stage, managing regulatory activities might be seen as a key activity and integrating them into the company's internal operation will in fact be crucial.

When entering the post-launch phase Coala Life's key activities changed from concerning product development to commercialisation. The product goes through several phases (BSI 2018), and as a result key activities shift. As mentioned by Casadesus-Masanell & Tarziján (2012) one reason to pursue parallel business models is when an organization is expanding into a new market. This was the situation for Coala Life six months after the initial launch at the pharmacies. Coala Life decided to target physicians and hospitals parallel to the pharmacies. This strategy is also consistent with Moore's (2001) theory Crossing the Chasm, which implies that companies must expand into a nearby market in order to reach the majority.

## Market Network Analysis

Siberg points out the importance of entire teams of physicians, nurses and healthcare administrators adopting the product in order for it to work. This is further discussed in Diffusion of Innovations by Rogers (1983) who describes an innovation's rate of adoption to depend on both compatibility and complexity. Therefore, ICTMPMSCS need to be compatible with patients, physicians and administrators, all at once.

In chapter 5.1.4 it is described how patients bought Coala Heart Monitor at LloydsApotek and brought the device to their physician, indicating the importance of interaction and relation between physician and patient. It might be that patients feel the need to validate the product in order to completely trust it. One way can be to double check with their physician, whose advice the patient most likely trusts. In Coala Life's case, involving patients helped increase the physicians' adoption of the product.

The fact that Coala Life has hired an external expert specialised in reimbursement strategies but not yet formed an internal market access team indicates that there are

several steps of market expansion. The first is to insource needed activities, and the second is to fully incorporate these activities into the organisation.

# 6.2 Dexcom

## 6.2.1 Development Phase

### Industry Dynamics and Macro-Environmental Analysis

Technological advancements in mobile telephone technology was necessary before the Dexcom G5 CGM System could be developed. This corresponds to the shift in the industry Gerhardsson[13] identified, namely that technological development is increasingly focused on electronics and digitalisation. These new industry dynamics also reshape the competitive landscape, by putting less emphasis on the quality of the sensors and more emphasis on managing the data. Similar to what Deloitte has identified, this indicates the industry will likely rely more on new software solutions rather than nascent hardware (Deloitte Center for Health Solutions 2015a).

In addition, these technological shifts also brought along changes in social attitudes. The abundance of data led to an incumbent fear among some physicians who were afraid they would be bombarded with huge amounts of data. This implies medical devices need to sophistically store and sort out data, making it manageable for the user. Further, with the implementation of GDPR, the importance of structuring and documenting otherwise unstructured data becomes utterly vital.

### Internal Analysis

Gerhardsson claims Dexcom's sensors have historically been better than those of competitors. This has been part of Dexcom's value proposition. A clear value proposition distinctively positions the company against competitors. However, the hardware itself is proving to be less important and well-functioning software solutions are what become the competitive edge for the company. Simply having a better

[13] Peter Gerhardsson, Vice President International Business Development, phone interview 5th of March 2018

glucose sensor may be enough to initially gain market recognition but is not a long term competitive advantage.

## 6.2.2 To-Market Phase

### Industry Dynamics and Macro-Environmental Analysis

At the time of launch of the Dexcom G5 CGM System, Dexcom was already a global company and sales channels were already in place in several geographical markets. Yet, because of differences in national regulations and various financiers, each geographical market needs its own business model. As financiers vary, so do incentives to adopt the solution. Although the product is the same regardless of geographical market, the value proposition may need to be somewhat modified to attract different kind of financiers. One example of this is public procurement processes in Swedish counties. For medical devices, MedTech companies must be able demonstrate the achievable cost savings for the healthcare through the use of the device. Otherwise counties will be reluctant to pay for the device.

As Gerhardsson has pointed out, MedTech companies rapidly develop new products but processes among certifying organisations and notified bodies are slow, such as the FDA. Companies develop the next generation of ICTMPMSCS before the first generation has barley received market approval. This indicates the technology is available, but regulatory barriers significantly slow down time-to-market. In the U.S., preparing for market approvals becomes particularly important. Slight changes to an already approved ICTMPMSCS requires the submission of PMA supplements. Long turnaround time for PMA supplement approvals leads to a certain degree of *lock-in* for the company, as they are unable to make further changes to the device until the submissions have been approved. This means incremental augmentations cannot continuously be implemented, as it would require costly approval processes. Companies should therefore make sure they are fully aware of what changes they wish to make to a device, before they submit PMA submissions or PMA supplement submissions.

### Internal Analysis

In order for Dexcom to launch the G5 CGM System, as well as other new devices, the company has a *Market Access* team specialised on overcoming regulatory barriers in new markets. Dexcom has vertically integrated activities dealing with market regulatory issues. Buzzell (1983) talks about how vertical integration can be used to achieve supply assurance. Although this is not directly a matter of assuring the delivery of supplies, it is a matter of assuring that market approval submissions are approved in time. By integrating the activity in-house Dexcom does not depend on an external party to prepare submissions on their behalf.

### Market Network Analysis

CGM is according to Gerhardsson adopted in a manner following Rogers' model, Diffusion of Innovation. There are however two customer segments here to analyse: the patients and HCPs. Patients who started using CGM were, according to Rogers (1983), so called innovators and early adopters. HCPs on the other hand can be seen as the early majority of the market, since they needed to see evidence that the product actually worked and that patients were willing to use the product before adopting it. Geoffrey Moore (2001) means the most critical factor for a product to be fully adopted by the market is that you manage to reach the early majority. In the case of CGM, patient groups were responsible for crossing the chasm and reaching the early majority in Sweden when they started putting pressure on the healthcare sector to adopt CGM. The reason why patient groups put pressure on the healthcare sector and physicians was bipartite. First, patients requested that the healthcare sector would finance CGM. Second, patients wanted to check in with their physicians to hear their opinion on CGM.

## 6.2.3 Post-Launch Phase

### Industry Dynamics and Macro-Environmental Analysis

CGM can lead to cost savings in healthcare. Despite this, the will to pay for solutions such as CGM is not always present. This is likely because the healthcare sector does not operate as one single entity. In Sweden, it consists of several entities such as counties, municipalities, primary care units and hospitals among others. Each entity has its own budget. The entity which ultimately decides to finance and pay for an

ICTMPMSCS, also expects to see a cost reduction in their own budget. However, in reality the reduction in cost might be experienced in another entity's budget. Additionally, there's another similar issue. Some cost savings may not be experienced until 20 years later. Cost savings that occur 20 years in the future are not strong enough incentives to adopt an ICTMPMSCS today. As Sundler[14] suggests, there seems to be a need for a compensation model that promotes adoption of ICTMPMSCS.

## Internal Analysis

At the start of Dexcom's global expansion, the company sold their products through partnerships and external distributors as a result of limited resources in the form of a constrained budget. Bullen & Rockart (1981) suggest companies should focus limited resources on those activities that are truly value-creating. At the time, most crucial for Dexcom was for their products to penetrate and establish new geographical markets. Managing sales within the company did not generate any additional value during that time. As Dexcom has established itself on more markets, it has integrated sales activities in-house. The reason for this could be that selling through third parties cuts into margins. As soon as the company has been assured their product has been embraced by the market, the risk of vertically integrating activities decreases. As vertical integration requires heavy initial capital investments (Buzzell 1983), it is possible companies hedge for this risk by waiting to vertically integrate activities until it has been proven that the market actually adopts the product. A cost-benefit analysis should be made before integrating activities that were previously done by external parties.

Dexcom's open data platform has opened up for new partnerships that can lead to an increase in sales as well as a stronger brand. Others can utilise the data collected by Dexcom to create their own digital tools and applications. When these tools and applications are adopted by patients, the demand for Dexcom's CGM systems increases as the tools and Dexcom's CGM systems can be seens as complementary products.

[14] Niklas Sundler, Business Unit Manager Cloud Services at Axians, phone call 2nd of March 2018

### Market Network Analysis

As seen in the case of CGM, physicians can put pressure on county councils to include a certain medical device in public procurement processes. This suggests targeting physicians may facilitate being included in public procurements. Naturally, this requires the device to fulfill the requirements the physician may exert on the device.

# 6.3 Diasend

## 6.3.1 Development Phase

### Industry Dynamics and Macro-Environmental Analysis

Like Thompson, Strickland & Gamble (2010) discuss, the rise of Diasend was pushed on by external driving forces in the industry. Technological advancements in sensors and an increase in stored patient data, paved the way for Diasend's analysis tool as a demand for data analysis was conceived. Diasend was observant to macro-environmental paradigm shifts. In accordance to what Holopainen & Toivonen (2012) have examined, the observation Diasend made early on in regard to increased stored patient data can be seen as the identification of a *weak signal*. Diasend saw this weak signal as a possible future opportunity to deal with data in an increasingly digitised industry.

### Internal Analysis

The development of Diasend's tools was done in collaboration with HCPs. Although there was an uncertainty over who the buyer of the tool would be, it was clear that physicians would be a primary user. Therefore, developing the tool side-by-side with the future user was a way to manage product features that could otherwise become factors of adoption resistance to customers. This is in alignment with what Larsson, Bill, Ingridsdotter & Olsson (2011) have stated, namely that MedTech companies should move away from solely working on a sales-purchasing relationship with the HCPs. Instead, companies should involve the HCPs in more collaborative activities, such as product development and refinement.

As previously mentioned in chapter 5.3.2, it can in hindsight be argued that part of Diasend's success in the development phase was the lack of large funding from investors. This made it possible for Diasend to take its time in development without answering to investors who expect fast pay-back times. Although this has been identified in this specific case, evidence is not strong enough to propose the lack of funding as a success factor behind market penetration in general. Using the Stakeholder Power/Interest Matrix, as suggested by Mendelow (1986, see Johnson et al. 2012, p. 91) to analyse the investor's position towards Diasend, reveals that investors likely did not have a lot of power to influence Diasend's decisions. This is because investors did not contribute with significant funding. If investors had contributed with more funding, their power to influence had increased, making it more likely they had proclaimed stricter criteria. Despite all this, it can still be argued that investors played an important part, as they needed to be committed to the concept. Long development, and long time-to-market requires investors who are loyal.

When Diasend started reaching out to potential customers such as clinics, the TLV and patients, they were met with positive attitudes towards the product but no incentives to pay for it. Who should finance the product would remain an issue. The customer needs to have strong incentives in order to adopt the solution. As Osterwalder & Pigneur (2010) mention, the company needs to have a clearly defined value proposition for the designated customer. The value proposition solves a problem the customer has experienced, or satisfies a need. Simply being regarded as a decent product does not give the customer enough incentives to purchase. The value proposition should be sculpted to address a specific customer segment. Additional customer segments might require a different value proposition, which leads to an altered business model.

## 6.3.2 To-Market Phase

### Industry Dynamics and Macro-Environmental Analysis

Deloitte Center for Health Solutions (2015a) identify increased computing power and large data storage capacity as buildings blocks for the future progression of medical devices. Parallel to these technological drivers, there is also a social aspect. People are becoming more used to the collection of data, and big data analytics. It is possible this shift in the MedTech industry as well as in other industries has elevated a general mind-set, that makes people more susceptible to devices that gather and analyse data.

These social changes in the macro environment need to be in place in order for solutions such as Diasend's to penetrate the market.

## Internal Analysis

By offering clinics free trial periods, Diasend managed to achieve two things which has played out to be important market penetration factors. First of all, the free trial periods functioned as pilot studies allowing Diasend to receive direct user feedback. Utilising this feedback, Diasend made necessary adjustments to the tool. Bigger corporations lack the flexibility to make those quick adjustments that Diasend was able to do. This proves to be a competitive advantage Diasend had towards other larger MedTech companies who might have been interested in developing a similar tool. Secondly, offering free trial periods to the clinics created a dependency from the clinics on the tool. By deeply embedding the tool in the physicians' daily work, this created a lock-in for the clinics, and physicians were reluctant to end their subscription once their free trial period ran out. It was not until physicians tried using the tool that the need was created. Rogers (1983) means *trialability*, i.e. the degree to which an innovation may be experimented with on a limited basis, has a positive effect on the rate of adoption. This suggests, making it easy for clinics to test Diasend's tools, can increase the rate at which the tools are adopted.

The partnership with Johnson & Johnson acted as a second sales channel. Bundling Diasend's tool as a complementary product to the sensors Johnson & Johnson offered generated revenue that Diasend had not reached on its own.

## Market Network Analysis

The interplay between physicians and patients has had an impact on the adoption of Diasend's tools. Patients started using *diasend® Personal* once physicians recommended them to. This means patients do not necessarily make decisions of adoption themselves, but instead rely on their physician. At the same time, patients can have preferences and can influence HCPs on what self-care solutions they wish to use. As mentioned before, patients do not want to constantly be reminded about their disease. According to the Stakeholder Power/Interest Matrix suggested by Aubrey Mendelow (1986, see Johnson et al. 2012, p. 91), Diasend's strategy towards patients should be to 'Keep Satisfied', since patients have a high power but not necessarily a high interest in the monitoring of their disease. Physicians on the other hand are 'Key

Players', as they are the ones making the decision to purchase the tools or not. This suggests Diasend should be particularly attentive to the needs of the physicians, while at the same time making sure patients are content with the tool.

Diasend has also focused efforts on a selected few physicians who have active roles in different counties' public procurement processes. This way, Diasend were able to focus limited time and resources to a few physicians who had significant influence on what medical devices were purchased by the counties.

## 6.3.3 Post-Launch Phase

### Industry Dynamics and Macro-Environmental Analysis

Compatibility with Diasend has become a criterion for glucose sensors & monitors in public procurement specifications in a few Swedish counties. As more and more sensors & monitors need to be compatible with Diasend's tools, barriers of competition are strengthened. By continuing to work in collaboration with counties, Diasend can assert a dominant position in the Swedish market. Climbing to that position, gives additional proof of concept, something that can then be taken advantage of when expanding to new geographical markets. This indicates there might be a need to be even more attentive to possible new entrants if Diasend wishes to maintain its dominant position in the competitive landscape. In particular, Diasend could expect to see increased competition from larger tech companies such as Google and Apple. One way to deal with this threat, is to collaborate instead of competing with these tech companies. This would however require Diasend to clearly define its core competence, in order to see what a potential collaboration would look like.

### Internal Analysis

The post-launch phase is partly characterised by market expansions. Diasend has entered new markets, where other market dynamics are in play. This may take its form in different reimbursement systems, such as in the U.S., or there could be a difference in the type of products used in the care settings of different countries. Adding to the thoughts of Johan Feltner[15], there seems to be a need to manage several parallel

[15] Johan Feltner, Project Manager - Service Development at SCA, phone call 7th of March 2018

business models for the same product, depending on what dynamics are at play in a certain geographical market. Casadesus & Tarziján (2012) mention *expanding into new markets* as one situation where addressing more than one business model is appropriate. Even though the core value proposition may be the same across borders, there is a need to refine the choice of channels, customer segments and the way the company works with customer relations. Slight adjustments to the value proposition may need to be made to address different type of financiers.

As Diasend has grown in size, it has also added new activities. Activities that were previously done by external parties are now done in-house. This includes the three employees working full-time with regulatory matters. This is similar to the vertical integration discussed by Buzzell (1983). The main reason behind this integration in the case of Diasend, is to guarantee quicker to-market times and to avoid bottlenecks in approval processes. A secondary reason is that as Diasend has grown, the products being developed and augmented are increasingly complex. This usually means they fall within a higher classification of medical devices and in turn approvals will be more difficult to obtain. As a company, this means Diasend needs to be ready to allocate resources to activities dealing with such regulatory matters. Although this may come naturally, companies may want to start off with regulatory processes for products that have a lower classification in order to build up knowledge in the in-house team before proceeding to approvals for higher classified devices.

Although none of the founders had any connection to diabetes, Diasend has attracted employees who have the chronic disease. There seems to be an emotional factor that attracts people who are willing to work for a better life for those suffering from diabetes. This is likely to build dedication towards common goals and objectives the company sets up.

## Market Network Analysis

Geoffrey Moore (2001) describes in his book *Crossing the Chasm*, that in order to reach the mass market, you first need to become the dominant player in a selected niche market before expanding. This logic can be applied here too. By initially targeting only a few clinics, and getting them to the point where they were heavily dependent on the solution acted as a gateway to reaching other clinics and foremost reaching the patients. It is important to note that Diasend's tools, be it *diasend® Personal* or *diasend® Clinic*, are mostly beneficial to the HCPs at the clinics. That is

why in order for the rate of adoption to keep growing, targeted initial customers should be clincis. The product is then gradually adopted by others as physicians tell patients to start using the tool, and naturally the patients do what their physician tells them. This means, even if Diasend is pursuing market expansions and needs to adopt new business models, the core user of the tool still needs to be in center. Regardless of what geographical market Diasend is trying to enter. Channels may be different, financiers may be different, but the user is still the same. Despite this, there may be differences in how patient behaviour is influenced. As Feltner discusses, patients may seek medical advice at different places depending on market dynamics. It is possible the physician in southern European countries has less influence over the patient, as the patient is more likely to seek assistance at a local pharmacy prior to seeking help from primary care. These market network dynamics may be significantly dissimilar from one geographical market to another. No matter what new market the company is looking to enter, the ICTMPMSCS must satisfy the criteria set up by Rogers' (1983) five attributes: relative advantage, compatibility, complexity, trialability and observability.

# 6.4 Aggregated Analysis

In this subchapter, the analyses from each case are aggregated. The aggregation follows the same structure as the cases.

## 6.4.1 Development Phase

### Industry Dynamics and Macro-Environmental Analysis

All cases indicate that changes in the industry and macro environment have had an impact on the commercialisation success of the ICTMPMSCS. These changes include new social attitudes, advancements in mobile technologies and emerging academical studies. However, the cases do not share any mutual experiences on external drivers that have had an impact on success.

### Internal Analysis

The studied cases show that developing medical devices together with industry experts is necessary to obtain a final device that the market will adopt. Diasend continually

collaborated with HCPs when they developed their tools. Coala Life depended heavily on the expertise of Sigma Connectivity.

Another aspect that has been evident in the the two cases of Coala Life and Diasend, is the entrepreneurial drive. Coala Life needed to continuously make progress in order to raise further funding. Diasend found itself in another situation, where low funding required them to keep pushing and striving although resources were scarce. The case of Dexcom does not directly contribute to this analysis here, as it was already a global company at the time of development of the Dexcom G5 CGM System.

## 6.4.2 To-Market Phase

### Industry Dynamics and Macro-Environmental Analysis

A common feature among the studied cases is their ability to enable cost savings in the healthcare sector. The Coala Heart Monitor can free up time in primary care as well as in cardiology. Dexcom G5 CGM System can prevent hypoglycemia, thereby reducing pressure on acute care. Diasend's tools remove the need for clinics to utilise multiple analysis tools for all their patients. The healthcare sector is reluctant to adopt new technology and devices unless cost savings are made visible.

### Internal Analysis

Although all cases today sell their ICTMPMSCS to different customers and through different channels, even though the geographical market is the same, they started by only targeting one customer segment and selling through one channel during market entry. Most commercialisation activities, such as sales and overcoming regulatory barriers were performed by external parties during initial market entry for all cases.

### Market Network Analysis

In the case of Coala Life, patients brought their newly purchased Coala Heart Monitors to their physicians, requesting their opinion on the device. Clinics and physicians were Diasend's primary customer, and these then recommended their patients to start using *diasend® Personal*. In the case of Dexcom, physicians pushed for CGM to be publicly procured. It is apparent by studying all these cases that the physicians play an important role in the adoption of ICTMPMSCS.

## 6.4.3 Post-Launch Phase

### Industry Dynamics and Macro-Environmental Analysis

The cases can give predictions on how the industry is changing. Patients will keep pushing for new technological adoption in the healthcare sector, either by purchasing ICTMPMSCS themselves or by putting pressure on government financed healthcare sectors to finance the self-care solutions. A major barrier however, will be determining who finances the ICTMPMSCS. Countries usually have their own unique healthcare model, each financed through different means.

### Internal Analysis

There are two aspects that clearly stick out from all three cases. The first aspect indicates there is a need to pursue multiple parallel business models when entering new geographical markets. The second aspect is the in-house integration of activities as the business grows and the ICTMPMSCS has proved to gain market traction. These activities seem to be activities revolving around commercialisation and reaching new markets, such as sales and overcoming regulatory barriers.

The case studies also suggest that these regulatory barriers to market entry pose a large risk as bottlenecks. Market approvals are time-consuming. Preparing for more than one market approval at a time can increase chances to reach a market within a reasonable time-frame. Waiting for a market approval may otherwise result in a major bottleneck.

The patient data these ICTMPMSCS collect and store has a value. Coala Life speculates researchers may have an interest in the anonymous data the Coala Heart Monitor gathers. Similarly, Dexcom's open data platform potentially provides the company with added revenue streams. The way the company is able to manage and capture value from this data can lead to new sources of income. But more so, by letting others take part of the data, complementary products can be developed which leads to an increased adoption of the ICTMPMSCS. Successfully utilising the data and creating value from it requires a business model suitable for the purpose.

One possible channel to reach a new market is to bundle the ICTMPMSCS in a product offering along with another device, solution or service. Coala Life believes

their Heart Monitor could be included in a life or health insurance package. Diasend has already proven that bundling helped them, when they collaborated with Johnson & Johnson.

## Market Network Analysis

Once the market has been initially penetrated, the ICTMPMSCS should establish its position for the long run. For this to be possible, the ICTMPMSCS must not only be compatible with the primary user. Secondary users, whether these are physicians, patients or administrators, must be pleased and content with the ICTMPMSCS. Mistrust in the solution can lead to secondary users pressuring the primary user to stop using the ICTMPMSCS.

# 7. Discussion and Conclusions

*In this chapter, 12 factors of success are presented (see table 7.1). These factors have been aggregated from the cases analysed in the previous chapter. Each factor will be further discussed as to how it answers the research questions. The chapter is structured to answer each research question and the order will follow same structure as chapter six, starting with industry specific and macro-environmental factors, moving on to internal factors, and finally presenting factors regarding market network. By presenting identified industry specific and macro-environmental factors, research question one is answered. Further, the internal factors presented below answer research question two. Last but not least, research question three is answered by the identified market network factors. The final part of this chapter presents the fulfilment of purpose, reliability and validity, contributions to theory and suggestions for future research.*

| | |
|---|---|
| Industry specific and Macro-environmental factors | 1. The ICTMPMSCS must be able to demonstrate cost savings within the healthcare sector<br>2. Patients will likely drive the adoption of ICTMPMSCS, not the healthcare sector |
| Internal factors | 3. Ability to pursue multiple parallel business models for the same ICTMPMSCS when expanding<br>4. Target one customer segment and go through one channel during market entry<br>5. Ability to prepare multiple market approval submissions simultaneously<br>6. Insource necessary activities from external parties but integrate key activities gradually as business expands.<br>7. Bundling may speed up adoption of ICTMPMSCS<br>8. Ability to create value from collected data<br>9. Development of ICTMPMSCS together with HCPs<br>10. Strong belief in your idea and ability to communicate belief to investors |
| Market network factors | 11. Physicians have an important role in the adoption of ICTMPMSCS and bring legitimacy to the device<br>12. Design ICTMPMSCS for primary user, but keep secondary user satisfied |

*Table 7.1. The 12 identified factors behind successful market penetration and establishment of ICTMPMSCS.*

# 7.1 Identified Industry Specific and Macro-Environmental Factors

## 7.1.1 Factor number one: The ICTMPMSCS must be able to demonstrate cost savings within the healthcare sector

Because the major cost savings due to implementation of ICTMPMSCS might not be visible until years after introducing the device, short term improvements must be shown as well. The empirics and analysis of this study suggests the entity in the healthcare sector who finances the solution, must also be the same entity who experiences the reduction in costs. In other words, the reduction in cost that can be experienced through the implementation of ICTMPMSCS needs to reflect on the same budget as the initial cost of purchasing was charged on. If the cost savings are not experienced until several years on in the future, incentives to finance the ICTMPMSCS today may not be strong enough. In summary, not only do ICTMPMSCS need to generate cost savings, these cost savings must be easily proven and within a reasonable time frame. This factor is applicable both in markets that are mostly government financed, and in markets mostly financed through insurers. However, incentives may differ between the two making one more susceptible than the other.

## 7.1.2 Factor number two: Patients will likely drive the adoption of ICTMPMSCS, not the healthcare sector

This factor is a weak signal of what is yet to come. In the case of Dexcom it appeared to be patient groups who put pressure on the healthcare sector to adopt CGM. In addition, it was the patients who first brought the Coala Heart Monitor to their physicians. The indications from these case studies show that patients can influence the healthcare sector's adoption of new medical devices. The collective strength of patients

and patient groups is necessary to convince the slow and conservative healthcare sector to adopt said devices. As means of financing may differ between geographical markets, so might patient incentives to purchase ICTMPMSCS and thereby patients' push to adopt new solutions may differ as well.

# 7.2 Identified internal factors

## 7.2.1 Factor number three: Ability to pursue multiple parallel business models for the same ICTMPMSCS when expanding

Whether the company behind the ICTMPMSCS decides to expand into new geographical markets or if they wish to further penetrate an existent geographical market, it needs to be able to manage multiple business models simultaneously. This does not necessarily imply product features need to be altered, but the company will need to target new users, new financiers, add new sales channels and may need to consider alternative revenue models, e.g. bundling (*see chapter 7.2.5)*.

## 7.2.2 Factor number four: Target one customer segment and go through one channel during initial market entry

Companies should target physicians as the primary customer segment if the ICTMPMSCS mostly facilitates their work, and target patients as the primary customer segment if it foremost facilitates their daily life. Further, the company should choose the channel which to the greatest extent will serve that specific segment. This strategy is further favorable in cases where resources are limited, which often is the case in new companies. Thus, this internal strategy does not depend on what geographical market the company operates on.

### 7.2.3 Factor number five: Ability to prepare multiple market approval submissions simultaneously

In the case of Dexcom, this strategy was favourable because approval process could be slow, and by applying for approvals in several countries simultaneously, time was saved. Parallel applications can serve as a way to hedge for risk. If one submission is denied or rejected there is still an opportunity to succeed with the other. All cases have highlighted market approvals as a major barrier and bottleneck in the to-market phase. The way companies prepare for submissions of market approvals therefore becomes crucial. Knowledge gained from one market approval process can aid in coming market approvals.

### 7.2.4 Factor number six: Insource necessary activities from external parties but integrate key activities gradually as business expands.

Until the ICTMPMSCS has penetrated and established itself in a market, companies do best in insourcing certain activities such as regulatory and sales. This is to avoid the capital risk from large initial investments in completely new work teams. Once the ICTMPMSCS has gained legitimacy and it has been proven that the product is accepted by the market, companies should integrate key activities in-house. This makes companies less dependent on external parties, which can both help cut costs as well as ensure that processes are dealt with in time. An aggregation of the studied cases shows that most commonly, activities dealing with market regulatory barriers are often insourced in an early to-market phase, and then integrated in a post-launch phase. Similar to factor number four, this is a matter of limited resources and therefore the geographical market on which the company operates is irrelevant.

### 7.2.5 Factor number seven: Bundling may speed up adoption of ICTMPMSCS

The studied cases suggest adoption of ICTMPMSCS could be sped up by including the product in a bundled offer. An example of this from the case studies is that of Diasend.

Their analysis tools were included in a product offering of Johnson & Johnson's sensors. Additionally, nowadays several manufacturers of insulin pumps include Diasend's tools in a bundled product offering. It is also speculated by Coala Life that their heart monitors could be bundled with life & health insurances from insurance companies.

### 7.2.6 Factor number eight: Ability to create value from collected data

Although this study only identifies one case, Dexcom, where the company actually lets other parties take part in the collected data, weak signals from the other cases suggest the data itself holds great value. Dexcom has its open data platform, and Coala Life has shown an interest to cooperate with research institutes. Different markets however have differing legal regulations on data privacy and storage. With the implementation of GDPR in the EU, criteria on data handling become stricter compared to e.g. the U.S. In this study, the value of the data has presented itself, incentives to acquire said data has presented itself, but the actual transaction where another party pays for the data has not yet been fully identified. For companies to reach the final stage of transaction, business models need to be remade to include data as a source of revenue.

### 7.2.7 Factor number nine: Development of ICTMPMSCS together with HCPs

Being a MedTech device, industry specialists are needed during the development phase of an ICTMPMSCS. HCPs are trained to aid patients medically and can in this case therefore be called industry experts. Involving HCPs in product developments partly ensures that the device solves an actual problem, and partly ensures future HCPs' usage of the solution.

### 7.2.8 Factor number ten: Strong belief in your idea and ability communicate belief to investors

This study has found indications that implicates strong belief in the solution has a more significant impact on the product reaching market establishment than financial means. When Diasend developed their product, they lacked large funding from external

investors. However, Diasend had a strong belief in the product's potential, and this belief kept them going. A strong belief in the idea has also attracted employees who themselves suffer from diabetes, employees who are dedicated to making life easier for those with the chronic disease. This suggests that apart from funding and a viable idea, there is also a strong need for an entrepreneurial drive and emotional bond within the company.

# 7.3 Identified Market Network Factors

## 7.3.1 Factor number eleven: Physicians have an important role in the adoption of ICTMPMSCS and bring legitimacy to the device

Patients as well as others in the market network, such as municipalities and regional counties place a high trust in physicians. The physician's perception of an ICTMPMSCS has a strong impact on both whether the patient will use the device or not, and on the municipalities' & counties' decision to adopt said device. In other words, both users and buyers of the ICTMPMSCS will listen to the professional opinions of the physician. This factor is applicable in Sweden, but may not be as vital in other countries where physicians do not have the same status. An example of this could be the south of Europe as Johan Feltner explained, where patients at first hand seek medical advice from their local pharmacies rather than visiting their physician.

## 7.3.2 Factor number twelve: Design ICTMPMSCS for primary user, but keep secondary user satisfied

In order for the ICTMPMSCS to be fully adopted throughout the market it needs to serve the need of HCPs, administrators and patients. The solution should: aid the HCPs in their professional tasks, help the entire healthcare sector to become more efficient, facilitate the daily life of the patient and finally offer incentives for administrators to adopt the solution. It should however be noted that these stakeholders have different interest in the ICTMPMSCS, and varying power to influence adoption of the device. The ICTMPMSCS should therefore be designed with the primary user in mind, but

secondary users also need to be kept content. This factor can be seen as a general take-away and does not necessarily only address one geographical market.

## 7.4 Fulfilment of Purpose

Factors, preconditions and dynamics behind successful market penetration and establishment of ICTMPMSCS have been studied throughout this study. The purpose along with its accompanying research questions were set out to be answered through a literature review, case studies, and interviews with industry experts. The study has presented 12 factors that can impact on the success of an ICTMPMSCS' market penetration and establishment. The 12 factors offer indications on what dynamics in the industry & macro-environment are needed, what company internal activities and decisions need to be pursued, and finally what stakeholders are involved and how they through various incentives and methods influence the adoption of ICTMPMSCS. The study also included the aspect of time. More specifically what phase of market entry the ICTMPMSCS was in, and how company internal activities as well as external factors differed over time, throughout these phases. The 12 identified factors build upon the definition of success presented in chapter 3.1. However, aspects regarding long-term success and sustainable expansions are yet to be studied.

## 7.5 Reliability and Validity

The 12 identified factors have an impact on the success of an ICTMPMSCS' market penetration and establishment. With the merged definition of success given in chapter 3.1, the factors presented in table 7.1 have an impact on the initial commercialisation of the ICTMPMSCS, sustained market establishment and increased sales. The factors have been identified through the analysis of the case studies and industry insights which are both based on ICTMPMSCS targeted towards the healthcare sector in Sweden. Therefore, the 12 identified factors apply to market penetration and establishment of ICTMPMSCS in Sweden, but some factors may be applicable for other geographical markets as well, especially other OECD countries. However, the degree to which those factors are applicable in other geographical markets may differ. The degree of applicability will depend on each country's organisational structure of healthcare, means of financing, sales channels, patient-physician interplay and domestic regulatory aspects.

ICTMPMSCS are a fairly new phenomenon, and suitable cases to study were therefore scarce. This scarcity can partly be explained by the barriers ICTMPMSCS face that this study identified. Regulatory barriers, conservatism in the healthcare sector and lower than expected incentives to finance the devices means the number of ICTMPMSCS in use are few, despite the fact that the technology for such solutions exists. Although a larger sample of cases to study would have been desirable, it is apparent that the chosen research strategy of qualitative case studies was the most appropriate choice of methodology as the phenomenon of ICTMPMSCS is still rather new and unexplored.

In order to uphold reliability of this study, the actions stated in chapter 2.3.1 were taken. As an example, all interviewees were given the same questions and the same freedom to answer the asked questions. Additionally, all interviews were held without any disturbances or interruptions. The validity of the study was ensured by executing proposed actions in chapter 2.3.2. A spreadsheet was used to track research questions and litterature. The two supervisors were continuously updated throughout the process. Data triangulation was used in the analysis, which was built upon collected data from the cases and a literature review.

This study has been exposed to a certain degree of bias in the empirically collected data. The purpose of the study has been to identify characteristics of successful market penetrations and establishment of ICTMPMSCS. All studied cases were successful in the sense that they all had products that had penetrated one or more geographical markets. This has led to a kind of survivorship bias as no unsuccessful cases have been studied. Additionally, the interviewees in each case were either the entrepreneur behind the device, or held a senior management position in the company. This means the interviewees may have provided a biased image of their ICTMPMSCS, which in turn means there is a risk for an embellished version in the story they have told.

Data triangulation provides a good basis for analysis and discussion if the empirics are contrasting from one case to another. However, if the empirics from all cases suggest the exact same thing, there is a risk for exposure to survivorship bias.

The study has not addressed any ethical aspects, particularly ethical aspects regarding the collecting and storing of patient data. There is a possibility ethical dilemmas are

present, and that these have a negative impact on the success and market adoption of studied ICTMPMSCS.

## 7.6 Contributions to Theory

The study has presented a method to break down and analyse what enables market penetration and establishment of ICTMPMSCS. The study makes a distinction between factors and dynamics during a development phase, a to-market phase and a post-launch phase for the ICTMPMSCS. The study further breaks down each phase into industry dynamics, company internal and market network factors. This method provides a broad, but not in-depth, analysis on the success of the company and its industry. The method is suitable when conducting exploratory studies, and when the aim is to understand the dynamics of an industry and how the company and its customers fit in. The market network aspect is especially useful in industries where there are multiple customer segments with different needs for the same product. Market network dynamics also come into play when the same product is sold through various channels simultaneously, and when it is financed by different types of payers.

MedTech companies who develop ICTMPMSCS or other medical devices that are used in healthcare can learn from this study by examining the cases, along with considering how the 12 identified factors (*see chapter 7 'Discussion and Conclusions')* match their specific situation. The factors are most applicable for ICTMPMSCS marketed in Sweden and countries with similar healthcare structure and means of financing, e.g. Denmark. However, other factors, especially internal factors are highly applicable in other geographical markets whereas industry dynamics and market network factors may differ.

For companies who develop high-tech products in new industries, or who are looking to expand into new markets, this study can provide insights on what factors to watch out for.

## 7.7 Suggestions for Further Research

Being an exploratory study, one purpose of the study is to provide a foundation for future research. The study has presented a broad understanding of the factors at stake

in successful market penetration and establishment of ICTMPMSCS, and it has offered indications, or trends, through so called weak signals of what is yet to come. A future study could perform a more quantitative study based on this report and the 12 identified factors, in order to single out which of these factors have the most effect on the market penetration and establishment of the ICTMPMSCS.

The study has also taken an inductive approach, originating from observations and then graduating towards a theoretical contribution in the form of the 12 identified factors. A future study should adopt a more deductive approach in an attempt to confirm these factors, or adjust them if new insights are obtained.

Due to the study's exploratory nature, some insights and topics have not been addressed in-depth. Future studies could be of a more descriptive or explanatory nature on these specific topics. A few suggestions on such topics are presented below:

- How strict should market regulatory barriers be in order to allow quick to-market times, without jeopardizing patient safety?
- Are ICTMPMSCS adopted at a quicker rate in markets financed by insurers or governments?
- How are medical devices adopted by different age groups, and is there a correlation between adoption in MedTech and technology adoption in other industries?
- From a venture capital-funding perspective: What are the success rates of ICTMPMSCS and how long are expected payback times when investing in MedTech start-ups?
- What are the mechanisms that make the healthcare sector conservative and slow to adopt new ICTMPMSCS? What would it take to change this conservatism?
- What would a governmental compensation model look like, in order for it to promote adoption of ICTMPMSCS?

# Reference List


AICGS. (2012). Structure of the U.S. Health Care System. https://www.aicgs.org/2012/03/structure-of-the-u-s-health-care-system/ [2018-04-25].

Aue, G., Biesdorf, S. & Henke, H. (2016). How healthcare systems can become digital-health leaders. *McKinsey & Company*. https://healthcare.mckinsey.com/how-healthcare-systems-can-become-digital-health-leaders [2018-02-17].

Bansal, M. & Gandhi, B. (2017). IoT based smart health care system using CNT electrodes (for continuous ECG monitoring). *2017 International Conference on Computing, Communication and Automation (ICCCA), Computing, Communication and Automation (ICCCA), 2017 International Conference on*, pp. 1324-1329 May, 2017.

Biesdorf, S. & Niedermann, F. (2014). Healthcare's digital future. *McKinsey & Company*. https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/healthcares-digital-future [2018-02-17].

Boston Consulting Group. (2018). *Six Steps to Transform a Medtech Commercial Model*. https://www.bcg.com/industries/medical-devices-technology/six-steps-transform-medtech-commercial-model.aspx [2018-02-16].

BSI. (2018). Where are you in the product development lifecycle? https://www.bsigroup.com/en-GB/medical-devices/our-services/product-lifecycle/ [2018-02-21].

Bullen, C. V. & Rockart, J. F. (1981). *A Primer on Critical Success Factors*. Center för Information Systems Research, Sloan School of Management.

Business Wire. (2017). A Renowned Cardiac Pacemaker Manufacturer Leveraged Customer Segmentation to Understand End-Users' Demands. *Business Wire*. Dec 07, 2017. https://www.businesswire.com/news/home/20171207005460/en/Renowned-Cardiac-Pacemaker-Manufacturer-Leveraged-Customer-Segmentation [2018-02-21].

Buzzell, R.D. (1983). Is Vertical Integration Profitable. *Harvard Business Review*. January issue 1983. https://hbr.org/1983/01/is-vertical-integration-profitable [2018-04-09].

Brownsell, S. (2009). Measuring the 'success' of telehealth interventions. *Journal of Assistive Technologies*. Vol. 3. Issue 4. pp. 12-20.

Casadesus-Masanell, R. & Tarziján, J. (2012). When One Business Model Isn't Enough. *Harvard Business Review*. January-February 2012.

Center for Medicare & Medicaid Services (2018). National Health Expenditure Data. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html [2018-04-04].

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

Coala Life. (2018). Om Coala Life AB. https://www.coalalife.com/om-coala/ [2018-04-04].

Coala Life. (N/Aa). Coala Heart Monitor. https://www.coalalife.com/coala-heart-monitor [2018-04-04].

Coala Life. (N/Ab). Coala Pro. https://www.coalalife.com/pro/ [2018-04-04].

Cooper, R.G. & Kleinschmidt, E.J. (2007). WINNING BUSINESS IN PRODUCT DEVELOPMENT: THE CRITICAL SUCCESS FACTORS. *Research Technology Management*. Vol 50. Issue 3. pp. 52-66.

Creswell, J. W. (1998). *Qualitative Inquiry and Research Design: Choosing Among Five Research Traditions*. Sage Publications, Thousand Oaks, California. pp. 13-26.

Deloitte Center for Health Solutions (2015a). Next-generation "smart" devices: preparing for an increasingly intelligent future. Washington DC.

Deloitte Center for Health Solutions (2015b). Connected health. How digital technology is transforming health and social care. Washington DC.

Denscombe, M. (2010). *The good research guide: for small-scale social projects.* 4th edition., Maidenhead: Open University Press.

Dexcom. (2018a). About Dexcom. https://www.dexcom.com/about-dexcom [2018-04-04].

Dexcom. (2018b). Continuous Glucose Monitoring. https://www.dexcom.com/continuous-glucose-monitoring [2018-04-04].

Dexcom. (2018c). Apps. https://www.dexcom.com/apps [2018-04-04].

Di Benedetto, C.A. (1999). Identifying Key Success Factors in New Product Launch. *Journal of Product Innovation Management*. Vol. 16. pp. 530-544.

Diage, T. (2013). *Planning for Successful Medical Device Reimbursement*. NAMSA. White Paper. https://www.namsa.com/wp-content/uploads/2015/10/NAMSA-Planning-for-Successful-Medical-Device-Reimbursement.pdf [2018-04-04].

Drucker, P. (2002). *Management Challenges for the 21st Century*. Oxford: Butterworth-Heinemann.

E-hälsa 2025 (2017). Om e-hälsa 2025.https://ehalsa2025.se/om-e-halsa-2025/ [2018-02-05].

Eklind, H. (2017). A hub clinician's perspective on supported self-care through technology. *Primary Health Care*. *27*(1), pp. 20-25.

EMERGO. (2016). Worldwide Spending on Healthcare. https://www.emergobyul.com/resources/worldwide-health-expenditures [2018-04-25].

EUGDPR. (N/A). GDPR Key Changes. https://www.eugdpr.org/the-regulation.html [2018-04-04].

European Commission (2018a). CE-marking. https://ec.europa.eu/growth/single-market/ce-marking_en [2018-04-04].

European Commission (2018b). CE-marking - Manufacturers. https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en [2018-04-04].

European Commission, Joint Research Centre (2017a). *World's top 50 health care equipment and services companies based on profit growth in 2016/2017*. https://www-statista-com.ludwig.lub.lu.se/statistics/524991/top-health-care-companies-by-3-year-profit-growth/ [2018-03-12].

European Commission, Joint Research Centre (2017b). *World's top 50 health care equipment and services companies based on sales growth in 2016/2017*. https://www-statista-com.ludwig.lub.lu.se/statistics/524932/top-health-care-companies-by-highest-3-year-cagr-in-sales/ [2018-03-12].

FDA. (2018a). Premarket Notification 510(k) https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm [2018-04-04].

FDA. (2018b). PMA Approvals. https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm#GI [2018-04-04].

FDA. (2018c). PMA Supplements and Amendments. https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm050467.htm [2018-04-12].

Fjärstedt, U. (2017). Upphandling [Medicintekniska produkter]. http://www.vardhandboken.se/Texter/Medicintekniska-produkter/Upphandling/ [2018-02-21].

Ghodeswar, B. M. & Vaidyanathan, J. (2007). ORGANISATIONAL ADOPTION OF MEDICAL TECHNOLOGY IN HEALTHCARE SECTOR. *Journal of Services Research*. Oct2007-Mar2008. Vol. 7. Issue 2. pp. 57-81.

Golicic, S. L., Davis, D. F. & McCarthy, T. M. (2005). A balanced Approach to Research in Supply Chain Management. *Research Methodologies in Supply Chain Management*. pp. 15-29.

Greener, M. (2016). Commercialisation in the medical devices market. *MedTech Engine*. Oct 6, 2016. https://medtechengine.com/article/cambridge-consultants-commercilisation/ [2018-02-17].

Holopainen, M. & Toivonen, M. (2012). Weak signals: Ansoff today. *Futures.* April 2012. Vol. 44. Issue 3. pp. 198-205.

Höst, M., Regnell, B. & Runeson, P. (2006). *Att genomföra examensarbete.* Lund: Studentlitteratur.

Johnson, K., Whittington, R. & Scholes, K. (2012). *Fundamentals of Strategy.* 2nd edition., Pearson Education Limited.

Larsson, A., Bill, S., Ingridsdotter, J. & Olsson, A. (2011). Collaborative Healthcare Innovation in Sweden. *Sustaining Innovation*. pp. 49-62.

Lekvall, P. & Wahlbin, C. (2007). *Information för marknadsföringsbeslut.* 4th edition., IHM Publishing.

Levit, T. (1965). Exploit the Product Life Cycle. *Harvard Business Review*. Issue Nov 1965. https://hbr.org/1965/11/exploit-the-product-life-cycle [2018-02-21].

Llewellyn,C., Podpolny, D. & Zerbi, C. (2015). *Capturing the new 'value' segment in medical devices*. McKinsey & Company.

Lupton, D. (2014). The commodification of patient opinion: the digital patient experience economy in the age of big data. *SOCIOLOGY OF HEALTH & ILLNESS.* Jul 2014. pp. 856-869.

Läkemedelsverket. (2014). Medicintekniska produkter. https://lakemedelsverket.se/malgrupp/Foretag/Medicinteknik/ [2018-02-21].

Mendelow, A. (1983). Setting Corporate Goals and Measuring Organizational Effectiveness - A Practical Approach. *Long Range Planning*. Vol. 16. No. 1. pp. 70-76.

Moore, G. A. (2001). *Crossing The Chasm*. Revised edition. HarperBusiness, a division of HarperCollins Publishers.

OECD. (2017). *Health at a Glance 2017*. https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance_19991312 [2018-04-24].

Osterwalder, A. & Pigneur, Y. (2010). *Business Model Generation: A Handbook for Visionaries, Game Changers, and Challengers.* John Wiley & Sons, Inc Hoboken, New Jersey.

PR Newswire (2011). Northwestern Survey Finds FDA Predictability a Top Concern Among Medtech Firms; Europe Preferred for Product Approval. https://www.prnewswire.com/news-releases/northwestern-survey-finds-fda-predictability-a-top-concern-among-medtech-firms-europe-preferred-for-product-approval-122514653.html [2018-02-26].

PwC (2016). Den digitala patienten är här - men är vården redo? Sverige.

Regeringen (2016). E-hälsa - Digitaliseringi socialtjänst och hälso- och sjukvård. http://www.regeringen.se/artiklar/2016/12/e-halsa---digitalisering-i-socialtjanst-och-halso--och-sjukvard/ [2018-01-30].

Regeringen (2015). Indelning och uppgifter i kommuner och landsting. http://www.regeringen.se/artiklar/2015/05/indelning-och-uppgifter-i-kommuner-och-landsting/ [2018-02-06].

Region Skåne (2017). Vårdcentraler och annan primärvård. https://www.skane.se/Halsa-och-vard/hitta-vard/Vardcentraler-och-annan-primarvard/ [2018-02-06].

Rogers, E. M. (1983). *Diffusion of Innovations*. 3rd edition. The free press, A Division of Macmillan Publishing Co., Inc. New York.

Rouse, M. & Pratt, M. K. (2017). ICT (information and communications technology, or technologies). TechTarget. http://searchcio.techtarget.com/definition/ICT-information-and-communications-technology-or-technologies [2018- 03-01].

Rowley, J. & Slack, F. (2004). Conducting a literature review. *Management Research News.* vol. 27, issue 6. pp.31-39.

SCB (2017). Kommunalskatter 2017. https://www.scb.se/hitta-statistik/statistik-efter-amne/offentlig-ekonomi/finanser-for-den-kommunala-sektorn/kommunalskatterna/pong/statistiknyhet/Kommunalskatter/ [2018-01-31].

SCB (2018). Befolkningsstatistik. https://www.scb.se/hitta-statistik/statistik-efter-amne/befolkning/befolkningens-sammansattning/befolkningsstatistik/#_Tabellerochdiagram [2018-04-17].

Seuring, S., Müller, M., Westhaus, M. & Morana, R. (2005). Conducting a Literature Review - The Example of Sustainability in Supply Chains. *Research Methodologies in Supply Chain Management*. pp. 91-106.

Shih-Jung, W., Rui-Dong, C., Shih-Hao, C., & Wei-Ting, C. (2017). An Interactive Telecare System Enhanced with IoT Technology. *IEEE Pervasive Computing*, *16*(3), 62-69.

Socialstyrelsen (2013). Socialstyrelsens föreskrifter om bedömningen av egenvård. *Meddelande.* Nr 6 April 2013, pp 1.

Stuart, I., McCutcheon, D., Handfield, R., McLachlin. & Samson, D. (2002). Effective case research in operations management: a process perspective. *Journal of Operations Management*. 20(5), pp. 419-433.

Swedish Competition Authority (2018). Direktupphandling. http://www.konkurrensverket.se/upphandling/utan-annonsering/direktupphandling/ [2018-04-04].

Swedish Medtech (2018). Om branschen. http://www.swedishmedtech.se/sidor/om-branschen.aspx [2018-01-30].

Technavio (2016). Global Self-care Medical Devices Market 2016-2020. https://www.technavio.com/report/global-orthopedics-and-general-medical-devices-self-care-medical-devices-market [2018-02-17].

Telia IBD Home. (2017). https://www.telia.se/dam/jcr:30b29793-b5e7-4958-8c46-266bbaf975a9/O52803_IBD_Home_Folder_A5_TSP-4429_1_1705_HI.pdf [2018-02-20].

The Atticus Group. (2017). Understanding Reimbursement for Medical Devices: Coding, Coverage, Payment and Payors. [Blog]. http://theatticusgroup.net/understanding-reimbursement-medical-devices-coding-coverage-payment-payors/ [2018-04-04].

The Economist. (2018). Surgical Intervention. *The Economist.* Feb 3rd-9th 2018. pp. 51-53.

The Ministry of Health. (2017). Healthcare in Denmark- An Overview. Copenhagen.

Thompson, A.A., Strickland, A.J. & Gamble, J.E. (2010). *Crafting and Executing Strategy. The Quest for Competitive Advantage*. 17th edition. McGraw-Hill Irwin, New York, NY.

Tieto (2011). Integrated digital care and self care model pays off. https://www.tieto.com/customer-cases/integrated-digital-care-and-self-care-model-pays [2018-02-26].

Van Donk, D. P. & Van der Vaart, T. (2005). A Critical Discussion on the Theoretical and Methodological Advancements in Supply Chain Integration Research. *Research Methodologies in Supply Chain Management.* pp. 31-46.

Wicklund, E. (2017). mHealth Wearables Market to Surge Over Next 4 Years. *mHealth Intelligence*. Feb 6, 2017. https://mhealthintelligence.com/news/mhealth-werables-market-to-surge-over-next-4-years [2018-02-20].

World Health Organization. (2016). FROM INNOVATION TO IMPLEMENTATION - eHealth in the WHO European Region. http://www.euro.who.int/__data/assets/pdf_file/0012/302331/From-Innovation-to-Implementation-eHealth-Report-EU.pdf?ua=1 [2018-03-01].

Yin, R. K. (2003). *Case Study Research - Design and Methods*. 3rd edition. Sage Publications, Thousand Oaks.