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# Digital Therapeutics Solution and Business Model Creation

*—Multiple-case study through VISOR Lens*

Master's Thesis in Governance of  
Digitalization  
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Åbo Akademi University

Åbo 2019

## ACKNOWLEDGMENTS

First and foremost, I want to thank my supervisor, Shahrokh Nikou, Docent, Information Systems Åbo Akademi University, who has been an invaluable help in the thesis writing process. I highly appreciate the effort and time devoted to offering academic support, motivation, and encouragement throughout the process.

I also want to express my gratitude to the client company and my two supervisors who have offered this unique and educational experience by allowing me to be part of this interesting project. The thesis would have lacked many vital elements without the two supervisors' guidance, support, and knowledge. Furthermore, I want to thank all the interviewees and respondents that provided me their time and valuable insights.

I am thankful for all my fellow students and new friends that made the study time enjoyable, enhanced the learning, and contributed to my knowledge base. I want to thank my family and friends for the unconditional support and encouragement during the process. Most importantly, I want to thank Arttu Linnavuori for always believing in me, supporting when most needed, and encouraging to carry on.

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December 2019

Subject: Governance of Digitalization	
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Title: Digital Therapeutics Solution and Business Model Creation: Multiple-case study through VISOR lens	
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<p><b>Abstract:</b></p> <p>The demographic changes in societies are pressurizing governments to offer high quality health care with reduced costs. Digital solutions and technologies can provide cost-effectiveness, increased accessibility, and personalized treatment. However, the novelty of such solutions results in uncertainty of business models and market access. This thesis contributes in finding feasible business model for a client company that is developing a digital therapeutics solution. For supporting the business model decisions, business environment scanning is essential. The characteristics of existing digital therapeutics companies' business models provide vital information regarding the business model creation.</p> <p>This thesis covers companies internationally owing to global markets of client company and case companies. The chosen research methodology includes a multiple-case study and in-depth interviewees through VISOR framework about the most important characteristics of a business model in the digital therapeutics companies. 5 case companies' business models were researched and analysed through comparison. 8 in-depth interviewees were conducted, and 4 additional written responses were received for gaining stakeholder perceptions about the important characteristics of the business model. Finally, a suggestion for a business model was created based on the analysed results and taking into consideration the most feasible characteristics.</p> <p>Digitalization can provide solution for current needs in health care such as personalization, cost-effective treatment, and easy accessibility. The gathered health data contributes in transparent and better-quality health care. Because medical professionals remain as essential actors in recommending and delivering the digital solution to patients, they need to be convinced through clinical trials that support the effectiveness of such solutions. The challenges regarding the legal, regulatory, pricing, and cost-related aspects were recognized by the stakeholders as well as supported by the literature. The developed business model does not provide straightforward solutions, but rather supports in decision-making processes when the feasibility between several options are considered. A feasible business model is dependent on various factors, such as the chosen technical solution, demographic location of the company, capabilities, and partnerships. However, eventually everything comes to the customer, and their willingness to adopt, use, and pay.</p>	
Keywords: Digital Therapeutics, Business Model, Business Model Innovation, VISOR Framework, Digitalization in Pharmaceutical Industry, Digital Solutions	
Date: 17.11.2019	Number of pages: 142

# TABLE OF CONTENTS

LIST OF FIGURES .....	V
LIST OF TABLES .....	VI
1 INTRODUCTION .....	1
<b>1.1 Motivation and Research Objectives .....</b>	<b>3</b>
<b>1.2 Structure of the Thesis .....</b>	<b>4</b>
2 LITERATURE REVIEW .....	5
<b>2.1 Delivering Health Care .....</b>	<b>5</b>
2.1.1 Health Care Systems .....	6
2.1.2 Reimbursement Systems .....	10
2.1.3 Needs in Health Care .....	13
<b>2.2 Digitalization in Pharmaceutical Industry .....</b>	<b>15</b>
2.2.1 Digital Solutions and Technologies .....	16
2.2.2 Pricing Digital Content .....	19
3 THEORETICAL BACKGROUND .....	21
<b>3.1 Health Care in the USA .....</b>	<b>21</b>
<b>3.2 Health Care in the EU .....</b>	<b>22</b>
3.2.1 Health Care in Finland .....	23
3.2.2 Health Care in Germany .....	24
3.2.3 Health Care in France .....	25
<b>3.3 Regulations .....</b>	<b>26</b>
3.3.1 Regulating Medical Devices in the USA .....	27
3.3.2 Regulating Medical Devices in the EU .....	29
<b>3.4 Business Models .....</b>	<b>30</b>
3.4.1 Business Model Ontologies .....	35
4 RESEARCH METHODOLOGY .....	40
<b>4.1 Research Methods .....</b>	<b>40</b>
<b>4.2 Data Collection Methods .....</b>	<b>41</b>
<b>4.3 Research Method Used .....</b>	<b>42</b>
4.3.1 Sample .....	43
4.3.2 Data Analysis Method .....	43
5 CASE INTRODUCTIONS .....	45
<b>5.1 Client Company .....</b>	<b>45</b>
<b>5.2 Case Companies .....</b>	<b>46</b>
5.2.1 Kaia Health .....	46
5.2.2 XRHealth .....	47
5.2.3 MindMaze .....	48
5.2.4 SilverCloud Health .....	49

5.2.5	Happify.....	50
6	RESULTS .....	51
6.1	<b>Multiple-case Study .....</b>	<b>51</b>
6.1.1	Kaia Health.....	51
6.1.2	XRHealth .....	54
6.1.3	MindMaze .....	56
6.1.4	SilverCloud Health.....	59
6.1.5	Happify.....	61
6.2	<b>In-depth Interviews .....</b>	<b>63</b>
6.2.1	Value Proposition.....	64
6.2.2	Interface.....	74
6.2.3	Service Platform.....	78
6.2.4	Organizing Platform.....	81
6.2.5	Revenue Model .....	86
6.2.6	Product Cost Structure .....	93
6.2.7	Challenges .....	95
7	ANALYSIS .....	99
7.1	<b>Comparison of Case Companies .....</b>	<b>99</b>
7.1.1	Value Proposition.....	99
7.1.2	Interface.....	101
7.1.3	Service Platform.....	102
7.1.4	Organizing Model .....	102
7.1.5	Revenue Model .....	103
7.2	<b>Stakeholder Perceptions .....</b>	<b>104</b>
7.2.1	Value Proposition.....	104
7.2.2	Interface.....	106
7.2.3	Service Platform.....	107
7.2.4	Organizing Model .....	107
7.2.5	Revenue Model .....	108
7.3	<b>Business Model .....</b>	<b>109</b>
8	DISCUSSION AND FINAL CONCLUSIONS .....	113
8.1	<b>Key Findings .....</b>	<b>113</b>
8.1.1	Research Questions .....	114
8.2	<b>Conclusions .....</b>	<b>115</b>
8.2.1	Limitations and Future Research .....	115
	REFERENCES.....	117
	APPENDICES .....	124

## LIST OF FIGURES

Figure 1 Healthcare Triangle (Mossialos & Dixon, 2002) .....	7
Figure 2 The Process of Funding Healthcare (Mossialos & Dixon, 2002).....	8
Figure 3 Regulatory Process for Market Access in the USA (Federal Trade Commission, 2016) .....	27
Figure 4 Regulatory Process for Market Access in the EU .....	29
Figure 5 Business Model Canvas (Osterwalder & Pigneur, 2010) .....	36
Figure 6 The VISOR Model (El Sawy et al., 2013).....	38
Figure 7 Interview Demographics.....	64
Figure 8 Compelling Factors.....	64
Figure 9 Division of Considered Target Groups.....	67
Figure 10 Division of Organizations.....	68
Figure 11 Complementary Factors .....	71
Figure 12 Factors of Co-Creatibility .....	72
Figure 13 Personalization Based on Health Data Assessment.....	73
Figure 14 Functionality Factors .....	75
Figure 15 Interaction Possibilities.....	76
Figure 16 Interface Characteristics .....	77
Figure 17 Service Platform Characteristics.....	78
Figure 18 Points of Acquisition .....	79
Figure 19 Core Business Processes.....	81
Figure 20 Partnerships .....	84
Figure 21 Pooling of Resources .....	85
Figure 22 Inner Capabilities.....	86
Figure 23 Pricing Options .....	87
Figure 24 Low Price versus High Price .....	89
Figure 25 One Price versus Many Prices .....	90
Figure 26 Factors Affecting Price .....	91
Figure 27 Options for VR Headset Acquisition.....	92
Figure 28 Factors Affecting the Product Cost Structure.....	94
Figure 29 Challenges.....	96

## LIST OF TABLES

Table 1 Components of Business Model Canvas (Osterwalder & Pigneur, 2010).....	36
Table 2 VISOR Model Components (El Sawy et al., 2013) .....	38
Table 3 XRHealth's products (www.xr.health) .....	47
Table 4 SilverCloud Health's Programs (www.silvercloudhealth.com) .....	49

# 1 INTRODUCTION

Digitalization has already affected many industries, and the new digital technologies are expected to change the used business models. People, matters, and industries are more connected to each other and information can be copied without errors infinite number of times which offer companies new types of value creation and capture, leaner processes, and improved customer experience. However, such as lack of funding, existing IT systems' limitations and regulatory concerns create barriers for many industries in regards of digitalization (Chircu, Sultanow & Sözer, 2017).

In many developed countries, the healthcare industry is continuously developing and accommodating to new technologies and trends (Shakshuki & Reid, 2015). New technological and medicinal advances offer innovative opportunities to create cooperative networks between public and private practices (e.g. in health care domain) and most importantly, opportunity to offer improved quality services for the patients (Länsisalmi, Kivimäki, Aalto, & Ruoranen, 2006). These innovative medicines and technologies can benefit everyone globally (Garrisson & Towse, 2017). Furthermore, it is important for healthcare organizations and systems to stay current with new technologies because, as all the information, also medical information is rapidly increasing (Länsisalmi et al., 2006).

The pharmaceutical industry has also recognized the potential of digitalization and the opportunities it brings, but the companies are still figuring out the required capabilities that are needed to develop and further capitalize these new opportunities (Chircu et al., 2017). One opportunity that digitalization in the pharmaceutical industry can bring is the digital health. Digital health means the use of internet, digital and mobile technologies in improving health and/or treating some specific medical condition (Afra et al., 2018). Kvedar et al. (2016, p. 240) describe the benefits of digital medicine as: "Patients can now be reached before, during and after chronic disease development, interventions can be delivered continuously, and deployment can occur either inside or outside the healthcare system. This is the promise of digital medicine" (Kvedar, Fogel, Elenko, & Zohar, 2016). A closely related term, digital therapeutics, refers to a treatment where digital systems are used to treat medical conditions. Digital health data that is gathered through the digital therapeutic tools, can be recognized as a considerable opportunity for



patients, pharmaceutical companies, and clinics (Sverdlov et al., 2018). Digital technologies and therapeutics have shown evidence in pain relief using Virtual Reality (hereinafter referred to VR) technology as well as drug-device combination therapies. The focus of digital therapeutics is usually on behavioural therapies and selfcare, whereas adding the pharmaceutical drugs could offer considerable benefits for the patient (Afra et al., 2018).

The effectiveness of digital therapeutics can especially be found in the areas of chronic diseases as well as diseases with behavioural and physical aspects because these diseases are able to receive value from real-time behaviour and health status monitoring. Furthermore, these diseases are usually not managed appropriately by the healthcare systems and expose them to vast expenses. Hence, compared to more conventional therapies, the digital solutions can be accessed more easily and with substantially lower costs (De Luca, 2019). Individuals suffering from chronic illnesses can have challenges with their self-esteem and mental health. For being able to prevent some of these challenges, digital platforms can be used as an enhancement tool to motivate and engage the patient and at the same time increase their self-esteem. Furthermore, this kind of intervention can increase the results of the physical treatment (Bedrov & Bulaj, 2018).

One of the most significant challenges that the pharmaceutical companies is facing with regard to digital therapeutics are the complexity and slowness of regulatory processes. Because of the novelty of digital therapeutics, regulatory requirements and authorization are not yet developed (Afra et al., 2018). Moreover, companies are struggling to find feasible reimbursement models for digital therapeutics. Existing reimbursement models do not necessarily work, and new and yet innovative business models need to be created, developed, and studied (Kvedar et al., 2016). Business models are not yet established either because of the complexity or diversity of digital medicine. Companies are unsure whether these technologies should be the core product or just as an enhancement tool. The increasing competition in the digital health space makes it difficult for companies to choose a development path and commercialization strategy to distinguish their product. Validation and regulation still remain as key determinants (Hird, Ghosh, & Kitano, 2016). Furthermore, not only the new health technologies and development of them might increase the quality requirements (Lameire, Joffe, & Wiedemann, 1999), but also, the technology itself might create some difficulties for the provider and delivery systems

because they lack experience and do not receive any guidance about the use of these technologies. Because of this, the providers do not have any estimations about the effectiveness of the technology. Moreover, the maintenance and installation of these technologies create additional work for the IT staff in the organization. Moreover, cost calculations and return on investments do not exist because of the lack of these assumptions and financial models (Coye, Haselkorn, & DeMello, 2009).

## **1.1 Motivation and Research Objectives**

As presented in the introduction, the need for this research is in this growing business area and its various potentials that are not much researched. Thus, this research will contribute to uncertainty of existing regulations and needs for business models in the digital therapeutics field. Furthermore, the need for this research has arisen from a client company that is developing a digital therapeutics solution for chronic low back pain. The main objective of this thesis is to find a feasible business model for the digital therapeutics solution being developed by the client company. The business model needs to convince the various stakeholder groups within and outside the client company. Because of the novelty of digital therapeutics solutions, the already existing business models in other digital therapeutics companies are able to provide vital background information regarding the development of the business model.

In order to support the decisions made for the business model, analysing and scanning the business environment is essential. This thesis covers companies internationally and does not only focus on digital therapeutics companies in the EU. The USA is the leading national market for pharmaceutical products (Dubois, de Mouzon, Scott-Morton, & Seabright, 2015) and thus, it is a compelling market for many global pharmaceutical companies, as it is for the client company as well as the case companies presented in this thesis.

The objectives of the research have motivated the development of research questions that will support the overall perspectives of this thesis. The research questions are:

- RQ1: What kind of business environment exists for the client company?
- RQ2: From the business model perspective, what type of characteristics arise in existing digital therapeutics companies?

- RQ3: Which of these characteristics are feasible in the client company's business model?
- RQ4: Which characteristics are perceived important by different stakeholder groups within and outside the client company?

## **1.2 Structure of the Thesis**

The thesis commences with an introduction to the thesis topic and defines a research gap that motivates the research objectives and questions. The second chapter consists of a literature review that aims in providing a thorough understanding of the business environment. This is followed by an introduction of theoretical background that presents frames for the conducted research and for further analysis of the results. The fourth chapter explains the research methodology by describing the research and data collection methods as well as motivates the chosen research methods for this thesis. For the purpose of multiple-case study and in-depth interviews, the fifth chapter provides background information about the client company and five case companies. In the following chapter, the results from multiple-case study and in-depth interviews are introduced and supported by theoretical background. The seventh chapter contributes in analysing the results through comparing the case companies and combining the stakeholder perceptions. Based on the results, a suggestion for a business model is described. In conclusion, the key findings from the research based on literature are presented and discussed. Finally, the practical and theoretical implications are considered followed by limitations and future research suggestions.

## **2 LITERATURE REVIEW**

This literature review aims at describing the business environment that exists for the digital therapeutics solution. The understanding of the environment supports the business model design and contributes in more informed decision-making (Osterwalder & Pigneur, 2010). The literature review describes the demographic changes resulting in a requirement for transforming the delivery of health care. Furthermore, the different health care and reimbursement systems are introduced and the arising needs for health care value delivery are discussed. Then, the digitalization's possibilities for pharmaceutical industry and digital therapeutics are introduced. Lastly, the various means of pricing digital content are considered.

### **2.1 Delivering Health Care**

Demographics of the population are changing (Länsisalmi et al., 2006) while in many countries, the aging population increases the demand of health care by typically being more dependent on the services offered by the state (Shakshuki & Reid, 2015; Lameire et al., 1999). Moreover, people are dependent on the economy at the beginning as well as end of life because their consumption exceeds the income generated through labour input (Hammer, Prskawetz, & Freund, 2015; Wendt, Kohl, Mischke, & Pfeifer, 2010). However, the aging population does not only mean that the number of patients and acute trauma levels are increasing but also that the workforce, especially nurses, are retiring which results in a lack of skilled staff (Länsisalmi et al., 2006). Current health care systems will be pressurized because the number of elderly people is increasing, and they need to be covered by government funds. However, the population in working age is shrinking due to lower fertility and aging population (Hammer et al., 2015).

Due to this change in age structure, economies need to consider the economic life cycle and economic age pattern of economic activities such as consumption, the generation of labour income, and saving. Consequently, societies need to reallocate their resources as well as reallocate the age system (Hammer et al., 2015). Physical inactivity, unhealthy diets, and other changes in lifestyles in addition to aging population have increased the amount of chronic conditions. Additionally, even more patients suffer from multiple morbidities (OECD, 2016). Thus, personalized healthcare will be important due to these

complex diseases and differences in responding to treatments by each patient. Innovation and improvement regarding medicine, treatment, and health care are essential in order to answer the patients' needs (Garrison & Towse, 2017).

In the European countries, social values that are embedded in societies guide the public attitudes with regard to the state's responsibility in health care. In most European countries, thus, health care funding comes from the public. Satisfaction for health care is more a personal experience and hence the institutional differences matter for citizens. At the individual level the more satisfaction towards a health care system is felt when the patient feels that the doctor actually gave time for the patient (Wendt et al., 2010). Hence, the need for quality in health care is rising among patients and citizens (Bodolica, Spraggon, & Tofan, 2016; Lameire et al., 1999). When patients and third-party payers become more aware of value of health care, value-based pricing and reimbursement become more important (Garrison & Towse, 2017). In addition, governments are pressured to increase the quality of healthcare while reducing costs (Länsisalmi et al., 2006).

### **2.1.1 Health Care Systems**

Health care systems reflect on the citizens' social and cultural expectations because they are affected by the values and norms in society. The unique history, traditions and political systems have modified different health care systems to each country. In some societies, health care is viewed as a social or collective good accessible for every individual regardless of his status, need or age, whereas some see it as a commodity bought and sold on the open market. Despite this difference, each health care system aims for a perfect balance of access of healthcare, quality of care, and cost efficiency (Lameire et al., 1999).

Health care delivery and finance can be depicted as a triangle. In Figure 1, the exchange and transfer of resources between parties is illustrated. The providers transfer health care resources to patients, and patients or third parties then transfer financial resources to providers. In the simplest form, the consumer (the first party) pays directly to the provider (the second party) in exchange for the service or good (Mossialos & Dixon, 2002). However, the health care systems have been developed to share the consumer's financial risk of falling ill and uncertainty of actions taken in such an event. Thus, a third party (a

public or a private body) collects direct or indirect payments from the population it protects in order to reimburse the patient or the provider. The third party's responsibility is to determine a health benefit package or health plan that covers the correct and relevant medicines, tests, and procedures (Garrison & Towse, 2017; Mossialos & Dixon, 2002).

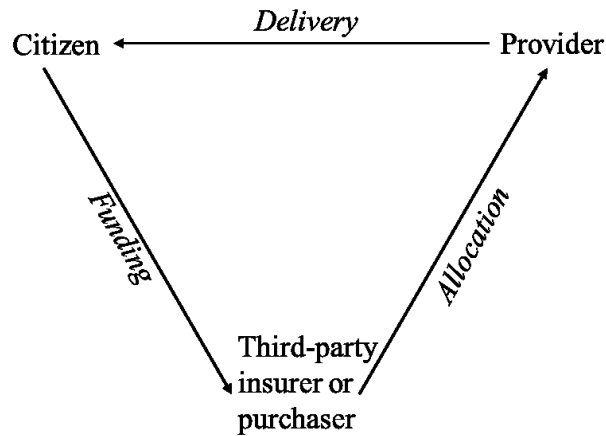


Figure 1 Healthcare Triangle (Mossialos & Dixon, 2002)

There are three functional components in health care systems that can be either integrated or separated in several combinations: revenue collection, fund pooling, and purchasing and provision of health care. When these functions are separated, the resources are allocated between entities that have focused either in collecting and pooling of funds or purchasing and providing the services. The revenue collection is the process of collecting funds for the health care system (see Figure 2) (Mossialos & Dixon, 2002).

Mainly the funding comes from individuals or corporate entities in the means of taxes, social health insurance contributions, private health insurance premiums, medical savings account or out-of-the-pocket payments. Taxes and social health insurance funds are usually compulsory payments collected through e.g. income, payroll and commodities by the government or employer and reserved for health and social service expenses. Private health insurance premium's price is determined by risk ratings based on different assessment and criteria of requiring health care. Private for-profit or not-for-profit insurance companies and funds collect the payments from individuals, employers, or the combination of these two. An individual can reserve funds into a medical savings account which usually is combined with a high-deductible catastrophic insurance. Out-of-the-pocket payments are collected by the service provider as a flat rate payment for each service or co-insurance payment as a percentage of the total cost of the service. In some

cases, the insurer covers the remaining costs if the patient has reached the so-called ceiling amount of payments (Mossialos & Dixon, 2002).

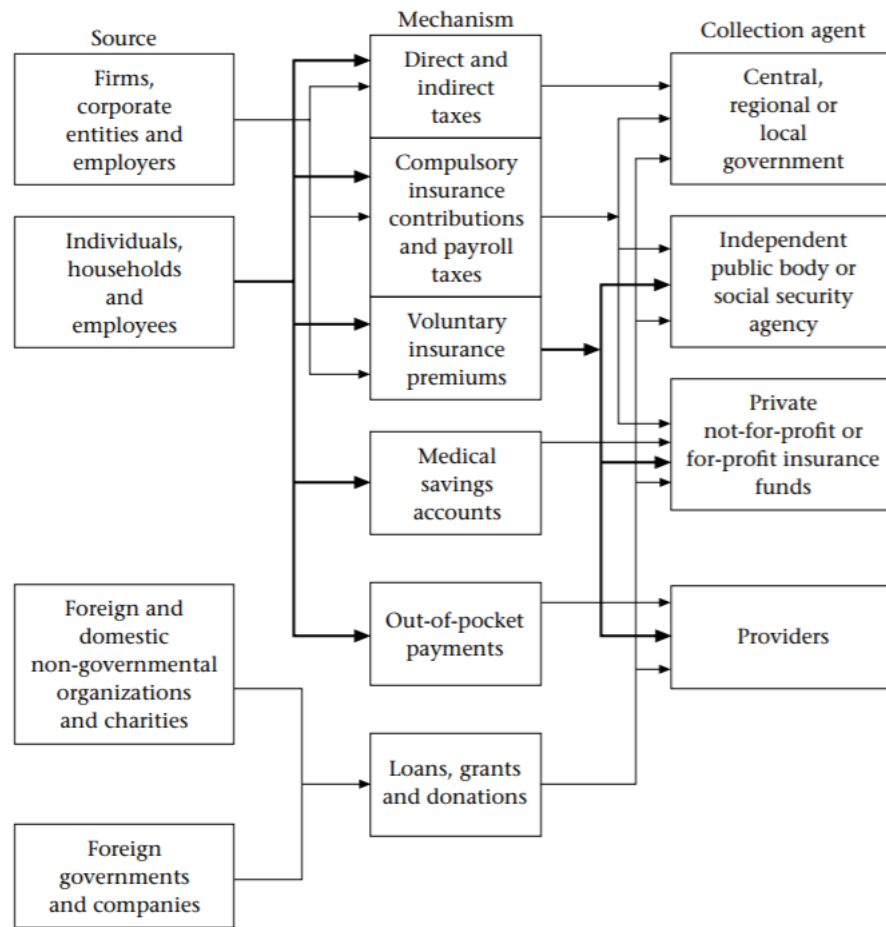


Figure 2 The Process of Funding Healthcare (Mossialos & Dixon, 2002)

In the fund pooling function, the financial risk is pooled across the population or a defined subgroup. Taxes are collected and used by the same agent which makes the allocation from collection agent to pooling agent internalized. However, a mechanism is required to distribute the resources from the collection agent to the pool in case different agents carry out these functions. Furthermore, in case of multiple pools the risk profile and needs of population covered by each pool determines the allocation of resources. This enables equal access of health care to each individual. In the private health insurance model, the funds are pooled between the subscribers of the same insurance provider, whereas in the medical savings account the pooling is not possible. Hence, these individuals usually acquire an additional catastrophic insurance. Out-of-the-pocket payments do not either have the pooling function, but they serve as a revenue for the healthcare provider to maintain the service and cover costs. In some cases, however, the user charges might be

account for the insurer or government and out-of-the-pocket payments are used to meet any gap between premium or tax revenue and expenditure (Mossialos & Dixon, 2002).

In the purchasing of the service function the pooled resources are transferred to service provider on behalf of the population for which the funds were pooled. Many health care systems allocate the resources based on political negotiation, historical standard, and lowest bid even though they should be allocated according to the health care need of each population. This would support the equity and efficiency of healthcare systems (Mossialos & Dixon, 2002).

Three models of healthcare systems can be recognized based on the source of funding of healthcare: Beveridge model, Bismarck model and the private insurance model. Funding in the Beveridge model is based on taxation and the services are mainly provided by public health providers (hospitals, community doctors, etc.) (Lameire et al., 1999). The hospitals and clinics are owned, and some doctors are employed by the government. However, there can also be private doctors that are paid by the government. Moreover, government monitors and controls doctors' work and fees to high extent (Reid, 2009). In the Beveridge mode, the budget of health care is competing with other spending priorities, but it offers the access of health care to each citizen of the country (Lameire et al., 1999).

The Bismarck model is based on a non-profit social or mandatory insurance system that is financed with employers and employees through payroll deduction. The services are provided by the mix of private and public health providers and the system is regulated by the government. However, the system does not cover everyone's healthcare, which means that the difference needs to be compensated with additional private insurance (Lameire et al., 1999; Reid, 2009). Nevertheless, Lameire et al. (1999) argue, that the population in the countries with Bismarck system, are wealthy enough to be able to invest such money on the additional private insurance.

In the private insurance model, the financing comes from the premiums paid for private insurance companies and the health care providers are mainly from private sector. This type of model creates inequality between citizens by leaving many citizens, that are not able to afford a private insurance, out of the health care system (Lameire et al., 1999). In developing countries, out-of-the-pocket models are most common with the lack of mass



medical care. The result is that only the people who can afford healthcare, are able to receive it (Reid, 2009).

National health insurance model has elements from both Bismarck and Beveridge models. The healthcare providers are from the private sector, whereas the funding comes from an insurance program that is run by the government. Each citizen contributes into the insurance program. This non-profit insurance program is simple administratively and less expensive because the costs can be negotiated to very low level by the single-payer's market power (Reid, 2009).

### **2.1.2 Reimbursement Systems**

Reimbursement refers to the payment method and the amount the third-party payers are willing to pay for services and products covered for their health plan subscribers. Price is the amount that the health care providers charge for providing the product or service for members of health plan. Thus, the price needs to be accepted by the third-party payers who reimburse the health services and products accepted into the health plan. Otherwise, the patient needs to provide a co-payment for the difference. The reimbursement is highly regulated in some countries where the reimbursement agents negotiate and set the prices. In addition, the use of licenses and quality of products or services are monitored by the national regulating agents (Garrison & Towse, 2017).

The healthcare reimbursement methodologies can be divided in two main categories: fee-for-service reimbursement and episode-of-care reimbursement. Fee-for-service reimbursement is the payment healthcare provider receives for each service offered, whereas the episode-of-care reimbursement refers to one payment amount for all the services provided related to a condition or disease. Additionally, the reimbursements can be further divided into retrospective payment method, where the provider receives the payment after the rendered service, and prospective payment, where the cost is based on an average rate calculated from historical data (Casto & Forrestal, 2015).

Prospective payment systems have been established in order to enhance healthcare industry's efficiency through financial incentives to promote a more cost-efficient management of healthcare. However, there are some biases imposing these reimbursement systems that might benefit the hospitals financially but, at the same time, diminish the trust of patients. Upcoding means that the patient is classified to a category

that produces a higher reimbursement, whereas cream skimming means either that the hospitals select the patients that would be more profitable for them or they choose to provide more profitable and less severe treatments. Readmission refers to a practice where the same patient is discharged and admitted again after a short period for hospital to receive more than one reimbursement for the same treatment (Berta, Callea, Martini, & Vittadini, 2010).

The traditional mechanisms of paying for health care providers are fee-for-service (hereinafter referred to FFS), capitation, salary, global budget, and diagnosis-related groups (hereinafter referred to DRGs) (OECD, 2016). Physicians often receive the payment through salary or fee-for-service per encounter or per procedure (Garrison & Towse, 2017). FFS encourages providers to rise their activity-levels which in turn increases the associated costs (OECD, 2016). One type of FFS is self-pay in which the patient pays a specific amount for each service received directly to the providers. If that person then has a health insurance or receives benefit from governmental programs, the reimbursement needs to be claimed from that third party afterwards. Otherwise, the person needs to pay for that service themselves (Casto & Forrestal, 2015).

Payment per case is a method where a predetermined rate is defined for a patient group, that has similar diagnosis and treatment and, consequently, use of resources and length of stay (Casto & Forrestal, 2015; OECD, 2016). The payment is a fixed sum for patients that fall into a particular illness category, i.e. a DRG (Garrison & Towse, 2017). Each of these groups receive a payment rate where the higher weight refers to more demanding disease that require more resources (Casto & Forrestal, 2015). DRGs incentivise the health care providers use their resources more efficiently and decrease the average time spent in the hospitals. However, health care providers might try to upcode in order to get more reimbursements (OECD, 2016).

Capitation refers to a fixed, per capita amount, that a third-party payer reimburses for the health care provider. Capitation is not affected by the volume and intensity of provided services nor the complexity of the care. This means that the provider receives the capitated rate sum per every individual under the health insurance plan whether or not they use the services and regardless of the complexity of disease or illness (Casto & Forrestal, 2015). This type of payment helps to control costs, but providers might not deliver the required amount of health care that is optimal for patients (OECD, 2016).

Global budget, in turn, refers to one amount that is paid for the provider of range of services, but is not affected by the actual volume that is provided (OECD, 2016). The third-party payer reimburses all the services of multiple providers that are treating a single episode of care with one combined payment. A total-episode-of-care is the most inclusive version of this and covers all the costs across the continuum of care. However, there are fewer comprehensive options in which, for example, only in-patient or ambulatory care is covered (Casto & Forrestal, 2015). This type of payment is quite usual in public hospitals in many countries and it can help to control the total costs. However, global budget might increase the waiting times and create access problems (OECD, 2016).

The managed care reimbursement method means an FFS reimbursement method where the third-party payers control and manage the costs of healthcare and the outcomes of care. This type of reimbursement allows the third-party payers to be able to reduce the costs of healthcare that it reimburses for the providers while still ensuring a good quality of care (Casto & Forrestal, 2015).

In most developed countries, these systems are established and administered by the government, thus called administered pricing and reimbursement systems. Their goal is to provide incentives for appropriate provision of services, rewarding productivity as well as maintain cost control (Garrison & Towse, 2017). However, the salary system does not have any incentive for providing a specific degree of care and FFS might promote cream skinning even though the individual elements of care are reimbursed retrospectively (Britton, 2015). Furthermore, the reimbursement systems are generally more based on cost than value (Garrison & Towse, 2017). Because the payment systems alone can result in cream skinning and upcoding, many countries have mixed systems that include combinations of the traditional payment systems (OECD, 2016). Nevertheless, no universal system has been established and the design process of a feasible reimbursement system can be challenging because it should be accountable for quantity, complexity, and quality of care (Britton, 2015).

New payment trends are arising alongside the traditional payment systems that foster the outcomes and quality of health care. Add-on payments are paid on top of the main payment for a single provider who co-ordinates the care of a chronic patient. Payment-for-performance (hereinafter referred to P4P) are bonus or penalty payments for meeting quality and efficiency targets (OECD, 2016). Compared to FFS, P4P and DRG

reimbursement mechanisms are much more complex when functioning properly. P4P and DRG both require well-designed patient identification, classification, recording and monitoring systems (Ikegami, 2015). To assess the performance, processes, and outcomes of care, strict measures need to be in place. (Britton, 2015). Furthermore, upcoding is a serious issue in DRG, whereas P4P performance indicators do not necessarily take into consideration the individual effect (Ikegami, 2015). Also, not enough evidence is yet to support that with P4P it is possible to receive positive results (OECD, 2016).

Complexities become when the value of care is assessed. On the one hand, individuals do not see the cost of service because they do not pay anything at the point of care which may lead to care over-use. On the other hand, the providers, especially the competing private insurers, seek for the low-risk patients, whereas the high-risk patients are the ones seeking for health insurance (Garrison & Towse, 2017). However, these innovative payment systems promote for decrease in fragmentation of care, better value and quality of care, and controlled costs. Even though, these methods might not improve the broader health outcomes, they can help in increasingly better data collection and having more informed dialogue with purchasers and providers (OECD, 2016). The establishment of electronic medical record (hereinafter referred to EMR) system can promote the accuracy, efficiency, and feasibility of any reimbursement system. The real time information would benefit third party payers by giving data to determine reimbursement rates and healthcare providers to assure the quality of care, outcomes and projecting future resource allocations (Britton, 2015).

### **2.1.3 Needs in Health Care**

Business models in health care can be divided into three categories: solution shops, value-adding processes, and user-network models. Solution shops rely on the insight of the highly skilled professionals who deliver the value through problem analysis and solution offering based on their expertise. As the traditional model of health care, the unique services of solution shops attract customers to pay high prices. Value-adding processes aim at delivering high quality at low cost through repetitive nature of the processes and guaranteed outcome, whereas, in user-network models, the trade happens only among the members of that network (Hwang & Christensen, 2008).

Value-adding processes enable a more detailed focus in a specific type of care after the diagnosis has been done in the solution shop. Additionally, user-network models can benefit especially patients with chronic diseases where help can be found from other members with similar disease. Affordability, accessibility, and higher quality could be further enhanced with technological enablers by simplifying the work of solution shops and increasing the predictability of the processes. Ideally, technology can even move the work more to patients themselves (Hwang & Christensen, 2008).

Healthcare systems can reduce social risks and inequality among populations within countries. At the time, the health care systems in various countries are undergoing changes regarding their policies and regulations (Wendt, Kohl, Mischke, & Pfeifer, 2010). Various governments, policymakers and countries are emphasizing the need for reducing costs of health care (Bodolica, Spraggon, & Tofan, 2016) and are searching for new methods that could make the provision of health care more affordable (Shakshuki & Reid, 2015). Furthermore, many governmental reforms are focusing on cost and cost control (Bodolica et al., 2016; Lameire et al., 1999). The political discussion and social conflict are centred around these financial issues regarding the health policies and health policy measures (Wendt et al., 2010).

However, the increased demand for quality and amount of health care does not impose any relief for the governments. With the current model of health care, new methodologies and innovative technologies are needed for achieving required levels of service. Efficient allocation of resources can improve patients' experience with medical services (Bodolica et al., 2016; Shakshuki & Reid, 2015). Moreover, the involvement of health care service users into planning processes, would increase their experience and satisfaction. The partnerships and collaboration between managers, medical personnel, and patients would support the delivery of more effective health care as well as culture of openness and mutual learning. However, the implementation of health care systems and processes should be left on health care professionals' judgment and understanding (Bodolica et al., 2016).

According to Bodolica et al. (2016), there are two perspectives that explain the drivers for involving the public into health policymaking – consumerist and democratic. On the one hand, buyer's choice, preferences, and satisfaction are enforcing the competitiveness of health-care providers in the consumerist perspective. On the other hand, democratic

perspective emphasizes that everyone has the right to use the public goods but as citizens they also have the duty to enhance the public accountability and contribute to societal well-being. Consumerism could enhance quality of care when patients' choice of the health care provider increases the competition. The health care providers would become more transparent through the increased need for accountability and customer loyalty. However, in the existence of blurred professional ethics among different marketplaces and doctors' financial self-interest, the relationship between the patient and the physician can become dangerous. This could result in self-diagnosis and auto-medication for patients or demanding inappropriate services (Bodolica et al., 2016).

## **2.2 Digitalization in Pharmaceutical Industry**

The recent trends in the pharmaceutical industry consist of patient engagement, new competitors, focusing on outcome-based care, information availability and improved processes. These trends provide opportunities for more personalized solutions, round the clock care with real-time help through cross-channel interactions and data-driven insights (Chircu et al., 2017). The digital therapeutics can be personalized based on customers' preferences. In order to personalize the healthcare services, the patient is required to provide access to personal data which might arise the concern of privacy issues. Hence, there is a trade-off between the quality of delivered services and providing personal data for the service provider (Lee & Kwon, 2014). The healthcare systems should be encouraged for supporting people to reach personalized results that are designed in collaboration with the patient and the healthcare provider. This could be achieved by enabling the sharing of information between the healthcare provider and the patient as well as through more value-based reimbursement systems (Snowdon, Alessi, Bassi, DeForge, & Schnarr, 2015).

The personalization of healthcare and treatment is more probable in digital therapeutics. The collection of digital health data enables patients themselves, together with clinicians, analyse and further amend the treatment to meet the patients' needs. In addition, the progress of the treatment can be followed with the help of digital health data. Also, when the treatment or a therapy session is done via smartphone application, the treatment is less time-consuming. People might prefer taking the therapy session at home on their own time without the certain *stigma* that therapy might still have. Although the patient would

have a face-to-face therapy session, the collected data acts as a help to personalize the treatment and allows the therapist to more precisely consider the relevant issues (Sverdlov et al., 2018).

In the future, value-based healthcare will become more common which might lead companies more towards digital therapeutics. In the USA, the regulatory agencies are considering increasingly digital solutions, and, for example, diabetes can today be treated with digital solutions. The traditional pharmaceutical development process is time-consuming, whereas the digital platforms enable to launch products more efficiently and faster. Clinical trial management can be simplified with the use of digital platforms when the recruitment, communication, and patients' data are digitized. This allows the clinical trials to be conducted at home when the patients can be monitored remotely and fewer clinic visits are needed. Nevertheless, there are still challenges and uncertainties in the reliability and ethics of clinical trials via digital platforms. The authors conclude that while there is still much to be done and considered, the potential of digital therapeutics is formidable. The enhanced clinical operations, data quality, endpoints and outcome of the treatment can be considered as some of the opportunities of digital therapeutics and platforms (Sverdlov et al., 2018).

### **2.2.1 Digital Solutions and Technologies**

There are many different types of solutions available that differ in disorder focus and means of treatment. Examples of technologies and tools used in digital therapeutics are games, education material, triggers, monitoring and treatment through sensors, mobile apps or VR technology, just to name a few (Kataria & Ravindran, 2018; McSherry et al., 2018; Tashjian et al., 2017). These solutions allow patients to receive personalized and targeted care as well as caregivers to receive real-time information about their patients. Moreover, analytics provide the opportunity for predictive, prescriptive, and preventive care (Kataria & Ravindran, 2018; Kvedar et al., 2016).

The current health applications can be divided into consumer-based applications and health professional applications. While the consumer-based applications focus more on self-management through examining health results and enhancing health through personal training, the professional applications content is based on evidence-based methods of diagnosis and treatment. Healthcare providers can engage with the patients

more effectively with the use of healthcare applications. These can be used as means to reach the consumers with a tool that is convenient for them (Snowdon et al., 2015). The emerged business models utilize the indication factor and the digital therapeutics can be prescribed as monotherapy, the only treatment for one indication, or as pharmacotherapy, digital therapy combined with drug. The potential for pharmaceutical company lies in combining the drug development with digital technologies and making the treatment more effective (Sverdlov et al., 2018).

A multi-agent system (hereinafter referred to MAS) is a network of entities that work together to find solutions to problems that the entity's capabilities and knowledge would not be enough to resolve individually. An agent in the MAS can be software, hardware, or human in nature and each of them has unique properties and capabilities such as behaviour, data, goals, and motivation. In healthcare, MAS application can provide a tool for complex and diverse communication between groups of health care professionals and patients and support patients' independent lifestyle in remote areas. The benefit also lies for health care systems when overall costs can be reduced. One example of a MAS application is telemedicine applications where the biomedical monitoring remotely via sensor nodes in or on body and real-time communication with physician through phone, email, or video conferencing is possible. The wearable and implantable sensors record historical information, provide insights and report abnormality, and can be used in conditions such as diabetes, tumour, cancer, or physical disabilities. Moreover, the MAS application can have the functionality of detecting falls and further assistance can then be provided (Shakshuki & Reid, 2015).

Many MAS applications and research focus on fall detection, gait analysis, heart rate monitoring using electrocardiogram (hereinafter referred to ECG), pulse oximetry, and detecting Parkinson's episodes and their severity. This type of applications can help to maintain an independent lifestyle of the elderly population and disabled individuals. Moreover, these could help in cutting down on waiting and processing times for both patients and doctors in the healthcare system (Shakshuki & Reid, 2015).

Remote patient management (hereinafter referred to RPM) in chronic diseases has shown positive evidence for the patients. First of all, the RPM technologies can be seen as an early intervention and detect decline in patient's condition before any services are needed. When patients need health services, RPM technologies enable the integration of care with



exchanging the data between multiple providers about the states of disease. The use of RPM increases also patient's own understanding of the condition and makes them more confident in managing the condition by themselves. Throughout the care, the patients can be coached and motivated to support patients' behavioural change and selfcare. It supports patients' satisfaction when a connection is created with the providers and further increases trust and sense of security towards caregivers. With the help of RPM technologies, the productivity increases when there are less face-to-face meetings and documentation becomes more automated. Additionally, medical assistants, community health workers, and social workers become more important along the RPM technologies (Coye, Haselkorn, & DeMello, 2009).

Implantable biosensors are the future of measuring metabolic levels of the patients without the need for patient intervention and regardless of the patient's physiological state (e.g. sleep, rest, etc.). These sensors are implanted into the human body and require no further interaction from the user to operate and can be used, for example, with diabetes patients for glucose tracking. MAS applications possess many ethical, technical and social design challenges but it could provide an interconnected, real-time support and monitoring for entire populations. It can provide an opportunity for a wide-scale health care integration where health care services would be available for anyone from anywhere. The implantable sensors and wide-scale integrated healthcare systems could result in genetic analysis of diseases and detecting and preventing them through the medical, historical, and integrated data which could be further used in medical research (Shakshuki & Reid, 2015).

The increasing demand and awareness of quality in health care have created pressure for governments to identify health technologies that offer the best value for money (Oortwijn, Mathijssen, & Banta, 2010). Health Technology Assessment (hereinafter referred to HTA) tool has been adopted by many organizations, such as private companies and healthcare providers, for the purpose of gaining a better understanding and more information about the way these health technologies are performing (Turchetti, Spadoni & Geisler, 2010). This tool assesses not only the cost-effectiveness of the technologies but also aids in decision-making processes regarding health care system regulations, quality of care assessment, and reimbursement decisions. Because the HTA decisions

need to be based on scientific methods and research results, it helps in considering all related evidence in a systematic way (Henshall & Schuller, 2013; Oortwijn et al., 2010).

### **2.2.2 Pricing Digital Content**

The digital content is predominantly offered for free, because the marginal cost for reproducing the digital service or a product is practically zero. However, in the early development phase, the fixed costs can be high and thus, many digital service providers have developed strategies for receiving revenue (Na, Hwang, Hong, & Lee, 2017). Usually, a company in a monopoly situation chooses only one pricing scheme. In addition, when a company is introducing a new product or a service, marketing is simpler with only single pricing option (Wu, & Banker, 2010). The pricing is affected by various parameters, such as demand, value, and even competition. However, the customer attractiveness acts as an important determinant in pricing decisions (Lehmann & Buxmann, 2009).

Even though a digital product or a service would be offered free for the users, the company is able to generate revenue, for example, through advertising sales (Na et al., 2017). Additionally, the user can be offered complementary products or premium versions in the otherwise free platform (Lehmann & Buxmann, 2009). This freemium pricing model enables the customer to use the digital service or product for free as long as they like, and the revenue is generated through users that are willing to purchase additional products or services. The benefit for the company is in attracting a high number of customers by lowering the entry barrier. However, the number of customers that are willing to pay, remains low. Thus, it is essential to identify this type of customers in early stages and create means to have them stay as well as continue paying (Voigt & Hinz, 2016).

The pricing of a digital service or product is usually a single payment, that grants a full access, or regular repetitive payments, i.e. subscription fees, that vary in their frequency and duration (Lehmann & Buxmann, 2009). Additionally, a usage-based pricing refers to a method where, for example, a commission is paid only when the service is used. In a two-part tariff pricing the user is charged a subscription fee as well as a price for other services, such as maintenance or a single call (Wu, & Banker, 2010). A pricing strategy that is based on price discrimination means that the same digital product or service is

offered with various prices. The price can simply be based on different customer's willingness to pay, or different customer segments. In addition, there can be different prices according to customer's selection of price-product combination based on factors such as time, quantity, or performance. Furthermore, price bundling represents a collection of various sub-services from one or more service providers that are determined a total price (Lehmann & Buxmann, 2009).

When a company is willing to acquire a desired customer base, the dynamic pricing strategies can be used. One of them is the penetration strategy where lower prices compared to competitors attract customers in market entry. When the customer base has been generated, the prices are increased. In contrast, skimming strategy is used when a company starts with high prices and lowers them in the course of time in order to attract customers willing to pay high prices. However, the skimming strategy for digital services or products is rarely used (Lehmann & Buxmann, 2009).

The demographic and lifestyle changes in societies are pressurizing the governments deliver high quality health care with reduced costs, while the need for value-based pricing and reimbursement is increasing (e.g. Bodolica et al., 2016; Lameire et al., 1999; Lämsä et al., 2006; Wendt et al., 2010). However, the uncertainties with assessment of quality and value in health care still remain evident (e.g. Britton, 2015; Garrison & Towse, 2017; OECD, 2016). New health technologies and digital solutions provide opportunities for personalization, real-time help, and data-driven insights (e.g. Chircu et al., 2017; Kvedar et al., 2016; Snowden et al., 2015; Sverdlov et al., 2018), and their performance and quality are assessed through HTA. Moreover, the decisions regarding health care systems, reimbursement, and pricing of digital content can be supported through this assessment as well (e.g. Henshall & Schuller, 2013; Oortwijn et al., 2010; Turchetti et al., 2010).

### **3 THEORETICAL BACKGROUND**

The theoretical background aims at providing support for the conducted study, and a thorough understanding about the existing business environment. The thesis covers case companies internationally (the USA and countries in the EU) and they were chosen for the purpose of studying and comparing already established digital therapeutics companies according to their solutions and treatment possibilities. Moreover, the client company operates internationally, and aims at gaining the market access in the USA, Finland, Germany, and France. Thus, the introduction of the business environment with regards to the health care systems and regulative space in these countries is required for deeper understanding. Lastly, the business models and the choice for VISOR framework as a business model ontology is motivated.

#### **3.1 Health Care in the USA**

The health care system in the United States of America (hereinafter referred to USA) is complex and scarce in its nature. Health care is not accessible for everyone, and it is mainly covered through private health insurance which, in turn, is mainly offered by the employers. Nevertheless, there are around one thousand health insurance companies providing these private health insurances, whereas the private managed care sector consists of hundreds of licensed health maintenance organizations (hereinafter referred to HMOs) and preferred provider organizations (hereinafter referred to PPOs). In addition, the government of the USA administers two main public health insurance programs called Medicare and Medicaid (Shi & Singh, 2017).

At present, managed care is the leading health care system existing in the USA. Managed care refers to combining the core functions of effective health care delivery for managing the utilization and costs of medical services. The managed care organizations (hereinafter referred to MCOs), such as HMOs and PPOs, have contracts with both the health care providers, as well as the private and public health insurance programs. Then, these particular health care providers deliver health care for the managed care plan members. Furthermore, the arrangement between the enrolled individual and MCO is called a health plan where the reimbursement is mainly based on capitation. In a discounted fee

arrangement, the health care providers are promised a patient population in exchange of discounted services (Shi & Singh, 2017).

In the USA, public health care is provided only for specific groups of people such as elderly, children and disabled individuals. Furthermore, the community health centres, migrant health centres, free clinics, and hospital emergency departments, i.e. safety net providers, are targeted to so called special populations which are individuals in the need of health care but do not have the required resources. Medicare is one of the public health insurance programs that is for elderly, disabled and people with end-stage renal disease and it covers hospital care, post-discharge nursing care, hospice care, outpatient services, and prescription drugs. The other public health insurance program, Medicaid, covers low-income adults, children, the elderly, and individuals with disabilities as well as the long-term care for elderly and disabled individuals (Shi & Singh, 2017).

Despite these governmental options available, the growing number of poor and Medicaid-insured individuals create pressure for the safety net providers which are not available in every community. Furthermore, many individuals need to acquire separate insurance for long-term care because Medicaid covers only a certain population group and Medicare does not cover such care. However, the private insurance for long-term care cannot be afforded by most of the people. Integrated delivery systems (hereinafter referred to IDSs) is a health network consisting of health care providers and organizations that are held responsible and accountable for the quality of care. IDSs deliver a continuum of care that is more cost-effective and higher quality. The accountable care organizations (hereinafter referred to ACOs) are acting under new payment incentives that foster better quality outcomes while reducing costs (Shi & Singh, 2017).

### **3.2 Health Care in the EU**

In the EU, the individual countries have the main responsibility for organizing and delivering health services and medical care. However, the EU has a health policy for complementing national policies as well as to guarantee protection of health in all EU countries. Additionally, the EU provides funding through some investments programs as well as aims at improving the efficiency and accessibility of health care in each member state (European Commission, 2019). For the purpose of this thesis, the means of health care delivery in Finland, Germany, and France are presented.

### **3.2.1 Health Care in Finland**

In Finland, the health care system is universal, and each individual has the right for social welfare and health care services (Ministry of Social Affairs and Health, 2013). The municipalities and local authorities are responsible for organizing social and health services, and these are mainly provided publicly. However, some private and non-government organizations complement the service delivery. Thus, the municipalities can outsource their services either to another municipality, or private service provider. Primary care is offered in municipality health centres, secondary care in central hospitals and tertiary care can be accessed in five university hospitals. Furthermore, employers are required to organize preventive occupational health care for their employees, but most of the employers organize additional medical care in voluntary basis (Ministry of Social Affairs and Health, 2019).

Finnish health care is financed through municipal tax revenues and central government subsidies (Ministry of Social Affairs and Health, 2019). The Social Health Insurance (hereinafter referred to SHI) is coordinated by the Social Insurance Institution of Finland (Kela) and can be divided into medical care insurance and earned income insurance. The funding for medical care insurance comes from contributions that are withheld from the income, pension, and policy-holders' benefits (Ministry of Social Affairs and Health, 2013). Health care services are not free-of-charge and municipalities charge patient fees (Ministry of Social Affairs and Health, 2019). However, a maximum amount of paid fees has been established to provide free or discounted health care once this amount has been achieved by an individual patient. This ceiling applies not only to health care services, but also to prescription medicine (Ministry of Social Affairs and Health, 2013).

The medical care insurance covers tests and treatments requested by private doctors. However, the costs are only reimbursed according to the statutory reimbursement rate based on DRGs and the excess amount is paid by the patient as an out-of-the-pocket payment. Earned income insurance covers paid allowances for instances when employers not able to work, such as maternity or paternity leave and sickness (Ministry of Social Affairs and Health, 2013). In Finland, the Voluntary Private Health Insurances (hereinafter referred to VPHI) are not common and are only acquired for out-of-the-pocket payments that the SHI does not cover. Furthermore, the VPHI might be duplicate, which means that the same care is offered by both public and private health care

providers, but private care can be accessed without any waiting time. However, some health care services are not offered by the public health care providers and then supplementary VPHI covers such services in the private health care. The private insurance companies determine the services included in the health insurance and one of the criteria is individual's health history (Alexandersen, Anell, Kaarboe, Lehto, Tynkkynen, & Vrangbæk, 2016).

The main challenges regarding health care services in Finland concern the accessibility of health care and the quality of care for elderly people. For solving these issues, a health and social services reform has been discussed for over a decade. The goals of the reform are to decrease the inequality of people's wellbeing as well as to provide an equal access to high-quality services. However, the final decisions have not yet been made or reinforced (Ministry of Social Affairs and Health, 2019).

### **3.2.2 Health Care in Germany**

Germany has the oldest SHI system in the world by being the first one ever established. The government is not included in the health care delivery and the regulatory details regarding health care are issued by the Federal Joint Committee that makes decisions about SHI benefits, reimbursement systems and quality assurance (OECD & European Observatory on Health Systems and Policies, 2017b). The Federal Joint Committee consists of self-governing associations within sickness funds and provider associations. However, the state's own university hospitals and municipalities deliver the public health services (Mossialos, Djordjevic, Oxborn, & Sarnak, 2017). Moreover, the states oversee these self-governing bodies and are responsible for hospital planning and investments as well as medical education (OECD & European Observatory on Health Systems and Policies, 2017b).

In Germany, the health care system is almost universal, and the health insurance is compulsory for everyone. The health care is financed through SHI that is provided by more than hundred sickness funds. In turn, SHI is funded by contributions from wage and pooled together with some tax subsidies in the central health fund. Then, the revenues are reallocated into different sickness funds according to the risk of the population groups that the sickness fund covers (OECD & European Observatory on Health Systems and Policies, 2017b).

SHI covers automatically employees that earn less than a certain limit. Through a global budget, the SHI compensates ambulatory care, whereas individual physicians receive an FFS payment that is based on DRGs. Employees that earn more than the threshold, can either stay in SHI voluntarily, or they can choose a substitutive Personal Health Insurance (hereinafter referred to PHI). The PHI contributions are based on individual health risk and user fees paid for practitioners are usually higher (Mossialos et al., 2017).

The health care system in Germany is highly accessible by everyone with low out-of-the-pocket payments and high number of health care providers. In addition, the self-governing bodies assure that new decisions in institutions and health care professionals are well-informed. However, a gap exists between the ambulatory and hospital care as well as the primary and specialised care. These differences pose to challenges regarding the continuity of care and coordination of services (OECD & European Observatory on Health Systems and Policies, 2017b).

### **3.2.3 Health Care in France**

In France, the health care system is universal, and all legal residents are covered by the SHI. The regional health agencies are responsible for ensuring that health care is provided locally and meets the needs of the population. The funding of SHI comes mainly from employers and taxpayers' contributions based on income. Additionally, specific taxes have been earmarked for public health care spending (OECD & European Observatory on Health Systems and Policies, 2017a).

The SHI covers a vast array of medical goods and services such as hospital care and treatment by both public and private institutions as well as diagnostic procedures, laboratory test, pharmaceutical products and medical appliances prescribed by the doctors. However, health care services are not free-of-charge and the patients always need to pay either a percentage of the service fee or a specified flat rate (OECD & European Observatory on Health Systems and Policies, 2017a). Mostly, the payment is received as an FFS payment as well as a yearly capitated payment per person of chronic diseases, whereas some specialists receive salary from the hospital. In addition, P4P payments are received when disease-specific quality targets are met (Mossialos et al., 2017).

Even though the SHI covers most of the health care, a Voluntary Health Insurance (hereinafter referred to VHI) is acquired for complementary purposes. VHI covers out-



of-the-pocket payments as well as medical goods and services that are not covered by SHI. Most of these insurances are acquired from a publicly funded complementary coverage. Because most of the people have a complementary VHI, the amount of out-of-the-pocket payments remain lowest in the EU. However, some population groups do not have a possibility for a good, or any, complementary health insurance which creates financial barriers for receiving health care services (OECD & European Observatory on Health Systems and Policies, 2017a).

The challenge of the French health care system is in delivering health care for people in certain geographic areas. However, the French Ministry of Health has created incentives for doctors and other health care professionals for employment in such areas. Moreover, the shortage of doctors has resulted in accepting more people in medical schools and the roles of health professionals have been extended because of the inequal balance between generalists and specialists. Nonetheless, the main challenge remains in delivering quality health care for ageing population and people with chronic diseases (OECD & European Observatory on Health Systems and Policies, 2017a).

### **3.3 Regulations**

In the USA, regulations regarding the digital therapeutics have already been developed. The digital therapeutics tools mostly fall into the Food and Drug Administration's (hereinafter referred to FDA) Mobile Medical Applications (hereinafter referred to MMAs) group. Under this category, the digital therapeutics tools are classified according to their therapeutic benefit, safety, and risk factors, intended use or indication for use (Sverdlov et al., 2018). From the legal and regulatory perspective, digital therapies are considered as Software as a Medical Device (hereinafter referred to SaMD) (De Luca, 2019). According to Kirisits & Redekop (2013), for a device to be considered as a medical device, it has to fulfil two criteria: "it is used for prevention, diagnosis, monitoring or treatment of a certain health state; and its primary mode of action is not based on a pharmacological, metabolic or immunological process." (Kirisits & Redekop, 2013, p. 16).

Consumers and patients are reluctant to use a medicine when the evidence of the effectiveness is lacking, even though it could be beneficial for them. That is why the regulatory agencies certify the safety, quality, and efficacy of medicines (Garrison &

Towse, 2017). In some parts of the world, digital therapeutics solutions have been recognized as digital therapies, i.e. reimbursed, and prescribed by healthcare professionals. However, the regulations are still in its infancy in many parts of the world, including the EU (De Luca, 2019).

### 3.3.1 Regulating Medical Devices in the USA

In the USA, Federal Trade Commission (hereinafter referred to FTC) has developed an interactive tool that can be used in the mobile health application development process for analysing federal laws that might be applicable. This tool intends to help companies to examine the regulations regarding mobile applications aiming to diagnose or treat a disease or a health condition and that gather, produce, or distribute consumer information. The general process of determining laws and regulations regarding mobile health applications is illustrated in Figure 3 (Federal Trade Commission, 2016).

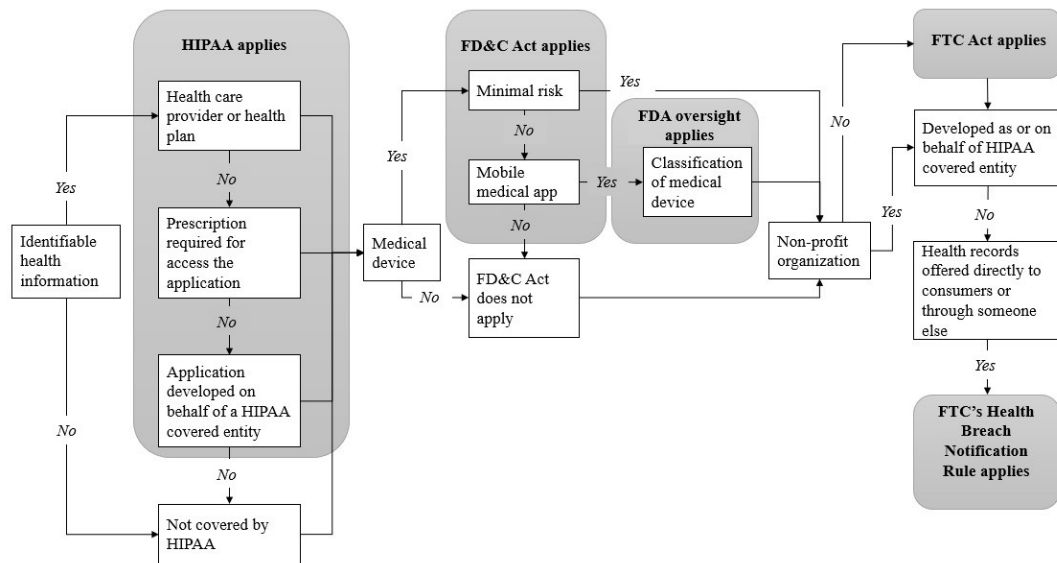


Figure 3 Regulative Process for Market Access in the USA (Federal Trade Commission, 2016)

Health Insurance Portability and Accountability Act (hereinafter referred to HIPAA) covers the privacy and security of personal health information that are applied by the Office of Civil Rights (hereinafter referred to OCR). The HIPAA rules concern HIPAA covered entities that include health care providers managing electronic transaction and health plans as well as health care clearinghouses receiving non-standardized health information for processing. Furthermore, a HIPAA business associate is an entity that generates, maintains, or acquires protected health information on behalf of another covered entity. These entities are required to secure personal health information that can

be tracked to identify a customer as well as notify the OCR about any breaches. In addition, the HIPAA rules give the customers a right for their own health information. The FTC Act maintains fair and reliable practice in commerce as well as secures the privacy and safety. Moreover, the FTC's Health Breach Notification Rules requires personal health records (hereinafter referred to as PHR) providers, PHR-related entities, or service providers to notify about PHR information breaches (Federal Trade Commission, 2016).

FDA applies the Federal Food, Drug, and Cosmetic (hereinafter referred to as FD&C) Act for the purpose of controlling the medical devices' safety and effectiveness. Medical applications, that focus merely on self-management or controlling, following, and accessing health information, are considered as minimal risk devices and the regulatory oversight is not applicable. However, the regulatory oversight applies to a mobile medical application that is used in conjunction with a regulated medical device (Federal Trade Commission, 2016). Moreover, the medical applications, that would present a high risk when working incorrectly, are subject to FDA's regulatory oversight and the medical device needs to be classified according to its risk, indication for use, and intended use (U.S. Food & Drug Administration, 2018).

A list of medical devices is maintained by the FDA and the classification of medical devices outlines the regulatory requirements for that general type of device. While Class I devices present the least risk and regulatory requirements, the devices in Class III present the highest risk. Moreover, most of the Class I devices are exempt from any premarket approval from the FDA. Companies commercializing Class II medical devices are required to deliver a Premarket Notification 510(k) and provide proof that the medical device is at least as safe and effective as a legally marketed device. Once a letter from FDA is received, stating that the device is substantially equivalent, the medical device is cleared for commercial distribution. Furthermore, Class III devices are required a Premarket Approval (hereinafter referred to as PMA) that consists of clinical trials and evidence that support the claims made for the device. In addition, the FDA approves the medical devices according to the PMA before they can be marketed (U.S. Food & Drug Administration, 2018).

### 3.3.2 Regulating Medical Devices in the EU

In the EU, the medical devices are mainly regulated by national competent authorities, but the European Medicines Agency (hereinafter referred to EMA) assesses a portion of the medical devices (European Medicines Agency, 2019). A company can market the medical device in the EU only, if it has a Conformité Européenne (hereinafter referred to CE) mark on the device which can be received by meeting the essential requirements requested by the EU Directive and passing the Conformity Assessment (European Commission, DG Health and Consumer, 2010). An accredited Notified Body designated by each EU member state conducts the Conformity Assessment in order to indicate the medical devices' safety and effectivity according to their intended use (European Medicines Agency, 2019). Clinical evaluation is an essential requirement for each medical device. The clinical evidence needs to confirm the side-effects as well as confirm the said characteristics of the medical device. The member states' own competent authorities are notified by the manufacturer about the clinical investigations (European Commission, DG Health and Consumer, 2010). The process of receiving a market authorization in the EU is illustrated in Figure 4.

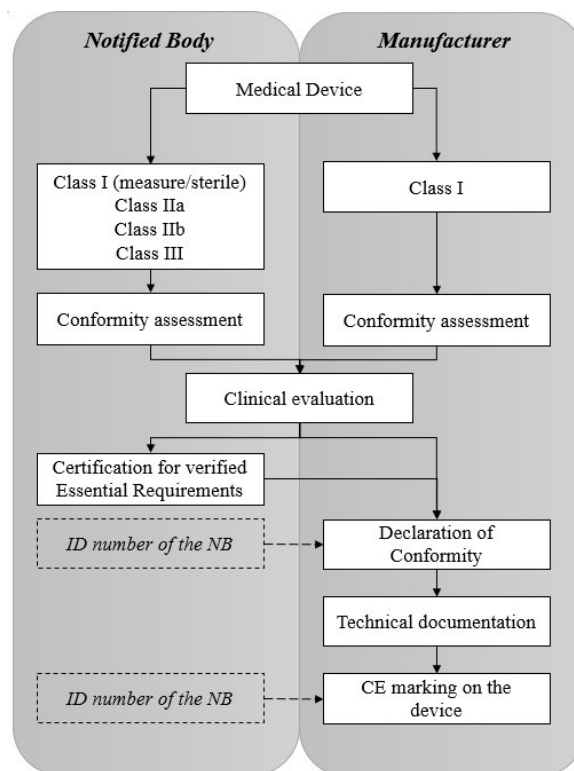


Figure 4 Regulatory Process for Market Access in the EU

For the purpose of Conformity Assessment, the medical devices are classified by the manufacturer based on their risk, characteristics and intended use. Furthermore, the classification specifies the level of control in the assessment (European Commission, DG Health and Consumer, 2010). The Class I medical devices pose the minimum risk to the patient and the companies can certify them by providing proof of requirement compliance, whereas the registration is done with the competent authority. However, the Class I medical devices that are sterile or have a measuring function, the Notified Body is required to assess the requirement compliance. The Class IIa devices are for short-term use, whereas the Class IIb devices may be used for longer than 30 days, and both devices pose a medium to high risk to the patient. Furthermore, the Class III devices pose the highest risk possible and are being monitored for their lifecycle continuously. All these devices are required for assessment by the Notified Body (Max Strålin, 2019).

In most cases, the Notified Body only assures that the quality management is compiled by the manufacturer. However, some of the Class IIa and Class IIb and all the Class III medical devices are examined by the Notified Body in accordance with their design and assured that they comply with the Essential Requirements as well (European Commission, 2017). Once the medical device is approved by the Notified Body, they provide a certification that the medical device fulfils the essential and technical requirements of the CE directives. Moreover, it makes the company responsible for obliging the requirements set by the CE mark. After this, the company is authorized for a Declaration of Conformity ([www.ce-check.eu](http://www.ce-check.eu)). When the CE mark has been certified, the company needs to place the CE mark into the product (Valvira, 2017).

### **3.4 Business Models**

Several studies and a vast amount of literature covering business models can be found (e.g. Bouwman, Nikou, & de Reuver, 2019; El Sawy & Pereira, 2013; Guo, Nikou, & Bouwman, 2015; Wirtz, Pistoia, Ullrich, & Göttel, 2016; Zott, Amit, & Massa, 2011;). Despite of this, no universal definition of the concept business model has been created and often business model is referred to as a tool or a concept rather than a unified theory (Lambert & Davidson, 2013). Furthermore, the definition and focus of the business model framework highly depend on its purpose, field of the business as well as the researcher's theoretical perspective (Lambert & Davidson, 2013; Zott et al., 2010; Pateli & Giaglis,

2004; Shafer, Smith, & Linder, 2005). The vast number of differing definitions of a business model create challenges for comprehending the vital components and analysing the business models systematically (El Sawy & Pereira, 2013).

The literature and research regarding the business model conceptualization has evolved through time from defining and classifying business models as well as listing the various components and describing the different elements of business models to creating business model ontologies, applications and conceptual tools. This development has allowed researchers to assess and examine the business models and ontologies, whereas the businesses have begun to apply them in management and IS applications. Consequently, the focus has shifted into building theory and modelling dynamically (El Sawy & Pereira, 2013).

Osterwalder and Pigneur (2010) emphasize that in order to discuss business models and compare, innovate or even change them it is important to find a business model concept that everyone is able to comprehend. However, it is very challenging to create a concept that is straightforward, applicable and intuitively comprehensible enough without drawing too simple a picture of how businesses function (Osterwalder & Pigneur, 2010). In fact, most of the research does not define the concept business model at all or simply just list the main components of the business model. The result is that in most research the meaning of the concept business model is assumed. Moreover, when the concept is defined, the definition refers to another researcher's definition of the concept (Zott et al., 2010).

A business model can be conceptualized through "building blocks" that describe the rationale for how the business plans to make profit. These building blocks take into account the main areas of a business: customers, offer, infrastructure, and financial viability. Thus, the business model acts as a sort of design for a strategy that is put into action through organizational structures, processes, and systems (Osterwalder & Pigneur, 2010). According to Osterwalder and Pigneur (2010, p.14) "a business model describes the rationale of how an organization creates, delivers, and captures value". Shafer et al. (2005, p. 202) define business model as "a representation of a firm's underlying core logic and strategic choices for creating and capturing value within a value network". Bouwman, and Haaker and de Vos (2008) focus on the services as well as emphasize that the service is rather created and delivered by a network of organizations or companies than by a

single organization or company. They define a business model as “a blueprint for a service to be delivered, describing the service definition and the intended value for the target group, the sources of revenue, and providing an architecture for the service delivery, including a description of the resources required, and the organizational and financial arrangements between the involved business actors, including a description of their roles and the division of costs and revenues over the business actors.” (Bouwman, Haaker, & de Vos, 2008, p. 33).

Morris et al. (2003) categorized the business model concept definitions into three entities based on their primary focus. These three categories are economic, operational, and strategic where each one is composed of different decision variables. The economic category focuses on the rationale in generating profit and comprises decision variables such as sources of revenue, margins, volumes, cost structures and pricing methodologies. The operational category emphasizes the value creation and the architectural design behind it. Internal processes and infrastructure design define the decision variables in this category. These are, for example, delivery methods of the product or a service, knowledge management, logistical streams, administrative processes, and resource flows. Finally, in the strategic category the business model definitions have the focus on the company’s position in the market, the company’s interaction between different organizational units, and expansion opportunities. How to have the competitive advantage and be sustainable are the key questions in these definitions. The decision variables include differentiation, vision, values and value creation, networks, alliances and stakeholder identification (Morris, Schindehutte, & Allen, 2005).

According to Morris et al. (2003), the most important category is the strategic one because it has the elements that eventually give the rules for capturing value in the company. However, in order to be successful, the company needs to be unique in the way it does business which means that it needs to have unique architectural design (i.e. operational category) or logic of generating profit. This means that eventually a business model is the combination of all of these three categories. Based on this, Morris et al. (2003, p. 727) proposes a definition that takes into consideration all of these elements: “A business model is a concise representation of how an interrelated set of decision variables in the areas of venture strategy, architecture, and economics are addressed to create sustainable competitive advantage in defined markets.”

Wirtz et al. (2016) takes a very detailed view on the concept of business model through a literature view by combining different definitions together. In general, a business model takes into consideration all the components within a company and creates value through the frames of a business, its processes and architecture. Simply put, business model describes the company's most relevant activities, i.e. in which ways the company's value-added component is used to produce their products and services. In addition, business model should aim at creating and, more importantly, securing the competitive advantage by taking into consideration the strategic, customer and market components as well. Wirtz et al. (2016) emphasizes the importance of dynamic perspective which means that the company should continuously evaluate the internal and external changes that might contribute to the need of modification of the current business model.

Chesbrough (2010) has defined business model through various functions it is comprised of. First of all, a business model expresses the company's service and/or product that creates value for the customer i.e. the value proposition. Then, the business model should recognize the customers that would find the service and/or product useful (i.e. market segment recognition) and for what kind of purpose (i.e. revenue generation mechanism specification). Business model should also specify the structure of the value chain that is expected to produce and distribute the service and/or product. Complementary assets supporting the different actors in the value chain are also specified. A business model needs to further specify in detail the revenue mechanism(s) which determine how the company is paid for the service and/or product. The cost structure and profit potential estimations are a part of a business model as well. In addition, the business model describes the company's position within the value network that links the suppliers and customers as well as identifies potential complementors and competitors. Finally, the business model defines the competitive strategy that enables the company to gain and hold advantage over the competitors (Chesbrough, 2010).

Some argue that a business model can directly be associated with the company's strategy (Teece, 2010; Lambert & Davidson, 2013; Cortimiglia, Ghezzi, & Frank, 2016), while it is strongly emphasized that it is not a strategy itself (Shafer et al., 2005). Business model acts as a middleman between the strategy and operational function. It defines and creates the working rules for how to achieve the objectives of a strategy (Cortimiglia et al., 2016). It is argued that a business model is mostly a planning tool or a communicator that a



business can use to evaluate and address its strategic choices chosen to take in a new business venture (Lambert & Davidson, 2013; Shafer et al., 2005). Then again, a business model can be used in mapping the existing business to answer concerns that might require reinvention (Jeansson et al., 2017; Johnson, Christensen, & Kagermann, 2008; Morris, Schindehutte, & Allen, 2005). Furthermore, many of the definitions put their emphasis on the value and creation of that value (e.g. Teece, 2010; Osterwalder & Pigneur, 2010; Shafer et al., 2005).

The importance of business models can especially be noticed in value creation of new technologies. The way a new technology is commercialized by the company further defines how much it creates value. In other words, the same technology can have different results depending on the business model (Chesbrough, 2010). Interestingly, value and creation of value does not necessarily need to be seen through gaining money. Value creation can also mean social and economic value. Thus, a new business model can aim at creating societal wealth such as reduce poverty (Zott et al., 2010).

Even though a business model can help the decision makers to evaluate and communicate strategic choices, it is similarly vital to understand the consequences of applying the business model in a wrong way. A business model's core logic should be based on tested and correct expectations about the future, i.e. the cause-and-effect relationships in the business model should be well supported and logical in order to create strategic choices that are internally consistent and support each other. Also, the strategic choices should be considered holistically in every aspect of a business model and not solely considering one aspect of it (e.g. value proposition) to create a realistic picture of the potential success. In addition, it is important to put the same amount of effort in the value creation part as in the value capture part for also capturing financial returns from the created value. Finally, the business model should consider the changes in the value network and not assume that it remains unchanged in the future (Shafer et al., 2005).

The increasing popularity of eBusinesses, has grown the need and interest towards Business Model Innovation (hereinafter referred to BMI) in general (Pateli & Giaglis, 2004). BMI is seen as an innovation that focuses on the business model itself. The current studies regarding BMI have focused on two separate approaches: business model design and business model development. Business model design refers to creating a whole new business model from scratch, whereas business model development concentrates on

improving the existing business model (Cortimiglia et al., 2016). However, the concept of BMI differs in its definition between researchers and the research is quite dispersed and industry specific. In addition, there is no clear understanding about BMI's impact on company's performance and innovativeness (Bouwman, Nikou, Molina-Castillo, & de Reuver, 2018).

In health care, the business models in different organizations are highly connected to each other and adding a new component to a single institution's business model can be challenging. Additionally, policies and regulations can restrict BMI or make it too expensive to carry out or maintain (Hwang & Christensen, 2008). Furthermore, regulations can slow the BMI process and might limit people and health care professionals to even start the change. However, the organizations seek for benefits that improve efficiency of internal operations as well as the quality of care (Länsisalmi et al., 2006). In fact, the benefit of BMI lies in realizing hidden efficiencies and saving costs (Hwang & Christensen, 2008). Through BMI, the patients can benefit from enhanced health care and less suffering due to illness (Länsisalmi et al., 2006).

### **3.4.1 Business Model Ontologies**

Many business model ontologies have been developed based on various needs and for different fields of business. Three widely used business model ontologies are STOF, Business Model Canvas, and VISOR. Bouwman et al. (2008) reviewed literature about the concept of a business model as well as the components included to the concept. They concluded that, in fact, the various different classifications of the components show that there is no shared framework of a business model which resulted in a creation of their own approach. This approach aims to emphasize the services, organizational networks, and innovation/emerging service ideas. This STOF model has its focus on four domains: service, technology, organization, and finance (Bouwman, Haaker, & de Vos, 2008).

Osterwalder and Pigneur (2010) have developed a business model concept that can be used in mapping not only the organization's existing business model but also that of competitor or any other organization. The tool, Business Model Canvas, helps organizations in business model innovation by creating an overall picture of the company and describing the logic behind creating value for customers and the company. Osterwalder & Pigneur (2010) identify customers, offer, infrastructure, and financial

viability as the four key areas of a business. Based on these areas, the Business Model Canvas (see Figure 5) has been divided into nine building blocks that are explained in more detail in Table 1.

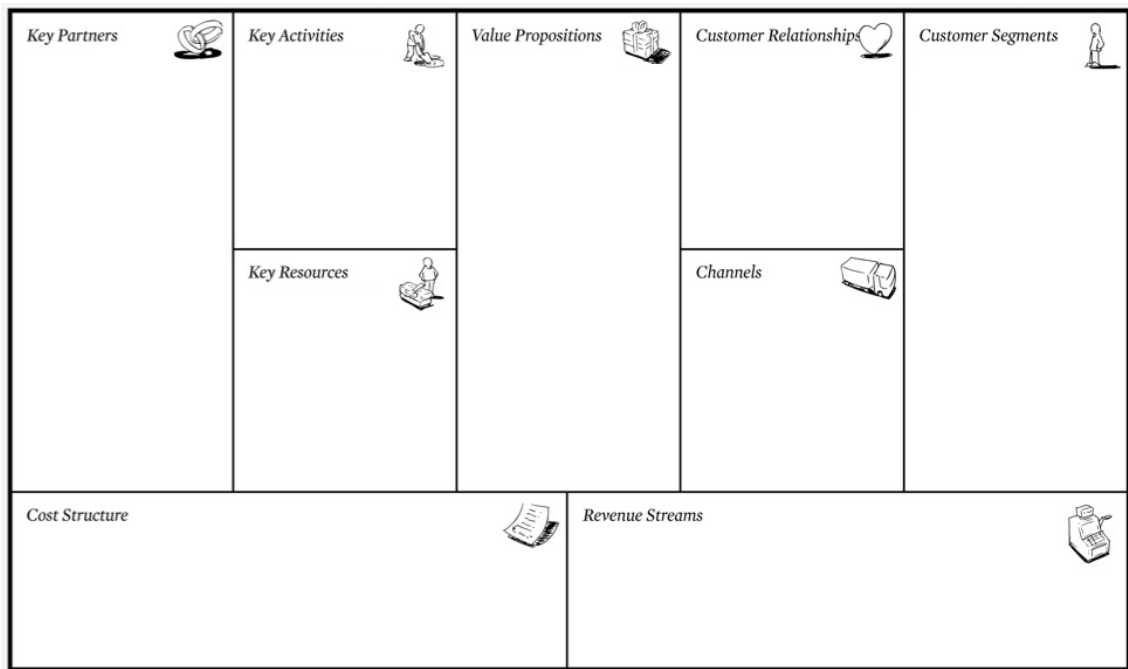


Figure 5 Business Model Canvas (Osterwalder & Pigneur, 2010)

Component	Description
<b>Customer Segments</b>	The groups of people or organizations aimed to be reached and served
<b>Value Propositions</b>	The bundle of products that create value for a particular customer segment
<b>Channels</b>	The means of communicating with customer segments and delivering the value proposition for them
<b>Customer Relationships</b>	The sorts of relationships established with particular customer segments
<b>Revenue Streams</b>	The money generated from each customer segment and the pricing strategy
<b>Key Resources</b>	The most important assets to make a business model successful
<b>Key Activities</b>	The most important actions the business need to take in order it to be successful
<b>Key Partnerships</b>	The network of partners and suppliers to make the business model successful
<b>Cost Structure</b>	The costs risen for operations the business model

Table 1 Components of Business Model Canvas (Osterwalder & Pigneur, 2010)

The main driver for a business model design differs between companies. A company might have recognized an existing but unanswered need in the market that should be

satisfied, or they want to introduce new technologies, products, or services to the market. Furthermore, the company is willing to develop, disrupt or change the market with an improved business model or they want to establish a whole new market. In the already established companies where the organizational structures and existing models already exists, the reasons differ to some extent. At times, the company might be facing a crisis with an existing business model which forces them to react to the situation with a new one. The business environment is changing constantly which might lead the company to adapt into the environment with altering, developing, and supporting the existing business model. Similarly, the established companies need to consider their business model's viability when introducing new technologies, products, or services into the market. Finally, the exploring and testing of new business models in the process of preparing for the future might result in replacing the old business model with a new one (Osterwalder & Pigneur, 2010, p. 244).

El Sawy et al. (2013) wanted to unify the different business model components that have been discussed in the literature. They found out that there are five broader categories in which the business model components can be categorized. The five categories are: "Value proposition", "Interface", "Service Platform", "Organizing Model" and "Revenue Model". This VISOR model was not only created in attempt to unify the various business model concepts introduced throughout the years but also to further include the key elements that have not yet been considered (e.g. user experience and interface factors) into the model.

The VISOR model (see Figure 6) describes the actions a business takes for answering customer needs by creating and delivering the best value with the most cost-effective approach. Therefore, in a profitable business model the components have been aligned to provide the best value proposition that the customers are prepared to pay the maximum amount possible. This is accomplished through optimizing the combination of interface experience, service platforms and the organizing model which, in turn, results in minimum costs possible to provide that service. The VISOR components are described in more detail in Table 2 (El Sawy et al., 2013).

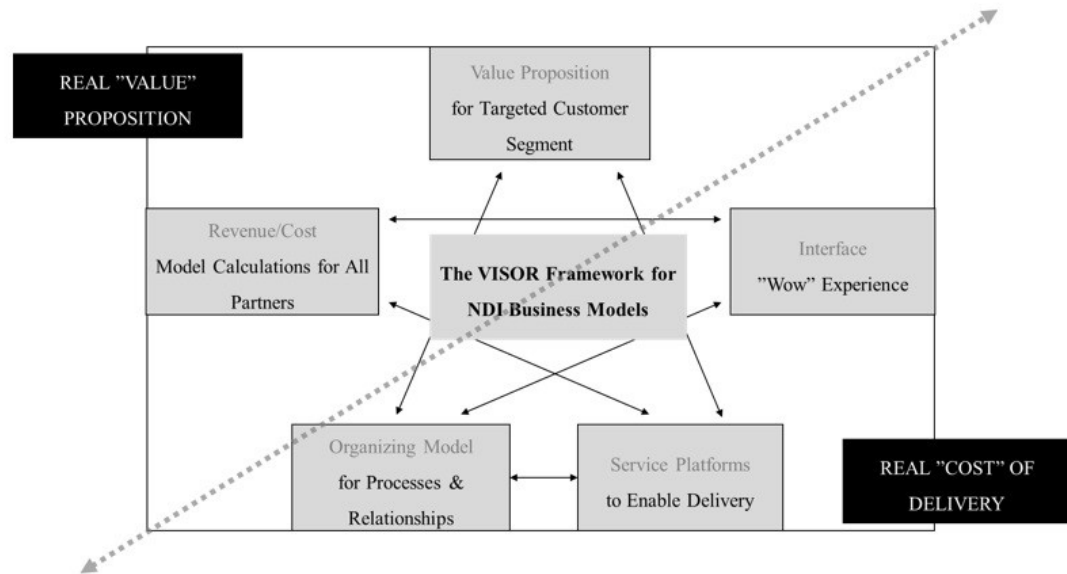


Figure 6 The VISOR Model (El Sawy et al., 2013)

Component	Description	Descriptors
<b>Value Proposition</b>	Explanation of customer segment's motivation for paying the product or service offered	Compelling, cohort, complementary, co-creativity
<b>Interface</b>	Interaction between the customer experience and service platform as well as the link between the customer and the company (hardware & software)	Functionality, form factor, fluidity, forgiveness
<b>Service Platform</b>	The infrastructure to deliver the products and services for the customer	Architecture, agnosticity, acquisition, access
<b>Organizing Model</b>	The organization and alignment of business processes, value chains, and partner relationships for effective and efficient product and service delivery	Processes, partnerships, pooling, project management
<b>Revenue Model</b>	A profitable revenue/cost sharing between the participants of the eco-system	Pricing, partner revenue sharing, product cost structure, potential volume

Table 2 VISOR Model Components (El Sawy et al., 2013)

The Business Model Canvas focuses on analysing a certain business as a whole whereas the VISOR framework considers the digital platforms, digital services, and digital economy (Nikou, & Bouwman, 2017). Furthermore, the VISOR model has been considered as a framework to capture the digital business model rather than a traditional business model. In a digital business model, the value dimensions are profoundly altered by triggers arisen from digital technologies and the value is created through the subscribed users. Moreover, the value is established in use and digital platforms need to have balanced incentives for numerous organizations and individuals involved participant in

an ecosystem (Remane, Hanelt, Nickerson, & Kolbe, 2017). In addition, the VISOR framework aids in studying and evaluating thoroughly the various aspects of the digital models supporting further analysis. This unified framework aims at providing a shared language for experts from various fields (El Sawy et al., 2013). Nikou and Bouwman (2017) used VISOR ontology in analysing mobile health care and well-being services and it was concluded as a suitable one for realizing the relationships between different business model components in the health and wellness applications' domain. Thus, for the purpose of this thesis, VISOR framework is used as a basis for illustrating, comparing, and otherwise researching different business models in the digital therapeutics space.

## **4 RESEARCH METHODOLOGY**

The research methodology chapter aims at motivating the chosen research and data collection methods by describing the various existing possibilities. Then, the research methods chosen for the purpose of this thesis are described and the support for the research objectives is validated. Furthermore, the sample and methods for analysing the data are presented.

### **4.1 Research Methods**

Quantitative research focuses on explaining, describing, and forecasting through measuring the area of interest. The data collected is usually coded, classified and cut to numbers for the purpose of transferring it to a further statistical analysis. The most commonly used data collection method in quantitative research is a questionnaire. In comparison, qualitative research aims at acquiring an in-depth understanding and building theory based on the acquired information (Sachdeva, 2008). Qualitative research, most importantly, studies the purpose of people's lives in their real-world settings and describes their opinions and perceptions in a study. The focus is on the contextual conditions in the real world by providing perspectives from existing or new concepts for helping to explain social behaviour and thinking. The qualitative research gathers the data from multiple sources of data instead of depending on a single source (Yin, 2015).

Case study is a research methodology that refers to a combination of interviews as well as history analysis and examination. The information is obtained from several sources of data for the purpose of acquiring multiple perspectives about e.g. organization, process, or event. Case studies can be single or multiple-case studies and rely on previously constructed theoretical propositions (Sachdeva, 2008). Multiple-case study means that various cases are analysed for the purpose of understanding the similarities and differences between the cases (Baxter & Jack, 2008). The aim is at creating, explaining, or analysing theory through mapping existing designs, structures, and features in a selected context. The chosen cases are used as means to study particular business-related phenomena and further develop to theoretical hypotheses that could be examined and generalized to other business contexts or to theory. Thus, the selected cases should be

sufficiently similar to create new theory or test the existing one or assure the balance of difference and similarity of the cases to make comparisons (Eriksson & Kovalainen, 2008).

## **4.2 Data Collection Methods**

Nowadays, there are an extensive amount of electronic material on the Internet that is used for academic research purposes. In the qualitative research, three main categories of electronic research can be identified: research literature in electronic media (e.g. working papers, conference papers, articles, etc.), existing electronic materials (e.g. annual reports, web pages, blogs, etc.), and materials generated for the objective of a particular research project (e.g. email interviews, electronic focus groups, etc.). This electronic material can be searched from the Internet with the help of search engines (e.g. Google and Yahoo!) and relevant key words. However, it is essential for the researcher to be able to evaluate critically the electronic material used. For example, the researcher can evaluate the electronic materials' currency, purpose, author, and accuracy in order to create an understanding about the relevance and credibility of the material (Eriksson & Kovalainen, 2008).

Interview is a qualitative data collection method that aims to gather insights and learn about the world of others. The research interview can be divided into three categories: structured interviews, semi-structured interviews, and unstructured interviews. In a structured interview, the interviewer asks the same predefined questions from each interviewee and accepts only a limited amount of response categories. This type of interview helps in the process of analysing the questions because it is less time-consuming and readily categorized. In contrast, the unstructured interview is based on a conversation about a given subject between the interviewer and the interviewee. However, the comparison of data can be difficult because the obtained information and discussed subject can vary substantially. In the middle of these two methods lies a semi-structured interview. It consists of a sequence of themes that are covered during the interview and the interviewee leads the conversation towards them. This helps to achieve the same theme between each interview and help in the analysis of the data (Qu & Dumay, 2011; Wilson, 2016).



For a face-to-face interview, problems with time and finance can occur, if the interviewee and the interviewer are not situated geographically close to each other. However, the technological changes have provided online interviews as an alternative for this more traditional interview method. Online interviews can be conducted as focus group or one-on-one interviews as well as real-time or non-real-time interviews. Skype can be used as an instrument for interviewing as it provides the opportunity for audio as well as video. In addition, the interview can be recorded through the program (Janghorban, Roudsari, & Taghipour, 2014).

### **4.3 Research Method Used**

In order to find answers to the first research question (*RQ1: What kind of business environment exists for the client company?*) a literature review has been done to provide insights about the existing trends and factors that affect the business environment of the client company. Additionally, these factors influence on the market entry decisions of the digital therapeutics solution.

For the purpose of answering the other research questions, the qualitative research method has been chosen. A qualitative research method allows an in-depth understanding about the existing business models for developing a feasible one for the client company. More specifically, for the attempt to answer the research questions two (*RQ2: From the business model perspective, what type of characteristics arise in existing digital therapeutics companies?*) and three (*RQ3: Which of these characteristics are feasible in the client company's business model?*), a multiple-case study approach has been chosen. Through a multiple-case study, similarities and differences between existing business models of the case companies can be discovered. Furthermore, the similarities between the client company and case companies' solutions can be identified in order to choose the feasible characteristics of the business model. The choice of using the multiple-case study supports the testing of existing theory to real-world cases as well as applying it to other business contexts.

To support the research question four (*RQ4: Which characteristics are perceived important by different stakeholder groups within and outside the client company?*), in-depth interviews are conducted to receive information about stakeholder groups' insights for developing a business model. The semi-structured one-on-one interviews are

conducted as an online interview due to geographical restrictions between the interviewer and the interviewees. The program used is Skype for Business for conducting a real-time interview, whereas the interviews are recorded using the recording function in Skype for Business and transcribed afterwards. The interviewees are sent information about the project and digital solution being developed. In addition, they receive a video that illustrates the outlook and functionality of the digital solution. The interview questions (See Appendix 1 and Appendix 2) are provided for the interviewees beforehand in order to receive more specific insights.

#### **4.3.1 Sample**

A sampling procedure used in a qualitative research called purposive sampling was chosen for this thesis. Purposive sampling refers to researcher deciding cases with a particular objective in mind or researcher relying on an expert's judgment of selecting cases. This type of procedure can be used in selecting exceptionally informative and unique cases; in selecting participants from a remote or specialized population; or in finding specific types of cases for thorough examination (Mohd Ishak & Abu Bakar, 2014). In the research, the researcher has relied on the judgement of two client company's experts which have selected the case companies as well as the interviewees to fit the purpose of this study. The five case companies represent the digital therapeutics businesses, whereas they differ in their developed solution's focus of treated condition and used technology. Thus, they are in balance in their similarity and difference for creating comparisons. Moreover, the eight interviewees were chosen to represent different stakeholder groups based on their expertise in different fields of business. Furthermore, the interview questions were sent to four people that are working closely with the project for replying in written format. This allows gathering insights and perceptions from various points of view.

#### **4.3.2 Data Analysis Method**

Coding serves as an organizing tool for systematically review the collected data and discover links between the concepts and experiences. These codes are allocated to specific sentences, paragraphs, or words that correspond predefined concepts while securing the context where they appear (Bradley, Curry, & Devers, 2007). The interview questions are developed through the VISOR framework. Thus, the pre-defined concepts, taxonomies,

and themes guide the interview for gaining more understanding about the specific characteristics that are viable for business model generation. The transcribed interviews are analysed by coding the recurrent concepts, characteristics, and taxonomies under themes based on VISOR framework. The NVivo software is used for storing and coding the interviews.

## **5 CASE INTRODUCTIONS**

The information about the case companies are acquired from their websites and through interviews published on the Internet. In this chapter, the client company and five digital therapeutics case companies are introduced.

### **5.1 Client Company**

The client company is a pharmaceutical company operating in a global market that develops, manufactures, and markets human and veterinary pharmaceuticals and active pharmaceutical ingredients. Continuous development of new drugs and treatment methods are a key part of the company's operations. The main customers are healthcare service providers and professionals as well as consumers who own pets. For the client company, the evidence-supported possibilities of digital therapeutics have created an opportunity to develop a digital therapeutics solution of their own. The solution being developed is targeted for treatment of chronic low back pain with the use of VR technology. The individuals who suffer from chronic low back pain experience a difficult combination of subjective physical feeling and mental locks and fears. Hence, the digital therapeutics solution aims at activating and encouraging the patients for motion that exposes them to the pain and further teaches them to tolerate it. This will help the patients to function in their everyday life with more ease and in improved mental state.

The solution is being developed by a partner company because the client company does not have the expertise in developing software. However, a multidisciplinary team that has consisted of the client company's own staff as well as expertise acquired from outside has been involved in the development of the solution based on customers' needs. The customer needs have been obtained through patient interviews and one of the key aspects of the solution is mentoring the patient throughout the process. Mental aspects are seen equally important as the physical ones and therefore the initial screen of the solution is a calming place where the patient can relax before entering the gamified exercises. The idea of gamification is to engage the patients in the exercises and motivate them to continue through adjusting the difficulty level according to the patients progress as well as rewarding them.

## **5.2 Case Companies**

The five case companies have been chosen for the purpose of analysing the companies that have already developed such digital solutions. The data of the case companies is collected from existing electronic material with the use of search engine Google. The main source of data is the websites of the case companies. However, some interviews regarding the case companies found from other websites will be used as a source of data.

### **5.2.1 Kaia Health**

Kaia Health is a German start-up founded in 2016 by Konstantin Mehl and Manuel Thurner. The company has its headquarters in Munich, Germany along with an office in the New York City. Company's solutions focus on the treatment of chronic back pain and COPD which are offered in a healthcare platform for patient's own device. Kaia Health's core is the use of innovative technology and artificial intelligence in their applications. The applications have been developed in an interdisciplinary team with experts in various medical fields. As a result, a mind-body approach has been developed that includes not only the physical exercises but also a mental coach encouraging the patient along the process ([www.kaiahealth.com](http://www.kaiahealth.com)).

Kaia Health's product portfolio includes Kaia Backpain application, Kaia COPD application and Kaia Personal Trainer application. Additionally, iPhone users have the access to a Kaia Motion Coach that uses the smartphone's camera to track the patient's movement to confirm the exercise is done correctly as well as counts the number of repetitions. Furthermore, Kaia Blue is an application for organizations to treat their employees' musculoskeletal (hereinafter referred to MSK) pain. It is promoted to reduce the organization's costs whilst increasing the working years of the employees. The products are CE marked in the EU and certified as Class I medical device. The company is in the process of being certified in the USA but has not yet received the FDA clearance. However, the company is performing clinical trials in order to receive evidence-based results to support the development of their products. Kaia Health has made reimbursement deals with German insurance companies which means that the application is free for the subscribers of the insurance ([www.kaiahealth.com](http://www.kaiahealth.com)).

### 5.2.2 XRHealth

XRHealth was founded in Israel in 2016 by Eran Orr and now they have offices in the USA and Israel. As a medical device company, the focus is on motor, cognitive, physical, psychological, postural ability, pain assessment and treatment. The solution combines medical application with data analytics in an XR (virtual reality and augmented reality) therapeutic platform. The patient's data about interaction with virtual objects in virtual environments is collected and further analysed by artificial intelligence (hereinafter referred to AI) cloud computing algorithms. The real-time analytics enable the clinics and patients to measure and follow the progress over time ([www.xr.health](http://www.xr.health)).

The products of XRHealth have been categorized as VR Portal, AR Portal, Data Portal and External Control. The VR Portal and AR Portal are platforms that contain several applications for different purposes. However, the AR Portal is still on the development phase and does not contain any application yet. In contrast, the VR Portal has gamified applications in three categories: Motor, Pain Management & Stress Relief, and Cognitive. Additionally, the company has opened the platform for third party developers whose applications are included in the platform as well. The applications are presented more detailed in Table 3 ([www.xr.health](http://www.xr.health)).

<i>Category</i>	<i>Application name</i>	<i>Description</i>	<i>Registration</i>
<b>Motor</b>	Balloon Blast	Upper extremity rehabilitation and active shoulder ROM assessment application	FDA Registered Medical Device
<b>Cognitive</b>	Re-Act	Cognitive training application	Quest registration due date: Q3-2019
<b>Motor</b>	Rotate	Neck training application	Registration due date: Q4-2019
<b>Pain Mngmt &amp; Stress Relief</b>	Relax8	Meditation for self-management of pain	Registration due date: Q4-2019
<b>Pain Mngmt &amp; Stress Relief</b>	Luna	CBT for symptom management	FDA Registered Medical Device
<b>Cognitive</b>	Memorize	Cognitive training application	Registration due date: Q4-2019
<b>3<sup>rd</sup> party developer</b>	The C.A.R.E Channel	Meditation, stress relief	Wellness Application
<b>3<sup>rd</sup> party developer</b>	VZfit	Virtual workouts, real results	Wellness Application
<b>3<sup>rd</sup> party developer</b>	Healium XR	Biometrically controlled, drugless solution for stress	Wellness Application

Table 3 XRHealth's Products ([www.xr.health](http://www.xr.health))

The Data Portal is an analytical tool that provides insightful data about each completed session. When the AR Portal is used in a clinical environment the clinician can access the

patient data in the External Control platform. In the platform, the clinician can also remotely control the intensity of the exercise based on patient's needs or mirror the patient's VR headset ([www.xr.health](http://www.xr.health)).

As a first certified virtual reality medical company, XRHealth has received both FDA and CE registration for medical applications. According to their websites, two of their applications are classified as FDA registered medical devices whereas rest of them are waiting for registration. Thus, their medical applications are currently distributed in the USA and Israel and wellness applications are distributed in the USA, Europe, Australia and Israel. There can be found a clinical evidence section in the company's website where independent articles and researches about the use of VR in healthcare have been listed. In addition, the company is performing clinical studies in the USA. XRHealth has received a CPT code for its devices and presumably some insurances and health plans in the USA reimburse the medical applications but there is no clear indication about that ([www.xr.health](http://www.xr.health)).

### **5.2.3 MindMaze**

In 2012, as a result of a spinoff from the Ecole Polytechnique Fédérale de Lausanne in Switzerland, the company MindMaze was founded by the current CEO Tej Tadi. Company's headquarters is still in the city of Lausanne, Switzerland but they also have offices in San Francisco, the UK, Germany, France, and Romania. With the expertise of a multidisciplinary team the company focuses on neurorehabilitation through technology based on virtual environment. The focus of their solutions is in helping patients that suffer from stroke, but the benefits have been discovered for other neurological conditions, such as Parkinson's, traumatic brain injury, multiple sclerosis, and cerebral palsy, as well ([www.mindmaze.com](http://www.mindmaze.com)).

MindMaze has a variety of innovative technologies and initiatives under development but this thesis will focus on their MindMotion product line. The MindMotion PRO is a neurorehabilitation device which intended use is after a stroke. It can be used while the patient is still in bed which enables the early intervention. The device consists of 3D motion tracking camera that simulates the patient's movements onto 3D avatar that is shown on the patient screen. In addition, a separate monitor for therapist allow him or her to assign and monitor the therapy sessions ([www.mindmaze.com](http://www.mindmaze.com)).

The MindMotion GO is designed for utilization in a clinical environment and focus on improving the motor and task functions through gamified activities related to neurorehabilitation. The therapist is the facilitator of the exercises by deciding the body part exercised, setting up the length of the exercise as well as the difficulty level of the exercise. The exercises are based on a 3D virtual environment that uses a 3D motion tracking camera and gives real-time visual and audio feedback. Both products are CE marked and approved for use in European clinics and hospitals. Furthermore, they are cleared by the FDA and thus, can be marketed in the USA as well ([www.mindmaze.com](http://www.mindmaze.com)). However, MindMaze's CEO perceives the reimbursement of medical devices irrelevant (Knowles, 2019).

#### 5.2.4 SilverCloud Health

SilverCloud Health was founded in 2011 and is headquartered in Boston, USA with two additional offices in the UK and Ireland. With over 15 years of research, the company has developed a digital mental health platform that is based on cognitive behavioural therapy (hereinafter referred to CBT) ([www.silvercloudhealth.com](http://www.silvercloudhealth.com)). CBT focuses on changing the behavioural and thinking patterns by presenting different coping skills and strategies (Armstrong, 2018). The platform includes over 30 programs targeting various mental health issues affecting people in different life situations. One program generally consists of 7-8 40-minutes long modules that are recommended to complete once a week. A health care provider assigns a personal supporter for each patient as well as decides, together with the patient, a most suitable program. In Table 4, the programs are illustrated and described in more detail (Health in Mind, 2014).

Program	Description	Modules
<b>Mental Health</b>	Wide range of common health conditions	<ul style="list-style-type: none"> <li>• Depression</li> <li>• Anxiety</li> <li>• Depression &amp; Anxiety</li> </ul>
<b>Chronic Health</b>	Focus on the mental health aspects of living with a long- term condition	<ul style="list-style-type: none"> <li>• Diabetes</li> <li>• Chronic Pain</li> <li>• Multiple Sclerosis</li> <li>• Rheumatoid Arthritis</li> </ul>
<b>Wellbeing</b>	The skills to deal with everyday issues that affect your emotional health	<ul style="list-style-type: none"> <li>• Insomnia</li> <li>• Stress</li> <li>• Resilience</li> </ul>
<b>Higher Education</b>	Adaptations specific to Higher Education	<ul style="list-style-type: none"> <li>• Depression</li> <li>• Anxiety</li> <li>• Stress</li> <li>• Resilience</li> </ul>
<b>Children &amp; Adolescents</b>	Adaptations for children and adolescents	<ul style="list-style-type: none"> <li>• Depression</li> <li>• Anxiety</li> <li>• Depression &amp; Anxiety</li> </ul>

Table 4 SilverCloud Health's Programs ([www.silvercloudhealth.com](http://www.silvercloudhealth.com))



The SilverCloud Health's platform is registered as a medical device and is cleared by the FDA as well as possesses a CE mark. In the UK, the platform can be accessed for free through the NHS system ([www.silvercloudhealth.com](http://www.silvercloudhealth.com)). However, the access for the platform can only be granted with the permission from the doctor (NHS, 2018). In addition, the platform is available for particular universities through partnerships with some US insurance companies (Armstrong, 2018).

### **5.2.5 Happify**

In 2012, Tomer Ben-Kiki, Ofer Leidner and Andy Parsons founded Happify that has the headquarter in the New York City. The company's product is a wellness application focusing on improving mental health through positive psychology, mindfulness, and CBT. This self-care tool consists of over 60 4-week programs ranging in various themes. The programs are built from approximately 300 guided meditations and more than 3000 activities and games ([my.happify.com](http://my.happify.com)). The company is seeking for clearance from the FDA but has not yet received it. However, they are performing clinical trials to gather evidence-based data to support the development of their solutions (O'Brien, 2019).

## **6 RESULTS**

This chapter presents the results attained from the multiple-case study as well as the in-depth interviews. The results are presented through the VISOR framework that has been the basis of the entire study.

### **6.1 Multiple-case Study**

The multiple-case study is conducted in order to find a feasible business model for the client company's digital therapeutics solution that is under development. The need for the development of a business model has risen from the novelty of such a business model for the company and thus, existing business models in the digital therapeutics field are studied.

#### **6.1.1 Kaia Health**

Kaia Health's business model is depicted in Appendix 3 with the use of the VISOR framework. Kaia Health's value proposition for an individual lie in the convenience of the application since the daily 15-minute-long exercises can be done at home with patient's own device. The value proposition for the businesses is the cost reduction of employees' health and risk reduction of employees' missing working days. Monitoring and analysing the progress motivates both individuals and businesses. Additionally, the Motion Coach confirms that the exercises are done correctly, safely, and sufficiently ([www.kaiahealth.com](http://www.kaiahealth.com)).

The Kaia Health's customer segments can be divided into B2C and B2B customers. The Kaia Back Pain application is targeted to individuals that suffer from chronic back pain, whereas the Kaia Personal Trainer application is for any individual interested in exercising at home. Alternatively, the Kaia Blue application is targeted to businesses where the end-user is the employee of those companies. Moreover, since the application is covered by some of the German private insurance companies, can these companies be

considered as customers of Kaia Health and subscribers of the insurance as the end-users ([www.kaiahealth.com](http://www.kaiahealth.com)).

The applications are based on non-medical and multimodal therapy where mindfulness and mental exercises are combined with physical ones. In addition, the application entails optional mentoring via chat with dedicated coaches and education about the condition the application focuses on. Compared to conventional therapies, all of this is achieved with less effort and time. The treatment is personalized according to patient's level and progress. These are measured with the help of AI technology as well as questions about patient's own perception of their level (e.g. patient's experienced pain level) ([www.kaiahealth.com](http://www.kaiahealth.com)).

The interface is easy to use, and the interaction is maintained through social media platforms such as Facebook, Instagram, and Twitter. In both application stores (i.e. App Store for iOS and Play Store for Android) customer reviews have been responded by the developers and can help them develop further their application. Through the application's chat function, the patients can be in contact with a real-life coach. Otherwise, the patients download the application, make the purchase, and start the exercise by themselves and without any assistance from the company. For businesses, Kaia Health provides the service for initiating the treatment by helping to recognize employees that would need such a treatment as well as implementing a marketing campaign to reach users within the company. In addition, they offer maintenance services of the application ([www.kaiahealth.com](http://www.kaiahealth.com)).

Interface's aesthetics have been considered and from a customer perspective, it has fact-based instructions as well as step-by-step guides for the exercises. Progress analysis and monitoring provides data that is used further to personalize the service with AI technology. Service platform is a closed software, but it is supported by different operating systems. The Kaia Back Pain application and Kaia Personal Trainer application are available for download in the Google's Play Store or Apple's App Store depending on the operating system on the patient's device. This can be recognized as the main channel of distributing the application. However, the Kaia Blue application is promoted on their websites without any indication for opportunity to purchase the product. Thus, it is most probably available by contacting the company ([www.kaiahealth.com](http://www.kaiahealth.com)).

The application can be used by the patient's own device and through a free trial period, can be accessed by everyone. However, after that period, only the subscribers are able to access the content. Moreover, since the application is reimbursed with some of the German private insurances, the subscribers of that insurance have access to the application for free. Kaia Health's key activities focus on the platform management including activities such as the maintenance and development of platform as well as platform promotion. In addition, they need the evidence-based results for promoting the platform for patients and thus need to conduct clinical trials ([www.kaiahealth.com](http://www.kaiahealth.com)).

Kaia Health's key partnerships include the medical professionals that help in developing the exercises to meet the patients' needs. By partnering with medical professionals, the company can acquire human resources and capabilities they might lack themselves. Kaia Health's partnerships with German insurance companies offers the subscribers of the insurance an opportunity for reimbursement. Furthermore, the partnerships with other private companies have allowed an access to new customers and generated funding ([www.kaiahealth.com](http://www.kaiahealth.com)).

In the knowledge-based industries the key resources are human resources, and this is the case with Kaia Health as well. Their applications have been developed with a well-designed interdisciplinary team and continuous development requires various experts from different fields. As a start-up company, the company needs financial resources for conducting clinical trials to receive evidence to support their development process. They have successfully raised funding already but, most certainly, are continuously searching for more ([www.kaiahealth.com](http://www.kaiahealth.com)).

The revenue is generated through subscription fees for the application. In the B2C sales, the pricing mechanism used is list pricing, i.e. fixed prices for individual products. In the Kaia Back Pain application, the patient can access the exercises for free in a seven-day trial period. After this, the patient needs to choose from three different options of subscription: 32,99 € per quarter, 51,99 € per half a year or 77,99 € per year. Other applications' prices could not be researched because of the non-availability in the Finnish app store. In the B2B sales, the prices are most probably negotiated between the companies because the data is not available on the website. However, they emphasize that the payment is per active user. The reimbursement in some German insurance companies

must influence the prices compared to other companies thus making it customer segment dependent ([www.kaiahealth.com](http://www.kaiahealth.com)).

The cost structure of Kaia Health is leaning towards a value driven instead of cost driven. The application focuses on generating personalized value for the customers more than on minimizing the cost of delivery. The costs include people, R&D activities, and maintenance of the application. The cost advantages can be described as economies of scope because the same distribution channels and marketing activities apply to company's product variety ([www.kaiahealth.com](http://www.kaiahealth.com)).

### **6.1.2 XRHealth**

XRHealth's business model is described in the Appendix 4 by using the VISOR framework. XRHealth's value proposition is the personalization of treatment through real-time data analytics and progress monitoring. The value is generated through gamification of exercises which ensures the longer and more intense engagement of patients in the treatment. Moreover, the company highlights the patient satisfaction and user-friendliness of the application. The use of application can result in cost reductions for the clinics, patients as well as the pharmaceutical companies. By using the calculators provided on their websites, these customer segments can calculate the ROI and cost savings achieved with the use of their applications ([www.xr.health](http://www.xr.health)).

The company's applications can be used in a clinical environment as well as at home. Nevertheless, the most important customer segment is the clinics and hospitals which then recommend the use of applications for the end-users – the patients. These patients are individuals that have challenges with motor, cognitive, physical, psychological, and postural ability as well as pain management. Because the solution is registered as medical application, the clinicians are usually the ones monitoring and analysing the patient's progress and guide them through the treatment. Alternatively, third party developed wellness applications are targeted to any individuals that are interested in exercising at home or meditating. The wellness applications are included in the platform but need to be purchased separately and directly from the third parties. Third customer segment

identified is the pharmaceutical companies that can use the information provided by the Data Portal in clinical trials and have substantial cost reductions ([www.xr.health](http://www.xr.health)).

Through the External Control, the health care professional can access the analysed health data of the patient in order to personalize the treatment according to their needs and level as well as follow the treatment in real time. Furthermore, the patient can himself choose the game that fits his needs, and by such alter the features of the platform. The XRHealth's interface is user-friendly and thus, easy to use by not only the patient but also the health care professional. The interaction is maintained via customers' own sites in their webpages in the section of "Login". The company provides its contact information on the website for personal assistance. Yet, the set-up process is a self-service with detailed instructions and setup tutorial in the Data Portal. The interface is well-designed, and the aesthetics are considered in order to be more user-friendly. Moreover, the Data Portal can be customized for providing the needed information ([www.xr.health](http://www.xr.health)).

The service platform's architecture is a web-based data portal with open API for partners to develop their own applications. However, VR headset is needed for the access of the applications, whereas the service platform supports different operating systems. XRHealth's applications are distributed through their websites where the interested customer can receive a quote from the desired subscription package. The software cannot be directly downloaded from the website, but it is assumingly delivered for the customer once the payment has been done. In addition, the platforms are supposedly distributed through partners such as the third-party developers, clinics and hospitals which recommend the solution for their customers. The access for the platform is granted only by the subscribers, but it can be used with the users' own devices ([www.xr.health](http://www.xr.health)).

Problem-solving is one of the key activities of XRHealth since they are developing new solutions for individual's problems. Also, platform being their key product, platform management and maintenance can be considered as their key activities. Platform promotion and networking with partners are required for creating new customer relationships. One of the XRHealth's key partnerships are the clinics and hospitals which promote the platform for the patients. In addition, the third-party developers create content into the platform making them an important partner for the company as well. The partnership with the VR headset company Oculus benefits both companies since the platform is compatible with only their VR headsets. Moreover, the clinical trials

conducted in hospitals or by pharmaceutical companies provide essential research material and clinical evidence about their platform which helps them in further development (www.xr.health).

In a knowledge-based industry, XRHealth's key resources are the human resources. The development of medical applications requires considerable amount of expertise from different fields. As a medical device company, evidence is needed from clinical trials to support the effectiveness of the solution. Thus, financial resources are essential for development of applications (www.xr.health).

XRHealth generates the revenue by offering its platforms in three types of solution packages with a monthly subscription fee: Essentials, Business, and Premium. Each of the packages include the Data Portal, VRHealth applications and the External Control. However, the packages vary in the amount of sessions and telehealth patients from limited amount (Essentials, Business) to unlimited (Premium). In addition, the Premium package includes a dedicated account manager and onsite training. The applications of third-party developers are not included in the packages and are available for an additional fee determined by the partner. The applications can only be used with specific set of VR headsets which can be bought from the websites or directly from the manufacturer. There are no price data available for the packages which indicates that the prices are negotiated between the companies. If the VR headsets are bought from XRHealth's websites, they offer a package solution for that as well which might suggest for bundled pricing mechanism. However, the list pricing is used in the manufacturer's own website for the same VR headsets (www.xr.health).

XRHealth's cost structure is more a value driven rather than cost driven because they aim at delivering personalized solutions for their customers. The company's costs contain people and R&D related activities. Their cost advantage is the economies of scope because the company can use their platform in delivering several applications for different purposes (www.xr.health).

### **6.1.3 MindMaze**

The VISOR framework is used for presenting the business model of MindMaze (see Appendix 5). The value proposition of MindMaze is the continuum of care which means that the products are developed for several intensities of care depending on the patients'

progress and needs. The products are calibrated before each session to recognize the user's movements and thus, personalize the care for patient's needs and level of activity. Based on evidence from clinical trials, the early involvement results in more effective care. Furthermore, a comprehensive management of care, with the help of MindMotion, can reduce costs for the clinics ([www.mindmaze.com](http://www.mindmaze.com)).

The most important customer segment of MindMaze are the clinics, rehabilitation centres and hospitals. The MindMotion solutions both require the involvement of a therapist or other trained healthcare professional although MindMotion GO can also be used in home environment and requires minimum supervision of a healthcare professional. The end-users of the product are patients that have experienced a stroke or have other neurological conditions such as Parkinson's, traumatic brain injury, multiple sclerosis, or cerebral palsy ([www.mindmaze.com](http://www.mindmaze.com)).

In the conventional therapies, the engagement of patients that have suffered a stroke can be difficult and early involvement can be hard. The gamified activities engage the patients in rehabilitation which can enhance the pace and intensity of rehabilitation. When patients are engaged in the activities, they are more willing to do the exercises more often and for longer periods. The different games for differing needs enable the treatment to be modified for the patient. In the MindMaze's website, the interface supports interaction with a customer support section which is a fillable form that can be sent to the company. Furthermore, people who are interested in the company's activities, can subscribe to their email list. Additionally, they provide the contact information of each office on the website. The games are user-friendly, and the aesthetics have been considered in the design. The personalization of treatment is achieved through the user-calibrated games ([www.mindmaze.com](http://www.mindmaze.com)).

The service platform's architecture is based on propriety hardware and software but is supported by different operating systems. The awareness of the products is raised in the MindMotion's websites where the customers can find extensive product information. However, information about purchasing the products does not exist and, instead, the interested customer can contact the company to receive more information. Hence, the main distribution channel of the products is their websites. In addition, MindMaze's partners act as the distributors of the solutions for the end-users as well as promoters of



the products for other potential partners and customers. The platform can only be accessed by subscription ([www.mindmaze.com](http://www.mindmaze.com)).

The mission of MindMaze is to solve complicated problems with the help of neuroscience and technology. Hence, the company's key activities include problem-solving through the data generated by the platform, clinical trials, and research and development. As a software company, key activities include platform management as well as networking with partners. The key partners of MindMaze are the rehabilitation centres because they are the ones delivering the solution for the patients. The partnerships with other companies have opened new customer segments and opportunities for MindMaze. The companies have developed together new solutions for customers as well as benefitted financially from each other ([www.mindmaze.com](http://www.mindmaze.com)).

MindMaze is in the knowledge-based industry and thus, its key resources are the human resources. They have stated that experts from various fields are involved in the development of the devices and platform. Because the products do not only consist of the platform but also the physical device, they must have physical resources such as manufacturing facilities, machines, and distribution systems. In addition, they need to provide evidence for the functionality of the solutions which means that many clinical trials are conducted that require financial resources ([www.mindmaze.com](http://www.mindmaze.com)).

MindMaze does not reveal any information about their revenue streams from the products. However, in an interview the CEO of MindMaze has mentioned that their products are affordable for individual patients and implies to a \$20 - \$50 per month fee (Knowles, 2019). Based on this, it can be assumed that they receive subscription fee for the use of their platform. In addition, the devices generate revenue either by the means of asset sale or possibly through renting or leasing the device for the customers. The pricing mechanisms assumingly are based on negotiations and the price is customer segment dependent. MindMaze's cost structure focuses largely on the value and delivering that for the customers through personalized care. Their costs include the people and R&D related activities. As with other companies, the benefit of the platform is that it is suitable for delivering various exercises for different needs ([www.mindmaze.com](http://www.mindmaze.com)).

#### **6.1.4 SilverCloud Health**

SilverCloud Health's business model is illustrated in the Appendix 6 by using the VISOR framework. SilverCloud Health's value proposition is the possibility for scalability of the solution according to each organization's mental health care needs. Moreover, the platform provides cost reductions for the customer organizations through patients' improved outcomes and digitality. The clinical engagement, outcomes, and patient satisfaction can be measured through data analytics and reporting tools. The platform enables more effective health care by reducing waiting time as well as providing easier accessibility. Over 15 years of clinical research supports the evidence-based solution and development. Gamification of the activities engages the patients into the treatment and some of the activities can only be accessed after certain progress has been made ([www.silvercloudhealth.com](http://www.silvercloudhealth.com)).

SilverCloud Health's solution is targeted for organizations that can further offer it to end-users with mental health issues. Thus, their most important customer segments are clinics and hospitals. Furthermore, their customer segment includes insurance companies that provide the solution for their subscribers as well as other companies offering the solution for their employees to increase their well-being. Additionally, the company's customer segment is universities which students can use the services offered by the solution ([www.silvercloudhealth.com](http://www.silvercloudhealth.com)).

SilverCloud Health's platform can be accessed conveniently and used at home on the patient's own time. The 8-week program has been divided in a way that the patient is recommended to complete one activity per week but according to their own time. Moreover, compared to more conventional therapy, the accessibility barriers, such as *stigma* for mental health issues, time availability, and transportation, do not exist. Each patient is assigned a supporter and the programs are developed for their specific needs. The supporter provides guidance, encouragement, and other support when needed and they are promised to contact the patient every two weeks. Based on the conversations between the supporter and patient, the activities are further amended and personalized for patient's needs ([www.silvercloudhealth.com](http://www.silvercloudhealth.com)).

The interface provides a possibility for interaction between the supporter and the patient through the chat function. In addition, the patient can contact the staff via phone in urgent cases. Most of the activities can be used at any time such as a journal provided for personal

use. The exercises are interactive which enhances the user's engagement and learning of provided educational content. Furthermore, the company uses social media platforms to interact with its customers as well as provides its contact details for further information ([www.silvercloudhealth.com](http://www.silvercloudhealth.com)).

The user-friendliness and aesthetics are considered highly in the interface. The content of the platform can be customized but mainly in the initial stages by a request arising from the customer organization. The customer can opt in a self-directed care or a coached care whereas some of the tools can be added. The service platform supports different operating systems and is based on an open API with a single sign-on and thus, the integration to other systems is straightforward. Nevertheless, the platform can be accessed through a member or patient portal as well as the website. The partner organizations deliver the solution through their own platforms which they are able to receive access by contacting the company via their website. The access is granted for individuals that are customers of SilverCloud Health's customers, for example students, employees, insurance subscribers and patients. However, the SilverCloud Health's customers need to acquire a subscription for the platform in order to receive the access ([www.silvercloudhealth.com](http://www.silvercloudhealth.com)).

In order for the company to deliver the solution for their customer, the platform needs to be maintained and developed continuously. Furthermore, their key activities include networking with partners for the purpose of gathering additional capabilities as well as new customer segments. The patients' problems are solved by conducting clinical trials and through feedback received from the platform. Company's key partnerships include clinics and hospitals that support the clinical trials and deliver the solution for the end-users. Additionally, the partnerships with insurance companies enables the provision of care for the subscribers of the insurance. Universities are helping the company in clinical trials as well as delivering care for the students. Moreover, the aim of partnering with pharmaceutical companies is to foster the compliance between selfcare and medication ([www.silvercloudhealth.com](http://www.silvercloudhealth.com)).

In a knowledge-based industry, clinical trials that provide scientific data require human resources. Nevertheless, the financial resources are needed for conducting the clinical trials and developing the products further. The pricing mechanism of SilverCloud Health is based on a fixed annual price which allows the customer an unlimited access to all the activities, services (e.g. maintenance, support, etc.), and future activities. However, the

website offers limited amount of information about pricing mechanisms and the potential customer needs to contact the company for receiving more information ([www.silvercloudhealth.com](http://www.silvercloudhealth.com)).

The cost structure is based on the value rather than cost, because they focus on customizing the solution according to each organization's needs. The costs, however, include maintenance and research and development related activities that arise from the conducted clinical trials. Furthermore, the human resources create costs whereas the economies of scope offer benefits for the company because the platform can be used for offering various solutions and differing activities ([www.silvercloudhealth.com](http://www.silvercloudhealth.com)).

### **6.1.5 Happify**

Happify's business model is illustrated in the Appendix 7 through the VISOR framework. Happify's value proposition focuses on patient engagement through gamified and evidence-based activities. Their platform provides scientific support for different activities through educational material, that the user can choose to access before each activity. Moreover, the platform emphasizes and encourages the social connection with others in the same situation for receiving additional support. For this purpose, they have integrated a Community section where the members can discuss, encourage, and support one another. The platform can also help in reducing costs when the medical and behavioural health care is combined. Furthermore, the platform is offered in 8 different languages and is also modified for local cultural needs of the company ([my.happify.com](http://my.happify.com)).

The customer segments of Happify have been divided into B2C and B2B customers. On the one hand, any individual that wants to feel happy, is a targeted B2C customer segment. On the other hand, the platform is mainly targeted for individuals that have the need for maintaining wellness of mental health through everyday life or chronic diseases. The platform also offers support for diagnosable mental health conditions. Pharmaceutical companies are one of the B2B customer segments because the platform has the potential for use alongside other pharmaceutical products. Moreover, insurance companies and other organizations are considered as Happify's customer segments because they provide the platform for their customers to maintain and develop their wellbeing ([my.happify.com](http://my.happify.com)).

In contrast to traditional treatment of mental health, Happify's platform allows the access for the treatment at the patient's own home at their own time. This is a more convenient way for the patient not only because of the easiness of accessing the treatment but also, the patient does not have to worry about a certain *stigma* that might still affect the patients suffering from mental health issues. Moreover, the platform provides real-time data and reports of patients' progress for the organizations which allows them to monitor the results. The assessment tools personalize the programs for individual's needs from the moment the platform is initialized. Furthermore, the user can choose from the different suggested programs which one is suitable for their needs at that moment (my.happify.com).

The Happify's interface allows the interaction with other members in the community to receive support. Then again, Happify interacts with its customers through social media platforms and customer support is offered via email. The platform is easy to use, and navigation is clear. The aesthetics of the interface have been considered and the customer can choose a game he sees fit, which provides flexibility and personalization of the interface. However, no other features of interface customization can be recognized (my.happify.com).

Happify's service platform is based on an open API architecture. Through this, the partnering companies can integrate the platform into their own platforms easily. The service platform supports various operating systems and can be accessed by the user's own device. The solution is distributed through both application stores, i.e. Google's Play Store or Apple's App Store, depending on the operating system on the patient's device. In addition, their website is used as a sales channel for the business customers. These customers can contact the sales representatives in order to receive more information about the solutions offered for companies (my.happify.com).

Happify has signed an accessibility agreement and, in fact, the platform can be accessed in eight different languages. Furthermore, they have taken into consideration the accessibility of visually impaired people. The platform has a freemium pricing strategy and the platform's activities can be accessed for free, but the premium activities are only available for the subscribers. As merely a software company, Happify's main activities include platform management. In order to deliver the solution for the customers, the company needs to maintain, develop, and manage the platform. Moreover, networking

with partners is essential for them for reaching new customer segments. The company also conducts research in order to solve the arising problems and to develop the products further (my.happify.com).

Happify's main partnerships include clinics and hospitals that help in delivering the solution for the end-users. Furthermore, the partnerships with pharmaceutical companies and clinical trial research enable reaching the end-users (my.happify.com). Recently, the company has partnered with a pharmaceutical company that supports in the process of FDA clearance and reaching new market segments. Additionally, the partnerships with other companies as well as insurance companies creates a channel for delivering the solution for the insurance subscribers and employees (O'Brien, 2019).

In a knowledge-based industry the human resources can be considered as important for developing the platform and also for delivering the evidence-based results to support that research. Furthermore, the financial resources are essential for conducting clinical trials. Happify offers its solution for free to some extent and a subscription fee needs to be paid in order to access all the features. The subscription fee is 15,99€ per month or 144,99€ per year. Additionally, a lifetime subscription is mentioned but the price is not visible. Moreover, the company offers a guarantee of 30 days for their services. For B2B, the price is presumably negotiated according to the customer segment (my.happify.com).

As the other case companies, Happify also follows a more value-driven cost structure by offering personalized solutions for the customers. The costs consist of people as well as the research and development related activities. The company's platform includes over 3000 activities and they are continuously developing more of them. Thus, they benefit from economies of scope as they are able to use the same platform for delivering a growing number of products (my.happify.com).

## **6.2 In-depth Interviews**

The demographics of the respondents in the interview are illustrated in the Figure 7. The total number of the respondents was twelve. Two of the respondents are outside of the client company, whereas the ten remaining respondents are employees of the client company. The two respondents from outside the client company act as providing insights that are not limited on the client company's culture that might potentially appear on the

responses provided by the employees of the client company. The majority, i.e. six, of the respondents are located in Finland, three respondents are in the UK, one respondent in France, one in Germany and one in the USA. A more detailed description of the respondents can be found in the Appendix 8.

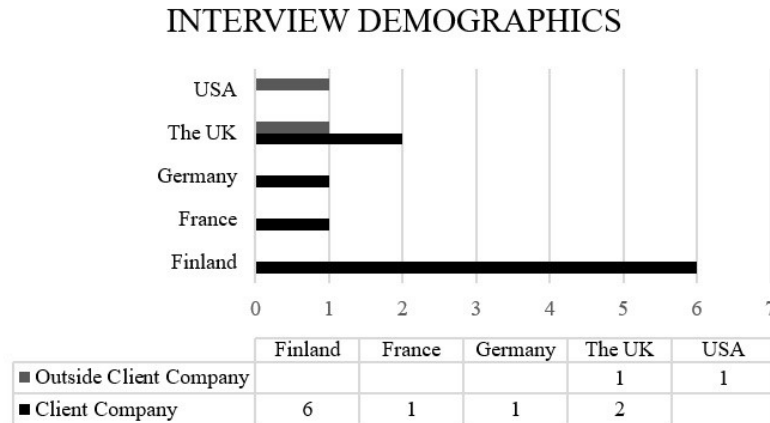


Figure 7 Interview Demographics

### 6.2.1 Value Proposition

Four of the respondents separately stated that the digital solution would be accepted by the customers, whereas non-medical and engagement were mentioned by most of the respondents as important factors that can enhance the acceptance of the patients towards the solution. Other compelling factors that were mentioned were effectiveness, novelty, and monitoring. Furthermore, other factors such as added value and increase of self-management were mentioned by the respondents. The factors that were perceived as compelling characteristics of the value proposition, are illustrated in the Figure 8.

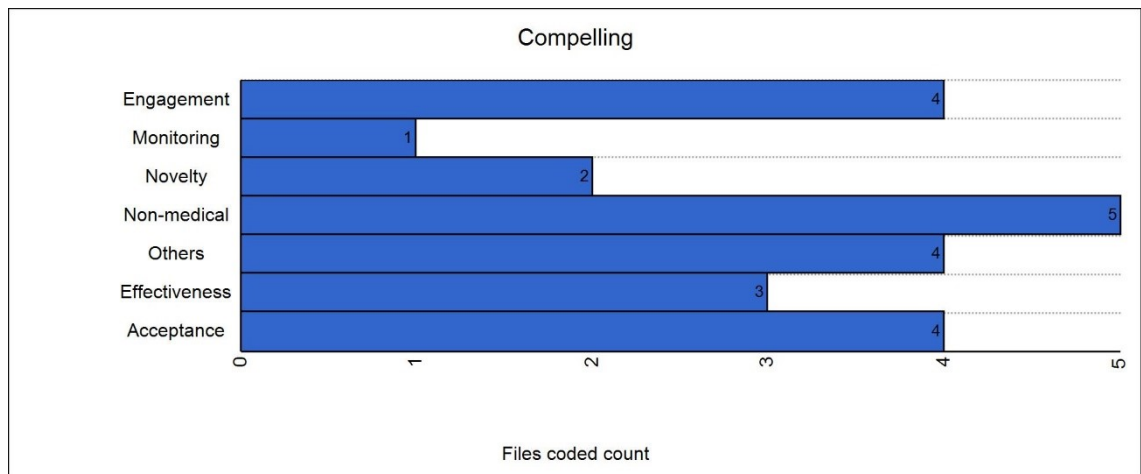


Figure 8 Compelling Factors

Non-medical aspect of the digital solution was perceived as positive by almost half of the respondents. People with back pain usually consume a considerable amount of medication that impose the patient to side effects. The digital solution, on the contrary, lacks such side effects which was perceived as a value-adding factor and increasing the acceptance level. One of the respondents considered that an existing opioid crisis could enhance the acceptance level of the digital solution for treating pain in the USA.

“I think there's quite a big opportunity in the US market to, especially around communications, bringing this as an alternative [...] to the opioid issue, right. [...] non-drug approach to alleviate pain and support patients that quite frankly may be concerned even to start taking painkillers because of everything that's happened.” —  
*Respondent 6, USA*

However, it was emphasized that research data needs to support the lack of side effects. By the support of clinical evidence, the digital solution may be perceived as an alternative to a more conventional type of treatment.

The engagement to the treatment was perceived as providing value for the customer through the digital solution. The gamification of the treatment makes the treatment entertaining and fun which results in higher motivation among patients to return to the therapy. Furthermore, the gamification was perceived to encourage the patients for movement through the various challenges and immersion of the VR environment. In addition, when patients feel that their needs have been acknowledged, for example, by asking some initial questions, the engagement is enhanced.

“But even if you added in the software [a] section at the beginning, that ask the patient [...] to describe the type of issue they're trying to deal with, and [...] what kind of movement gives them the most trouble [...] then, even just saying ‘Okay, we're going to be showing you a program that we think will be right for you’. Now, if that program is exactly the same, regardless what the answers are, most people will feel more satisfied with it regardless, because they felt they've been heard before they take something.” —*Respondent 6, USA*

Even though the older generation's acceptance towards the digital solution was perceived as a challenge by some of the respondents, the results from the conducted feasibility studies have argued otherwise. One of the respondents working closely with the project stated that there has not been any less interest among the older generation. The possibility for monitoring patients' progress was perceived as a value creating factor. The existence of monitoring tool was even perceived as enhancing the patients' quality of life.



According to the respondent, the medical professionals would be interested in receiving the generated health data, whereas the patient could see real-time results of the treatment.

The digital solution was perceived as offering a novelty treatment and new experiences for various generations. For example, the clean and white hospital environment could be experienced as more interesting, comfortable, and enjoyable by creating a new environment with the digital solution. Especially, among the younger generation, that is accustomed to use such digital platforms, the interest and acceptance could be high as well as engaging. In fact, it was perceived that this type of solutions would generalize increasingly as the younger population grows older. One of the respondents realized a clear need for treating pain with a digital therapeutics solution.

“And there are lots of people who face some kind of pain, and even really nasty pain, that is disturbing their daily life. So, there is really real need for this type of solutions.” —  
*Respondent 2, Finland*

The digital solution was perceived as a cost-effective approach for clinics and hospitals to treat low back pain patients. In addition, the insurance companies were considered as interested in providing such treatment that costs less than standard therapy, but is at least as effective, or even better. Furthermore, the digital solution was perceived as an effective treatment that reduces pain and, for example, prevents absenteeism at work.

The respondents perceived that the acceptance of the solution would be high, because it creates additional value for the customer. Furthermore, the increasing willingness for self-management increases the level of acceptance among the customers. However, the cost of the device or lack of the payer was seen as a barrier that needs to be undertaken.

“But I guess [...] patients would use the solution, especially if they do not have to pay for the solution.” —*Respondent 4, Germany*

Even though the likelihood of acceptance would be high, one of the respondents emphasizes that before deciding, the users need to see the digital solution. Another respondent adds that the solution and marketing must be based on medical device while many of the respondents highlighted that in order for consumers to be certain about the solution's functionality, it needs to be recommended by medical professionals.

Most of the respondents perceived the individual consumers as a viable option for target group. The division of the considered target groups are illustrated in Figure 9.

Nevertheless, the majority of these respondents argued that the individual consumers should not be focused first whereas the digital solution should be recommended by the medical professionals.

“— maybe in later stages when this is already shown to medical professionals and to the greater audience that this is a very good solution for pain management, [...] I would say that then to concentrate to individual consumers more, but I would start with the organizations.” — *Respondent 1, Finland*

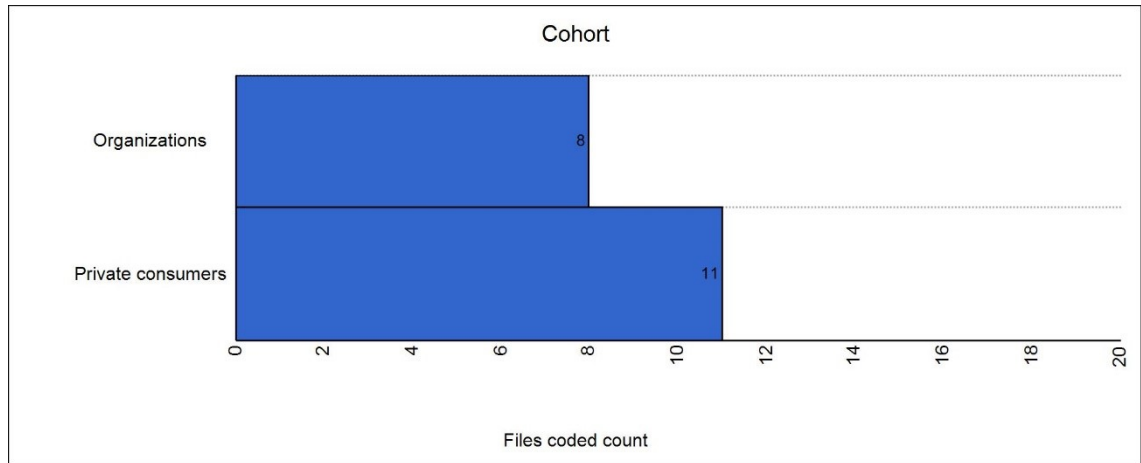


Figure 9 Division of Considered Target Groups

In many cases, the pain patients are individuals that stay at home and are familiar in using actively digital tools, such as smart phone and tablet. Thus, the digital solution was perceived as a natural way of treating pain for these people. However, the respondent stressed that it is vital to build a credible brand which could be achieved by carefully selecting partners. Moreover, some of the respondents emphasized that the digital solution might merely be purchased by the patients that have already tried everything. In the UK, it was perceived feasible to start with the individual consumers that would purchase the digital solution from the pharmacies as an over the counter product. However, the respondent addressed concerns related to the price as well as proven medical data.

“I mean, unless they are really, *really*, suffering and have huge burdens on their quality of life, and they're so desperate to try [...] and also the price point of this treatment is something that they feel it's [*sic*] acceptable.” — *Respondent 3, The UK*

On the contrary, the French respondent perceived that the payers would not necessarily be ready to pay for such a solution as an out-of-the-pocket payment in France. Furthermore, in case the individual consumers are focused on first, the digital solution cannot be marketed with clinical evidence supporting the claim and thus, prescribed by

the doctors. Thus, the target group of individual consumers can be used for collecting data and proving the digital solution's feasibility. The importance of affordability and simplicity for awareness building and allowing a widespread among the individual consumers were agreed by the majority of the respondents.

“It depends on the final solution. If we have a simple version which works already, but with which we want to collect more clinical evidence for, e.g. regulators and payers we might want to start with B2C.” —*Respondent 1, Finland*

“—if it's not hugely expensive and we can [...] provide it relatively cheap to wide audience, then you should go to the individual consumers, because then you get the widespread” —*Respondent 8, Finland*

The division of organizations considered as important stakeholders by the respondents are illustrated in Figure 10. The organizations were perceived as an essential link in delivering the solution for the end-users by most of the respondents. Additionally, it was agreed that the health care professionals are the ones instructing the patients for correct use of the solution.

“The first thing is you need the support of people who are important in the management of the disease. So, B2B first is critical for sure, because [...] your software will have a value and [...] the value of your software and program will be spread by the experts [...] of the disease [...], but this has a value that should be explained or [...] spread to the patient thanks to the expert in that. So, the credibility of your platform will come from them.” —*Respondent 5, France*

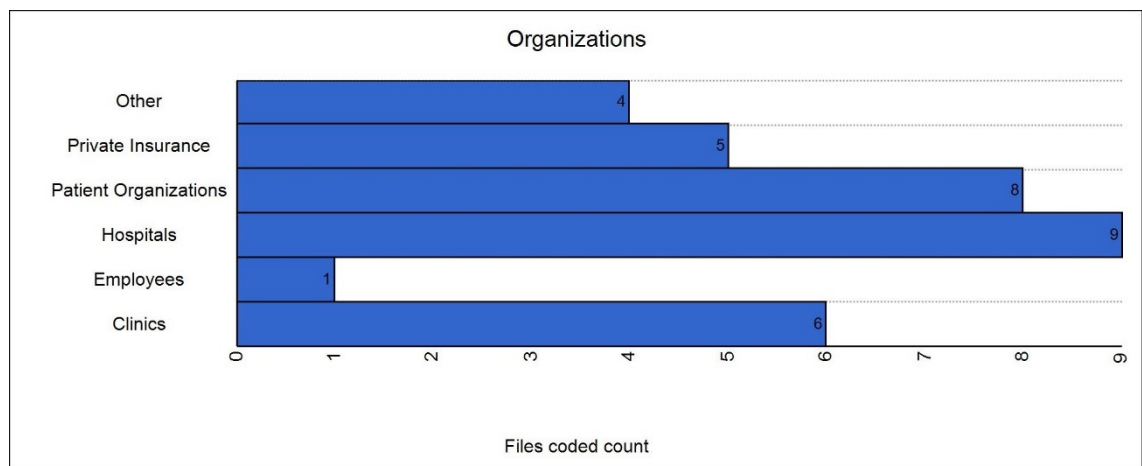


Figure 10 Division of Organizations

Almost each respondent mentioned the importance of patient organizations in delivering the solution.

“I would focus here on those associations which are working on opportunities to solve [...] those problems. Since we are talking here about a kind of therapy, so, you should work together with associations which are focusing on therapy opportunities, options, alternatives, and those would be, for example, more important.” —*Respondent 4, Germany*

Hospitals were also considered as one of the most valuable stakeholders by almost each respondent. It was perceived as an important delivery channel in terms of building credibility and awareness among the patients. In addition, hospital is a place from where the pain patients naturally seek for help, which makes it an obvious target group. Few of the respondents pointed out, that doctor’s advice is highly appreciated - especially in Europe. Hence, the health care professionals in hospitals should be convinced by the solution for them to recommend it to the patients.

“— you need to have the support of the physician. [...] probably all over Europe, if the physician said you should have that, you should use that, because it will be good for you, for your wife or—then the patient would use that.” —*Respondent 5, France*

“— even the nurses could recommend this or so. So, I think at that point, especially in Finland where the patients are really following the orders of doctors quite well, I think it could start, if the cost of this equipment is not too high or it would be compensated somehow.” —*Respondent 2, Finland*

Half of the respondents mentioned various clinics, and most importantly the ones concentrating in pain, as vital stakeholders that could offer the digital solution for pain management as either an additional or alternative treatment. The trials conducted in these clinics, and samples of the solution in some form were perceived as viable ways to deliver and build awareness of the digital solution.

“I think it should be in the clinics where [this] type of patients would naturally go first. So, I would target the clinics where are people suffering from the pain and where are the neurologist, orthopaedist, GPs, nurses, certain psychiatrists even. I think that, that would be the start.” —*Respondent 2, Finland*

Private insurance companies were perceived as an important target group because of their potential interest towards a cost-effective digital solution included in the health insurances. This is the case especially in countries like Germany and USA where the private health insurances are popular among the population.

“— do not forget here to involve in [...] quite early stage health insurances. Since at the end, it's necessary to get this solution also paid and here, especially in Germany, health insurances are important.” —*Respondent 4, Germany*

“— in countries where you have insurance companies like Germany, for instance, then I would certainly go and trying to target them, because really [...] if they have to pay out for people who have lost salaries and they have to compensate them because of back pain, then they probably will be more willing to look at paying for these kind of things, so that they can save on the other side.” —*Respondent 3, The UK*

“US consumers are much more used to paying for things out of pocket, rather than hoping you will be covered by like a national insurance program which doesn't exist in the US, so private insurance.” —*Respondent 6, USA*

Especially in the US markets, the importance of corporate welfare was emphasized by one of the respondents. There is a vast potential in the private organizations to deliver the digital solution in their health care package. The number of low back pain patients in companies is high whereas in a large company's scale, even a small percentage of people suffering from back pain, would imply hundreds of patients in one single company.

“So, I actually, of all the targets, I would really go after those first, more than anyone else because they have a direct savings and major interest in making sure that some of the missed workdays can be avoided. There's a real tangible financial benefit to these companies to where they might sponsor this internally. So actually, corporate welfare programs will be at the top of my list for this type of product.” —*Respondent 6, USA*

Other stakeholder groups that were mentioned by the respondents were professional societies and charities, pharmacists, and e-health providers. In addition, reimbursement organizations were mentioned, in case there is willingness for seeking reimbursement. Furthermore, one of the respondents emphasized the importance of technically oriented company that could provide assistance in building the road and granting access for a potential customer base.

When the digital solution was compared to a more conventional type of treatment, various factors were mentioned regarding the complementary aspects of the digital solution (see Figure 11). One of the benefits perceived by almost half of the respondents was the accessibility. The limited number of health care professionals and barriers regarding available time and financial resources were recognized as non-existence in the digital solution because it can be used at home. Furthermore, the type of treatment does not necessarily change, but the value is carried through this different type of accessibility and providing a different scenario for the patients.

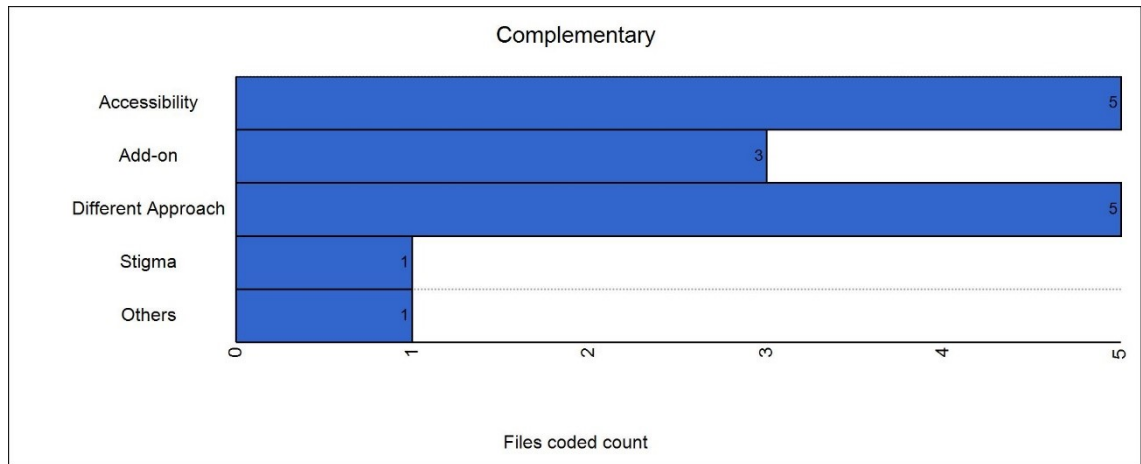


Figure 11 Complementary Factors

Almost half of the respondents perceived that the digital solution was approaching the chronic low back pain from a different angle and providing a new way of treating pain. The patient is taken into a different world which allows him to learn new things and possibly even forget the pain.

“Create a virtual world which cannot be created in the psychologist’s office” —  
*Respondent 11, The UK*

“I would see that this would have a greater impact to their quality of life, for these persons, than the conventional treatment.” —*Respondent 1, Finland*

Some of the respondents also emphasized, that the digital solution is not necessarily the only therapy, but rather an alternative, or an add-on therapy – a complement to medicine. One of the respondents mentioned the barriers regarding psychological issues and a certain *stigma* associated with mental health whereas the digital solution might lower this type of barrier for the patients seeking for treatment.

“— everything is basically nowadays connected, even the patients, which are [...] working with the mobile phones and smart devices everyday basis, and this [...], in my opinion, lowers the bar to seek help for certain issues, especially with people who have psychological issues and sort of feeling shame. And in chronic pain, there's some elements involved in that.” —*Respondent 7, Finland*

The co-creatability and personalization of the treatment according to the patient’s needs were seen as important by all the respondents. The personalization was perceived to create value for the customer through factors illustrated in Figure 12.

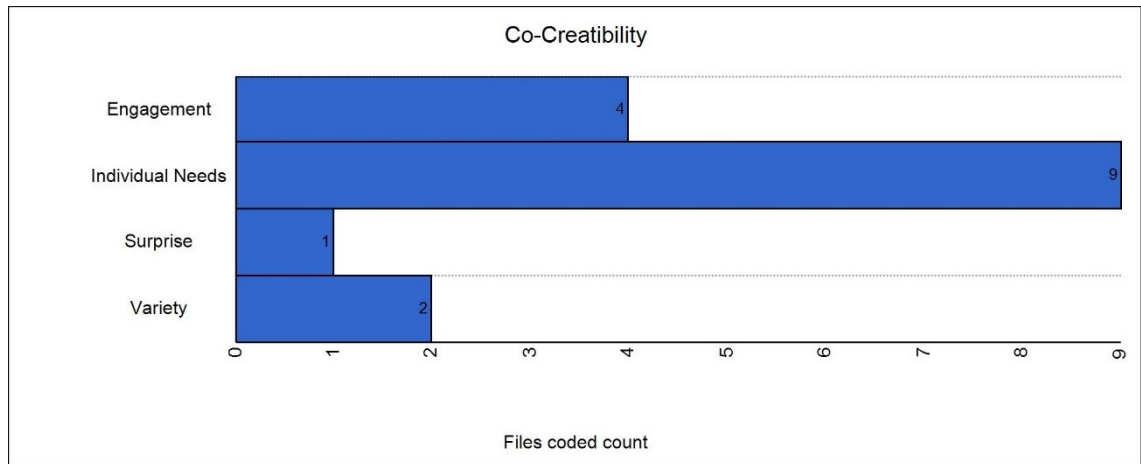


Figure 12 Factors of Co-Creatibility

Few of the respondents perceived the personalization as important but not in the first release whereas the personalization could be included in the later releases as an enhancing factor. The possibility for personalization of treatment according to patient's needs is identified as highly important by almost each respondent due to individual patients' differing levels, limitations, and expectations towards the treatment as well as different demographic groups' (e.g. gender, age and tech-savviness) requirements. Moreover, through personalization, the patient is able to feel that the treatment is addressed to him and not generalized to anyone's needs. This increases the patient's engagement into the treatment. In contrast, one of the respondents would only perceive personalization as important if the patient would have phobias that need to be taken into consideration.

One of the respondents proposed that the personalization should be based on person's needs examined by questions regarding the patient's condition. Then, the activities could be adjusted according to different types of patients, or conditions.

“So, I think it's important for any of these packages to have some way to first classify the patient or what things they might be having [...] smaller pain or more difficulty with, and then fine tune its recommendations accordingly. So, if it's a doctor that visits the patient, and then he's able to send to the software, some things saying [...] ‘lifting with the right arm is very difficult, so less do the lower stress type of movement with that.’ Then this, I think, would be helpful, but to just have a generic one size fits all approach, in this case may and may not get the results that we want, perhaps may even tell people that, this thing doesn't understand that, that hurts.” —*Respondent 6, USA*

The possibility for personalizing the treatment was perceived as an engaging factor that allows the patient to tailor the experience according to their own needs. This, in fact, increases the attractiveness of the solution itself.

“— personalization is more to do with trying to enhance patient compliance, so that patient will not abandon this.” —*Respondent 3, The UK*

One of the respondents emphasized the importance of making the platform interactive so that medical professional are able to see the patient’s progress and, when certain steps have been achieved, the patient is given the possibility to choose the additional features included into the platform. Two of the respondents emphasize the importance of offering a variety of different activities. A suggestion for further patient engagement could be achieved by providing different scenarios every day. This type of element of surprise could make the patients return to perform the activities day after day. Also, one of the respondents proposed that different elements from other applications, such as Spotify, could be combined with the platform.

“— music would be extremely important for elements like this because music has been proven [...] to decrease pain, for example, in a very efficient way. [...] you're doing certain kind of movements, but how do you do the movement - is there [...] terrible elevator music, or can you choose your own favourite [...] list.” —*Respondent 7, Finland*

For the purpose of personalize the treatment, the gathered health data is assessed, and the treatment is amended according to the patient’s needs. The personalization, then, can be done based on medical professional’s assessment, or technology’s assessment (e.g. AI changing the difficulty level according to patient’s progress) of that data. Furthermore, the patient can choose the activity based on his perception of needed treatment or the personalization can be based on a combination of these three aspects. The division of perceived factors affecting the personalization is illustrated in Figure 13.

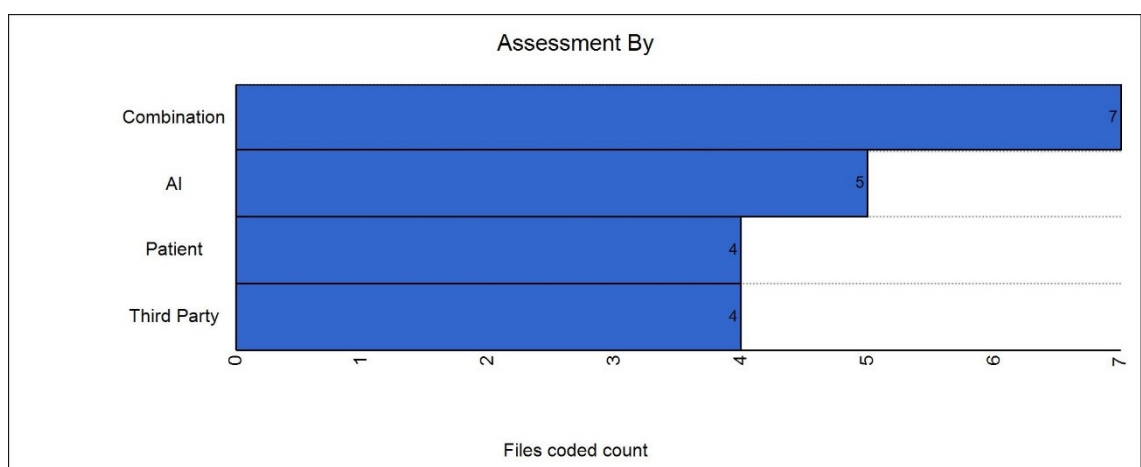


Figure 13 Personalization Based on Health Data Assessment



More than a half of the respondents perceived as the most feasible option a combination of the assessment possibilities. Even though the medical professional's assessment is important for delivering safe treatment for the patient, solution needs to still answer each stakeholder's need. One of the respondents perceives technology's assessment as the most beneficial one because it releases the patient or medical professional from manual work. In contrast, another respondent concludes that patient's assessment would enhance his compliance to solution while his motivation increases through the visibility of data, and accomplished progress. Furthermore, the possibility for patient to choose the intensity level of the activity was perceived as important.

One of the respondents stated that the patient must have the control over the process, but the medical professional can have the responsibility for setting the parameters. In fact, the medical professional's assessment was perceived as vital by many of the respondents, because the treatment is eventually based on medical data. Likewise, the digital therapeutic may pose a risk to the patient and make the pain worse, if the activities are done incorrectly. Some of the respondents perceived the human interaction important and recommended the medical professional's assessment included too. Furthermore, an encouragement from a medical professional can increase the patient's willingness to finish an activity or choose a higher intensity level exercise.

One of the respondents highlighted that the AI driven assessment cannot be in the first versions of the digital solution, due to the lack of gathered data. However, it was perceived that the AI can enhance the effectiveness of the solution as well as develop recommendations for the patients based on initial questions. Moreover, the AI can increase the patient compliance and engagement by following the patient's activity level and sending reminders based on the assessment.

### **6.2.2 Interface**

The factors affecting the functionality of the interface are depicted in Figure 14. Almost each of the respondent perceived the interface's user-friendliness as a vital factor of the digital solution.

*“User-friendliness is everything.” —Respondent 7, Finland*

“It has to be user friendly. Otherwise, I don't think it will work out. I think this is a must, *must*. And of course, that it's so easy to train and user friendly so that people are really doing the exercises what is needed and there are no [...] excuses or anything like that they would drop out. Yeah, so I think this is really crucial. [...] I would say, to get [...] high acceptance, user friendliness would be most important” —*Respondent 2, Finland*

“I think it's very important actually, that the solution is user friendly, because I think this is the whether it will be used or not. That it's very, very important because then [...] you get even more anger and you get even more pain if it's not [...] you have to struggle with the [...] solution.” —*Respondent 8, Finland*

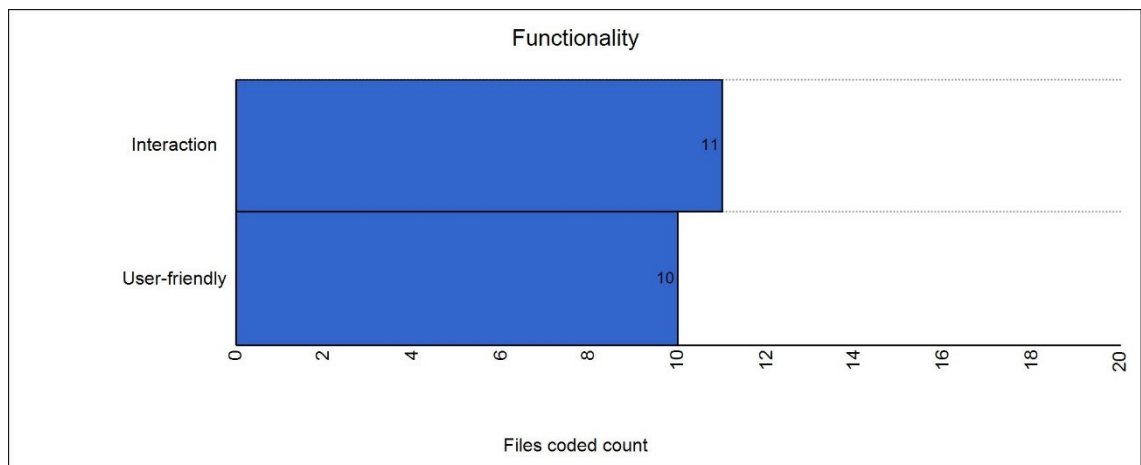


Figure 14 Functionality Factors

The respondent perceived the interface as user-friendly when there is no need for large manuals, or not a lot of effort is needed in the setup phase and, for example, the elderly population would be able to use the solution with ease. It was concluded that if the user-friendliness is not considered, the solution would not, most probably, be used. One of the respondents argued that the user-friendliness needs to be considered from the customers' point of view as well as improved continuously based on the customer feedback.

The different possibilities for interaction proposed by the respondents are illustrated in Figure 15. Data collection was perceived as a useful function that would benefit the service provider, patient as well as the medical professional. The collected data could be used for monitoring of patient's progress and also the actual benefits of solution. Furthermore, the saved data could be utilized in face-to-face interactions with the patients.

“It would be good to have visibility of the data for both the patient and the clinic so that they can follow the progress and e.g. before next clinic visit the HCPs [Health Care Professionals] would already know a lot of the basic data and could focus on the F2F discussion with the patient.” —*Respondent 9, Finland*

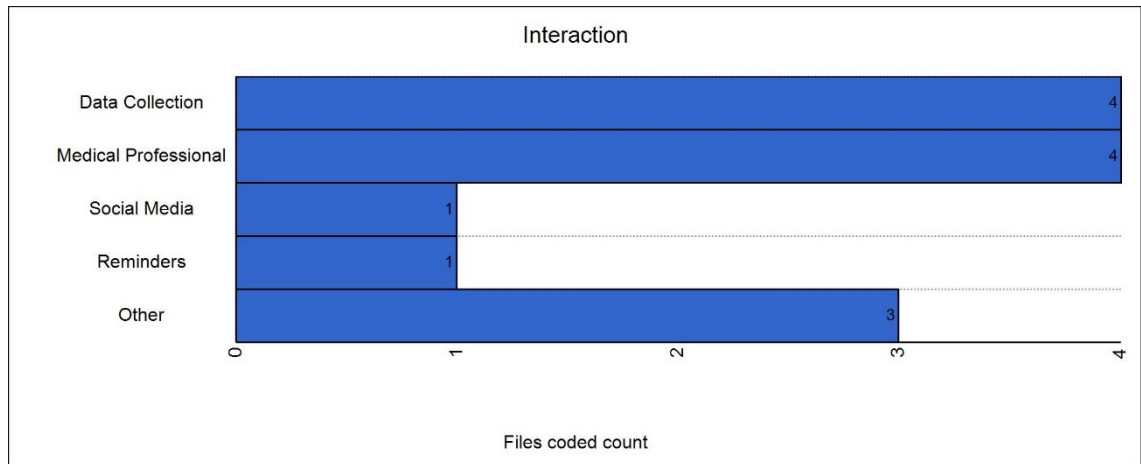


Figure 15 Interaction Possibilities

The respondents perceived a possibility for interaction with a medical professional as important. A contact point with medical professional would allow the patients to share their progress or ask for help in case of facing problems. In addition, one of the respondents proposed a possibility for Skype call with a friend during an exercise or sharing an accomplishment in social media. Moreover, the respondent emphasized the importance of interaction with a community of people suffering from a similar condition whereas another respondent proposed a possibility for multiplayer or group therapy.

Reminders and questions about patient's condition were perceived as a factor that creates an emotional bond between the interface and the patient. Moreover, the possibility for purchasing add-ons as well as giving customer feedback were proposed for possibilities of interaction. In comparison, it was perceived as important that the interface gives feedback to its user as well - either as sound or physically. For example, the haptic motors in the handsets would indicate the user that the movement is done correctly.

“Even if people might be moving things the wrong way, something that just by the way the device's shaking or clicking indicates to them ‘Yes, it's the correct motion’ or ‘No, it's not the correct motion’. I think [it] will be important from a design point of view. So even more than what you just visually see.” —Respondent 6, USA

The form factor and fluidity affect the interface's outlook and design. The division of respondents' perceptions regarding these characteristics are depicted in Figure 16. Half of the respondents perceived that the outlook and the aesthetics of the interface design should be considered by creating an attractive enough solution for the user. The patient's interest towards the solution is enhanced with a pleasant design. In addition, the cultural understanding in the design was perceived as an important aspect by one of the respondents and certain colours or words should be taken into consideration, such as the

colour red in China where it is considered as positive, but that might not be the case in every culture.

“I see yes, it's important. It's the look and feel of the—it's also part of the how much customer is going to use it, because if it's hard to use, and if it does not look modern and nice environment I see that has an effect to the amount how is it going to be used. So, I say it's very important.” —*Respondent 1, Finland*

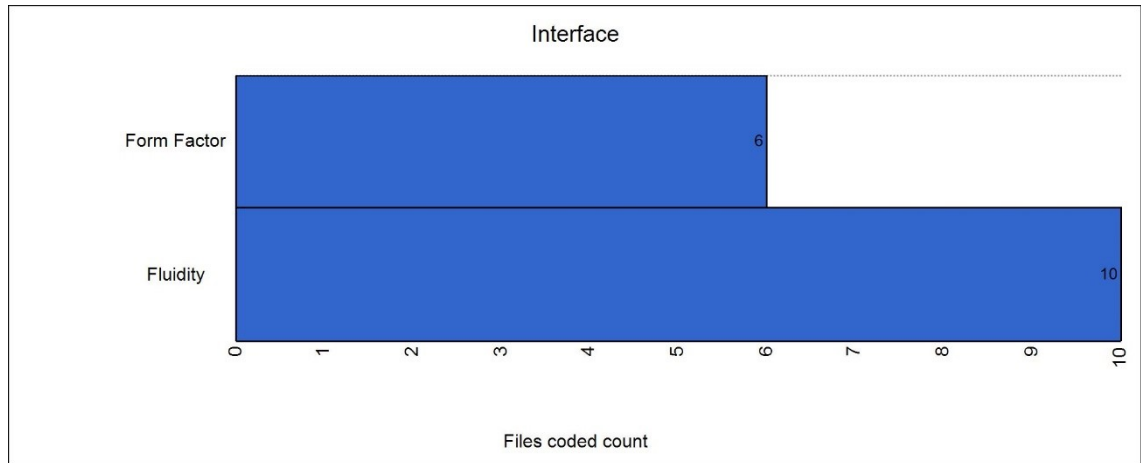


Figure 16 Interface Characteristics

The majority of the respondent perceived the possibility for customization of the content as important. On the one hand, the patient can set the scene, choose the colour of the background, or select their own avatar. On the other hand, the possibility for customization was perceived as essential for patients that have physical limitations and cannot perform certain tasks.

“I'm doing this like a movement in a meadow somewhere [...] in Wales or in a beach in Hawaii, so that kind of elements has to be, in my opinion, very carefully tailored in the software. The visual elements has to be extremely good, in my opinion, because patients who has these sort of elements; seeing [...] positive things that they like, and hearing things that they like, combining that they are moving, I think they're encouraging each other and they all sort of link to each other.” —*Respondent 7, Finland*

When patients have the opportunity to customize the content according to their own hobbies or interest, they are able to feel more relaxed and happier. Consequently, it would allow different types of people to commit into the solution.

“Yeah, yeah, no, I think it's critical, no, really critical. I mean, one thing is customized the types of exercise, but the other one is also the scenarios and the games or activities need to be entertaining enough and changing enough to keep people engaged.” —*Respondent 6, USA*

Nevertheless, few of the respondents perceived the possibility for customization as important, but they did not find it necessary for the first launch of the solution. Moreover, it was perceived as customer-dependent and the user would be able to choose whether they want it or not.

### 6.2.3 Service Platform

The division of respondents' perceptions about the characteristics of the service platform are depicted in Figure 17. The possibility for opening the platform for third parties was perceived as a possible or interesting suggestion. The features added by the third-party developers were perceived as value-adding factors, such as personalized solutions and easiness of use. However, the majority of the respondents were concerned about the regulatory and legal aspects regarding an open access platform. Thus, it would be crucial that the client company would be in charge of managing added features as well as the gathered data. Nevertheless, there was a fear of third-party developers damaging the brand image while the opening was not recommended by the respondents.

“— if it's opened to third parties, yes, that's really nice, if they can provide their added features, but it needs to be agreed and transparent. And [...] them [client company] managing this one and it's their product, then they need to be able to decide what is going to be added there. So, if something added, then it needs to be agreed separately.”  
—Respondent 1, Finland

“The content in our current developed device is carefully design by a trained CBT specialist. I would not open it up for anyone to develop further as one then could lose the intended benefit” —Respondent 12, Finland

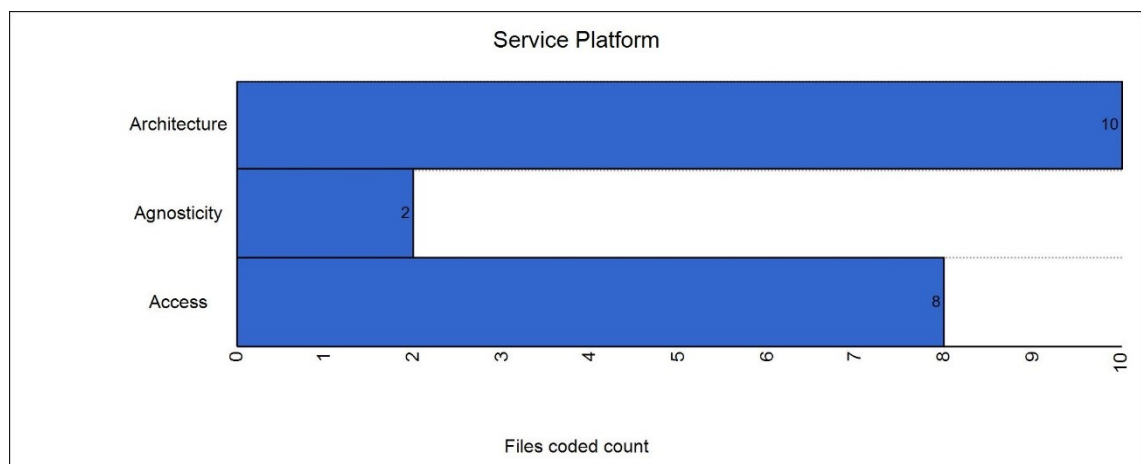


Figure 17 Service Platform Characteristics

Even though the architecture was mainly perceived to be maintained as proprietary, some collaboration with third parties was considered as beneficial. However, the majority

concluded that more knowledge and understanding need to be gathered before the client company would be ready for such a solution.

“Some kind of collaboration could be beneficial. We could e.g. have different pain treatments available via one platform and patients would be allocated to the one that is most suitable for them. We could also have some nutrition, physical exercise, music therapy etc. available to choose from.” —*Respondent 9, Finland*

The possibility for supporting different operating systems was not included in the interview questions, but two of the respondents mentioned that it would be important to consider different operating systems, especially iOS and Android.

“Yeah, definitely, because [...] the world is basically divided by Android users and iOS platform users. [...] it's very much depends the VR glasses, which technology they are actually functioning. So, it means that having both the iOS environment and Android environment is extremely important.” —*Respondent 7, Finland*

The respondents mentioned three main delivery channel options for the digital solution that are illustrated in Figure 18. More than a half of the respondents considered that the digital solution should be offered by different medical professionals, such as hospitals, clinics, and doctors.

“If we can win them, I guess it's easier for them to convince patients. [...] they are responsible for the success of such a solution and they are the ones which should use it regularly, but I guess they need guidance and they should get guidance from their medical doctors and I would start here with organizations in kind of hospitals.” —*Respondent 4, Germany*

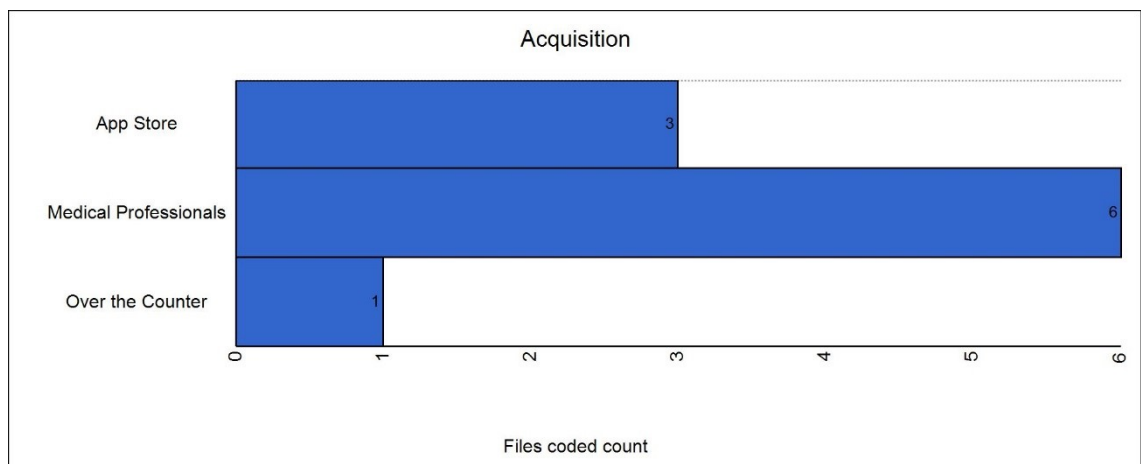


Figure 18 Points of Acquisition

The education about the solution and introducing it to the patients was perceived as the task of the medical professionals. After the patient has tried the solution in a safe environment, i.e. hospital, the patient could take the device home and have regular visits

to a rehabilitation centre or clinic. The feasibility of the different delivery channels is country specific and, for example, in the UK a credible solution was perceived as selling a device, that is downloaded beforehand, over the counter. Some of the respondents highlighted the need for various delivery channels for different target groups.

Few of the respondents considered that the digital solution should be downloadable from an application store, Amazon, or client company's website. In case the solution would be offered in a web-based store, the application or pre-configured device should be released with a code that is offered by a medical professional. However, in case the solution is available for patients' own device, the client company's website was perceived as the most viable delivery channel. In conclusion, few of the respondents emphasized that more research is required before a decision about the delivery channel can be established.

The majority of the respondents perceived that the accessibility of the digital solution should be convenient for the customer.

“— but the access has to be easy. Like now, I would be just downloading, while we're talking, I would download the application into my iOS, and I would start using it. That easy it has to be.” —*Respondent 7, Finland*

A possibility for trial period was perceived as a feasible option that allows the customer to feel and see how the solution looks like. Furthermore, the trial period would enhance the adoption and success of the solution as well. Most of the respondents argued that a free access could be granted, but not for a long time, for example, an access for a limited version and through subscription, the user would be granted an access to more features. In addition, this type of preview could also contain information about the decided option for acquiring the VR headset.

“Or I would develop some kind of element that you can preview the software when you download, for example, the application in your phone that you can actually use it to a certain extent, just by using your mobile phone, for example. So, you can have a trial out and then basically it says that, okay, but you need to have VR glasses to complete and see all of these elements.” —*Respondent 7, Finland*

The challenge with a free access comes to the revenue streams and one of the respondents was concerned about the number of advertisements that free applications normally have. Conversely, a restricted access would also limit the results for proving the clinical effectiveness. Thus, a balance between these two aspects were perceived as important in

order to provide a feasible access option for the patients. Furthermore, the possibility for trial period was perceived as country-specific and not important in each country.

“So, I think in the US, it may be easier to have people just buy directly without having this access first. I think in a lot of European markets, you may need to have the introduction to this device from a doctor or clinic, and then people adopted on their own.” —*Respondent 6, USA*

## 6.2.4 Organizing Platform

The core business processes perceived by the respondents are illustrated in Figure 19. The majority of the respondents perceived the sales and marketing as important business processes. On the one hand, the decision of delivery channels and the overall distribution are part of the core business processes. On the other hand, the marketing activities, such as the promotion, branding and awareness building was considered as an essential factor in delivering the solution and making it available for the customers.

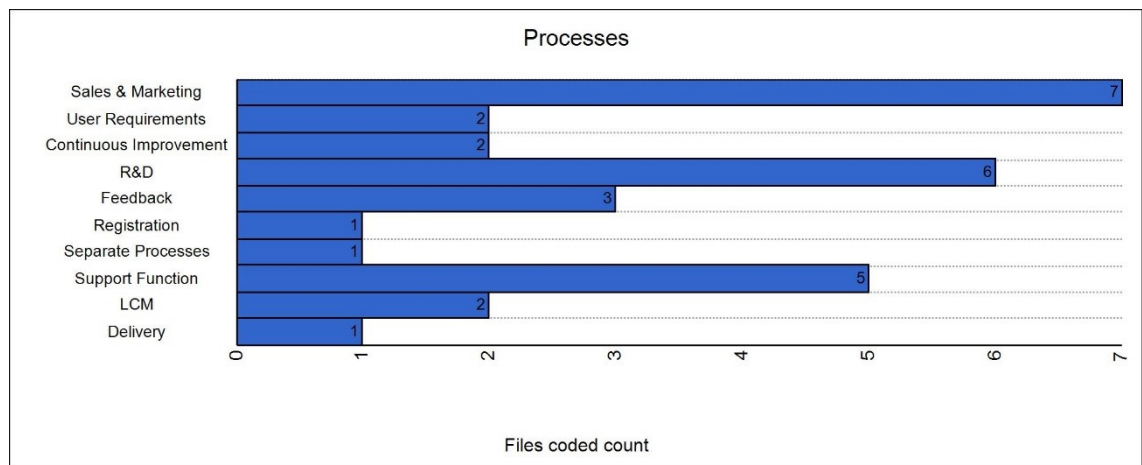


Figure 19 Core Business Processes

One of the respondents emphasized the importance of ensuring that the material about the solution is available for the customer. Moreover, the client company needs to carefully design the commercialization strategy in order to be successful. Trial period, patients' recommendations and showing the benefits on the internet were perceived as important awareness building activities.

“You have to also see from the patient perspective: the doctor recommends, the patient then decides whether he takes it or not. And where the patient looks for the confirmation, it is basically, you know, accessing Google and then finding the information. And you have to have the story built there, ready for the patient and sort of influencing the decision-making process.” —*Respondent 7, Finland*



Ultimately, the patients and potential end-users are in hospitals and clinics. Thus, it was perceived as important that the doctors and other medical professionals would be willing to recommend the solution for the patients. For this, the medical studies and clinical trials are needed in order to gather research evidence to support the digital solution. The majority of the respondents recognized the research and development activities as core business processes.

“— the strong data to support the rationale and the emotional part of the solution, I think this is the key.” —Respondent 2, Finland

Half of the respondents raised the concern about the hardware and its potential defects. Therefore, a support function was perceived as one of the core business processes required for delivering and supporting the value of the digital solution. Furthermore, a local support service should exist in case the customer breaks the device.

“If you're talking to something with a VR device either headset or things like that you need the local distributors. You cannot have something only web based because if the patient or someone has to pay [...] for the device, then you are expecting locally to have a support. If it doesn't work or if you fail to connect the device, to the solution or whatever problem you could have on a daily basis you should have a local support somewhere. It cannot only web based” —Respondent 5, France

Many of the respondents emphasized that such business process does not exist in the client company at the moment but is an essential service that is needed either in-house or, alternatively, offered by the VR headset partner company.

The continuous improvement of the digital solution based on the gathered results and customer feedback was perceived as part of the core business processes by the respondents. One of the respondents stressed the importance of multifunctional teams that should work together in developing the solution. Moreover, the medical professional's feedback was perceived as vital.

“— then you could ask easily for doctors that how likely it is that you would recommend this to patients, and to which type of patients, and how the nurse is feeling then in the pain clinic and so on. I think you could do this, type of questions to the customers, whether they would recommend this or not. And I think that is something. Maybe even patient associations for pain and something that you could approach also and asking how do they see that [...] So, I think those would be important.” —Respondent 2, Finland

The user requirement mapping was perceived as essential by two of the respondents for engaging the patient more into the treatment. Furthermore, the gathering of the health

data and customer feedback can be initiated by testing the solution with a proportion of customers.

“I think the focus should be really on coming up with the right types of exercises, the right type of interaction and visuals that really engage people to keep them using the program and actually being able to start collecting some real noticeable health results.” —*Respondent 6, USA*

One of the respondents considered that the value can be supported through defined processes of treatment which are a prerequisite for reimbursement. The respondent concluded that activities regarding medical and regulatory aspects need to be considered in the initial stages.

“Maybe you will get a certification, I guess it would be a CE certification for a medical product, but you also have to think about, what is really the concept behind and I would include here quite fast regulatory experts.” —*Respondent 4, Germany*

The life cycle management of a digital solution differs largely from the client company’s existing business processes and, according to one of the respondents, should probably be separated from other processes.

“— typically, our lifecycle management in pharma is still [...] we're talking about totally different time frames because this production [needs] to be [...] all the time also improved, and you need [...] all these taken into account. How you actually commercialize, how you manage it, because this comes— so, that you actually keep the competitiveness, I would think. Because otherwise there's another solution and you are there for a year and then you are out, or even less if you are kind of un-lucky.” — *Respondent 8, Finland*

The ecosystem partners perceived as viable for the digital solution by the respondents are illustrated in Figure 20. Almost each of the respondent considered a company offering IT solutions, IT development service, or a software company as a potential ecosystem partner. These companies were perceived as partners that could teach new things and offer services regarding such technical expertise that does not exist in the client company. Furthermore, consultancy could be acquired from Digital Therapeutics (hereinafter referred to DTx) companies for delivering, developing, and building a network for the digital solution. The development of digital capability with these companies, was considered as essential for success.

“— but really get into the DTx experts in terms of—maybe we need to talk to consulting firms who have more experience with dealing with this in the major European countries for advice because [...] we don't have the internal expertise on this I'm afraid at the moment.” —*Respondent 3, The UK*

“We may need to partner with someone who is already doing this or build this together with consultants who have some expertise in the area.” —*Respondent 9, Finland*

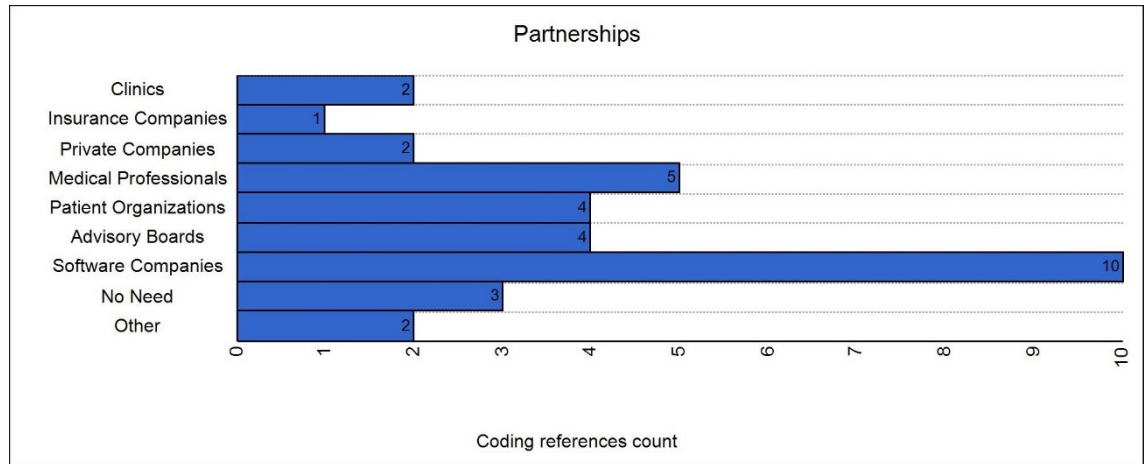


Figure 20 Partnerships

Moreover, different advisory boards were perceived as an essential partnership for providing further technical advice and consultancy in delivering the solution.

“And I would definitely not sit here at [client company] but I would go and sit somewhere like in Innovation House Finland and [...] going sit [with] them in terms of open community. Share about this and find people who can actually build awareness of this software and get the right people on board because you need like really tech savvy people promoting this and developing this.” – Interviewee 7

The advisory boards should consist of people from different functions as well as different areas of the world for gaining thorough understanding about a feasible delivery of the solution. These networks could offer the required added-value and knowledge. Patient organizations were perceived as important ecosystem partners for building awareness among potential customers and further targeting the correct patient groups easily.

Partnerships with insurance companies would allow digital solution to be offered in the health care packages which was perceived as beneficial by one of the respondents. In addition, almost half of the respondents perceived the hospitals, clinics, and medical professional networks as important ecosystem partners. Through these partnerships the solution could be offered for pilot patients as well as clinical evidence could be gathered through trials.

The respondents' perceptions about the inner capabilities and resources required to acquire outside are depicted in Figure 21. The resources regarding technology, digital content, or digital marketing were perceived as capabilities that should be acquired from outside or through partnership. However, one of the respondents highlighted the importance of understanding the purchased services and products in order to maintain the independency.

“—still we need other capabilities because we have to develop the digital capability, exactly this kind of understanding of the systems. We cannot even purchase them from abroad, if we don't have [...] sufficient understanding for all of these [...] matters, so [...] we need to build the capabilities, but not of course everything. It doesn't make sense to do everything in house but in order, even, to kind of purchase, we need to understand what we purchase because otherwise it's [...] totally reliant on the external partners and we cannot do the best choices because it depends on what we hear.” —Respondent 8, Finland

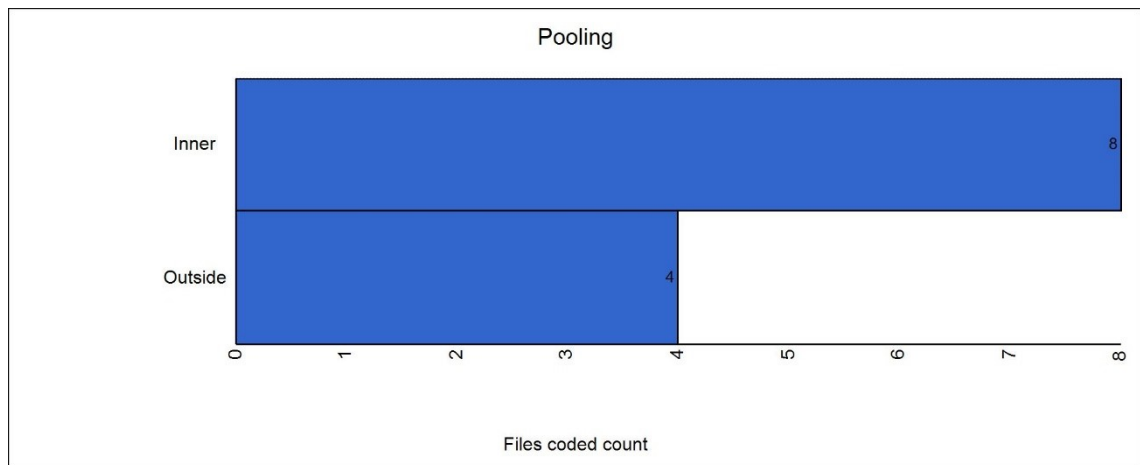


Figure 21 Pooling of Resources

The inner capabilities of the client company perceived by the respondents are depicted in Figure 22. Some of the respondents perceived that the client company does not have any inner capabilities for delivering the solution.

“— Because this is not a drug, this is not a medicine. It works in a totally different environment that [client company] has been working before. It means that we have to be making decisions that we haven't usually be making, it has to be— it means that we have to be more willing to adapt risk that we've been doing before because we are not, you know, any more manufacturing a drug with this.” —Respondent 7, Finland

“Because we do not have any process for actually [...] delivering this because [...] if you are talking about the device, there are many matters in [...] commercialization [...] that it is currently in— not in a business processes.” —Respondent 8, Finland

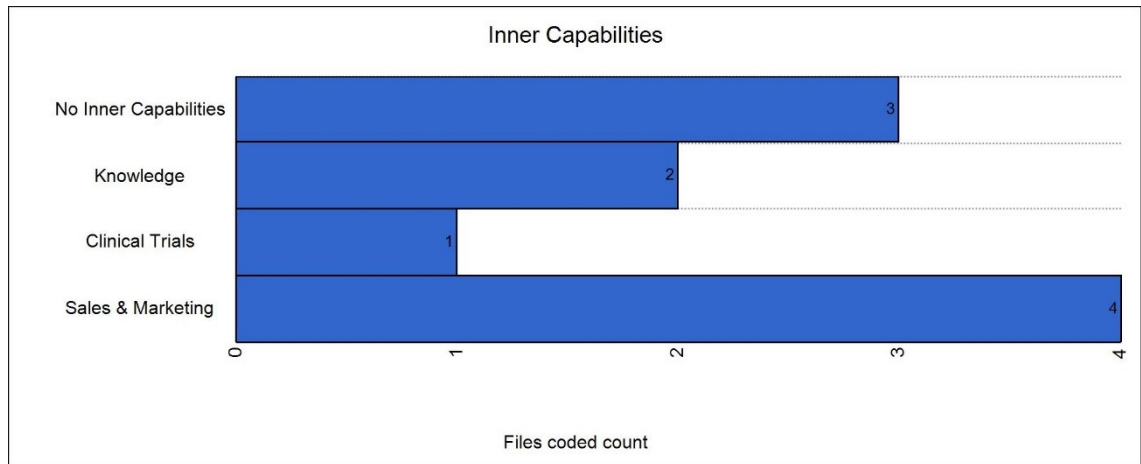


Figure 22 Inner Capabilities

Nevertheless, most of the respondents perceived that the client company does have inner capabilities that can be leveraged in delivering this digital solution for the customers. One of them is the knowledge and the expertise of people.

“— inner capabilities, we have so much knowledge in this company. So [...] people have long, long histories, they have a lot of knowledge. And I think that we should leverage that knowledge and from multiple sources and [...] from different functions working together and thinking, how we can deliver the best solution. That's something I see that we are really, really, good at. “—*Respondent 1, Finland*

Four of the respondents recognized the sales and marketing as client company's inner capabilities whereas the existing sales force and distribution channels need to be altered to some extent for the purposes of the digital solution. One of the respondents concluded that the client company is able to conduct clinical trials by themselves.

### 6.2.5 Revenue Model

The different options for pricing the digital solution perceived by the respondents are illustrated in Figure 23. The majority of the respondents perceived the subscription-based pricing mechanism as the most feasible one due to the engaging and committing effect. However, it was highlighted that the unsubscribing should be made effortless for the customer when they are not using the solution anymore.

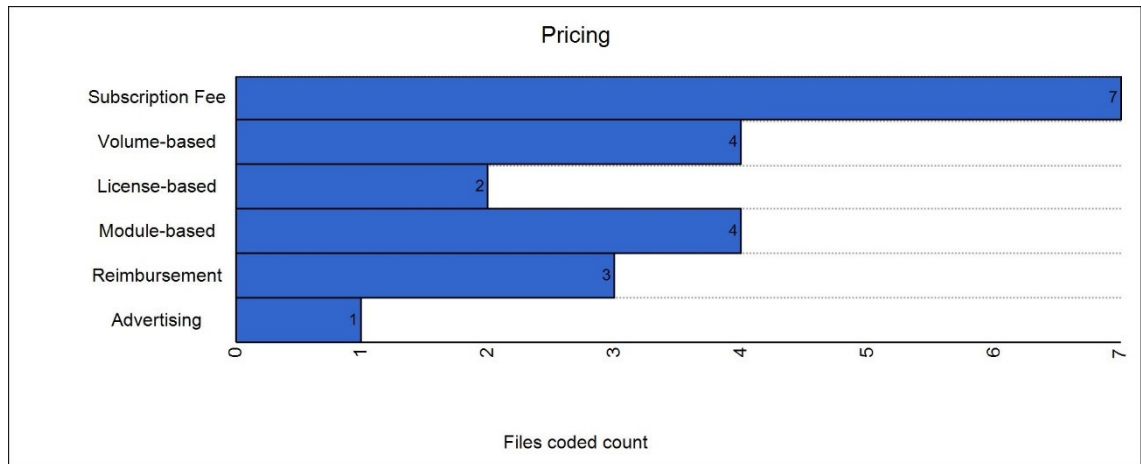


Figure 23 Pricing Options

Some of the respondents suggested a fee for the period of treatment and then a subscription fee would be charged for additional features and services, such as maintenance, follow-up, etc. In addition, one of the respondents proposed an annual fee for the first year and if the customer is willing to continue with the program, they would need to pay a subscription fee for access a certain number of features in the program.

“More than a subscription, I think it's a deletion of the payments in some markets where instead of having to pay 700 up front, you can pay 29-30 euros per month, over a year. This might be a model that lowers the barrier for some people to get access to it.” — *Respondent 6, USA*

For business-to-business (hereinafter referred to B2B) customers, the pricing mechanism was perceived to be different. The proposed pricing mechanisms were based on volume or license while a payment per active user was also mentioned.

“For B2B we could have an annual fee covering a certain number of evaluations (i.e. is the treatment suitable for the individual), licenses and possible also population data. There could also be a separate fee for all three components mentioned. [...] Prices could be volume-based i.e. if a clinic/insurance company is buying many licenses the price might be lower than for single user.” — *Respondent 9, Finland*

Some of the respondents perceived the module-based pricing mechanism as a feasible option for the digital solution. The access for different modules and features would be granted by an additional fee. Only one of the respondents considered the advertising in the platform as one of the feasible revenue streams. However, another respondent was concerned about an excessive amount of advertising which could result in poor reviews by the customers.

One of the respondents was implicit about receiving a reimbursement for the solution. In Germany, this type of model is important due to the compulsory insurance.

“Get reimbursement. [...] Try to get reimbursement. That would be the best model to get such a solution accepted. [...]—And sold, of course.”—*Respondent 4, Germany*

Additionally, two other respondents considered the possibility of reimbursement, and in France, the patients would be more willing to pay for an insurance company or a hospital in order to access the solution. In any case, the research data and clinical evidence is required for supporting the solution and receiving the reimbursement.

“But of course, this requires then that we have evidence to support the value of the system so that we can show that the pain is decreasing, the patients are more functional, they are maybe able to be less out of work or increase their work productivity or so. So, that you can show something concrete and then there’s willingness for the society to kind of compensate, reimburse, for that. If we think that this is feasible, this is the route we can take” —*Respondent 8, Finland*

The respondents were requested to either choose a high price with low number of customers or a low price with high number of customers. The division of responds are depicted in Figure 24. Five of the respondents were implicit about offering the solution with low price for reaching a high number of customers. The use of such pricing allows the client company to have variety on the feedback and further gain an understanding about the customers’ behaviour in the platform. Furthermore, low price would aid the high acceptance among the patients and support the aim of reaching a standard therapy with the solution. In contrast, high price would create a niche product and the competitors would simply do the same, but with a much lower price. Moreover, it was considered that the patient would not necessarily choose the digital solution, that has the same high price as the physiotherapist. There are numerous low back pain patients all over the world that can be reached with a low price. One of the respondents agreed on reaching high number of customers with a low price but concluded that the client company’s core competencies cannot be utilized in that case.

“But in a way, if it wasn’t [client company], I would maybe answer that probably the second because reaching [...] there’s lots of pain patients with reasonable pain, you could reach lots of patients. That [...] sound[s] very attractive but then it’s, like said that, it’s not utilizing at all what we know and our kind of people and the organizations in the countries which we have available.” —*Respondent 8, Finland*



Figure 24 Low Price versus High Price

In the US markets, the option of low price was considered as more attractive whereas in a smaller market the high price might be forced because the market penetration is more difficult. The digital solution would most probably be distributed through health care organizations where the volume might not be as high and, consequently, the price needs to be increased.

Two of the respondents did not choose either the low price or a high price, but rather gave the conditions under which either option would be viable. If the product is highly unique and difficult for competitors to copy or it is distributed by the hospitals, then the high price option was perceived as the more attractive one. However, if the solution can be copied easily or it is available at patients' homes, then a low price was considered as the more viable one. Even though the price was considered to be higher in the beginning due to a lower customer base, the price still needs to be reachable for the customers. Furthermore, one of the respondents perceived a medium price and reasonable number of customers as the best option, rather than offering the solution for a low price. Only one of the respondents was implicit about offering a high price for receiving the correct customers.

“— to be sure that at the beginning with the most appropriate price probably higher than expected you will send to the good people who are ready to pay your insurance. I mean, the stakeholders are ready to pay for what you will propose. Don't put a cheap price right from the beginning because if you don't have the customers, I mean enough customers right at launch, then you're dead.” —Respondent 5, France



The Figure 25 depicts the division of respondents' perceptions about providing only one pricing option against offering many pricing options. Half of the respondents preferred the option of many prices for different needs and customer segments. Firstly, the requirements of different countries were considered as a rationale for that. Secondly, various customers were considered to be using the solution for differing periods of time as well as have different preferences in regards of added features and used modules. Moreover, these several pricing options were perceived as an incentive for the patient. However, two of the respondents considered that only one price option is adequate because people would notice that the same product is offered for different prices.



Figure 25 One Price versus Many Prices

The factors that were perceived as affecting the price by the respondents are illustrated in Figure 26. The majority of the respondents considered that different features as well as the willingness to pay and attractiveness of the product influence the price the greatest. The features were considered as affecting the price increasingly, i.e. the customers are required to pay a higher price for different features and modules.

“you have like the, let's say, the basic model, that's that pricing and you get that kind of elements. And then the more you go [...] higher the more elements you get, the more you pay. It's very much from the gaming world. Or you want to purchase one element more, you have to pay more. I mean, you want to get [...] a new element, you have to pay more for it.” —*Respondent 7, Finland*

“— there can be different levels [...] there can be the basic level, but then also more advanced level and [...] with a slightly higher price. So it's really hard to say at this point, but I think that it depends about the features, if there is a lot of [...] interactive tools, like you can talk with the medical professional or you can contact us 24/7 easily access —of course, that needs to be easy access anyway. But still more, like, some additional services” —*Respondent 1, Finland*

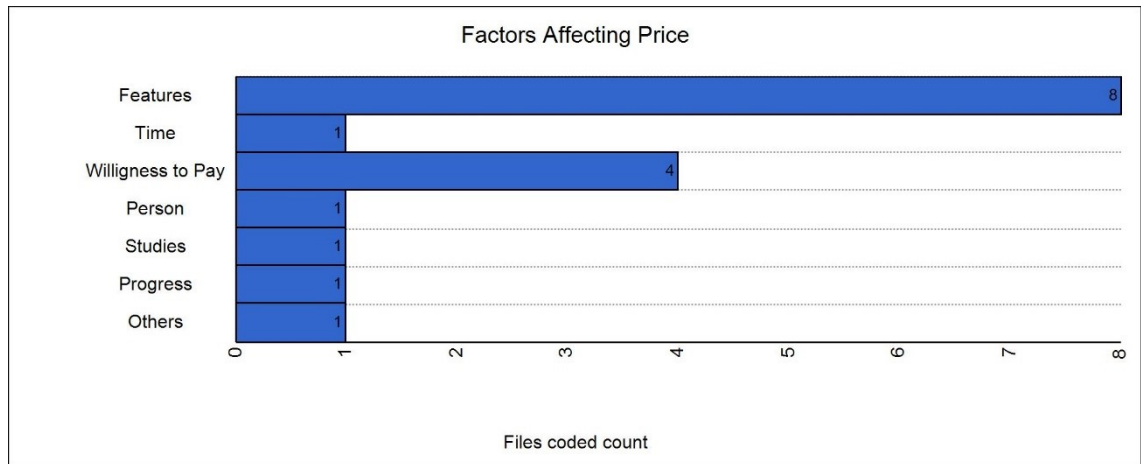


Figure 26 Factors Affecting Price

The progress and customer's accomplishments within the software were perceived as a decreasing factor affecting the price. After the customer has accomplished certain steps in the platform, he should be awarded, for example, by granting an access to additional features.

“— for example, if you accomplished some level, do you get like a free month, for example. There has to be like these triggers built within the software, in my opinion.”  
—Respondent 7, Finland

Many of the respondents considered the customers' willingness to pay as an important factor that affects the price. The price ranges that the customers find attractive and reasonable, could be investigated through further research of customer perceptions. However, the added value and the overall attractiveness of the solution were perceived as closely related values of this factor.

“I guess the added value has the most important influence on the price, maybe the attractiveness of your device as well as of [...] the software will affect the price” —  
Respondent 4, Germany

The clinical evidence supporting the digital solution was perceived as an important factor that is also highly linked to the attractiveness of the product. Other factors raised by the respondents were time and the person accessing the solution.

“— you cannot accept a high price, I would say. It depends on the added value; you have to show that there is an added value. That depends on your study of course. If you compare, for example, treatment of patients with or without such a digital solution, which use as an add on, for example, to their medical therapy and you can show, okay [...] have here much better results. You have then proven your concept and you can present [...] that people are benefit from such a digital solution. [...] that will have an influence on your price, but I do not know what is the price level at all.” —*Respondent 4, Germany*

The VR headset is a prerequisite for being able to access the digital solution and the respondents' perceptions about the possible option for acquiring the VR headset by the customer are presented in Figure 27. There was no unanimous or unambiguous opinion among the respondents, and they considered several differing and viable options for the VR headset delivery.

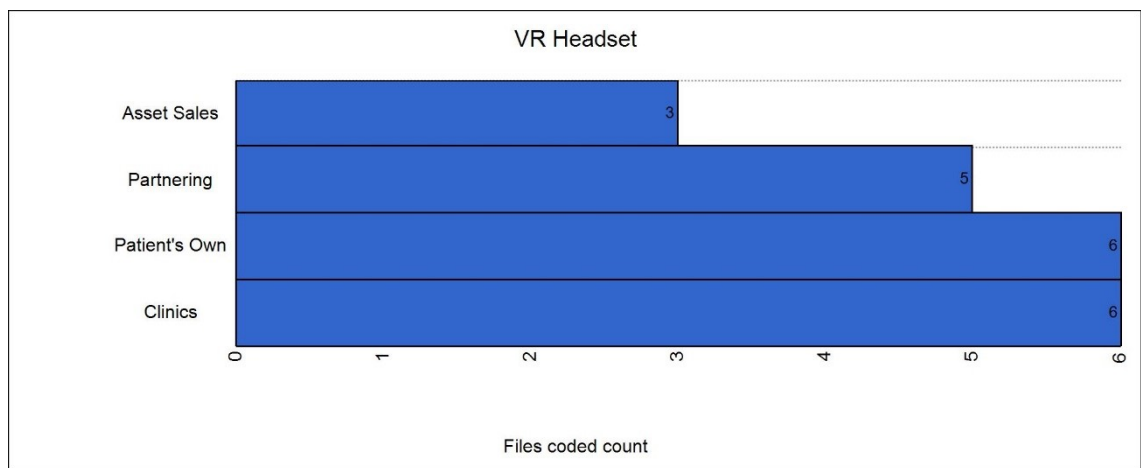


Figure 27 Options for VR Headset Acquisition

The majority of the respondents agreed that the VR headset should be available for renting or loaning in the hospitals, clinics, or rehabilitation centres. A unanimous perception was that the VR headset could be rented for the patient's treatment period and after that, returned to the health care centre. However, a concern of VR headset's durability was raised by the respondents.

“— if something that to do with rehabilitation or whatever, if they have to go to a clinic to do, then sometimes, [...] you can share the handsets, aren't you? [...] So, I think for the DTx for pain, then definitely from the customer's perspective they should be acquiring one of those.” —*Respondent 3, The UK*

“But then also in hospital settings, we need to think [...] if there is the VR headset, how many users we allow to one VR headset. And [...] then it can be controlled with this application on phone or something. But then they could use the same VR headset there, so that not everyone would need to purchase a VR headset, that would be probably the preferred option for hospitals, so that not everyone would have their own.” —*Respondent 1, Finland*

“Of course, the easiest would be that you get the VR glass, for example, you get like a trial out for 30 days, you get from the doctor, the VR glasses. That's one way of looking at this. And that's the easiest way.” —*Respondent 7, Finland*

Half of the respondents perceived that, while the VR headsets' prices are decreasing, each patient could acquire his own VR headset. However, the acquisition point and type varied between the respondents. On the one hand, if there are only few VR headset providers which products are compatible with the solution, the client company limits itself to those manufacturers and it can cause bottlenecks. On the other hand, if any VR headset can be used, the client company can be exposed to risks regarding non-tested hardware. One of the respondents proposed a list of compatible VR headsets that have been tested by the client company.

“— do we need to define the VR headsets that are compatible with the software solution. So, do we need to show, [...] make the validation and testing with these VR headsets that we are offering. So, if we have two or three different kinds of models of headsets” —*Respondent 1, Finland*

Partnering with a VR headset provider and outsourcing the manufacturing activities was perceived as a viable option by the respondents. In this case, the customer would either order the VR headset from the partner company's website or they are delivered directly to patient's home after the purchase in the client company's website.

“I mean, I think partnering, because I'm not sure that [client company] would want to get into the headset business. You know, as far as creating them.” —*Respondent 6, USA*

“— do we plan to have the agreement with the VR headset provider so that [...] they, for example, let us know if there is any changes in their VR headset, because these are also evolving, [...] and does this have an effect to the software use. [...] I think it should be as part of the package so, that if you login and [...] if you start this one where [...] you log in, you purchase this one, then you would be able to get the VR headset also through that link.” —*Respondent 1, Finland*

### 6.2.6 Product Cost Structure

The factors affecting the product's cost structure perceived by the respondents are presented in Figure 28. The majority of the respondents recognized the costs related to

the development and continuous improvement of the software as one of these factors. The respondents mentioned, for example, the initial building-up phase of the library of the activities, maintenance of the software, and adding features according to the customer feedback, as development related activities.

“Well, once you launch this kind of software, it's already old. So, you need folks [...] who are developing this on daily basis. So, [...] you come out with a version [...] 1.0, but you have to have [...] the next version ready in a couple of months, basically. So, you need folks who are all the time looking new elements to develop the software. And then also, in order to be really user friendly, you need constant feedback from the patients and the doctors what they're telling about the software. So, you need people who are also discussing [...] the customer aspect, the account managers who are talking [...] so what's the feedback we're getting— there's many elements.” — *Respondent 7, Finland*

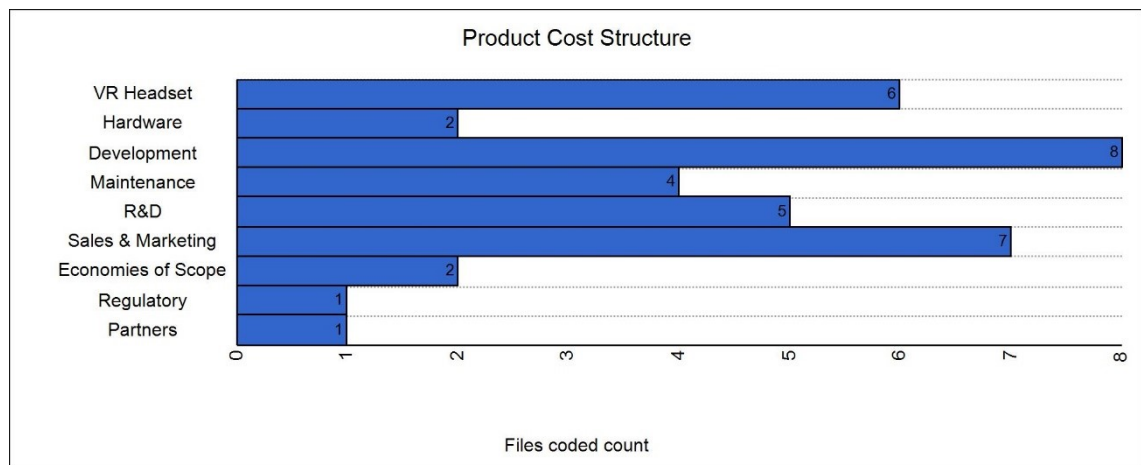


Figure 28 Factors Affecting the Product Cost Structure

The costs related to sales and marketing, such as building the brand, raising awareness, and eventually delivering the solution for the customers, were perceived as cost factors by most of the respondents.

“And then you need somebody in order to build the brand for this. You need somebody who's ready to allocate a certain amount of money for the branding and marketing and somebody who's willing to, in the future, build the brand for this.” — *Respondent 7, Finland*

Each respondent mentioned, one way or another, the costs related to the hardware and the VR headsets. Not only were the costs related to the hardware itself (e.g. manufacturing, payments for the partner, etc.) mentioned but also the costs related to the support services that need to exist for technical problems.

“— when you're dealing with anything hardware, then you're dealing also with product defects, repairs, returns [...] there's all sorts of organizational things need to go into place when dealing with hardware devices, that the company should be ready to deal with. So, almost like device companies have to deal with the stuff.” —*Respondent 6, USA*

“But the problem with your solution is that you will have a VR tool on your device in patient hands. So, for example, if the headset fall on the ground and get broken and the patient should have access to someone and you need to change the headset or to find a solution to change the headset quite quickly, because if it takes you two weeks or three weeks to change the device to the patient, the patient will switch and will never come to [...] your application again.” —*Respondent 5, France*

Furthermore, the costs related to the maintenance services of both hardware and software were mentioned by the respondents.

“— you should also take into account all the maintenance of your devices. So, who will pay for that? Who will do that? Do you have to move to the patient's home, or will you ask the patient to come back to the hospital or to [...] somewhere [...] to take care of the device.” —*Respondent 5, France*

The evidence is needed to support the business case as well as to increase the attractiveness of the solution and accountability for the customers. Thus, almost half of the respondents identified the research and development related costs as evident.

“But I would say that the biggest cost is the R&D project,” —*Respondent 1, Finland*

In addition, one of the respondents mentioned the regulatory costs arising in the beginning whereas another respondent considered the costs of the partners having an influence on the price. Furthermore, two of the respondents recognized the economies of scope as a benefit and believed in adding new features, indications, and activities to the same platform in the future.

“So, it's not just—It could also become a vehicle of secondary product to push the other [client company's] businesses.” —*Respondent 3, The UK*

### **6.2.7 Challenges**

The challenges regarding the digital solution perceived by the respondents are illustrated in Figure 29. Almost each of the respondent recognized the challenge of adopting the solution by some of the population groups as well as the prejudices that these groups might possess. Furthermore, the challenge of committing and engaging people into the platform was also perceived by many of the respondents. However, majority of the

respondents concluded that training and building awareness for the purpose of developing an understating about the platform's functionality, is crucial.

“— then is to do with convincing people [...] study data to show the efficacy. Because again [...] it's not traditional medicine, there will be people who can be quite sceptical. And thinking some of these things could just be placebo effect and playing with the mindsets and things like that. So, [...] I think to communicate the real benefit with evidence could be potentially challenging.” —Respondent 3, The UK

“So those are the areas that I would really concentrate on in the final execution of a project like this, because that's where I think most of the trouble will happen. In the adoption of this type of technique.” —Respondent 6, USA

“I think the challenge could be the belonging of the patient to your solution. If it's too complex or if it's not enough customer-oriented then [...] they [patients] will never adhere to the solution.” —Respondent 5, France

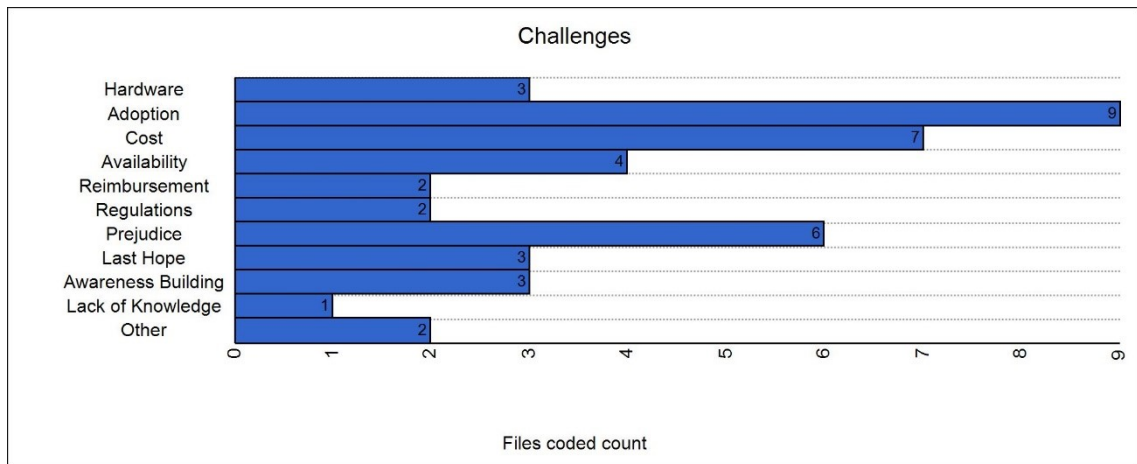


Figure 29 Challenges

It was perceived as vital that the medical community is acknowledged by the solution and the clinical evidence exists to support the solution for the professionals to accept the solution. Moreover, if a person is not tech-savvy, there can be increased concerns to use the solution as well as lack of knowledge in accessibility related issues (e.g. acquisition points). Many of the respondents considered the older population as such a population group.

“— there is maybe some kind of differences in acceptance of the digital technology. Like there is for anything related to digital [...] especially the older generation, consider it to [...] little bit strange to be doing something that they have used to. [...] [such as] wearing maybe virtual classes: “what is this?”.” —Respondent 8, Finland

One of the respondents mentioned that even the medical professionals might be concerned about a digital solution taking their jobs and due to that be reluctant towards the device.

Furthermore, the image of pharmaceutical company providing a digital solution could affect certain patients' adoption of the solution. However, some of the respondents perceived the challenges regarding adoption of the solution as merely a barrier. Therefore, the patients who have already tried several treatments, would be willing to try another one.

“So, you have to have really high motive to seek this kind of a treatment. [...] in my opinion, the patient has already gone through different kinds of steps. The person has tried different kinds of measures to fix [...] his or her problem.”—*Respondent 7, Finland*

“— if you have severe enough pain and there is no relief, and I think the [...] willingness to try anything [...] increases. So that maybe this is not then [...] obstacle in the end, but it might be, [...] that there is [*sic*] different levels of acceptance, I could think.”  
—*Respondent 8, Finland*

One of the respondents considered the new type of marketing, high competition, and various selection of products available as challenges in the digital economy.

“— what is crucially important [...] is also the branding so how do you brand this, how do you become [...] the brand [...] in the world, which is just noise of different kinds of products, how do you become the signal that ‘You should get this one.’? That's the element.” —*Respondent 7, Finland*

Availability issues and accessibility options for the customers were considered as challenges by some of the respondents. Furthermore, the challenge was linked to discovering the correct channel for delivering the solution as well as deciding on the appropriate price. In fact, the cost-related challenges, not only from the customer's point of view but also from the company's point of view, were mentioned by more than a half of the respondents.

“And if this equipment is not purchased by the single patients and that it's only in the clinics, then it's of course a question of how much that equipment would cost and whether it would be a business or not. Because if only [the] clinics would buy these equipments [*sic*], and the cost would be low, it will not be the big business enough for us to, let's say, fully capitalized this project,” —*Respondent 2, Finland*

Many of the respondents were concerned about finding a payer for the solution and the possibilities of reimbursement. Moreover, the regulatory and legal aspects were considered as challenges arising from such a digital solution.



“If you want to have a medical tool that will be reimbursed on in Finland or another European country, then the important stakeholders will be the payers. And you will need after that stakeholder who will convince the payers to take into your solution and propose it on a national basis for improving the management of the disease.” — *Respondent 5, France*

“I would say that the regulatory environment in each of these countries, like how these kind of VR tools [...] how these are regulatory related and, what kind of criteria does these need to fulfil in these countries so taking these into account in the development phase can also help to remove the barriers.” — *Respondent 1, Finland*

“— then I'm not familiar what type of IPR we have here. So how we can protect our position, because if we are selling this [...] and it would become some kind of treatment then it's quite soon I would guess that the Chinese company or some other would come with a similar type of equipment but with the simpler solution - cheaper solution and simpler.” — *Respondent 2, Finland*

Few respondents also raised the challenges that can be related to the hardware and their potential technical problems. Other challenges mentioned by the respondents concerned the loss or limited human interaction, as well as the lack of knowledge of the digital solutions by the client company at the moment.

## **7 ANALYSIS**

The results arisen from multiple-case study are analysed through a comparison of the case companies' business models. Furthermore, the analysis of results from in-depth interviews presents the important characteristics of the business models perceived by the stakeholders. Finally, the analysed results are summarized in the form of developed business model suggestion for the client company.

### **7.1 Comparison of Case Companies**

When comparing the five case companies' business model approaches, similarities can be identified even though the solutions, used devices and technologies differ between the companies. However, each case company is in the digital therapeutics line of business which could indicate that the business model approaches show similarities when compared with each other. For the companies to receive a clearance from the regulatory bodies, clinical trials need to be conducted in order to provide evidence to support their therapies and solutions. Each of the case company is performing clinical research for the purpose of receiving a clearance from regulatory agencies, supporting their solution's development, or supporting the accountability of the solution for the customers. The global markets can be reached through registering the solution as a medical device, receiving CE mark from the EU, and achieving FDA clearance. All these require clinical trials evidence to support the solution's functionality.

#### **7.1.1 Value Proposition**

The comparison between the case companies' value propositions is presented in Appendix 9. The value proposition of each case company contains the promise of cost reductions for the customer groups. Whereas the cost reductions for medical professionals and patients remain in fewer face-to-face meetings, the employees benefit from less absenteeism owing to the treatment. Furthermore, non-medical treatments, preventive care, external control, and home-based exercises allow the hospitals, pharmaceutical companies and patients benefit from the decreased costs. The analysis of generated data for the purpose of following the patient's progress is one of the target functions in each company's business model approach.

Almost each of the case company recognizes the gamification as a factor that engages the patients into the treatment. Kaia health emphasizes the importance of combining the mental and physical health whereas SilverCloud Health and Happify's solutions focus on treating mental health issues. All these three companies offer support, mentoring, and encouragement from either an assigned person, medical professional, or a community of other members. Gamification or motivating patients through coaching and mentoring encourage the patients to continue the treatment and can even intensify the treatment compared to traditional therapeutics. Furthermore, SilverCloud Health and Happify promote the non-existing entry barriers related to accessibility and *stigma* that might be associated to mental health issues. The hospital-based company MindMaze is the only case company that cannot provide the benefit of convenience and easy accessibility of the solution that can be used at home and with patient's own time. Furthermore, Kaia Health, Happify and SilverCloud Health offer educational material about the treated conditions which allows the patient to gain understanding about their state of health.

A clear difference can be noticed in the focus of different customer segments that the products are mainly targeted to. Kaia Health and Happify's products are most distinguishably divided between consumers and businesses, while MindMaze's devices and SilverCloud Health's solutions are targeted to rehabilitation centres, clinics, and hospitals. In contrast, XRHealth has not drawn a clear line between the business and individual consumer sales. Furthermore, Kaia Health, SilverCloud Health and Happify are all targeting the employees of private companies and their employees and the customers of insurance companies as the end-users of the solution. In addition, XRHealth and Happify are both considering pharmaceutical companies as their target groups because the solution provides efficiency and assistance for clinical trials. One of the SilverCloud Health's customer segments is the universities that offer the solution for the students.

The differentiation between the case companies can be recognized in their complementary value propositions. For instance, Kaia Health highlights the non-medical treatment of back pain and provides the Kaia Motion Coach as a digital personal trainer. In comparison, XRHealth promises patient satisfaction, and External Control platform is offered for medical professionals to monitor the treatment and patients' progress. Furthermore, MindMaze ensures the continuum of care from the early involvement

whereas SilverCloud Health offers scalable solutions for each customer group. Finally, Happify concentrates on providing easy accessibility for each individual by, for example, considering the cultural differences and physical limitations.

The case companies' value propositions contain the aspect of personalization and engaging the patients to the treatment. Happify and Kaia Health use initial questions, i.e. questions about the patient's condition when the service is initially entered, and data analytics to personalize the treatment according to the patient's level and progress. On the contrary, SilverCloud Health relies on the supporter's vision and assessment with the personalization. In addition, XRHealth and MindMaze's solutions rely on the medical professional's assessment of the level of personalization. All other case companies, except Kaia Health, allow the customer to choose the preferred game, module, or activity.

### **7.1.2 Interface**

The comparison of interface characteristics of each case company is presented in Appendix 10. Each case company contributes to providing a user friendly and easy to use platform. All other companies, except MindMaze, offer the opportunity for contact with a real-life person, such as a supporter, mentor, or a community of other subscribed members. Kaia Health and XRHealth trust in self-service of the patients and MindMaze, SilverCloud Health and Happify offer a customer support and contact information for the delivery of the solution. Social media is used by Kaia Health, SilverCloud Health and Happify to interact with the customers. However, some of the interaction possibilities differ between the companies. Whereas SilverCloud Health offers interactive exercises, the analytical tools by MindMaze offer a different kind of approach for the interaction. XRHealth offers customers' own sites in their websites and Kaia Health ensures to answer the reviews in the application stores. Moreover, Kaia Health offers B2B customers maintenance services and a Kaia Campaign to promote the solution for the end-users.

Each case company has considered the aesthetics of the interface. Furthermore, Kaia Health provides clear, factual, and stepwise guides for setting up the solution. In each company, the variety of games and activities makes the customization of the content possible. MindMaze offers user-calibrated activities whereas XRHealth's Data Portal can be customized according to the customer's needs. SilverCloud Health offers a possibility

for companies to have the solution customized based on their needs, and the care can be chosen to be self-directed or coached.

### **7.1.3 Service Platform**

The characteristics of service platform and their comparison in each case company is illustrated in Appendix 10. The case companies' architectural solutions vary between each other and have both similarities and differences. XRHealth, SilverCloud Health and Happify have an open API whereas Kaia Health and MindMaze trust in a closed propriety software. Furthermore, XRHealth has opened the platform for third-party developers that can develop additional games and activities into the platform. XRHealth, and SilverCloud Health' web-based portals can be easily integrated to customers' own devices. Nevertheless, XRHealth's platform can only be accessed with a VR headset. All the companies' solutions support different operating systems and, excluding MindMaze, the platforms can be used with patient's own device.

Each of the case company offers the solution in their own websites for purchasing. Kaia Health and Happify offer the solution in application stores for individual consumers to download, whereas XRHealth and MindMaze need to be contacted and sales representatives will offer the solution for the potential customers. Furthermore, XRHealth, MindMaze and SilverCloud Health provide the solutions for acquisition through their partners. Kaia Health's solution can be accessed for free through a trial period, after which the content can be accessed only after a subscription. In comparison, Happify's solution have a free access, but only to limited features, and the entire solution can be accessed by subscribing. XRHealth and MindMaze can only be accessed through subscription and SilverCloud Health's solution is only available through the partners such as insurance companies, hospitals, universities, or other private companies. Moreover, Kaia Health offers access to its customers through certain private insurance companies' reimbursement plans in Germany. In addition, Happify has considered the barriers for accessibility and offers the solution in eight different languages as well as for visually impaired individuals.

### **7.1.4 Organizing Model**

The comparison of case companies' organizing model is presented in Appendix 11. Each case company' core business process includes the problem-solving through results from

clinical trials and gathered health data by the platform. Additionally, all must manage the platform and network with partners. The importance of partnerships can be noticed from each business model where the partners are an essential link in delivering the solution for the end-users, developing the treatments through clinical trials as well as providing funding. Clinics, hospitals, health care professionals and rehabilitation centres are essential partners for each case company. As medical device companies, Kaia Health, MindMaze, and SilverCloud Health have partnered with private companies that offer the solution for their employees. Furthermore, all the companies, except MindMaze, offer the solution for subscribers of private insurance companies that they have partnership with. For the purpose of using the solution in clinical trials, Kaia Health, SilverCloud Health and Happify have partnered with pharmaceutical companies. Some differentiation can be noticed in case companies' partnerships as well. XRHealth offers an opportunity for third parties to develop additional applications to the platform through partnership. Furthermore, XRHealth has a partnership with VR headset manufacturing company Oculus which headsets are the only ones compatible with XRHealth's solution. Finally, SilverCloud Health's partnership with universities allows the solution delivery for the students.

The key resources required by each case company are the financial resources. Additionally, in a knowledge-based industry, where clinical evidence is required to support the medical claims, human resources are essential. However, as a device-based company, MindMaze requires physical resources as well, in case they are manufacturing the devices by themselves. In each case company, the partners contribute as offering the access to the end-users and eventually, deliver the solution for the patients. Kaia Health and Happify's partners provide capabilities that the case companies are lacking. The third-party developers deliver added value for XRHealth's customers and consequently, to the company itself. Furthermore, the partnership with Oculus supports the ultimate access to XRHealth's platform while Kaia Health has received financial resources from the partners.

### **7.1.5 Revenue Model**

The comparison of case companies' revenue models is illustrated in Appendix 11. As the main pricing strategy, each case company uses the subscription sales while the pricing mechanism is based on different factors. Kaia Health has different prices for B2C and

B2B customers. Kaia Health and Happify's pricing for B2C customers is dependent on time committed to the solution whereas Kaia Health's B2B customers pay per active user. MindMaze and SilverCloud Health pricing is based on one price that is paid in different time intervals – MindMaze monthly and SilverCloud Health yearly. Conversely, XRHealth offers different prices based on accessibility to features and modules of the platform. Furthermore, while XRHealth's VR headset is acquired from the partner company, MindMaze sells the devices themselves.

Each case company's cost structure can be recognized as value-driven and their main costs include people and research and development related activities. Furthermore, Kaia Health and SilverCloud Health identify the costs generated from the maintenance. Each case company's platform can be utilized for delivering additional features, activities, games, and treatments. Thus, the benefit from economies of scale exists for each case company.

## **7.2 Stakeholder Perceptions**

The stakeholders perceived barriers and challenges in delivering the digital solution for the customers. The major challenge of adoption was linked to the novelty of the treatment that may cause prejudices in certain customer groups such as the elderly and not tech-savvy people. Furthermore, the patients that have already tried everything are the ones acquiring the digital solution, if the price is affordable for them. The challenge of reimbursement as well as the legal and regulatory aspects can slow the process of market penetration whereas the availability and accessibility issues are potential concerns. In conclusion, there are many barriers that the client company needs to overcome before the digital solution can be delivered to the customers.

### **7.2.1 Value Proposition**

The increased interest towards self-management enhances the digital solution's attractiveness. The interviews established that the digital solution brings added value for the customer in terms of treating low back pain. The non-medical aspect of the solution and lack of side effects can increase the patients' quality of life. Moreover, the gamification of the treatment enhances the patients' motivation and commitment to the treatment through the factor of engagement. This engagement can further be intensified

by making the patients feel acknowledged and encouraged. Monitoring the patient's progress is one of the perceived value propositions that would be beneficial for both the patient and the medical professionals. The gathered health data is also attractive for the client company to receive results from the treatment. Furthermore, the novelty of the digital solution's treatment generates an interest to new experiences among patients whereas the cost-effectiveness attracts different organizations. The likelihood for acceptance could be high among certain population groups, i.e. younger generation, when the price is acceptable and enough clinical evidence supports the effectiveness.

The acceptance among patients can further be increased by receiving the acceptance from the medical professionals that recommend the treatment for the patients. Thus, the medical professionals and different organizations (e.g. hospitals, patient organizations, insurance companies, etc.) should be targeted on first, even though the individual consumers are a feasible target group too. The individual consumers reaching for the treatment provided by the digital solution can be used for data collection purposes and proving the feasibility. However, the credible brand and awareness building are essential for reaching a wide audience. The organizations are a vital connection between the digital solution and the end-user because these organizations deliver the solution for the patients, educate them about its functionality, and monitor the results. Hospitals and medical professionals are the most important stakeholders with their expertise in treating the patients and thus, having the credibility for recommending the digital therapeutics solution's treatment. Additionally, they support in awareness building among patients seeking for help. The patient organizations and pain clinics can provide the digital solution as an additional or alternative treatment of managing pain. Especially in Germany and the USA, the private insurance companies are important stakeholders for offering the digital solution in their health insurance packages. Furthermore, the private companies as a stakeholder can provide the solution for the employees through corporate welfare packages.

One of the complementary factors of the digital solution is the accessibility. The digital solution can be used at home by offering a different type of accessibility. Moreover, the digital solution provides a different approach for treating pain that does not expose the patient to the *stigma* related to mental health issues. The add-on therapy lowers the patients' perceived barriers for seeking help. The personalization of the treatment for the



purpose of meeting the patients' needs is essential owing to different levels, limitations, and expectations towards the treatment. When the personalized content is addressed to an individual patient, the engagement, attractiveness, and commitment are increased. Moreover, the possibility for choosing between various activities or creating an element of surprise through differing scenarios, motivates the patient to return the digital solution every day. The gathered health data can be used for the purpose of personalizing the treatment through a combination of AI, patient, and medical professionals' assessment. The AI's follow-up on the progress and reminders about the patient's activity level is an effective way to analyse the data. However, the medical professionals are needed for setting the parameters, monitoring the risk, and encouraging the patient for movement. Furthermore, the patient should choose the level of intensity or activity according to the condition.

### **7.2.2 Interface**

The clear and guided setup process support the interface's user-friendliness that is a vital aspect of the entire digital solution and a prerequisite for acceptance and adoption by the customers. Moreover, customers perception of a user-friendly interface should be continuously improved based on the feedback received. The outlook, design and the aesthetics need to be considered for enhancing the customers' interest towards the solution by making it attractive and encouraging them to use the interface. There needs to be a possibility to customize the content according to the patient's own interest for committing different types of people into the solution. Furthermore, the customization should not only be limited to changing the colour of the background or setting the scene, but also considering the limitations of patients.

The collection of data in the interface is one of the interaction possibilities that allows the monitoring of patient's progress. Furthermore, the saved data acts as a valuable source for medical professionals in face-to-face interactions. In fact, the interaction with medical professional is essential for the patient to share their progress and request help. The interaction with communities of patients with similar condition should be made available for further support from others. Furthermore, the motivation for achieving certain goals is enhanced when the accomplishments can be shared in social media. Reminders, purchasable add-ons, and questions about the patient's state tie the patient into the interface emotionally. The haptic motors in the handset ensures the correct movement.

### **7.2.3 Service Platform**

The service platform is a proprietary and closed software while having an opportunity for collaborating with third-party developers that provide additional features, activities, or personalized solutions. The service platform should be supported by different operating systems for larger customer adoption. One of the options for delivery channel of the digital solution are hospitals, clinics, and medical professionals in order to guarantee a safe service delivery. However, several options for different target groups as delivery channels should be available. For individual patients, the solution should be available for download, for example in an application store, or client company's website with a code provided by a medical professional. Through a trial period, the customer would be able to preview the solution before the purchase decision of either additional features or access to the solution itself. The limited free access would enhance the adoption and further success of the digital solution.

### **7.2.4 Organizing Model**

The core business processes include sales and marketing in order to deliver and making the solution available for the customers as well as promoting it to reach wider customer base. Research and development activities are essential business processes for creating the clinical evidence base for the digital solution. The support from the clinical trials further enhances the probability of recommendation by the medical professionals. The platform management related processes, such as a support function and maintenance services, are required in case of technical problems with either the software or hardware. Furthermore, a core business process is the continuous improvement of the solution for acquiring the commitment of the patients and credibility as a company.

The partnership with a software, IT consultancy, or DTx company is essential for offering technical expertise in developing and maintaining the digital solution. Furthermore, these companies are vital for acquiring customer base and building networks. Hospitals, clinics, and medical networks can provide support in clinical trials whereas the patient organizations assist in building awareness among potential customer groups. Partnerships with advisory boards offer networks for gathering insights, knowledge and acquiring a thorough understanding about the needs regarding the digital solution's delivery. In addition, insurance company partnerships allow the availability of the digital solution for

the subscribers of health insurances. The key resources of acquired from the partners are related to technology, digital content, and digital marketing. Client company's key resources include the sales and marketing as well as research and development in regards of conducting clinical trials. Furthermore, the existing personnel's knowledge and expertise are exceptional resources.

### **7.2.5 Revenue Model**

The revenue model of the digital solution should be based on a subscription fee because it engages and commits the customer into the product. However, the unsubscribing from the platform is made effortless when the customer does not use the solution anymore in order to avoid any poor reviews. The subscription fee based on modules and features is one of the feasible options for pricing the solution. The additional features, various modules, and other services could then be priced differently. Especially, for B2B customers the volume or license-based pricing would succeed due to the promise of certain number of customers. However, a payment per active user would be more attractive option from the customer's point of view. The reimbursement of the digital solution is a viable option in certain parts of the world, but requires extensive research, expertise, and clinical evidence which could postpone the market access.

A low price allows the high reach of the customers which results in acquiring a larger variety of customer perceptions about the platform. Furthermore, it would support the acceptance by the individual consumers and create a standard therapy for treating back pain. In contrast, high price would create a niche product that needs to be unique enough to prevent copies from the competitors. However, in the beginning the high price is inevitable due to a low customer base. Thus, the low-price suits for individual consumer target group whereas the high price is more suitable for target group of the organizations. Nevertheless, many price options and alternative methods are needed for different target groups and differing needs.

The features of the digital platform affect the pricing increasingly which supports the module-based pricing mechanism. The pricing can also be linked to time, treatment period, or the person. Moreover, the patients accomplished progress needs to be acknowledged by, for example, granting an access to additional features. The digital solution as well as the price range need to be attractive enough for patients in order to

enhance the willingness to pay. Furthermore, the attractiveness can be increased through clinical evidence supporting the product. The VR headsets should be made available for rent or loan in the health care centres and a partnership with a VR headset company could support this acquisition for the organizations. However, it would be feasible, especially for individual consumers, to make the platform compatible with several VR headsets to avoid limitations of one manufacturer. In this case, a list of compatible VR headsets should be made available for patients that are willing to acquire their own headset.

Eventually, the digital solution has a value-driven cost structure that emphasizes the importance of continuous development according to the user feedback. Thus, the development related activities, such as software maintenance, improving features, and mapping user requirements are costs arising from supporting the digital solution. Furthermore, the sales and marketing costs are relevant as building brand, raising awareness, and providing the solution for the customer are essential for value delivery. The costs related to the VR headset and hardware consist of partner payments, support services and maintenance. The most evident costs are related to research and development activities which are required for supporting the clinical evidence of the digital solution. However, the digital solution allows the additional features for the same platform and, thus, receiving benefit from economies of scope.

## **7.3 Business Model**

Based on the comparison of case companies and identification of similarities between them as well as the stakeholder perceptions, a suggestion for a business model has been developed using the VISOR framework. The VISOR business model for client company is presented in Appendix 12.

The *value proposition* of the client company includes a new, non-medical treatment that lacks side effects. Non-medical and digitalized treatment results in cost reductions for both the hospitals and the patients. The gamification of exercises fosters the engagement of patients in completing the activities and, also, returning to them. The pain can restrict the patients' movement considerably and thus, gamified exercises expose the patient into movement almost accidentally. The solution includes a mentor that encourages the patient during the physical exercises. The value proposition of mentoring is one of the essential ones and the importance of a multimodal therapy in the treatment of chronic low back

pain is emphasized. A monitoring tool for following the progress creates additional value for both the patient and the medical professional.

The client company's customer segments are individuals that suffer from chronic low back pain whereas the digital solution's focus is on the treatment of chronic low back pain. However, the main focus customer segment is the organizations that need to be convinced before targeting individual consumers. One of the customer segments is the medical professionals that recommend and, ultimately, deliver the solution for the patients. The clinics and hospitals can be considered as customers because the solution is offered through them. Furthermore, the patient organizations, private insurance companies, and employees are target groups that can build awareness among the potential customers.

The differentiating factors of the client company's solution include the easy accessibility that provides convenience for the patient as the solution can be used at home. The non-existence of *stigma* and other entry barriers enhances the customers' accessibility for the solution. Furthermore, to increase the effectiveness the digital solution can be used as an additional therapy for the more conventional type of treatment that includes, for example, face-to-face meetings with a medical professional and medication. The value proposition of the client company contains personalization of treatment. This is done by data analytics to monitor the patient's progress and altering the treatment according to the patient's needs and level. A medical assessment of the health data is also included in the digital solution and the patient is able to choose different modules and features.

The setup process can be done as a self-service with the help of clear instructions and guides whereas the user-friendliness is considered by developing an *interface* that is easy to use. The interaction possibility with a mentor or supporter is provided as well as the interaction with a community with other members. Additionally, the customers are able to receive help when problems occur through support services. Social media platforms are utilized in interacting with the existing and potential customers as well as reacting to reviews and development ideas. The solution's websites will have customer's own pages which includes account details such as gathered and analysed data. The aesthetics, design and outlook of the interface are considered for increasing the attractiveness of the software. In addition, the patient will be able to personalize the initial screen's environment by choosing a place that they find the most calming. Other possibilities for

customization, such as colours and backgrounds are offered. The patient's limitations are also considered through possibilities of customization.

The **service platform** is a closed proprietary software due to legal and regulatory aspects. The client company needs to manage the content in the software in order to be accountable and credible. The platform supports various operating systems to offer the solution for a wider audience. The channel for creating awareness about the solution is the client company's website which will have access to solution's own pages. The website will act as the distribution channel of the solution too by including client company's sales representatives' contact information there. In addition, the awareness is created through partnerships with other companies and healthcare professionals. These partners are the distribution channel of the solution as well. For the preview of the solution, a limited free access is granted through a trial period. After the trial period, the customer needs to subscribe to the solution in order to have a full access.

Client company's **core business processes** are sales and marketing as well as research and development activities. The clinical trials create important evidence and results about the solution's effectiveness. An essential business process is the platform management, developing the platform and promoting it. Thus, the partnerships and networking are important for acquiring capabilities and knowledge. These activities contribute in environment scanning that results in improving the solution continuously. In addition, support and maintenance processes are required for both the software and hardware.

The **key partnership** for the client company is with a software company that is developing the digital platform. The company is managing and maintaining the technical aspects of the platform. Nevertheless, the partnership with the VR headset provider will be essential because the solution cannot be utilized without them. In addition, the healthcare professionals, clinics, and hospitals form a partnership group that recommend and deliver the solution for the end-user. Patient organizations are for building awareness among the customers whereas the partnerships with DTx companies and advisory boards contribute in providing valuable knowledge and consultancy.

The human resources, that deliver and develop the value proposition for the customer, are considered as the **key resources**. People's expertise and capabilities are essential in creating not only medical devices but also digital platforms in general. Also, clinical trials

and researching require a substantial amount of specialised knowledge. For the client company, the existing intellectual resources are an advantage. The company already has an established customer base with hospitals, clinics and healthcare professionals which facilitates in creating partnerships with these institutions. In addition, the potential customers, that would benefit from this type of treatment, can be contacted, and identified from the existing databases.

**Revenue** is created by collecting subscription fees for the use of the platform. Business customers can have the possibility to choose from differently priced packages that vary in included features. The VR headsets are acquired from the partner but there are two opportunities in delivering the product to the customer. First option is that the client company purchases the VR headsets from the partner and then further sells them to the customer using bundled pricing mechanism. The second option is to guide the customer into the VR headset manufacturing company to acquire the product directly from them. Furthermore, the healthcare professionals could have the opportunity to purchase the VR headset for the business and rent or lease them for their patients. Pricing mechanisms used for B2C customers is list pricing which means that predetermined prices are offered for the subscription of the solution. As in the Kaia Health's case, the prices can be fixed for different subscription periods. For B2B customers, the prices are negotiated and are customer segment dependent for example differing according to the number of subscribed patients.

Value-driven cost structure creates the potential for creating the best value for the customer and making the solution a personalized experience. People, R&D related activities, platform management and outsourced services establish the costs of the solution. Also, if the VR headsets are acquired by the client company, it creates costs. The platform, though, benefits from economies of scope because the same distribution channels can be utilized when new exercises and activities are developed.

## **8 DISCUSSION AND FINAL CONCLUSIONS**

The final chapter of this thesis draws conclusions by presenting key findings from the research in relation to the reviewed literature. Moreover, the ability to answer the research questions is examined. Lastly, the theoretical and practical implications are presented as well as the limitations and future research are discussed.

### **8.1 Key Findings**

The current needs in health care include personalization, cost-effective treatment, and easy accessibility. According to the literature (e.g. Chircu et al., 2017; Kvedar et al., 2016; Snowden et al., 2015; Sverdlov et al., 2018) and findings from the multiple-case study, the digital solutions can provide a solution for these needs. In addition, similar benefits were recognized in the client company's solution by the stakeholders. Furthermore, the increasing necessity for value-based pricing and quality of care can be supported by a more transparent assessment and monitoring of treatments' results through the gathered health data that can be accessed by both the patient and the medical professional. An easy-to-use and user-friendly interface combined with a thorough training and education might lower the barrier for adoption, especially among non-tech-savvy people. Moreover, the research results from clinical trials that support the digital solution's effectiveness lower the barrier of medical community's acceptance. Medical professionals remain as essential actors in recommending, building awareness, and delivering the digital solution for the patients.

In the USA, the out-of-the-pocket payments of health care and private insurances are more common which can result in higher acceptance by individual consumers than in the EU. In the EU, the public health care systems and highly regulated reimbursement schemes require more convincing of policymakers. However, cost reductions, effectiveness, and lower accessibility barriers, can attract private organizations and insurance companies to include the digital solution in their portfolio. The challenges regarding the legal, regulatory, pricing, and cost-related aspects were recognized by the stakeholders as well as supported by the literature (e.g. Afra et al., 2018; Chircu et al., 2017; Coye et al., 2009; Hird et al., 2016; Lameire et al., 1999). The costs regarding the maintenance of hardware and software as well as developing a support function, create



additional costs and require company's effort and time. The pricing mechanisms between the health care and digital content can create contradictions. Thus, novelty pricing and reimbursement schemes that combine a traditional business (i.e. health care and pharmaceutical industry) and arising businesses (e.g. digital therapeutics, digital health) need to be fully addressed in order to accomplish acceptance in a wider public scale.

### 8.1.1 Research Questions

The first research question (*RQ1: What kind of business environment exists for the client company?*) was answered through a literature review that considers the challenges, barriers, and needs that exist in the business environment. The existing health care and reimbursement systems as well as the pricing strategies of digital content provide the understanding of underlying design space for business model creation. The health care needs and digitalization opportunities in pharmaceutical industry, contribute to recognizing not only the benefits of the digital therapeutics solution and but also the existing competition. Moreover, the health care systems and regulatory demands presented support the potential markets of the client company and existing markets of the case companies.

The second research question (*RQ2: From the business model perspective, what type of characteristics arise in existing digital therapeutics companies?*) was answered by a multiple-case study. The business model characteristics could be recognized properly and supported the research aim as providing essential information about the existing digital therapeutic solutions. The third research question (*RQ3: Which of these characteristics are feasible in the client company's business model?*) was answered through an analysis of the multiple-case study results that were compared to identify similarities and differences. Then, this comparison was utilized in the final business model creation as a confirmation of already used solutions that were perceived as feasible by the stakeholders as well in the context of the client company's solution.

The final research question (*RQ4: Which characteristics are perceived important by different stakeholder groups within and outside the client company?*) was answered through in-depth interviews. The results were analysed, and perceived characteristics were further utilized in the final business model creation.

## **8.2 Conclusions**

The aim of this thesis was to find a feasible business model for the client company and contribute to the needs of business model in the digital therapeutics field. A suggestion for a business model was developed based on the research of existing business models in the field as well as stakeholder perceptions about the important aspects of a business model, whereas the challenge with a reimbursement model remains to be further studied. Nevertheless, the developed business model does not provide straightforward and specific solutions, but rather supports in decision-making processes when the feasibility between several options are considered. Thus, it can be concluded that there is no one single solution for every digital solution company and a feasible business model is dependent on various factors, such as the chosen technical solution, demographic location of the company, capabilities, and partnerships. However, the awareness needs to be built among the customers and create an attractive enough solution, because, eventually, everything comes to the customer, and their willingness to adopt, use, and pay.

This thesis contributes to the literature by providing new insights and knowledge about the business model characteristics of digital therapeutics companies. Furthermore, the combination of health care systems and digital content approaches digitalization from a relatively new angle. The practical implication of this thesis includes an opportunity for companies to innovate their current business model based on their product and service portfolios. More specifically, this thesis provides insights about the characteristics of a business model based on VISOR framework perceived as important in the pharmaceutical industry regarding the digital therapeutics solutions.

### **8.2.1 Limitations and Future Research**

This thesis has potential limitations. The limited access to case companies' information has restricted a complete understanding about the business model characteristics. Due to this limitation, some of the case company information is biased to researcher's own interpretation of data acquired from the internet. Furthermore, the sample might not contribute to generalized results, because they might be biased to client company's organizational culture and respondent's personal level of knowledge and interest towards digital solutions and technologies. Thus, the future research should contribute in finding the customer and end-user perceptions about the digital solution as well, in order to find

out a more comprehensive business model. More specifically, the research about acceptable price levels and feasible delivery channels from the customer perspective, should be investigated further. In addition, in-depth interviews in existing digital therapeutics companies could be conducted for gaining a detailed understanding about their business models and feasible characteristics. Moreover, a country or region-specific research about market access opportunities with regards to the underlying reimbursement and regulatory processes could contribute in understanding the requirements for receiving a broader acceptance in the public health care systems. For the researcher's own interest, a future research could be conducted about the motivation for final business model choices and their feasibility in a real-life context.

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## APPENDICES

### Appendix 1 Interview Questions Page 1

#### VALUE PROPOSITION

*More conventional type of treatment could include e.g. face-to-face meetings with medical professionals (such as physiotherapist) and use of medication for e.g. pain or mental disorders.*

1. **What kind of benefits would you perceive in digital therapeutics solutions when compared to the conventional type of treatment of chronic low back pain? What about challenges?**
2. **In your opinion, what is the likelihood of acceptance and acquisition for the solution by the patient? What about the organizations offering the solution for the patient (e.g. hospitals, clinics, insurance companies)? What could be the barriers?**

*Personalization of content usually means altering the treatment according to the patient's progress which is measured through the gathered health data.*

3. **How important would you consider the personalization of content for the purpose of meeting the patient's needs?**
4. **Would you consider that this personalization should be based on (1) medical professional's assessment of analysed data; (2) technology's assessment of analysed data (e.g. AI changing the level of difficulty); (3) patient's own perception of needed treatment (e.g. choice of the needed activity); or (4) a combination of all/some of these? Why?**

*The end-users of digital therapeutics solutions are always the individuals suffering from the condition the treatment is targeted to. However, in existing digital therapeutics companies, the key target groups vary from organizations (B2B2C) to individual consumers (B2C).*

5. **Which target group would you focus on first? Why?**
6. **In your country, which organizations would you consider as important stakeholders in this use case?**

#### INTERFACE

7. **How do you perceive the importance of solution's user-friendliness? What about the outlook of the interface and its design?**

*In some cases, there is a possibility for customizing the digital solutions to meet user's own preferences. This could mean for example choosing different layouts and personalize the content.*

8. **Do you think it is important for the user to have the possibility for customization of solution? Why/Why not?**
9. **What kind of interaction possibilities between the user and service provider would you consider as important to exist in the interface?**

## Appendix 2 Interview Questions Page 2

### **SERVICE PLATFORM**

10. What kind of distribution channels for the digital solution would you recognize as the best option? Why?

*To whom the existing solutions grant their access, can vary in the continuum from being available for everyone (free access, but not to all features) to only subscribers.*

11. What kind of option for access would you consider as the most viable one? Why?
12. What is your opinion about opening the platform for third parties to develop their own applications in addition?

### **ORGANIZING MODEL**

*In a digital ecosystem, the organizing model defines the arrangement and alignment of business processes, value chains, and partner relationships for effective and efficient product and service delivery.*

13. From the company's point of view, what kind of core business processes are essential for delivering the solution for the customers as well as supporting the value delivery?
14. When you consider the developed solution, what kind of ecosystem partners could be used in delivering the solution?
15. CLIENT COMPANY: What kind of inner capabilities do we have as a company for delivering the solution? Which capabilities would you consider to be better to acquire from outside?

### **REVENUE MODEL**

*Pricing mechanisms can be e.g. a subscription fee, payment per active user, advertising, asset sales, etc.*

16. When you consider the developed digital solution, what kind of pricing mechanism would you consider as the most feasible one? Why?
17. Do you think that there should be only one price option, or should there be many options for differing needs and with different prices? Why?
18. When you consider the developed digital solution, what kind of factors could affect the price?
19. What kind of costs can you recognize in developing and maintaining this type of digital solution?
20. Would you prefer (1) "high price and low number of customers"; or (2) "low price and high number of customers"? Why?

*The acquisition of VR headset is a prerequisite for being able to access the solution.*

21. From the customer's perspective, what kind of solution would you see as the most viable for acquiring the VR headset?

## Appendix 3 Kaia Health's Business Model

VISOR Component	Descriptor	Comments
Value Proposition	Compelling	<ul style="list-style-type: none"> <li>Convenience; at home, own device, "only 15 min. per day"</li> <li>Cost and risk reduction</li> <li>"without medication"</li> <li>Motion coach</li> </ul>
	Cohort	<ul style="list-style-type: none"> <li>Individuals: patients with chronic back pain</li> <li>Companies (end-user: employees)</li> <li>German private insurance companies (end-user: subscriber of the insurance)</li> </ul>
	Complementary	<ul style="list-style-type: none"> <li>Multimodal therapy: coaching and physical</li> <li>Education</li> </ul>
	Co-creatability	<ul style="list-style-type: none"> <li>Personalization through the initial questions</li> </ul>
Interface	Functionality	<ul style="list-style-type: none"> <li>Coaching through application (chat)</li> <li>Self service (download app, purchase, exercise)</li> <li>FB, Twitter, Instagram</li> <li>Reviews in the App store</li> <li>B2B, implement Kaia campaign, maintenance</li> <li>Easy to use</li> </ul>
	Form Factor	<ul style="list-style-type: none"> <li>Considered</li> <li>Fact-based introductions</li> <li>Clear (step-by-step guides)</li> </ul>
	Fluidity	<ul style="list-style-type: none"> <li>Personalization through AI tech</li> <li>Monitoring &amp; analyzing progress</li> </ul>
Service Platform	Architecture	<ul style="list-style-type: none"> <li>Closed software</li> </ul>
	Agnosticity	<ul style="list-style-type: none"> <li>iOS &amp; Android operating system</li> </ul>
	Acquisition	<ul style="list-style-type: none"> <li>App store</li> <li>Web Sales</li> </ul>
	Access	<ul style="list-style-type: none"> <li>Own device</li> <li>Everyone (free trial), after that subscribers</li> <li>Subscribers of specific insurance</li> </ul>
Organizing Model	Processes	<ul style="list-style-type: none"> <li>Platform management</li> <li>Clinical trials → evidence-based</li> </ul>
	Partnerships	<ul style="list-style-type: none"> <li>Medical professionals developing treatments</li> <li>German private corporations (reimbursement)</li> <li>Other private corporations</li> </ul>
	Pooling	<ul style="list-style-type: none"> <li>Human resources (knowledge-based industry)</li> <li>Financial resources</li> </ul>
	Project Management	<ul style="list-style-type: none"> <li>Capabilities acquisition</li> <li>Customers</li> <li>Funding</li> </ul>
Revenue Model	Pricing	<ul style="list-style-type: none"> <li>Subscription fees:             <ul style="list-style-type: none"> <li>B2C:                 <ul style="list-style-type: none"> <li>32,99 €/quarter</li> <li>51,99 €/0,5 year</li> <li>77,99 €/1 year</li> </ul> </li> <li>B2B:                 <ul style="list-style-type: none"> <li>Reimbursement in GE</li> <li>Pay per active user</li> </ul> </li> </ul> </li> </ul>
	Product Cost Structure	<ul style="list-style-type: none"> <li>Value-driven cost structure</li> <li>People</li> <li>R&amp;D</li> <li>Maintenance</li> <li>Economies of scope</li> </ul>



## Appendix 4 XRHealth's Business Model

VISOR Component	Descriptor	Comments
Value Proposition	Compelling	<ul style="list-style-type: none"> <li>Gamification: engagement of the patient</li> <li>Cost reduction</li> <li>At-home monitoring; convenience, time reduction, preciseness</li> <li>Patient satisfaction</li> </ul>
	Cohort	<ul style="list-style-type: none"> <li>Clinics, hospitals</li> <li>Individuals with motor, cognitive, physical, psychological, postural ability, pain</li> <li>Pharma companies</li> </ul>
	Complementary	<ul style="list-style-type: none"> <li>Data analytics and external control</li> </ul>
	Co-creatability	<ul style="list-style-type: none"> <li>Choice of games to fit individual's needs</li> </ul>
Interface	Functionality	<ul style="list-style-type: none"> <li>User-friendly</li> <li>Data portal for help</li> <li>Self-service with setup tutorial</li> <li>Customers' "own sites" in their websites (Login)</li> </ul>
	Form Factor	<ul style="list-style-type: none"> <li>Considered</li> <li>Games</li> </ul>
	Fluidity	<ul style="list-style-type: none"> <li>Personalization of treatment</li> <li>Customization of data portal view</li> </ul>
Service Platform	Architecture	<ul style="list-style-type: none"> <li>Web-based data portal</li> <li>Open API for partners to develop own applications</li> <li>VR headset enables the access</li> </ul>
	Agnosticity	<ul style="list-style-type: none"> <li>Supports different operating systems</li> </ul>
	Acquisition	<ul style="list-style-type: none"> <li>Websites, sales representatives</li> <li>Partner sales</li> </ul>
	Access	<ul style="list-style-type: none"> <li>Own device</li> <li>Subscribers</li> </ul>
Organizing Model	Processes	<ul style="list-style-type: none"> <li>Problem-solving through the platform and clinical trials</li> <li>Platform management</li> <li>Networking with partners</li> </ul>
	Partnerships	<ul style="list-style-type: none"> <li>Third-party developers</li> <li>VR headset partnership Oculus</li> <li>Insurance companies</li> <li>Clinics and hospitals</li> <li>Pharmaceutical companies</li> </ul>
	Pooling	<ul style="list-style-type: none"> <li>Financial resources</li> <li>Human resources (knowledge-based industry, evidence-based)</li> </ul>
	Project Management	<ul style="list-style-type: none"> <li>VR Headset company for access of the platform</li> <li>Third-party developers giving value-added</li> <li>Others, clinical trials and access to customers</li> </ul>
Revenue Model	Pricing	<ul style="list-style-type: none"> <li>Subscription fee packages (monthly):             <ul style="list-style-type: none"> <li>"Essentials"</li> <li>"Business"</li> <li>"Premium"</li> </ul> </li> </ul>
	Product Cost Structure	<ul style="list-style-type: none"> <li>Value-driven cost structure</li> <li>People</li> <li>R&amp;D</li> <li>Economies of scope</li> </ul>

*Appendix 5 MindMaze's Business Model*

VISOR Component	Descriptor	Comments
Value Proposition	Compelling	<ul style="list-style-type: none"> <li>Continuum of care</li> <li>Cost reduction (management of care)</li> <li>Effective, evidence-based care with early involvement</li> </ul>
	Cohort	<ul style="list-style-type: none"> <li>Clinics, rehabilitation centres, hospitals</li> <li>Patients with stroke, neurological conditions e.g. Parkinson's, traumatic brain injury, multiple sclerosis, cerebral palsy</li> </ul>
	Complementary	<ul style="list-style-type: none"> <li>Gamification of rehabilitation → engaging patients</li> </ul>
	Co-creatability	<ul style="list-style-type: none"> <li>Different games for different needs</li> </ul>
Interface	Functionality	<ul style="list-style-type: none"> <li>Customer support</li> <li>Analytical tools</li> </ul>
	Form Factor	<ul style="list-style-type: none"> <li>Games</li> <li>Considered</li> </ul>
	Fluidity	<ul style="list-style-type: none"> <li>User-calibrated games → personalization</li> </ul>
Service Platform	Architecture	<ul style="list-style-type: none"> <li>Propriety hardware and software</li> </ul>
	Agnosticity	<ul style="list-style-type: none"> <li>Operates in different operating systems</li> </ul>
	Acquisition	<ul style="list-style-type: none"> <li>Websites</li> <li>Sales representatives</li> <li>Partners</li> </ul>
	Access	<ul style="list-style-type: none"> <li>Subscribers</li> </ul>
Organizing Model	Processes	<ul style="list-style-type: none"> <li>Problem-solving through the platform and clinical trials</li> <li>Platform management</li> <li>Networking with partners</li> </ul>
	Partnerships	<ul style="list-style-type: none"> <li>Rehabilitation centres</li> <li>Other companies</li> </ul>
	Pooling	<ul style="list-style-type: none"> <li>Financial resources</li> <li>Human resources (knowledge-based industry, evidence-based)</li> <li>Physical</li> </ul>
	Project Management	<ul style="list-style-type: none"> <li>Partners offer the access for the patients</li> </ul>
Revenue Model	Pricing	<ul style="list-style-type: none"> <li>Asset sales Lending/renting/leasing <ul style="list-style-type: none"> <li>Motion camera</li> <li>Monitor in PRO</li> </ul> </li> <li>Subscription sales for the platform <ul style="list-style-type: none"> <li>\$20-\$50/month</li> </ul> </li> </ul>
	Product Cost Structure	<ul style="list-style-type: none"> <li>Value-driven cost structure</li> <li>People</li> <li>R&amp;D</li> <li>Economies of scope</li> </ul>

*Appendix 6 SilverCloud Health's Business Model*

VISOR Component	Descriptor	Comments
<b>Value Proposition</b>	Compelling	<ul style="list-style-type: none"> <li>• Scalable</li> <li>• Cost reduction</li> <li>• Accessible</li> <li>• Evidence-based care</li> <li>• Data analytics</li> <li>• Gamification → engagement</li> </ul>
	Cohort	<ul style="list-style-type: none"> <li>• Clinics, hospitals</li> <li>• Universities</li> <li>• Insurance companies</li> <li>• Employers (other companies)</li> </ul>
	Complementary	<ul style="list-style-type: none"> <li>• In-home programs</li> <li>• Stigma and accessibility barriers non-existent</li> </ul>
	Co-creatability	<ul style="list-style-type: none"> <li>• Programs for specific needs</li> <li>• Supporter for personalize the treatment</li> </ul>
<b>Interface</b>	Functionality	<ul style="list-style-type: none"> <li>• Supporter in the platform</li> <li>• Interactive exercises</li> <li>• Social media</li> <li>• Contact information</li> <li>• Customer support (mental)</li> </ul>
	Form Factor	<ul style="list-style-type: none"> <li>• Considered</li> <li>• User-friendly</li> </ul>
	Fluidity	<ul style="list-style-type: none"> <li>• Self-directed or coached-care</li> <li>• Customization</li> </ul>
<b>Service Platform</b>	Architecture	<ul style="list-style-type: none"> <li>• EHR, member/patient portal, website</li> <li>• Open APIs, single sign-on</li> </ul>
	Agnosticity	<ul style="list-style-type: none"> <li>• Supports different operating systems</li> </ul>
	Acquisition	<ul style="list-style-type: none"> <li>• Websites</li> <li>• Partners</li> </ul>
	Access	<ul style="list-style-type: none"> <li>• Subscribers of a certain insurance</li> <li>• Employee/Student/Customer of an instance that has the subscription</li> </ul>
<b>Organizing Model</b>	Processes	<ul style="list-style-type: none"> <li>• Platform management</li> <li>• Networking with partners</li> <li>• Problem-solving through the platform and clinical trials</li> </ul>
	Partnerships	<ul style="list-style-type: none"> <li>• Clinics, hospitals</li> <li>• Insurance companies</li> <li>• Other companies</li> <li>• Universities</li> <li>• Pharmaceutical companies</li> </ul>
	Pooling	<ul style="list-style-type: none"> <li>• Financial resources</li> <li>• Human resources (knowledge-based industry, evidence-based)</li> </ul>
	Project Management	<ul style="list-style-type: none"> <li>• Providing access for the patients</li> </ul>
<b>Revenue Model</b>	Pricing	<ul style="list-style-type: none"> <li>• Subscription fee: <ul style="list-style-type: none"> <li>• Yearly subscription (UK)</li> </ul> </li> </ul>
	Product Cost Structure	<ul style="list-style-type: none"> <li>• Value-based cost structure</li> <li>• Maintenance</li> <li>• R&amp;D</li> <li>• People</li> <li>• Economies of scope</li> </ul>



## Appendix 7 Happify's Business Model

VISOR Component	Descriptor	Comments
Value Proposition	Compelling	<ul style="list-style-type: none"> <li>• Patient engagement with gamification</li> <li>• Social connection and support</li> <li>• Education</li> <li>• Evidence-based</li> <li>• Cost reductions</li> <li>• Cultural aspects</li> </ul>
	Cohort	<ul style="list-style-type: none"> <li>• Individuals: mental health needs, maintain wellness, chronic diseases, support for diagnosable mental health conditions</li> <li>• Pharmaceutical companies</li> <li>• Insurance companies</li> <li>• Other companies (end-user: employee)</li> </ul>
	Complementary	<ul style="list-style-type: none"> <li>• In-home care, convenience</li> <li>• Real-time reporting for organizations</li> <li>• No stigma</li> </ul>
	Co-creatability	<ul style="list-style-type: none"> <li>• Personalization through initial assessment, data analytics</li> <li>• Choice of modules based on needs</li> </ul>
Interface	Functionality	<ul style="list-style-type: none"> <li>• Easy to use</li> <li>• Community with other members</li> <li>• Social media</li> <li>• Customer support; email</li> </ul>
	Form Factor	<ul style="list-style-type: none"> <li>• Considered</li> </ul>
	Fluidity	<ul style="list-style-type: none"> <li>• Choice of games based on the need</li> </ul>
Service Platform	Architecture	<ul style="list-style-type: none"> <li>• Open API</li> </ul>
	Agnosticity	<ul style="list-style-type: none"> <li>• Various operating systems</li> <li>• Own device</li> </ul>
	Acquisition	<ul style="list-style-type: none"> <li>• App store</li> <li>• Websites</li> </ul>
	Access	<ul style="list-style-type: none"> <li>• 8 languages</li> <li>• Visually-impaired</li> <li>• Some free games, others for subscribers</li> </ul>
Organizing Model	Processes	<ul style="list-style-type: none"> <li>• Platform management</li> <li>• Networking with partners</li> <li>• Problem-solving through clinical trials</li> </ul>
	Partnerships	<ul style="list-style-type: none"> <li>• Clinics, hospitals</li> <li>• Pharmaceutical companies</li> <li>• Insurance companies</li> </ul>
	Pooling	<ul style="list-style-type: none"> <li>• Financial resources</li> <li>• Human resources (knowledge-based industry, evidence-based)</li> </ul>
	Project Management	<ul style="list-style-type: none"> <li>• Offering an access for the customers</li> <li>• Help in the clinical trials</li> </ul>
Revenue Model	Pricing	<ul style="list-style-type: none"> <li>• Subscription fee: <ul style="list-style-type: none"> <li>• 15,99€/month</li> <li>• 144,99€/year</li> <li>• Lifetime</li> </ul> </li> </ul>
	Product Cost Structure	<ul style="list-style-type: none"> <li>• Value-driven cost structure</li> <li>• People</li> <li>• R&amp;D</li> <li>• Economies of scope</li> </ul>

*Appendix 8 Details of the Interview Respondents*

<b>Case</b>	<b>Position</b>	<b>Company</b>	<b>Country</b>	<b>Response Type</b>
Respondent 1	Market Intelligence Analyst	Client Company	Finland	Interview
Respondent 2	Head of Region Finland	Client Company	Finland	Interview
Respondent 3	Head of Region Western Europe	Client Company	The UK	Interview
Respondent 4	Head of Region Central Europe	Client Company	Germany	Interview
Respondent 5	Country Manager France	Client Company	France	Interview
Respondent 6	General Partner, Consultancy in Digital Health	Outside Client Company	USA	Interview
Respondent 7	Trademark and Design Counsel	Client Company	Finland	Interview
Respondent 8	Director of Market Access and Business Support	Client Company	Finland	Interview
Respondent 9	Business Director, CNS Business	Client Company	Finland	Written Format
Respondent 10	Professor of Medical Psychology	Outside Client Company	The UK	Written Format
Respondent 11	Pain Development Director	Client Company	The UK	Written Format
Respondent 12	Pain Research Director	Client Company	Finland	Written Format

## Appendix 9 Comparison of Case Companies' Value Proposition

VISOR components		Kaia Health	XRHealth	MindMaze	SilverCloud	Happify
Company specifics		CE mark	CE mark	CE mark	CE mark	Clinical trials
			FDA	FDA Clearance	FDA clearance	No FDA, CE
		Medical device	Medical application	Medical device	Medical Device	Wellness application
		Reimbursement Platform-based	Reimbursement? Device/Platform-based	Device-based	Reimbursement Platform-based	Platform-based
Value Proposition	Compelling		Gamification: engagement of the patient	Gamification of rehabilitation: engaging patients	Gamification: engagement	Patient engagement with gamification
		Cost and risk reduction	Cost reduction	Cost reduction (management of care)	Cost reduction	Cost reductions
		Convenience; at home, own device, “only 15 min. per day”	At-home monitoring; convenience, time reduction, preciseness		Accessible, in-home programs	In-home care, convenience
		Education			Education	Education
				Effective, evidence-based care	Evidence-based care	Evidence-based
			Data analytics		Data analytics	Real-time reporting for organizations
		Multimodal therapy: coaching and physical			Own supporter	Social connection and support
					Stigma and accessibility barriers non-existent	No stigma
	Cohort	Individuals: patients with chronic back pain	Individuals with motor, cognitive, physical, psychological, postural ability, pain	Patients with stroke, neurological conditions e.g. Parkinson’s, traumatic brain injury, multiple sclerosis, cerebral palsy	Individuals with difficulties in mental health	Individuals: mental health needs, maintain wellness, chronic diseases, support for diagnosable mental health conditions
		Companies (end-user: employees)			Employers (other companies)	Other companies (end-user: employee)
		German private insurance companies (end-user: subscriber of the insurance)			Insurance companies	Insurance companies
			Clinics, hospitals	Clinics, rehabilitation centres, hospitals	Clinics, hospitals	
			Pharma companies			Pharmaceutical companies
					Universities (end-user: students)	
		Complementary	Motion coach	External control	Continuum of care	Scalable
	“without medication”		Patient satisfaction	Early involvement		
	Co-creativity	Personalization through the initial questions			Supporter for personalize the treatment	Personalization through initial assessment, data analytics
			Choice of games to fit individual’s needs	Different games for different needs	Programs for specific needs	Choice of modules based on needs

## Appendix 10 Comparison of Interface and Service Platform

VISOR components		Kaia Health	XRHealth	MindMaze	SilverCloud	Happify
Interface	Functionality			Customer support	Contact information	Customer support; email
		Self service (download app, purchase, exercise)	Self-service with setup tutorial			
		Social media			Social media	Social media
		Coaching through application (chat)	Data portal for help		Supporter in the platform	Community with other members
		Reviews in the App store				
		B2B, implement Kaia campaign, maintenance	Customers' "own sites" in their websites (Login)	Analytical tools	Interactive exercises	
		Easy to use	User-friendly	User-friendly	User-friendly	Easy to use
	Form Factor	Considered	Considered	Considered	Considered	Considered
		Fact-based instructions				
		Clear (step-by-step guides)				
	Fluidity	Personalization through AI tech	Personalization of treatment	User-calibrated games: personalization		
					Customization based on company's needs	Choice of games based on the need
			Customization of data portal view		Self-directed or coached-care	
Service Platform	Architecture		Open API for partners to develop own applications		Open APIs, single sign-on	Open API
		Closed software		Propriety hardware and software		
			Web-based data portal		EHR, member/patient portal, website	
			VR headset enables the access			
	Agnosticity	iOS & Android operating system	Supports different operating systems	Operates in different operating systems	Supports different operating systems	Various operating systems
		Own device	Own device		Own device	Own device
	Acquisition	Web Sales	Websites	Websites	Websites	Websites
			Sales representatives	Sales representatives		
			Partner sales	Partners	Partners	
		App store				App store
	Access	Everyone (free trial), after that subscribers				Some free games, others for subscribers
			Subscribers	Subscribers		
		Subscribers of specific insurance			Subscribers of a certain insurance	
					Employee/Student/ Customer of an instance that has the subscription	Visually-impaired, 8 languages



## Appendix 11 The Comparison of Case Companies' Organizing and Revenue Models

VISOR components		Kaia Health	XRHealth	MindMaze	SilverCloud	Happify
Organizing Model	Processes	Problem-solving through clinical trials	Problem-solving through the platform and clinical trials	Problem-solving through the platform and clinical trials	Problem-solving through the platform and clinical trials	Problem-solving through clinical trials
		Platform management	Platform management	Platform management	Platform management	Platform management
		Networking with partners	Networking with partners	Networking with partners	Networking with partners	Networking with partners
	Partnerships	Medical professionals developing treatments	Clinics and hospitals	Rehabilitation centres	Clinics, hospitals	Clinics, hospitals
		Other private corporations		Other companies	Other companies	
		German private insurance companies (reimbursement)	Insurance companies		Insurance companies	Insurance companies
			Pharmaceutical companies		Pharmaceutical companies	Pharmaceutical companies
			Third-party developers		Universities	
			VR headset partnership Oculus			
	Pooling	Financial resources	Financial resources	Financial resources	Financial resources	Financial resources
		Human resources (knowledge-based industry)	Human resources (knowledge-based industry, evidence-based)	Human resources (knowledge-based industry, evidence-based)	Human resources (knowledge-based industry, evidence-based)	Human resources (knowledge-based industry, evidence-based)
				Physical		
	Project Management	Customers	Others, clinical trials and access to customers	Partners offer the access for the patients	Providing access for the patients	Offering an access for the customers
		Capabilities acquisition				Help in the clinical trials
		Funding	Third-party developers giving value-added			
			VR Headset company for access of the platform			
Revenue Model	Pricing	B2C Subscription fee, price dependent on time				B2C Subscription fee, price dependent on time
				B2B subscription fee, one price (monthly)	B2B Subscription fee, one price (yearly)	
		B2B Subscription fee, pay per active user	B2B/B2C Subscription fee, price dependent on features (monthly)	Asset sales Lending/renting/leasing		
	Product Cost Structure	Value-driven cost structure	Value-driven cost structure	Value-driven cost structure	Value-based cost structure	Value-driven cost structure
		People	People	People	People	People
		R&D	R&D	R&D	R&D	R&D
		Maintenance			Maintenance	
		Economies of scope	Economies of scope	Economies of scope	Economies of scope	Economies of scope
		The significance of the background colours	Similarity	Differentiation	Same target group, but differing conditions	

## Appendix 12 Client Company's Business Model

VISOR Component	Descriptor	Comments
Value Proposition	Compelling	<ul style="list-style-type: none"> <li>Non-medical</li> <li>Gamification → engagement</li> <li>Monitoring</li> <li>Novelty</li> <li>Cost reductions</li> <li>Effectiveness</li> <li>Coaching, mentoring</li> </ul>
	Cohort	<ul style="list-style-type: none"> <li>Individuals, patients with chronic low back pain</li> <li>Medical Professionals</li> <li>Hospitals, Pain Clinics</li> <li>Patient Organizations</li> <li>Private Insurance Companies</li> <li>Employees</li> </ul>
	Complementary	<ul style="list-style-type: none"> <li>Accessibility</li> <li>Non-existent barriers, such as stigma</li> <li>Add-on therapy</li> </ul>
	Co-creatability	<ul style="list-style-type: none"> <li>Different modules and features</li> <li>Health data assessed by combination of AI, patient &amp; medical professionals</li> </ul>
Interface	Functionality	<ul style="list-style-type: none"> <li>Easy to use</li> <li>Clear guides for set-up</li> <li>Community with other members</li> <li>Social media</li> <li>Customer support</li> <li>Mentor/Supporter</li> </ul>
	Form Factor	<ul style="list-style-type: none"> <li>Considered</li> </ul>
	Fluidity	<ul style="list-style-type: none"> <li>Possibility for customization according to interest (colours, scenes, etc.) and limitations</li> </ul>
Service Platform	Architecture	<ul style="list-style-type: none"> <li>Closed/Proprietary Software</li> </ul>
	Agnosticity	<ul style="list-style-type: none"> <li>Various operating systems</li> </ul>
	Acquisition	<ul style="list-style-type: none"> <li>Website</li> <li>Partners</li> <li>Sales representatives</li> </ul>
	Access	<ul style="list-style-type: none"> <li>Limited free access through a trial period</li> </ul>
Organizing Model	Processes	<ul style="list-style-type: none"> <li>Sales &amp; Marketing</li> <li>R&amp;D</li> <li>Continuous improvement</li> <li>Platform management</li> <li>Networking with partners</li> </ul>
	Partnerships	<ul style="list-style-type: none"> <li>Software company for platform management</li> <li>DTx companies</li> <li>VR headset provider</li> <li>Clinics, hospitals, etc.</li> <li>Advisory Boards</li> <li>Patient Organizations</li> </ul>
	Pooling	<ul style="list-style-type: none"> <li>Knowledge</li> <li>Intellectual Resources</li> <li>Sales &amp; Marketing</li> <li>R&amp;D</li> </ul>
	Project Management	<ul style="list-style-type: none"> <li>Developing the software</li> <li>Consultancy</li> <li>Offering the solution for the patients</li> <li>Providing the access for the solution</li> </ul>
	Pricing	<ul style="list-style-type: none"> <li>Subscription fee: <ul style="list-style-type: none"> <li>Different packages</li> </ul> </li> <li>Asset sales through partnership</li> <li>Bundled pricing</li> <li>B2B: Renting/Leasing for the end-user</li> </ul>
Revenue Model	Product Cost Structure	<ul style="list-style-type: none"> <li>Value-driven cost structure</li> <li>Economies of scope</li> <li>People</li> <li>R&amp;D</li> <li>Maintenance, set-up, other outsourced services</li> <li>VR headsets</li> </ul>