International market selection: Assessing opportunities in the European Union for a mHealth consumer medical device start-up

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Abstract

To date, there are no existing models for evaluating foreign markets, adapted to mobile health (mHealth) consumer medical device (CMD) start-ups seeking to launch their products or services in new countries. This calls for the development of a suitable international market selection (IMS) model that captures the complexity of and opportunities for mHealth. mHealth is a sub-segment of electronic health (eHealth), which furthermore is part of the wider phenomenon of digital health. mHealth covers medical and public health practice supported by mobile devices.

This paper proposes a multidimensional IMS model comprising both macro and micro level factors. Our specialized approach integrates tools and theories by a number of researchers and is showcased in the assessment of the European Union (EU) for the mHealth CMD company AdhereBox. AdhereBox is a Swedish start-up that has developed a CMD consisting of a “smart” pillbox and a complementary mobile software application.

We propose a number of dimensions that should be evaluated when assessing the potential of the different EU health care markets in regards to mHealth CMD start-ups. Our suggested approach includes factors which are categorized into two groups of parameters: (i) stakeholders (which comprises consumers, providers, payers, distributors and collaborators) and (ii) barriers & enablers (consisting of incentives, reimbursement models, technological infrastructure, regulations and existing solutions).

In summary, our study identifies critical factors that mHealth CMD start-ups should consider when evaluating foreign markets in an IMS. By applying our IMS model on AdhereBox, we illustrate how our model can be used, its parameters assessed and the interdependencies between these analyzed in order to arrive at a set of recommendations for further market analysis and conclusions on country attractiveness. As such, we believe that our research could provide valuable insights and guidelines for firms within mHealth seeking to expand their business within the EU, as well as for governmental organizations that want to better leverage and stimulate the potentials of a flourishing domestic mHealth ecosystem.
Key-words

International market selection, internationalization, mobile health, mHealth, consumer medical device, European Union, adherence
Foreword and Acknowledgements

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Stockholm, May, 2016
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<th>Abbreviations</th>
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<td>2G</td>
<td>Second Generation Wireless Telephone Technology</td>
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<tr>
<td>3G</td>
<td>Third Generation of Mobile Telecommunication Technology</td>
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<td>4G</td>
<td>Fourth Generation of Mobile Telecommunication Technology</td>
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<td>API</td>
<td>Application Programming Interface</td>
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<td>CE</td>
<td>Conformité Européenne</td>
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<td>CEO</td>
<td>Chief Executive Officer</td>
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<td>CMD</td>
<td>Consumer Medical Device</td>
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<td>COO</td>
<td>Chief Operating Officer</td>
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<td>DESI</td>
<td>The Digital Economy and Society Index</td>
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<td>EEA</td>
<td>European Economic Area</td>
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<td>eHealth</td>
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<td>EKG</td>
<td>Electrocardiogram</td>
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<td>ePrescription</td>
<td>Electronic Prescription</td>
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<td>EU</td>
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<td>GDP</td>
<td>Gross Domestic Product</td>
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<td>GNP</td>
<td>Gross National Product</td>
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<td>GP</td>
<td>General Practitioner</td>
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<td>GPRS</td>
<td>General Packet Radio Service</td>
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<td>GSM</td>
<td>Global System for Mobile Communication</td>
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<td>ICT</td>
<td>Information and Communication Technology</td>
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<td>ID</td>
<td>Identity Document</td>
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<td>IEWM</td>
<td>Improvement and Efficiency West Midlands</td>
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<td>IMS</td>
<td>International Market Selection</td>
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<tr>
<td>IoT</td>
<td>Internet-of-Things</td>
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<td>IT</td>
<td>Information Technology</td>
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<td>LTE</td>
<td>Long Term Evolution (telecommunication)</td>
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<td>MedTech</td>
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<td>mHealth</td>
<td>mobile health</td>
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<td>MNO</td>
<td>Mobile Network Operator</td>
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<td>NHS</td>
<td>National Health Service</td>
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<td>NICE</td>
<td>National Institute for Health and Care Excellence</td>
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<td>NMS</td>
<td>New Medicine Service</td>
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<td>OJEU</td>
<td>Official Journal of the European Union</td>
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<td>OOP</td>
<td>Out-of-pocket</td>
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<td>PDA</td>
<td>Personal Digital Assistant</td>
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<td>PPS</td>
<td>Purchasing Power Standard</td>
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<td>RQ</td>
<td>Research Question</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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<td>WiMAX</td>
<td>Worldwide Interoperability of Microwave Access</td>
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1. Introduction

This chapter provides a background to the digitalization of consumer health care in regards to the internationalization of consumer medical device start-ups in the European Union. As such, it is dedicated to providing a background to the research phenomenon that we intend to study. It also provides some insights into the client company AdhereBox, a Swedish mHealth start-up that is investigating a future international expansion. Furthermore, we will in this chapter present the purpose of our study, its expected contribution and the research questions we intend to answer. Finally, we present why mobile health innovation is important from a sustainable perspective and the delimitation of our study. In Chapter 2. we will provide some additional background to mobile health and consumer medical devices.

1.1. Digital health

Digital health care, or digital health, has arisen from the intersection of health care services, information and communication technology (ICT) and mobile connectivity (Monitor Deloitte, 2015). It represents the emerging phenomenon encompassing connected health, quantified self, genomics, and core health care IT trends (Atluri et al., 2015).

There are a range of domains that span digital health, including both hardware and software solutions. Among these is electronic health (hereafter eHealth), which leverages on the technological advancements of smartphones, tablets, and other portable devices, as well as mobile data connectivity including mobile broadband and 4G networks, new sensor technology, big data analytics and cloud computing (Dervojoeda et al., 2015).

According to the European Commission, eHealth consists of the following four interrelated categories of applications (cited in Callens, 2010, pp. 561-562):

i. clinical information systems;
ii. telemedicine and home care, personalized health systems and services for remote patient monitoring, teleconsultation, teleradiology;
iii. integrated regional/ national health information networks, distributed electronic health record systems and associated services such as e-prescriptions or e-referrals; and
iv. secondary usage of non-clinical systems (such as specialized systems for researchers, or support systems such as billing systems).

mHealth (an abbreviation for mobile health) has emerged as a sub-segment of eHealth and is thus included in the broad scope of digital health. Although there is no standardized definition of mHealth to date, the World Health Organization (WHO) defines it as the
“medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs) and other wireless devices” (WHO, 2011, p. 6) as well as applications such as lifestyle and wellbeing apps, personal guidance systems, health information and medication reminders provided by sms or wirelessly. As such, mHealth also includes mobile applications (apps) that may connect to hardware medical devices and sensors (European Commission 2014a).

Driven largely by the proliferation of smartphones and tablets, as well as the growing importance of personal health monitoring, mHealth solutions are today being developed and deployed to solve several key health care issues, such as medication adherence and compliance. These sensors, wearables and applications exploit new technological phenomena such as ICT and the Internet-of-Things (IoT). They are believed to contribute to creating more patient centric medication and treatment, whilst simultaneously contributing to the shift towards prevention and improving efficiency of the health care system. (European Commission, 2014) Through sensors and mobile apps, mHealth also allows the collection of valuable medical, physiological, lifestyle, daily activity and environmental data, which are valuable for multiple stakeholders (European Commission, 2014).

1.2. Internationalization and start-ups

Companies, facing globalization and technological revolution, are constantly forced to search for new ways to grow and develop. A profitable growth strategy can be built through international expansion, which is an effective way to develop and enhance the competitiveness of a company in response to the changing dynamics of the global economy. (Górecka and Szalucka, 2013)

Today, many entrepreneurial and young firms, such as start-ups, can go global almost instantly from the day of inception (Bailetti, 2012). Falling trade barriers, deregulation and privatization, faster information flows, improved communication and transportation networks as well as social developments are examples of factors behind this behavior (Laanti, Gabrielsson and Gabrielsson, 2007). This change in environment has had a fundamental impact on the strategies of most firms in the world (ibid).

According to the Global Entrepreneurship Index 2016, all 28 members of the European Union (EU) rank in the top 50 percent globally when it comes to entrepreneurship (GEDI, 2016). With its harmonized rules and “single market”, the EU aims to increase the free flow of goods and services between its member states (European Commission, 2015a). A single market across the EU stimulates competition and raises quality among other things and this is true in many sectors (ibid). However, there are several industries in which regulation has not caught up with the digital development, amongst which health care is one of them (Aue, Biesdorf and Henke, 2016). This is apparent for the digital health industry, and is being addressed by the European Commission through several initiatives that aims to tackle regulation and other
barriers for both established actors and start-ups within digital health (European Commission, 2015b).

1.3. mHealth market in the EU

The EU covers over 500 million people in 28 countries (European Union, 2016). Among its top ten priorities, as stated by the President of the European Commission, Jean-Claude Juncker, in 2015, is to create a connected digital single market (Szczepański, 2015). To achieve this, the EU has created several initiatives including EU Policy Documents such as Europe 2020, Innovation Union and Digital Agenda as part of its project Europe Towards 2020 (European Commission, 2016a). In order to promote mHealth solutions and innovation, the EU has adopted various funding schemes and incentives that aim to support its development (Albertino et al., 2015). For instance, mHealth funding is driven under the so-called Horizon 2020, which prioritizes mobile technologies and applications for “integrated, sustainable, citizen-centered care” with the key objective to “enable citizens to become co-managers of their health and wellbeing with the help of ICT,” (European Commission, 2014, p. 17). The EU is also carrying out several legal reforms in order to facilitate mHealth deployment across its member countries (European Commission, 2015b).

The EU could be considered as a fairly good market for digital health companies due to its harmonized rules when it comes to different aspects of health care technology (Callens, 2010). Nonetheless, it is still a very diverse market: the health care systems (Stroetmann, Artmann and Stroetmann, 2011), and how digitalized they are (WEF, 2014), vary between member states as well as do the consumers which inhabit them (Rechel et al., 2011). Healthcare markets vary from country to country and have many different aspects to consider when it comes to assessing international expansion opportunities (Callens, 2010). Healthcare systems are part of wider systems, such as social welfare systems and society (ibid). Therefore, evolutions in society will influence health care systems (ibid).

Although the EU strives for a more harmonized market to ease trade and movement, there are still a certain set of barriers that mHealth firms need to overcome if wanting to expand their business to other EU countries (European Commission, 2015b). All of the Union’s member states have their own reasonably unique health care regulations and financing models as well as cultures (Rock Health, 2013). This can make it difficult for start-ups to scale efficiently by expanding into foreign markets countries in the EU (ibid).

Considering the above, we believe that there may be some countries that offer better market conditions for mHealth to flourish based on their level of digital health adoption and overall market attractiveness. Other markets may be hindered by lack of regulations, digitalization and mHealth adoption (by consumer and practitioners) that diminish and complicate their market potential and growth prospects.
1.4. Problematization

Many firms fail to internationalize, often due to poor market selection. This is often caused by inadequate or inappropriate evaluation of markets, which could have been prevented by a more systematic market evaluation (Papadopoulos and Martín, 2011). Many models have been developed on how to evaluate and select international markets but there are not any examples in current literature on how market selection frameworks and theories can be applied to the phenomenon of mHealth. Nor are there previous studies that examine how existing theories can be used in the international market selection process of mHealth firms.

As outlined in the previous section, market conditions for mHealth vary greatly across the EU. As such, the prerequisites for mHealth companies in the 28 EU countries differ significantly. All of the Union’s 28 member states have their own reasonably unique market for mHealth, which can make it tough for health start-ups to scale efficiently (Rock Health, 2013). Where other sectors have embraced and integrated new technology in a fast pace, the health care sector tends to be more conservative and complex, involving more stakeholders (Groves et al., 2013).

Despite this, there are several start-ups that have emerged in the field of mHealth. They are important innovators in mHealth, but with limited resources such as financial and managerial capabilities (Cohn, 2014). However, and thanks to technology and globalization, start-ups can today go international almost instantly, especially in the EU, which is developing as a single market through its low trade barriers and harmonization of several laws and regulations (Canoy, Liddle and Smith, 2005). However, the complexity of the health care market and differences in the digitalization of the EU member states suggests that mHealth start-ups should evaluate certain parameters when assessing the potential of new markets.

Researchers in international market selection (IMS) theory (e.g. Kumar, Stam, and Joachimsthaler, 1993) have stressed the importance and the need for systematically evaluating and selecting potential foreign markets. A number of researchers have either developed decision frameworks (frequently referred as models in the literature) and methods for IMS or applied existing ones (Moyer, 1968; Walvoord, 1980; Cavusgil, 1985; Vargas-Carcamo, 1986; Root, 1987; Walsh, 1993; Kumar, Stam, and Joachimsthaler, 1993; Hoffman, 1997; Daniels and Radebaugh, 1998; cited in Rahman, 2003). However, there is no agreement among scholars on which parameters should be used and how they should be measured when it comes to IMS. The lists of suggested parameters that are available in the literature are based on the respective author’s perception. Furthermore, there is no academic research that in a coherent way depicts the critical factors that must be considered in the IMS of start-ups in this relatively new arena of digital health.
1.5. AdhereBox

In the midst of the growing arena for mHealth is AdhereBox. AdhereBox is a Stockholm-based consumer medical device (CMD) start-up founded in early 2015. AdhereBox has developed a connected pillbox aimed to solve the problem with medication adherence. Their yet-to-launch CMD comprises a so-called pillbox that, together with a medical device software application (app), incorporates modern hard- and software with integrated IoT features and a user-friendly design (AdhereBox, 2015). This enables the user to gain a holistic view over his or her medicine regimen. Among other features, its app will give medication reminders, keep an updated list of current medications and have functions enabling its user to purchase more medication online when needed. The product is thus a connected, “smart”, medical device. AdhereBox’s offering can be defined as an mHealth CMD that cuts across the boundaries between IoT, medical technology, consumer goods and health care.

A pillbox (also referred to as pill dispenser or -organizer) is a medicine storage device that serves as an aid for individuals with scheduled doses of medication. The pill organizer has traditionally consisted of a box with compartments where medication can be organized and stored for 7 to 28 days or dosage occasions. The pill container has throughout the years taken different forms and developed additional features thanks to advances in technology and its integration with health care product (Kallman, 2010).

Like several of today’s entrepreneurial firms, AdhereBox plans for international expansion in order to increase its user and revenue base. AdhereBox has not yet commercialized its product in its domestic market Sweden. However, it aspires to access countries beyond Sweden in the future and would therefore want to evaluate potential foreign markets within the EU. The main reason for AdhereBox’s internationalization preparation is to quickly and non-exhaustively be able to commercialize its product in markets beyond Sweden. AdhereBox sees this as critical for its future survival as the Swedish market is fairly small, and because the firm desires to be early to market in foreign countries in order to have competitive advantage. (Workshop, 2016)

The client company has wished to remain anonymous in this thesis. Its name has therefore been replaced with ‘AdhereBox’.

1.6. Purpose

This thesis aims to identify critical factors that should be considered in an IMS model for mHealth CMD start-ups, when evaluating the EU market in an IMS. By applying our IMS model on AdhereBox, we hope to illustrate how the model can be used and its parameters assessed. In addition, we believe that our research will illustrate how existing theories in international market selection can be applied and used in the emerging field of mHealth and international market selection.
1.7. Expected contribution

*Our study intends to contribute with the following five aspects.*

Firstly, we expect that our thesis will contribute to literature surrounding the phenomenon of digital health and in particular mHealth, especially in regards to internationalization theory. We hope that this will contribute to research and innovation in mHealth, as well as help governmental bodies and institutions in creating a more attractive marketplace for health care innovation.

Secondly, we will, in our research, evaluate which parameters that should be included in an IMS model for mHealth and how theory can be used to provide a more realistic view of mHealth in the EU. As such, we hope with our paper to be able to develop the body of knowledge on IMS and contribute to studies on the market potential for mHealth in the EU.

Third, our assessment of EU countries will also contribute to illuminating the barriers and opportunities in certain member states in hope for improvement. Previous studies from industry reports on mHealth have mainly focused on portraying the obstacles that exist in the health care system that prevents adoption of mHealth solutions, but do not necessarily assess individual countries in a systematic way or describe their interdependencies with other influential aspects. Moreover, these reports are not based on theories or models from academia. Our resulting model will not only be built upon existing theories, it will also be showcased in an evaluation of the EU countries.

Fourth, as our research will cover a market analysis of the health care industry in regards to consumer mHealth, the findings of our research may possibly be helpful for other mHealth companies seeking to expand within the EU. Especially those with limited resources (such as start-ups) selling CMDs and/or health related mobile applications.

Finally, this thesis will, at the least, provide academia with an IMS framework for a CMD start-up in the process of expanding its geographical market within the EU, by conducting both a screening and an identification assessment of its member states.
1.8. Research questions

The main question that our thesis serves to answer is the following:

RQ1: What parameters should be assessed in an international market selection model for mHealth consumer medical device (CMD) start-ups, in order to identify attractive countries in the EU to launch their products in?

Applying the model on AdhereBox will enable us to answer the subsequent follow-up question to RQ1:

RQ2: How can these parameters be assessed in order to identify opportunities in the EU for mHealth CMDs?

1.9. Sustainability aspects

IoT technology and digitalization have in many ways revolutionized several industries, e.g. financial services and retail, as well as democratized services for consumers by making them more available and cheap. In a time when many health care systems of the EU are facing significant challenges, mHealth has great potential to contribute to a more sustainable delivery of health care. Challenges include a demographic transition to an aging population and an increased prevalence of chronic diseases. These combined are putting burden on costs associated with health care across several of EU member states. However, many believe that the use of mobile technology in health care can address these issues.

mHealth has great social impact. By acting as a valuable tool in the provision of care, it can help support patients’ empowerment and motivation, facilitate contacts between physicians and patients living in remote areas, as well as improve the quality of health service delivery. (European Commission, 2014)

The main economic aspect of mHealth is that there are a lot of cost savings to its implementation in the health care system. This is especially accurate for those that are mainly publicly financed (which the majority of EU health care systems are). Furthermore, mHealth can reduce medical costs and foster independent living, especially in remote areas.

In addition, the environmental aspects of mHealth include the many saved resources a more digitalized health care implies. As such, we aim to identifying any barriers for mHealth adoption in the EU with our study.

As we intend to contribute to the market analysis behind a mHealth start-up’s internationalization plan as well as illuminate factors that create opportunities and barriers for
mHealth adoption, we believe that our findings will contribute to increased sustainability in health care.

1.10. Delimitation

We will not make a fully generalizable IMS model.
As IMS is largely dependent on the characteristics of the internationalizing firm’s offerings and capabilities, we acknowledge that the resulting IMS framework of our study may not be suitable for all mHealth CMD start-ups. This is largely due to the fact that we analyze the market from the perspective of the client company AdhereBox. As we will present in our theoretical review, previous research suggests that relevant criteria and evaluation procedures to be used in an IMS, are usually determined in relation to the specific objectives, constraints and idiosyncratic characteristics of the internationalizing firm.

We will not include the final selection stage of an IMS process.
In addition to creating an IMS model for mHealth CMD start-ups (presented in Chapter 5.), our paper also includes a country evaluation using the proposed framework (showcased in Chapter 6.). The model and evaluation comprise a so-called screening and identification - two stages of an IMS process (presented in Chapter 4.2.1.). These two assessment stages precede a final selection of markets to enter. As such, we do not include the final assessment stage in our analysis, in which one arrives at a final set of countries to enter. This is due to the fact that such a conclusion would require further insights about the country, preferably from country experts, as well as an established network in the market. However, our research will provide the groundwork for a final selection and identify countries that offer more potential than others. The screening assessment uses quantitatively measurable variables that enables firms to filter out less attractive countries, whereas the identification stage analyzes the remaining countries qualitatively. We will not present the complete results from the country analysis of the identification stage in our report. We will however demonstrate how this can be done, by presenting the identification stage assessment of the United Kingdom.

We will not evaluate markets beyond the European Union.
Our study aims to evaluate member states of the EU. AdhereBox has chosen this set of countries due to their proximity to the company’s home market (Sweden) as well as for their accessibility.

In our evaluation, we assess markets as countries.
We choose to evaluate markets as countries to decrease complexity. A criticism of evaluating markets as countries is that it rests on the assumption that countries are indivisible, homogeneous units. However, we believe that we will be able to identify and highlight heterogeneity in the identification stage of our evaluation process.
1.11. Outline

We have now introduced the reader to our research phenomenon. In it we presented our research questions, purpose, as well as expected contribution and delimitation. The remaining parts of the report are as follows. In Chapter 2, we provide a more detailed account of mHealth. This information can help the reader grasp the technical concepts presented in Chapter 5, but is not crucial in order to understand the overall study. Chapter 3 presents the research methodology used in our study. Chapter 4 covers the theoretical review. The Methodology chapter precedes our theoretical review as it is described as a step in our research process. The results of our empirical observations for creating the IMS model are presented in Chapter 5. In Chapter 6, we show how our developed model can be used by screening the EU market and presenting an identification of the United Kingdom. Chapter 7 discusses some of the main conclusions of our research and concludes with ideas for further research.
2. mHealth and the European Union

This chapter aims to provide the reader with a conceptual background on mHealth, putting it in relation to our research topic by first introducing mHealth, then the relationship between CMDs and mHealth and finally regulations and directives on mHealth. This information can help the reader understand the topics touched upon in Chapter 5.

2.1. mHealth

In general, mHealth covers health practice supported by mobile devices. It encompasses the use of mobile devices and networks for delivering care or medical information as well as mobile health applications. (European Commission, 2015c)

Technically mHealth implies: wireless broadband electronic communications infrastructure; an electronic platform; downloadable software and specialized applications; connected mobile terminal equipment whether common (telephones, tablets, PDA) or specific (implantable or non-implantable) (ITU, 2014). Thus, mHealth information is carried by technologies related to these devices, such as mobile telephone networks (GSM, GPRS, 3G and 4G-LTE), computer-based technologies (Wifi and WiMAX) and short-range communications technology (e.g. Bluetooth). These technologies operate on hardware e.g. mobile phones, mobile computers (including netbooks, tablets, and personal digital assistants), pagers, digital cameras, and remote sensors. (Altman et al., 2011) The progress of these technologies, as well as their usages and the widespread uptake of LTE networks, have helped spread and develop the mHealth industry (Adibi, 2015).

mHealth solutions can for instance include software incorporated into medical hardware, such as devices that leverage data from the cloud and external sensors automatically. mHealth products can also include stand alone software such as mobile applications (apps) (Buttarelli, 2015). When it comes to health related apps, these can be distinguished into two broad categories (Rübsamen and Sakellariou, 2015): (i) medical apps: apps for the purpose of prevention, diagnosis and treatment of diseases; and (ii) non-medical apps: apps relevant to lifestyle, fitness and well-being. The main difference between the two groups concerns the sensitivity of the data generates and managed (Monitor Deloitte, 2015).
The table below exemplifies the different fields of mHealth applications.  

<table>
<thead>
<tr>
<th>mHealth Applications</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public information/ education</td>
<td>Active spread of health information to general public</td>
</tr>
<tr>
<td></td>
<td>Helplines for medical and health questions</td>
</tr>
<tr>
<td>HC worker information/ education</td>
<td>Remote education for aspiring healthcare personnel</td>
</tr>
<tr>
<td></td>
<td>Up-to-date information/guidance to healthcare workforce</td>
</tr>
<tr>
<td>Public wellness</td>
<td>Applications to improve public wellness by encouraging improved diet,</td>
</tr>
<tr>
<td></td>
<td>physical activity, quitting smoking, etc.</td>
</tr>
<tr>
<td>Public health surveillance/ tracking</td>
<td>Surveillance and tracking of disease outbreaks and epidemics</td>
</tr>
<tr>
<td></td>
<td>Monitoring of pollution levels</td>
</tr>
<tr>
<td>Remote data recording/access</td>
<td>Recording/accessing patient journal data remotely</td>
</tr>
<tr>
<td></td>
<td>Supply chain management, e.g. authentication of medicine</td>
</tr>
<tr>
<td>Diagnostic and treatment support</td>
<td>Mobile telemedicine, consultations between healthcare professionals,</td>
</tr>
<tr>
<td></td>
<td>decision support systems</td>
</tr>
<tr>
<td>Patient monitoring/compliance management</td>
<td>Monitoring patient health condition and treatment compliance</td>
</tr>
<tr>
<td></td>
<td>Alarm systems for individuals in need of clinical care</td>
</tr>
</tbody>
</table>

Table 1: Categories of mHealth applications.

As pictured in the table, one category of mHealth can for instance relate to patient monitoring and compliance management (BCG, 2012 p. 11). Such solutions are described to monitor patient health conditions and treatment compliance or create alarm systems for individuals in need of clinical care (ibid). AdhereBox can be categorized into this application of mHealth. As mentioned in Chapter 1.5., AdhereBox’s product incorporates a hardware device with a medical device software application that is connected through Bluetooth and LTE networks, and is described as a patient centric patient monitoring and compliance management medical device for consumers (Workshop, 2016).

1 By applications we do not mean mobile “apps”.

11
2.2. mHealth and consumer medical devices

Some mHealth products and applications fall under the EU regulatory framework for *medical devices*. As such, both hardware and software can be considered to be medical devices (European Commission, 2014). The term medical device covers a very broad range of products intended for use within many types of health and medical care areas (European IPR Helpdesk, 2015). It is defined as being any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination with software, intended by the manufacturer to be used for human beings for the purpose of (Medical Devices Directive 93/42/EEC, 1993):

i. diagnosis, prevention, monitoring, treatment or alleviation of disease;

ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;

iii. investigation, replacement or modification of the anatomy or of a physiological process; and

iv. control of conception.

These can include consumer-centric medical devices, which in broad terms are medical devices, consumers use on their own to solve health issues and improve quality of life (FDA, 2015). In our paper, we refer to them as consumer medical devices (CMDs).

In the EU, medical devices are regulated under the Medical Devices Directive and the In Vitro Diagnostic Medical Devices Directive (together, hereafter the Directives). The Directives set out procedures for harmonized certification and inspection of medical devices, as well as standards of performance, safety and health protection. mHealth related hardware and software fall under the Directives for medical devices if they have an intended "medical purpose” (Rübsamen and Sakellariou, 2015). The manufacturer's intended purpose and use is "medical" if the hardware or software application is specifically designed for a medical setting and for performing a medical task (European Commission, 2016b).

Depending on its intended purpose, use and the level of governance that a firm wishes to apply, medical devices can fall under four different product classes with corresponding procedures for evaluating conformity and requirements (EUR-Lex, 2012). The regulatory authorities recognize different classes of medical devices based on their design complexity, their use characteristics, and their potential for harm if misused. These four classes that medical devices can be classified as are the following, ranging from low risk (class I) to high risk (class III) (MDC, 2009):

i. Class I medical devices;

ii. Class IIa medical devices;

---

2 AdhereBox classifies itself as class 1 medical device, and an integral part of its work prior to launching is conforming to EU regulations such as CE-marking.
iii. Class IIb medical devices;  
iv. Class III medical devices

2.3. mHealth and legal frameworks

In order to commercialize a medical device, it needs to conform to certain rules and standards. In order to sell medical devices in the EU, the product must have a so-called CE marking (Conformité Européenne). The CE marking indicates to EU regulators that the device meets requirements of the EU Directive such as the Medical Devices Directive (MDD). All EU member states require medical devices to bear CE marking. It is a symbol of free marketability in the European Economic Area (EEA), where the EU is included (CE marking, 2015).

As many mHealth products and applications have the ability to collect, retain, and transfer personal information, they are most likely to contain intimate details of patients’ private lives (ITU, 2014). As such, the mHealth industry is rife with legal issues, primarily that of data protection.

As mHealth solutions and companies within the EU has increased, there has been a greater demand for more specific and harmonized regulatory framework as developers have found it hard to navigate many of the product safety, data protection, medical device, consumer protection and e-commerce laws that can apply to their products (Bradley-Schmieg, 2015). As such, the EU is working on several initiatives in order to facilitate trade for eHealth companies within its borders, despite the heterogeneity amongst its member states’ health care systems (Callens, 2010).

One such initiative is the so-called “Digital Single Market” (European Commission, 2015d). The EUs main objective with this initiative is to bring down barriers to unlock online opportunities in order to eradicate existing barriers that hinder companies, e.g. start-ups in digital health, from reaching more citizens (ibid). One step towards the Digital Single Market is the reform on data protection proposed by the European Commission. It is aimed on strengthening “citizens’ fundamental rights in the digital age and facilitate business by simplifying rules for companies” within the EU” (European Commission (2015e). The new reform aims to facilitate for companies wanting to expand their business within the EU as this single, pan-European law for data protection, replaces the current inconsistent patchwork of national laws. As such, companies will only have to deal with one single supervisory authority, not 28, making it simpler and cheaper for companies to do business in the EU (European Commission, 2015e).
3. Methodology

This section of the report describes the conducted methods used in our study. The research approach and procedure is presented and visualized in order for the reader to get an overview of the paper. Both the research process and our different sources of collected data is explained. Furthermore, the advantages and disadvantages of our methodological approach is discussed in terms of its validity, reliability and generalizability. Finally we discuss the ethical questions that we have considered in the design of our study.

The aim of this report is to develop an IMS model that incorporates dimensions that affect the market evaluation for mHealth CMD start-ups. In addition, the report will present ways one can use this model in order to identify attractive countries in the EU and provide potential insights into how they can be entered.

Our study explores mHealth within its real-life context. We investigate international market selection in regards to mHealth where the start-up AdhereBox forms a firm-specific context. We classify our study as exploratory research as it examines a fairly new phenomenon (mHealth), on which there is no existing academic research in regards to IMS. Exploratory research is conducted in research problems where there are few or no earlier studies that can offer information about the problem (Collis and Hussey, 2014). Case studies, observation and historical analysis are common techniques used in exploratory research (ibid). Furthermore, exploratory research examines if existing theories and concepts can be applied to a problem or if new ones should be developed. The approach to research is often open and concentrates on gathering a wide range of data and impressions. As such, exploratory research rarely provides conclusive answers to problems or issues, but gives guidance on what future research, if any, should be conducted (Collis and Hussey, 2014).

3.1. Research paradigm

It is necessary for researchers to conduct research according to a research paradigm as it serves as a guiding framework for the research (Collis and Hussey, 2014). Collis and Hussey (2014) have identified two main research paradigms that can be used when carrying out research: (i) the positivist paradigm; and (ii) the interpretative paradigm. The positivist paradigm rests on “the assumption that social reality is singular and objective, and is not affected by the act of investigating it” (Collis and Hussey, 2014, p. 43). As such positivist studies consider the world to be external and objective and are purely based on facts. The interpretative paradigm on the other hand involves research following an inductive process “with a view to providing interpretive understanding of social phenomena within a particular context” (Collis and Hussey, 2014, p. 44).

We find the interpretative paradigm to be more suitable for our intended research approach as we focus on exploring the complexity of IMS in the context of mHealth. Using the
interpretivist approach, we build up our specialized IMS model by conducting a theoretical review and qualitative studies prior to gathering empirical data to validate and build our model. This is an abductive approach, which is commonly associated with an interpretative paradigm (Collis and Hussey, 2014).

### 3.2. Research approach

This section will further explain the process of our research. In Chapter 3.2.1. we describe the pre-study that was conducted in order to gain an overview of internationalization and digital health, especially mHealth. Chapter 3.2.2. introduces the reader to the framework development of our preliminary IMS model. Chapter 3.2.3. presents the methodology to how we chose to validate the dimensions of our IMS model. In this section we describe the steps that we took to gather secondary data that we used to produce a set of countries that qualified for the identification stage and how data was collected to perform this evaluation (see Figure 1 below for a visual representation of the process). Following this section, we present the methods we used for scoring countries according to their attractiveness in the screening stage of our IMS model.

![Figure 1: Visualization of our methodological approach.](image)

Our main findings can be divided into two main parts. The first part being the development of the IMS model (Chapter 5.) and the second part being the outcomes from the country evaluation using the developed IMS model (Chapter 6.).

#### 3.2.1. Pre-study

A pre-study was conducted prior to the literature review in order to better grasp the width and depth of internationalization in regards to mHealth CMD start-ups. There were four steps to the pre-study: (i) Representatives from AdhereBox were interviewed to gain key insights into their product, their strategic vision as well as the digital health and health care market. This totaled three interviews with the Head of Business development, Head of Technology and Lead Developer. (ii) A literature review of articles on mHealth and internationalization was conducted in order to better grasp the research phenomenon. (iii) We attended seminars on digital health and related medical technological areas that generated
leads to potential interviews with knowledgeable individuals (see Table 2 below). (iv) In order to test and receive feedback on our initial hypotheses of research parameters, we held informal interviews with Philip May from InnovationToHealth, an organization that works with bringing Swedish medical innovations to the UK, as well as Sjoerd Hassl, Director at Clinical Innovation Fellowship. The pre-study enabled us to limit the research scope and identify key areas for further research.

<table>
<thead>
<tr>
<th>Seminar</th>
<th>Description</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accelerated Innovation and go-to-market by joining forces</td>
<td>Seminar focusing on entrepreneurs and established firms that join forces to leverage unforeseen synergies. Arranged by H2 together with Helsinki based incubator Vertical Acceleration, Samsung Nordics, TeliaSonera Healthcare.</td>
<td>2016-01-19</td>
</tr>
<tr>
<td>Focus UK: Entering the British market</td>
<td>Seminar arranged by the Stockholm based medical technology incubator Frogleap on entering the British market and working with the NHS. Among the participating organizations were UK Trade &amp; Investment and HealthToInnovation.</td>
<td>2016-01-20</td>
</tr>
<tr>
<td>EIT Health</td>
<td>EIT Health is a new branch of EIT in Sweden. This seminar related to the process of starting up the new EIT Health organization and challenges that lay ahead and grants that could be applied for.</td>
<td>2016-02-11</td>
</tr>
<tr>
<td>Patientsäkra appar</td>
<td>Stockholm Innovation (STING) and Stockholms Läns Landsting (SLL) Innovation presented challenges for mHealth in Sweden as well as stakeholders and regulations that are important to comply with when working with the healthcare system.</td>
<td>2016-02-29</td>
</tr>
</tbody>
</table>

Table 2: Seminars that were attended during the pre-study.

3.2.2. Theoretical review and framework development

By reading up on existing literature on internationalization and IMS theory, we were able to identify key areas to be considered in an IMS process. In this part of the research process we identified theories and tools for creating a preliminary framework for our IMS model. We accumulated dimensions through the literature review together with the pre-study which we were able to construct an initial multidimensional IMS model for the subsequent validation and development phase of our study. In general, we noticed that there is fairly little existing literature on IMS theory focusing purely on start-ups and digital health and that there therefore are few secondary empirical data to compare our findings with.

We used the search engines KTH Primo and Google Scholar to explore and find relevant articles from academia. A list of search words was created and used to generate an initial pool of articles in which various internationalization theories and previous studies on IMS were identified and back-tracked through references. Search words were, for example, ‘internationalization’, international market selection’, ‘start-ups’, ‘mHealth’, ‘mobile health’ and ‘screening’.

3.2.3. Model development and country evaluation

This section presents the techniques we used to develop our IMS model and evaluate countries. We choose to present these two stages of our research in the same section as they share several methodological means of collecting and evaluating data.
We revised, refined and validated the initial multidimensional IMS model iteratively by: (i) reviewing industry reports and agency papers; (ii) gathering qualitative data through interviews with industry experts and representatives from relevant organizations; (iii) compiling case studies with mHealth companies that have commercialized; and (iv) workshops with the client company AdhereBox. Qualitative interviews were chosen as the main tool of primary data collection. There is little academic research on the researched subject and thus exploratory questions were needed in order to focus our study, something that is supported by Collis and Hussey (2014). Semi-structured interviews were preferred, as we wanted to explore areas that were identified in the pre-study. Furthermore, we wanted the qualitative data obtained from the semi-structured interviews to be fairly comparable. This is also aligned with the research paradigm we have chosen for our study. In this process, different criteria as well as quantitatively and qualitatively measurable indicators were identified for each dimension of our IMS model. The two mHealth case studies that were compiled are presented in Chapter 5.1.

After having constructed and validated our model, we categorized each of its parameters under either the screening or identification stage. We first evaluated each EU member state in the screening stage, by collecting quantitative secondary data from publicly available databases. This approach was chosen so that mHealth start-ups conducting their own IMS screening would be able to replicate our methodology using few resources. After we had gathered the set of data for the screening indicators, we then summarized each country's individual score (for further details, see Chapter 3.2.3.3. Scoring). The screening score resulted in a second set of EU member states that could be qualified to enter the subsequent in-depth review of the remaining dimensions of our IMS model. In the identification stage of the IMS process, the set of countries were evaluated using qualitative data from different publications. In this paper we have chosen to present the identification assessment of one country.

### 3.2.3.1. Primary data

Primary data have been collected from several sources. In this chapter we present the sources of primary data used in our research. Ethical questions regarding primary data are presented in Chapter 3.6.

**Workshop with AdhereBox**

As successful IMS assessments tend to include product and firm-specific features, we carried out a workshop together with representatives from the client company in order to gain valuable insights and input to the dimensions we had identified in an initial version of our IMS model. Participants included were the Head of Business Development, Head of Technology and Head of Design.

The goal of the workshop was to discuss the parameters that we had identified so far, and list potential indicators for evaluating and measuring these dimensions. In addition, AdhereBox
was asked to separate “nice-to-have” parameters from “need-to-have” parameters, which we in our assessment stage of the project, would apply when evaluating the EU market. This was done in order to ensure that the IMS model was as aligned with company objectives and capabilities as possible. We stated the deliverables of the workshop prior to the workshop and gave a more thorough description of the high level dimensions that we had identified at the beginning of the session. We also went through the indicators that we currently had identified.

**Interviews**

Qualitative interviews are the most common approach for obtaining information for qualitative inquiry (Collis and Hussey, 2014). The interviews carried out for this study were semi-structured, starting with open questions. The interview lasted between 45-75 minutes. Semi-structured interviews combine the two interview formats *structured* and *unstructured* interviews. The structures serve different purposes. Structured interviews bear much similarity with standardized questionnaires, as questions are prepared in advance. In contrast, unstructured interviews are conducted without prepared questions from the interviewer. Semi-structured interviews are conducted with prepared subjects to talk around rather than questions, which enable the interviewer to “stumble” upon previously unknown areas for further analysis (Collis and Hussey, 2014). These open-ended questions are highly suitable for interpretivist research as they give a greater depth to the answers and allow analysis and interpretation by the researcher (ibid).

During the interview we had an interview-guide as a supportive tool to ensure that all relevant issues were covered. This is considered good practice and recommended by researchers (Hill et al., 1997). Most interviews were held face-to-face, a few being conducted through Skype. Some of the interviews were recorded on tape with permission from the interviewees and subsequently transcribed. The reason why we did not record all interviews is because we prefer to take notes during the interview, in order to keep track of topics throughout the interview as well as avoid technical issues. The interviews that were recorded were recorded if notes could not be taken in parallel.

Before initiating an interview, the purpose and research question of our study was presented. Upon completion of analyzing the interviews, the insights and notes were sent to the respective interviewees for correction and commenting. Some telephone and email contact was used to clarify points from the interviews. In addition, some informal interviews with informants from relevant areas were also conducted in order to better cross check the findings.

Interviewees were approached in order to gain different insights and fill in gaps where information was currently unavailable or lacked certain informative aspects, which we needed in order to validate our choice of IMS dimensions, sub-dimensions and indicators from the theoretical review. The interview questions were categorized into the different dimensions
which we had uncovered in the preceding theoretical review as important aspects to consider in our initial\(^3\) IMS model; *country market potential, customer receptiveness, market readiness, existing competition and distribution channels*. Firms and start-ups within mHealth were interviewed (in total three – Brighter AB, Kiwok Nordics AB, Nordic AB and Natural Cycles Nordic AB) in order to gain insights from real internationalization and commercialization cases within mHealth and CMDs. Informal interviews were conducted with knowledgeable people working within digital technology innovation and with experience from working with start-ups within digital health or connected consumer products.

Besides the two interviews in the pre-study, the gathering of primary data resulted in 11 interviews where one included a workshop with the client company and two interviews formed the basis for two case studies: Scherwitzl (2016) and Björlin (2016), (see Chapter 5.1.). Our intention with these case studies is to provide the reader with an account of two mHealth firms’ journey towards internationalization and gain insights into the parameters the firms look at when assessing foreign markets. In the majority of cases, the interviewees were identified through referrals from people in the medical technology and digital health industry as well as innovation and entrepreneurship incubators and accelerators. These could in turn give us further recommendations of additional people to interview. The interviewees were selected on the basis of the relevance of their background as well as knowledge within internationalization and mHealth. In summary, primary qualitative data was collected from the following interviews (see table below).

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\(^3\) This was the initial outline of our IMS framework and changed over the course of the research. Therefore it does not match to the dimensions presented in later chapters.
# Conducted Interviews

<table>
<thead>
<tr>
<th>Empirical method</th>
<th>Purpose of interview</th>
<th>Interviewee / organization / position / date of interview</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Informal interview, face-to-face</td>
<td>To gain general overview insights of digital health phenomenon and consumer medical device startups</td>
<td>EIT Digital / Business Developer / Tobias Vahlne / 2016-02-03</td>
<td>Besides working at EIT Digital where he also is responsible for their sub-business Digital Health, Vahlne is an owner of two startups - one startup being in the IoT and consumer goods sector.</td>
</tr>
<tr>
<td>2. Informal interview, face-to-face</td>
<td>To gain general overview of digital health phenomenon and healthcare systems</td>
<td>EIT Digital / Assistant Manager / Karoline Beronius / 2016-02-22</td>
<td>Beronius has a background within IT, but is today engaged in digital health. Among other projects she has worked in an NGO aiming to digitalize healthcare in Uganda.</td>
</tr>
<tr>
<td>3. Semi-structured, face-to-face</td>
<td>To gain insight from mHealth firm in foreign market selection</td>
<td>Brighter AB / CEO &amp; COO / 2016-03-04</td>
<td>Brighter is a digital health firm launched in 2007 to develop a method that facilitates self-monitoring and self-treatment of diabetes.</td>
</tr>
<tr>
<td>4. Workshop, face-to-face</td>
<td>Workshop with AdhereBox (3 representatives)</td>
<td>AdhereBox / Head of Business Development, Head of Technology, Head of Design / 2016-03-04</td>
<td>-</td>
</tr>
<tr>
<td>5. Semi-structured, face-to-face</td>
<td>To gain insights into barriers of EU in regards to mHealth startups</td>
<td>FrogLeap / CEO Lars Iversen / 2016-03-21</td>
<td>Iversen has worked with business development and innovation as well a global strategy in large corporation. Is today CEO for a innovation lab for startups within digital health.</td>
</tr>
<tr>
<td>6. Semi-structured, face-to-face</td>
<td>To gain insight into internationalization from mHealth consumer medical device firm in foreign market selection</td>
<td>NaturalCycles / CEO &amp; Founder Raoul Scherwitzl / 2016-03-22</td>
<td>NaturalCycles has created an mHealth app that analyzes women body temperature to tell them whether or not they are ovulating. (More information in Chapter 5.1.1.)</td>
</tr>
<tr>
<td>7. Semi-structured, Skype</td>
<td>To gain insight into data protection laws in EU, health service structure &amp; delivery and procurement &amp; reimbursement models</td>
<td>Chino / Co-founder &amp; CEO Iovan Sterovic / 2016-03-22</td>
<td>Chino is a software &amp; technology startup that provides services and tools to solve security and compliance issues for mHealth firms. The service ensures compliance for data storage of medical data in the EU.</td>
</tr>
<tr>
<td>8. Semi-structured, Skype</td>
<td>To gain insights on Kiwok’s expansion in the Nordics. Kiwok has launched a portable EKG that connects to smartphones</td>
<td>Kiwok / CEO Anders Björnlin / 2016-03-23</td>
<td>Kiwok is a mHealth company that has developed a EKG platform for remote heart monitoring (Please find Case study in chapter 5.1.2.).</td>
</tr>
<tr>
<td>9. Semi-structured, Skype</td>
<td>To gain insights into internationalization and market selection of innovative firms seeking opportunities outside Sweden.</td>
<td>Acreo Swedish ICT / Innovation specialist Adam Edström / 2016-04-04</td>
<td>Edström has worked with internationalization in the last 4-5 years. He is currently a coach at Enterprise Europe Network which helps SMEs to “make most of business opportunities in the EU and beyond”.</td>
</tr>
<tr>
<td>10. Semi-structured, face-to-face</td>
<td>To gain insight into technological and regulatory aspects on mHealth as well as insights into how AdhereBox assesses countries.</td>
<td>Hotswap / Senior VP Oliver Trepte / 2016-04-06</td>
<td>Hotswap is an engineering consultancy specializing in life science technology and medical device development, where Trepte currently is Senior VP. Trepte has worked in medicine technology his whole career, and has experience from working with startups. Trepte has also been mentor in the product development phase of AdhereBox.</td>
</tr>
<tr>
<td>11. Semi-structured, face-to-face</td>
<td>To gain insights into the development of digital health in the EU</td>
<td>SICS Swedish ICT / Manager International Cooperation, Area eHealth Silas Olsson / 2016-04-13</td>
<td>Olsson has worked with integrating technology in healthcare for several years. Among other places, he has worked in Brussels at the EU Commission. Olsson has worked within healthcare his whole career, usually from a technical perspective towards developing and improving care. Today Olsson works with strategic EU-projects related to eHealth.</td>
</tr>
</tbody>
</table>

Table 3: Interviews that were conducted during the research to create and validate the IMS model.
3.2.3.2. Secondary data

Secondary data was used in both the screening and identification stages of our country evaluation. Our aim with these two IMS stages was to illustrate how our model could be used to assess the EU member states. As it is intended to be adapted to and used by mHealth start-ups, we wanted to use widely available secondary sources from the public domain, requiring low resources put in by the evaluating firm.

Using quantitative and qualitative approaches

In the gathering of secondary source information for different criteria in an IMS evaluation process, Denis and Papadopulos (1988) differentiate between two general types of approaches for international market selection, which they refer to as qualitative and quantitative approaches. The first involves a more rigorous and systematic gathering and analysis of qualitative information about one or a handful of potential country markets. The second is based on analyzing large amounts of secondary statistical data about many or all foreign markets. (Denis and Papadopulos, 1988) In our proposed IMS model we use both qualitative and quantitative approaches. We choose to focus more on quantitative measures in the screening stage and on qualitative data collection in the identification stage.

Screening

After creating and validating the final version of our IMS model and categorizing its different evaluation criteria into either the screening or identification stage, we performed a screening of the EU countries using statistics collected from Eurostat and Google Consumer Barometer. Below follows a presentation of these two sources.

In conclusion, complete sets of data for the screening of all EU member states were collected from Eurostat and Google Consumer Barometer (except for Cyprus, Luxembourg and Malta, that are regardless very small markets). We considered other sources (e.g. OECD Better Life Index and HFA-DB [WHO]) but few had data available for all of the countries that we are covering.

Eurostat

Eurostat is the statistical office of the European Union. Its mission is to be the leading provider of high quality statistics on Europe and to be the main provider of statistical information to institutions in the EU. Their databases are publicly available online (Eurostat, 2016a). Eurostat gathers complete sets of data for countries through different national institutions and organizations. As such, methodologies tend to differ from country to country. However, quality management of the data submitted to Eurostat follow the Quality Assurance Framework for the European Statistical System, which describes the conditions under which institutions and organizations should review and control data that are reported into Eurostat.

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4 Examples of method descriptions for collections can be found through these links: http://ec.europa.eu/eurostat/cache/metadata/en/demo_pop_esms.htm#quality_mgmnt1453902787596
(European Statistical System, 2012). In this sense, we deem Eurostat to be source with high credibility.

**Google Consumer Barometer**

The data from Google Consumer Barometer is composed of data from two sources: the Consumer Barometer Survey and Connected Consumer Study, both of which were administrated by TNS Infratest (Google Consumer Barometer, 2015). TNS Infratest is one of the world's largest research agencies (TNS Infratest, 2016).

The Consumer Barometer Survey was carried out January - March 2014 and January - March 2015 using online surveys and face-to-face interviews. It focused on population samples having at least one online device, purchased at least one item online and being at least aged 16 (18 for some countries). The sample size contained on minimum 3000 individuals for European countries, which were distributed by quotas on age, gender online activities, region and educational level. The survey was performed in the local language. The survey was carried out in small batches over the course of several weeks to ensure inclusion of less frequent online users. For further details on data collection, see Google Consumer Barometer’s methodology at Google Consumer Barometer (2015a). (Google Consumer Barometer, 2015)

The Connected Consumer Study was carried out during the same time period as the Consumer Barometer Survey through either telephone or face-to-face interviews. It targeted individuals that together could represent the characteristics of the nation’s digital literacy. These could be classified as both offline and online and were at least the age of 16 (18 or 20 in some countries). The sample size contained 1000 individuals from European countries and were selected randomly using random-digit dialing via telephone interviews. The interviews were held in the local language and were allocated 25 minutes each. For further details on the data collection methodology, see Google Consumer Barometer’s methodology at Google Consumer Barometer (2015a). (Google Consumer Barometer, 2015)

Overall, we believe that the data collected in the Google Consumer Barometer contain the required properties to represent the larger population. However, there is no indication of that this survey will be reproduced annually and therefore updated data may not be accessible for CMD start-ups to use in their screening.

**Identification**

The screening stage enabled us to produce a new set of countries that would enter the identification stage of our analysis. In the identification stage, qualitative data from other secondary sources such as reports and articles were analyzed.

In the identification stage we evaluated countries using several secondary sources, reviewing their credibility along with the data collection. As these are mainly qualitative, we refer to Chapter 6.2., which contains references to each cited source. Although we will not give a full
account of each source in this section, we chose to present the most recurring source of country information, namely The Health Systems in Transition (HiT) series.

The Health Systems in Transition (HiT) series consists of country-based reviews provided by the European Observatory on Health Systems and Policies (EOHSP, 2016). The Observatory is a partnership hosted by the World Health Organization (WHO) Regional Office for Europe including European governments, the European Commission, the World Bank and the London School of Economics and Political Science (LSEPS). The series provide detailed descriptions of different health systems and of reform and policy initiatives in progress or under development in the specific country. These reviews are produced by experts in the country in collaboration with the Observatory’s staff (EOHSP, 2016). These are based on templates in order to facilitate country comparisons (ibid).

3.2.3.3. Scoring

Screening stage

The screening stage of our IMS model includes 10 indicators, which we used to evaluate the EU countries on certain dimensions. In this stage the overall score of countries was derived from the different weights they had been given for each indicator. Each indicator \( i \) in the screening stage was assigned an individual weighting. The weightings were determined in a workshop with AdhereBox. Representatives from the firm were given the task to assign a weight to each indicator on a scale from 1 to 5 depending on the specific objectives, constraints and idiosyncratic characteristics of the company. After having set the indicator weights \( w_i \), an additional country weight \( w_c \) was assigned to each country depending on its performance relative to the other countries in the specific indicator. This was also done using a scale from 1 to 5, resulting in an overall score ranging from 1-25 for each country and each indicator. The relative country weightings within each indicator \( w_c \) were set up using thresholds for each score (see example in table below). The thresholds were decided in accordance with AdhereBox. The weighting procedure was set up using IF-statements in Microsoft Excel.

<table>
<thead>
<tr>
<th>Smartphone Penetration</th>
<th>Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>80%</td>
</tr>
<tr>
<td>4</td>
<td>70%</td>
</tr>
<tr>
<td>3</td>
<td>60%</td>
</tr>
<tr>
<td>2</td>
<td>50%</td>
</tr>
<tr>
<td>1</td>
<td>0%</td>
</tr>
</tbody>
</table>

Table 4: Thresholds for the ‘Smartphone penetration’ in countries.

---

5 http://www.euro.who.int/en/about-us/partners/observatory/about-us
In some sub-dimensions we had access to multiple indicators of similar properties. For instance, when assessing the performance of smartphones activities of countries, we chose to use two different indicators. In these instances a third percentage weighting \( w_p \), ranging from >0% to =<100%, was assigned to indicators that described a similar phenomenon. On the contrary, as population size age 10 - 65 was our only indicator of market size it was assigned a \( w_p \) of 1 (100%).

We conducted a sensitivity analysis where we adjusted the thresholds in order to see how a percentage change in each threshold would affect each country’s overall screening score. The goal with this exercise was to identify any substantial changes to the overall score and thus ranking of countries if the original thresholds were changed ±10% and ±20%.

The total overall screening score for each country \( c_s \) was calculated using following equation:

\[
\begin{align*}
    c_s &= \sum_{i=0}^{i=n} w_i \times w_c \times w_p_i \\
    w_i &\in [1,5] \\
    w_c &\in [1,5] \\
    w_p_i &\in (0,1) \\
    n &= \text{number of indicators that are evaluated}
\end{align*}
\]

To ensure that no sub-dimension was weighted too high or too low we analyzed the contribution of each indicator in the screening stage by comparing the maximum value of each sub-dimension. The maximum value was calculated by multiplying \( w_i \times w_p_i \).

The results of the screening stage, the sensitivity analysis and the contribution analysis are presented in Chapter 6.1.

### 3.3. Validity

Collis and Hussey (2014) define validity as how well a test measures what the researchers want to assess and how well the results reflect what is studied. There are several sources that can decrease validity; if, for instance, a sample or interview object is corrupt or inaccurate his or her validity decreases (Collis and Hussey, 2014).

Our interview objects were carefully selected and only those with relevant background and knowledge within internationalization and mHealth were interviewed. As such, we believe that validity of our primary data is high.

Conducting interpretive research based on interviews requires trust in that interviewees can provide a full account of their perspective and do not feel limited by confidentiality or lack of
anonymity. We have at a couple of instances noticed that some interviewees tended to not want to be quoted on certain subjects. These were usually prejudices or assumptions. In such circumstances we find it fairly natural that interviewees wish not to be quoted. In each interview we clarified the purpose of our research and asked if the interviewees wanted to be anonymous in any instance. Contrary to being met by reluctance, interviewees were often enthusiastic and comfortable in sharing their knowledge and experience. As such, we do not believe that this lack of anonymity has affected the accounts of interviewees.

We believe that the methods we have chosen in order to study IMS in the context of AdhereBox enable us to answer our research question. Over time, however, we believe that the study is subject to some change. Although there may exist mHealth start-ups and recently internationalized mHealth companies that can provide accounts of their IMS process, we believe that more case studies as well as other empirical data will exist on our research topic in the future. This was not available during the process of our research and consequently the majority of analysis and empirical data gathering had to be compiled by us. Nonetheless, such data and accounts are important sources to understand IMS.

To avoid low validity we have aimed to collect as much secondary statistics as possible from the same reliable source and not perform any major alteration to the data. However, one could argue that some of the indicators (presented in Chapter 5.) and quantitative secondary data (presented in Chapter 6.) do not sufficiently capture what we intend to measure. The validity of our study would increase if we conducted a survey in each country to collect empirical data that would better answer our main research question. However, this approach is very resource intensive and not aligned with the resourcefulness we try to adopt to make our IMS model applicable for CMD start-ups. The added advantage of validity does not outweigh the additional effort of collecting this data in our research.

3.4. Reliability

Reliability measures the repeatability of the research findings. We have aimed to explain the process of the research as thoroughly as possible to increase the replicability of our research, as supported by Collis and Hussey (2014). However, it should be noted that several interviewees that have contributed to our research are a result of attending seminars and networking to connect to relevant individuals that can contribute with important insights to our IMS model. Therefore, it adds complexity to the task of replicating our research. Reliability is very important in positivist studies but not as important in interpretivist studies as the results are up for interpretation by the researcher (Collis and Hussey, 2014). To increase reliability in an interpretivist paradigm, emphasis is put on protocols and procedures for data collection (ibid).

Another concept of reliability that should be discussed is that of time. As mHealth is a contemporary phenomenon that is developing in several countries simultaneously we believe
that, with time, performing the same study as conducted here, would result in other insights. Firstly, the interviewees are bound to be different, or if the same, have more knowledge in the field and perhaps different opinions. Secondly, several quantitatively measured indicators are time-dependent and will develop over time (e.g. smartphone penetration). Some of them are likely to develop in a different pace than others (e.g. amount of online purchases compared to Gross Domestic Product). Thus, we believe that several of the parameters evaluated in our research would give different results if they were to be evaluated in the future, given that sufficient time passed between the the studies.

3.5. Generalizability

We argue there are a couple of factors that would increase the generalizability of our study: (i) the set of interviewees could have consisted of more, and established, CMD start-ups from a larger variety of countries in the EU, in order to strengthen our findings of how CMD start-ups have evaluated EU countries; and (ii) start-ups, with different consumer-centered product offerings that influence the user of the product, stakeholders and technological infrastructure, could have been included. However, (ii) would add great complexity to our study as several conditions would be added that other CMD start-ups, using our model, are better suited to evaluate.

We acknowledge that the two case studies conducted in our research (presented in Chapter 5., as well as the analysis included in Chapter 6. together with primary data from other interviews do not ensure any statistical generalizability. However, this property is not as important in the interpretivist paradigm as in the positivist paradigm (Collis and Hussey, 2014; Blomkvist and Hallin, 2015). Instead, Blomkvist and Hallin (2015) present analytical generalizability in which conclusions from one case study can be applicable to other cases (Blomkvist and Hallin, 2015).

Statistical generalizability has not been the goal with our research. The result of our study does however possess generalizability in similar settings; although this study is adapted to fit the CMD start-up AdhereBox, aspects that are firm specific can be altered and adapted to other CMD start-ups. We suggest that these firm specific characteristics relate to the interrelationship between the start-up, the users of its product and other stakeholders as well as the technological systems that the product relies on.

3.6. Ethics

Throughout our study, we have considered several ethical issues. Blomkvist and Hallin (2015) stress the importance of complying with the Swedish Research Council’s principles of ethical research for the humanities and social sciences, an ethical code that apply to all researchers that study the social sciences (Blomkvist and Hallin, 2015). The code presents four areas that researchers need to be followed. These are (i) the information requirement; (ii) the consent
requirement; (iii) the confidentiality requirement; and (iv) the Good Use requirement (Blomkvist and Hallin, 2015).

i. **Information requirement:** we have informed the interviewees what the purpose of our study is and that we are conducting it with the start-up AdhereBox in mind.

ii. **Consent requirement:** all interviewees were informed that they were being studied and for what purpose.

iii. **Confidentiality requirement:** all information gathered through interviews was carefully handled and we collected consent for how it could be used before using it in any way. Furthermore, all interviewees could choose to be anonymous and opinions were censored if requested by the interviewee.

iv. **The Good Use requirement:** all interviewees were informed that the information collected, through our research, would be used to develop an IMS model for CMD start-ups.

Furthermore, we have considered the way we quote interviewees and previous research as well as separating our conclusions from summaries of previous research and other sources of data. Blomkvist and Hallin (2015) stress that both these practices are important in order to avoid plagiarism.

Bell and Bryman (2010) present several areas that align with the previously mentioned code (Bell and Bryman, 2010; cited in Blomkvist and Hallin, 2015). These include confidentiality, anonymity and affiliation to organizations, such as the client company AdhereBox.

To ensure that these principles were followed, we included requests for consent and confidentiality in our interview guide. We also iterated our notes from the interviews with the respective interviewee, and provided each interviewee a copy of the report draft in order for them to revise their statements. In this version of the report, all other interviewees were censored.
4. Theoretical review

In this chapter we introduce the reader to existing theories within internationalization and international market selection (IMS). Chapter 4.1, provides the reader with an overview of internationalization (and related) theory. Chapter 4.2, introduces international market selection (IMS) as a field within internationalization theory. The chapter concludes with presenting market selection criteria that we have identified as relevant for our study and will relate to our research topic in our empirical findings.

The concept of assessing and selecting new markets has been widely studied in previous literature. Key frameworks and theories that cover different perspectives on international market selection (IMS) theory will in the preceding section be reviewed. What we have observed in our theoretical review is that existing literature fails to, in a coherent way, capture and explain the spectra of dimensions that should be taken into consideration when evaluating international markets for mHealth consumer medical device start-ups.

Nonetheless there is existing literature that provides frameworks and theories concerning what a firm should focus on when evaluating and identifying attractive markets for expansion. These have been adopted in, and developed from, business practice, industry analysis, and international marketing. Such theories and models will be presented in this chapter. These will later on, in our report, be complemented with findings from interviews and reports focused on the mHealth phenomenon, as well as the EU health care market, and will create the foundation upon which we build our IMS model.

4.1. Internationalization theory

Internationalization theory portrays the process of firms expanding their business to foreign markets (Andersen, Ahmad and Chan, 2014). We believe that it is relevant to study the findings of previous researchers in internationalization theory in order to better understand the logic behind it, prior to studying IMS theory.

Academics differ in the way they categorize internationalization theory. Barbosa, Fuller and Ferreira (2005) categorize them as; (i) the economy-based (Eclectic Paradigm, Transaction-Cost Approach and Internalization Theory and (ii) the behavioral-based (stage based models such as the Uppsala Model and the Innovation Model). The economy-based theories explain modes of entry and assume that these are based on rationality and the pursuit of optimal solutions given the internal and external factors of the firm (Barbosa, Fuller and Ferreira, 2005). In behavioral-based theories researchers describe the internationalization of firms as a successive progress from psychically similar to more dissimilar markets is at focus (ibid).
Ahokangas (1998; cited in Ruzzier, Hisrich, and Antoncic, 2006), on the other hand, presents the internationalization theories divided into three approaches: traditional approaches, network perspectives and resource-based perspectives. The traditional approaches can further be subcategorized as eclectic decision making models and learning and innovation adoption models. Many of the models and theories developed in this category are based on the Uppsala School model (Ahokangas, 1998; cited in Ruzzier, Hisrich, and Antoncic, 2006).

Resource-based approaches focus on studying how the resources of a firm (often multinationals) can lead to competitive advantage (Ahokangas, 1998; cited in Ruzzier, Hisrich, and Antoncic, 2006). The Uppsala School model describes a firm’s internationalization as an incremental process divided into stages where established relationships are of importance (Johanson and Vahlne, 1977, 1990).

Early explanations of internationalization theory employ the interrelated concepts of psychic distance and experiential learning (Johanson and Vahlne, 1977). In the Uppsala school model, a firm’s choice of market to enter follows a sequential entry pattern into successive culturally-close markets where companies select foreign markets that exhibit similar economic, cultural, and political systems (Johanson and Wiedersheim-Paul, 1975; Johanson and Vahlne, 1977). This can also for example include small differences in language, culture, level of education, legal and business culture (Blomstermo, Johansson and Pahlberg, 2002). Psychic distance means that the firm starts its internationalization process by targeting the foreign country that it understands best, and thereafter continuing by applying itself in concentric circles to markets of greater and greater psychic distance (Moen, Gavlen and Endresen, 2004).

Andersen, Ahmad and Chan (2014) note, however, that many of these theories may not be able to explain the international behavior of firms today, as business environments are rapidly changing today with new markets and industries more frequently emerging. However, we believe that the network-based perspective of internationalization offers several insights that can be used to understand the internationalization behavior of start-ups. Therefore this aspect of internationalization is further presented in the following section. In addition, we will also present a relatively modern aspect of internationalization theory, namely that of “born globals” - a name that has been given to firms that internationalize rapidly by e.g. developing and leveraging international networks (Antoldi et al., 2011).

4.1.1. Network theory

In the network perspective of internationalization, firms are engaged in networks of relationships with a number of different actors (competitors, suppliers, customers, government and others). These relationships are seen as the firm’s most important assets and source of foreign market knowledge and opportunities (Axelsson and Johanson, 1992).

Central in the network theory perspectives (which partly grew out of the Uppsala School Model) is the influential power of relationships when it comes to the strategic decisions of an internationalizing company, especially smaller ventures. In these studies researchers find that
smaller firms do not commonly follow the stage process that is described in the Uppsala School Model (Ruzzier, Hisrich, and Antoncic, 2006).

In their research Barbosa, Fuller and Ferreira (2005) study the internationalization of small- and medium-sized enterprises (SMEs) and observe these smaller sized firms tend to enter markets that are known to partners in their network. As a company internationalizes, the relationships become stronger and new ones are created; as such, international knowledge, resources and access to markets as well as to other networks are acquired through relationships (Johanson and Vahlne, 1990).

A firm’s network is said to consist of all the actors that contribute to the end product (Gadde and Håkansson, 2001). These can be e.g. agents, distributors, licensees, and foreign subsidiaries (Moen, Gavlen and Endresen, 2004). Firms can benefit from the social, technical, and commercial resources of their networks, resources that would take individual companies years to accumulate on their own (Baum et al., 2000 cited in Laanti, Gabrielson and Gabrielson, 2007). In today’s increasingly sophisticated but also volatile and competitive environment – successful internationalization may require the firm to leverage the skills and resources of other organizations (Moen, Gavlen and Endresen, 2004). In this sense, networks are seen to help small firms with limited resources to overcome many barriers associated with small firms (Laanti, Gabrielson and Gabrielson, 2007).

4.1.2. Born globals

Over time, the conditions for internationalization change and thus the ways that it is viewed by researchers. New technological advances and globalization have in many ways come to influence both market selection and the choice of entry form of firms seeking to expand their business. Falling trade barriers, deregulation and privatization, maturity in domestic markets, faster information flows, improved communication and transportation networks, social developments and globalizing competitors are just some examples of influential factors that have had a fundamental impact on the internationalization strategies of most firms in the world (Laanti, Gabrielsson and Gabrielson, 2007). Technology, like the Internet, has made the notion of proximity less influential in the choice of international markets. This makes the notion of psychic distance less relevant as new communication technology makes global markets more homogenous (Moen, Gavlen and Endresen, 2004).

Leveraging on these conditions, many new ventures are today able to internationalize very rapidly after inception. There have been several studies since the millennia that have focused on this new type of phenomenon (Moen, Gavlen and Endresen, 2004). Researchers argue that this “new” type of internationalization behavior is not entirely consistent with the process described by traditional models e.g. expansion to adjacent markets by the Uppsala School model (Moen, Gavlen and Endresen, 2004).
Researchers have described this phenomenon using different names. For instance, Lindqvist (1991) calls these types of firms infant multinationals; Oviatt and McDougall (1994) classify them as international new ventures (INV), whereas Rennie (1993) proposes the name born globals (Moen, Gavlen and Endresen, 2004). Oviatt and McDougall (1994, p. 49) define born globals as companies that “from inception, seek to derive significant competitive advantage from the use of the resources and sales of outputs to multiple countries”.

In their findings from analyzing the entry forms and market selection of born globals, Moen, Gavlen and Endresen (2004) suggest that a firm’s network relationships can be a determining factor with regard to which markets they decide to enter. They suggest that a firm’s selection of market (as well as entry mode) highly depends on available networks (Moen, Gavlen and Endresen, 2004). Sakarya, Eckman and Hyllegard (2007) add that the presence and characteristics of a network environment is suggested to be influential in the decision as to which markets the firm will enter and the organizational structure for market entry.

### 4.1.3. Clusters

Given the information landscape that exists today, it is possible for firms to source funds, information, technology and goods quickly and from a distance (Porter, 1998). Although globalization has increased accessibility, one cannot necessarily undermine the competitive strength of geographical proximity and location (ibid). Instead, it is common to find concentrations of industries in geographical regions; e.g. the tech industry in Silicon Valley or the hardware industry in Yongkang City in China. These critical masses of adjacent industries are called clusters (Porter, 1998). Globalization and outsourcing only diminishes the advantage of local resources and low input costs of certain regions (ibid). What instead endures in clusters is the advantage of knowledge, relationships, motivation - things that a distant rival cannot easily match (ibid). These are capabilities that can be used to increase productivity with input through innovation (ibid).

### 4.2. International market selection (IMS)

When a company seeks to expand its business to foreign markets, a number of strategic decisions must be evaluated (Górecka and Szalucka, 2013). The company must define what type of product or service it wants to market. Furthermore, it needs to decide where (to which country markets) it wants to enter with its offering. Also, the company has to decide the timing of entry (when) as well as entry mode (how) (Górecka and Szalucka, 2013). In our study we seek to determine the “where” in this decision making process. That is, how to assess and select new geographical markets. This is what researchers refer to as international market selection (IMS), which is a field within the broader area of internationalization theory.

Denis and Papadopoulos (1988) define IMS as the development of efficient and effective methods for selecting a foreign target market(s). Identifying promising international markets
worth entering in an IMS process is a critical task for companies wanting to ensure the future success of their business (Górecka and Szalucka, 2013; Rahman, 2003).

Nonetheless, the assessment of foreign countries in an IMS is an often complex and difficult decision requiring the company to analyze a wide spectrum of factors. However, there are few generic and holistic models or frameworks identified in literature to assess and identify countries in an IMS (Russow and Okoroafo, 1996). Furthermore, the parameters which should be evaluated when assessing foreign markets are most often based on the respective author’s perception of what criteria would be most suitable in a given situation (ibid).

4.2.1. The processes and methods of IMS

Existing literature is fairly consistent when it comes to describing the process of evaluating foreign markets (Rahman, 2003). In evaluating the viability of a market, IMS is often described as a sequential process consisting of several strategic steps and there are varying suggestions when it comes to the number and structure of these (Gould, 2002).

For instance, Toyne and Walters (1993) suggest a four-stage approach that ends with a short list of exploitable market opportunities. Gould (2002) suggests an IMS methodology that selects highly attractive markets comprising of two steps; the first step being screening and producing a short list of countries and the second one being an in-depth assessment of the short-list of countries.

In general, most models illustrating IMS view the assessment of global opportunities in foreign markets as a three-stage process composed of screening (or preliminary screening), identification (or in-depth screening) and final selection (Koch, 2001b; Kumar, Stam, and Joachimsthaler, 1994; Root, 1994; Cavusgil, 1985).

![Figure 2: Visualization of a three-stage IMS process.](image)

The initial stage of preliminary screening identifies the prospective target markets for subsequent in-depth analysis. It is a process for identifying potential markets that are prime candidates for the subsequent in-depth assessment (Douglas and Craig, 1983; Root, 1994).
This stage often uses more macro-level indicators in order to eliminate countries that do not meet certain criteria (Rahman, 2003). Macro level indicators can for instance be economic statistics, political environment, socio-cultural factors and geographic features (ibid). The screening stage minimizes the risk of allocating too much time investigating countries that offer low prospects (Gorecka and Szalucka, 2013). Gorecka and Szalucka (2013) proposes the usage of widely available quantitative data in order to time-efficiently eliminate a large number of countries from the preceding in-depth analysis. The objective of screening is thus “to identify potential markets quickly and inexpensively without regard to method of entry.” (Russow, Lloyd and Solocha, 1993, cited in Gould, 2002, p. 67)

In the subsequent identification stage of the IMS process, researchers suggest that the company should focus more on industry and firm-specific information in order to be able to highlight the country market which best matches the company and its field. During this stage, the attractiveness of the specific industry is evaluated. This stage focuses more on product-specific variables and the dynamics of the industry of the country, or market, in consideration. In the identification state, industry specific information on market factors and competition is used to cull and name potential countries for market entry (Rahman, 2003). This assessment enables one to create a short-list of high-market-potential countries for the final selection stage (Górecka and Szalucka, 2013).

In the final stage, firm-specific information, e.g. profitability and product adaption to the firm’s existing portfolio, form the basis of the decision (Rahman, 2003).

**4.2.2. Evaluation criteria in IMS**

The basic principle of IMS methods is usually the evaluation of markets based on a chosen set of selection criteria. These allow for the ranking of the countries and help to facilitate the selection decision of identifying relevant markets (Chadraba, 1995). In a systematic approach to IMS, the decision-making process of selecting target countries is structured and formalized where relevant criteria is identified and evaluated amongst the alternative countries (Andersen and Buvik, 2002).

There is no agreement among scholars on what factors an IMS assessment of foreign markets should consider or how they should be measured. The lists of suggested criteria are often based on the respective author’s perception of what criteria would be most suitable in a given situation (Russow and Okoroafo, 1996).

We will in the sections that follow introduce factors from previous research that we identify as relevant to our specialized IMS approach. In the subsequent chapter we will argue how they are relevant and applicable to achieve the intentions of our study.
4.2.2.1. Macro environment factors

Despite there not being a universal approach to IMS, there is a dominating interest in the external environment’s influence on the selection of overseas markets (Koch, 2001a). Macro environment factors are surrounding forces that indirectly influence the business of a firm (Gould, 2002). Several authors use aspects of the external macro-marketing environment as evaluation criteria in IMS (Russow and Okoroafo, 1996; Gould, 2002). For instance, Gould (2002) identifies macro environmental matters as influential aspects of a country’s market attractiveness. Gould (2002) identifies economic, cultural, political and legal influences as variables that affect all types of products, whilst technology is a variable that only may affect some. In determining market attractiveness Russow and Okoroafo, (1996) recognize environmental aspects such as trade barriers, the existence of investment incentives, political stability and culture as factors, which may have an impact on a company’s market entry decision.

Internet and globalization has, as previously described, had a large impact on IMS as it has made market knowledge easily transferable, making some environmental aspects less important (Moen, Gavlen and Endresen, 2004). However, geographical distance and cultural factors may still have an important impact on business operations outside the domestic market. For instance, Moen, Gavlen and Endresen (2004) found that many of the small Norwegian firms that they studied chose to go to English speaking countries after having expanded to Scandinavian countries first. This is aligned with findings and observations that the Uppsala School model is based on.

However, some researchers suggest that these macro approaches to IMS often fail to include product specificity in their indicators as they tend to rely too much on aggregate, general country indicators rather than on specific market indicators (Sakarya, Eckman and Hyllegard, 2007). Consequently, models have been developed that contain more industry- and product-specific parameters (Douglas et al., 1982; Root, 1994; Whitelock and Jobber, 2004; Sakarya, Eckman and Hyllegard, 2007; Kumar, Stam, and Joachimsthaler, 1994). This suggests that an IMS model should consider parameters that not only assess the external company environment but also evaluates industry and product-specific factors.

We argue that an analysis of certain macro environmental aspects is suitable in our IMS model. As the environmental factors that need to be covered in an IMS depends on the type of industry and market of analysis, we would need to identify these external forces in our gathering of empirical data. However, in accordance with researchers e.g. Sakarya, Eckman and Hyllegard (2007), Root (1994), etc. an IMS also needs to cover other aspects when evaluating the foreign markets. In regards to environmental aspect of technology, the level may vary between countries considered in IMS where the technology of the offering is central. As technological innovation is key in mHealth, this suggests that this parameter would be an important aspect to consider in our evaluation model.
4.2.2.2. Market size

Existing literature on international market selection are fairly aligned when it comes to using market size and the level of economic development when assessing market attractiveness (Cavusgil, 1985; Connolly, 1987; Young et al., 1989; Ball and McCulloch, 1993; Papadopoulos and Jansen, 1994; Daniels and Radebaugh, 1998; Rahman, 2001; cited in Rahman, 2003). Market attractiveness is often determined by market potential and market capacity, which is measured as the total real or potential demand in the market (Chadraba, 1995). Several academics have cited this as a common criterion used in market selection (Hodgson and Uyterhoeven, 1962; Johansson, 1997; Moyer, 1968; Root, 1994; cited in Koch, 2001b).

Root (1994) separates market size into two components. One being more product-specific (direct market size) and the second component being a more general macro-economic measure (indirect market size). Rahman (2003) finds, from observing successful IMS cases, that businesses tend to evaluate market attractiveness not on the basis of the market’s absolute size, but often in relation to the firm’s own capabilities. They assess the target country’s market size and growth attractiveness by looking on a set of macro-variables and indicators. The most commonly occurring being GNP, growth rate, inflation rate, population size, size of middle class, etc. In addition the firms look a number of product significant indicators, as well as cultural variable and traditional links with the product company.

Gould (2002) writes that segment demand is the most fundamental of all data when assessing a market, as an organization should not be active in a market which has less than some minimum threshold level of demand that justifies overcoming the costs of market entry (Gould, 2002). However, low demand should not exclude a market if other highly attractive features, say high profitability, compensate it. As such, Gould (2002) also advocates the use of both economic development and volume, in terms of users, when assessing countries an IMS evaluation process.

4.2.2.3. Market readiness

A similar but yet different dimension as customer receptiveness is that relating to market’s readiness. This parameter incorporates aspects surrounding the critical factors that must be in place in the specific market in order for the internationalizing business to function. Rahman (2003) identifies a country’s structural attractiveness as a critical dimension in an IMS evaluation. A country market might have desirable size and growth, but still lack the necessary infrastructural compatibility required for successful market entry. Rahman (2003) observes that once the attractiveness of a foreign market’s size is established, firms tend to try to evaluate its structural attractiveness at the second stage of the IMS process. Indicators or variables that explain the factor of structural compatibility are e.g. business structure compatibility and distribution system compatibility (Rahman, 2003).
In addition to the observations of Rahman (2003), Porter (1990) suggests that a nation’s competitiveness and readiness depends on the capacity of its industry to innovate and upgrade. In regard to mHealth, we suggest that market readiness would incorporate an assessment of the health care system’s readiness for such innovation and solutions.

4.2.2.4. Customer receptiveness

Another potentially important, but not as discussed, factor to evaluate when it comes to assessing market potential is customer receptiveness. This aspect covers the consumers’ attitudes toward new goods and services (Sakarya, Eckman and Hyllegard, 2007). Sakarya, Eckman and Hyllegard (2007) argue that customer receptiveness has important implications that need to be considered when assessing foreign markets. This includes customers’ receptiveness to foreign or new products, businesses for a specific industry as well as its country of origin.

Sakarya, Eckman and Hyllegard (2007) use the criteria customer receptiveness in their assessment of emerging markets as international expansion opportunities. They argue that this parameter accounts for the dynamism and future potential of the market (Sakarya, Eckman and Hyllegard, 2007). Emerging markets can be described as markets with high growth expectations or a market in transition (Mody, 2004). The mHealth industry shares many of these characteristics, and digital health is seen as an emerging field and market in several industry reports (Monitor Deloitte, 2015; European Commission, 2014). As mHealth technology requires certain acquaintance with mobile technology and digital skills amongst its users, assessing customer receptiveness in regards to mHealth CMDs would preferably need to include measures of digital literacy amongst the country’s consumers.

4.2.3. Indicators and measurement variables

After having identified the criteria to be evaluated when selecting appropriate foreign markets, a later issue relates to the choice of indicators and variables used to measure the applied criteria and if the parameters should be assessed quantitatively and qualitatively (Sakarya, Eckman and Hyllegard, 2007). Again, theory offers a large array of macro-indicators that help assess quantitatively measurable variables. As in the case of choosing the evaluation criteria, the author’s perception is a key influence in defining the list of indicators used in a market assessment (Sakarya, Eckman and Hyllegard, 2007; Papadopoulos et al., 2002).

Proxy variables are often used as indicators. These are indicators that are not themselves directly relevant but that serves in place of unobservable or immeasurable variables. In order to use proxy variables as indicators in our evaluation model, they must have close correlation with the variable of interest (Upton and Cook, 2002). Proxy variables are often used in IMS evaluation models. For instance, market size is usually not directly measured but assumes that aggregated, general country indicators will reflect it (Sakarya, Eckman and Hyllegard, 2007).
Proxy variables for this criterion may include population, economic indicators as well as product significant indicators (Rahman, 2003)

4.2.4. Scoring

Another issue that arises and should be addressed in an IMS evaluation process is that concerning the question of scoring and rating the countries in each parameter (Gorecka and Szalucka, 2013). A recommended method for evaluating and selecting potential markets in the initial stages of the IMS process is *ranking*.

A critical issue when ranking countries in the evaluation process is the question of weighting the different parameters. There is no general description of how to assign weights to parameters to reflect their relative importance (Russow and Okoroafo, 1996; Papadopoulos et al., 2002). Some studies recommend an approach that weighs all parameters equally; others state that some parameters may be more important than others. In accordance with AdhereBox - we suggest that the firm assign weights to the respective indicator - ranking their degree of importance. These weightings can then be applied to the IMS model in order to be able to filter countries that meet firm requirements in the screening stage.

4.3. Conclusion

There is a clear difference between the internationalization theory - explaining how firms historically have expanded - and international market selection - explaining the process of *market evaluation*. Nonetheless, we believe that network theory is relevant, as many start-ups tend to have limited capabilities and resources.

Actors in networks, such as distributors and institutions, play an important role in the internationalization process of smaller mHealth companies. As such, we believe that theories from the network perspective of IMS are also relevant in the internationalization process of mHealth start-ups. The presence of preferable clusters may also be an influential factor in the IMS of an mHealth start-up as these are said to enable firms to distribution efficiency and enhancing a firm’s potential for successful internationalization (Porter, 1990, 1998; cited in Sakarya, Eckman and Hyllegard, 2007)

As brought up in theory on internationalization and networks (e.g. by Moen, Gavlen and Endresen, 2004; Laanti, Gabrielsson and Gabrielsson, 2007), networks can help small firms with limited resources to overcome barriers of international expansion. This suggests that attractive markets would require the existence and characteristics of network actors such as distributors when selecting countries to expand to for mHealth start-ups. This emphasizes the impact of network relationships on the internationalization of small firms, which would suggest that a network perspective ought to be included in an IMS analysis for mHealth start-ups.
We believe that the behavior of born globals resonate with many of the entrepreneurial mHealth firms today, which thanks to the different advancements of society are able to rapidly expand their business to foreign markets if they so wish. However, existing literature on internationalization of born globals tend to focus on describing the processes and patterns of internationalization of small entrepreneurial forms with regards to networks, rather than suggesting complementary dimensions and criteria that should be regarded and evaluated when assessing foreign markets (e.g. Zahra, Ireland and Hitt, 2000; Moen, Gavlen and Endresen, 2004; Laanti, Gabrielsson and Gabrielsson, 2007; Sharma and Blomstermo, 2003).

4.3.1. Going forward

We position our study in the two initial stages of a three-stage IMS process, namely the screening and identification stages. As mentioned in Chapter 1.10 Delimitation., we have chosen to evaluate the EU market due to its lower barriers in terms of trade, regulations and geographic proximity as well as the perceived political, social and cultural similarities which the Union offers. The set of countries that are deemed attractive after the initial screening of the EU will collectively comprise the set on which the identification analysis will be conducted. We will begin our assessment with an initial screening comprising of statistics from secondary sources that are readily accessible through various trustworthy databases. This is a commonly used mean by start-ups of assessing countries as it is less resource demanding (Rahman, 2003; Russow, Lloyd and Solocha, 1993 p. 67). This stage allows one to filter a limited list of countries for the more in-depth identification stage. As proposed by Gould (2002), this assessment stage will contain indicators that require a more rigorous collection of data.

![Diagram](image)

Figure 3: Visualization of the IMS process we will conduct in our research.

Keeping in mind important insights from the literature review, we move forward to developing our IMS model for mHealth CMD start-ups, with the aid of interviews and secondary sources in Chapter 5.
5. Development and validation of the IMS model

This chapter presents empirical findings from our interviews supported by theories obtained from the theoretical review. These are complemented with insights from qualitative secondary sources from the public domain. Together, these findings form the basis of our IMS model. By interviewing representatives from CMD companies within mHealth, experts in the digital health industry and conducting workshops with AdhereBox we are able to identify, develop and validate critical factors that should be assessed when examining foreign markets in regards to mHealth. These parameters are categorized into two main dimensions that we have chosen to call Stakeholders and Barriers and Enablers. We will in the subsequent chapter of our report demonstrate how these parameters can be assessed. In this section of the report we aim to answer our main research question, namely:

RQ1: What parameters should be assessed in an international market selection model for mHealth consumer medical device (CMD) start-ups, in order to identify attractive countries in the EU to launch their products in?

5.1. Case studies

We begin this chapter by presenting findings from the two case studies of NaturalCycles and Kiwok. The case studies are based on interviews with the CEO of the respective company. With our case studies we want to provide the reader with an account of two mHealth firms’ journey towards internationalization and insights from these. Although both interviews were conducted using similar semi-structured questions, they are presented differently as to portray their individual journey.

5.1.1. NaturalCycles

The case study of NaturalCycles Nordic AB (hereafter NaturalCycles) is based on our interview with the company CEO and co-founder Raoul Scherwitzl (hereafter Scherwitzl), and was held in person at their headquarter in Stockholm. (Scherwitzl, 2016)
NaturalCycles is a consumer-oriented mHealth company that has created a mobile application that can inform women where in the monthly biological cycle she is. Over the period of a menstrual cycle a woman experiences slight changes in her body temperature. The analytical algorithm of the app can analyze the temperature fluctuations that are recorded by the user each morning. Based on this, the user is informed whether or not she is ovulating and if there is an increased chance of pregnancy as a result of intercourse. As such, NaturalCycles markets its product as a hormone free birth control. In addition, NaturalCycles sells a sensitive thermometer that is used to measure body temperature each morning. However, other thermometers can also be used for measuring temperature, which is manually entered into the mobile application. NaturalCycles’ mHealth product is currently used by 90,000 women in 161 countries (however, it is not sold directly to all of these countries). (NaturalCycles, 2016)

First expansion

NaturalCycles launched in Switzerland, 2013, where it received its first round of financing. At first, the firm focused its efforts on testing and commercializing in one single country in order to reduce complexity. When the managing team of NaturalCycles began looking for new markets to test their product, later the same year, they assessed factors related to the digital evolution of the population and the market for contraceptives. Scherwitzl explains that they looked at indicators of digitalization level such as smartphone coverage and credit card usage. These measurement variables were chosen as they are essential parts of the product offering (smartphone to log data and credit cards to purchase the application and pay the monthly subscription fee). They also looked at more industry-related parameters, such as the market size for contraceptive pills and consumer related issues such as hormonal problems caused by contraceptives. They observed that markets where hormonal problems were common tended to be more receptive to NaturalCycles’ solution. At this point in time, assessing the market size of the target population was not as important as it is today. The analysis resulted in the conclusion that Sweden was the second most promising country after Japan. Due to factors such as personal connections and networks, geographical proximity and prior market knowledge, Sweden was selected as the second market to introduce the product to after Switzerland.

Second expansion

Sweden is a fairly small market where NaturalCycles quickly gained a 4-5% share of the market for birth controls. As growing the market share even further was considered difficult, Scherwitzl wanted to perform a new due diligence on countries in order to identify other potential markets to expand to. Learning from previous market selection analyzes, NaturalCycles was now looking for larger markets in terms of users, in order to gain economies of scale. Scherwitzl tells us that it is important to keep investors in mind at this expansion phase, and as they tend to have an exit agenda a large market size is critical in order to maximize return on investment.
As such, the IMS analysis behind the second expansion incorporated a more systematic approach when assessing countries. Also, assessing additional factors, such as market size became more relevant. They also assessed parameters such as logistics (for selling the thermometer), regulatory barriers, factors related to product development and the organizational impact of expanding to a new country. Again Scherwitzl, looked at the digital evolution of the country (in terms of smartphone coverage and credit card payments - two requirements for the application to function) and the contraceptive market. Each parameter was measured and gathered in an excel spreadsheet and was weighted 1-5 according to attractiveness. Data was collected for each country - the most promising market being scored the highest.

In our interview, Scherwitzl discusses two countries that were evaluated in their second international market selection analysis, namely Brazil and Germany.

He tells us that, despite Brazil’s large population, regulations for mHealth have not caught up with the developments in the field. Also, expanding to the country would cause logistical complications and prove to be difficult, as NaturalCycles would need to have a local subsidiary in the country. In addition, it would be difficult finding and hiring suitable people. Therefore Brazil scored low in the organizational fit category.

Germany also has a large population compared to many other European countries. Being a member of the EU means that entering it would be fairly easy due to the lower trade barriers as NaturalCycles’ medical device risk assessment and CE-marking was in place. However, German consumers proved to be a lot more disciplined in taking contraceptive pills than Swedes, which would make them less inclined to change birth control solely based on comfort. Also, Germans tend to be more concerned with privacy issues related to data security and the product would require certain changes to its design (due to language differences) if it was to be launched in Germany. Therefore Germany (as a country to expand to) was scored low. When prompted, Scherwitzl said that if NaturalCycles was to enter the German market, it would probably do so by distributing through pharmacies rather than through its own e-commerce channels. He added that this would probably be necessary as it would increase NaturalCycles’ credibility - something that is valued highly in Germany. Scherwitzl believes that consumers of Germany are not as digitally mature as other countries and selling their product online would probably not be feasible. However, distribution using intermediaries, such as pharmacies, decreases the profit margin that can be gained by NaturalCycles compared to directly selling to the end-consumer.

**Future expansion initiatives**

Scherwitzl concludes that NaturalCycles’ product is fairly easy to test in foreign markets as the application can be downloaded through online app stores and because users can use other
thermometers for daily monitoring. NaturalCycles has for instance tested the product in the UK where it was met by certain skepticism. In the UK, NaturalCycles conducted a market survey and received certain publicity and exposure. Scherwitzl recommends start-ups to perform smaller pilots in the country that they are interested in, prior to expansion. “You have to be there to get feedback on your product and the people’s reactions to your offering” says Scherwitzl, and this is something that they plan on continuing doing in the future.

**Difficulties in the public health care system**

NaturalCycles is a consumer-oriented company where the consumer is the one financing the purchase of the application. NaturalCycles has considered entering public health care system. However, there are certain challenges to this. Contraceptives such as pills are subsidized in several countries (e.g. Sweden) and condoms are often free in many EU countries (e.g. UK).

NaturalCycles has performed a number of clinical studies but not sufficient enough to enter the process of becoming reimbursed by the health care system. As such, Natural Cycles has chosen to focus on selling directly to the end-consumers.

Scherwitzl explains to us that publicly financed health care systems, or places where medication is largely subsidized or for free, affects the mentality of people because they tend to be less willing to pay for your product. As such, you need to adapt your marketing strategy to each individual country.

In the end of our interview, Scherwitzl (2016) concludes with stressing the importance of conducting a field study and testing the potential country before deciding upon a final market selection.

"**You need to be present in the country in order to understand the market. It doesn’t work from behind the desk.**"

- Raoul Scherwitzl
5.1.2. Kiwok

The case study of Kiwok Nordics AB (hereafter Kiwok) is based on our interview with Anders Björlin (hereafter Björlin), the CEO of Kiwok, and was conducted over Skype.

*Kiwok is a Swedish mHealth company that was founded in 2003 and began developing the BodyKom EKG - a mobile heart monitoring platform - in 2004. Over the years, Kiwok has won several awards for its innovation, which is currently sold to the Swedish health care system. The BodyKom EKG, is used as a 24h EKG by patients concerned about the health of their heart. In Sweden you cannot get a 24h EKG without having to be admitted to a hospital. Historically, the BodyKom EKG has been sold exclusively to practitioners and not to private consumers. In the future, Kiwok aims to sell its product exclusively to markets where it is possible to connect the health care system and the consumer. In other words, the patient should be able to bring personally collected data from a BodyKom EKG directly to a doctor or health center for analysis.* (Kiwok, 2016a)

Kiwok has not yet launched any of its products in markets outside of Sweden. They have, however, tested its solutions internationally in about 25 different markets. Some of the trips to these countries have been in cooperation with multinationals such as the computer hardware giant Hewlett-Packard, the telecommunication company Ericsson and the organization Business Sweden. Kiwok have during the course of these trips gathered sufficient knowledge to construct a strategy for evaluating and entering new markets.

**Strategy document guiding Kiwok’s market evaluation**

The knowledge from these trips has been formed into a strategy document that Kiwok uses to evaluate potential markets that are proposed to them by third parties. The document consists of three major areas:

i. Can we find an ambassador on this market?;
ii. Are there regulatory barriers?; and
iii. How will we reach the users? Do they like these types of products? Are they cost conscious?

Ambassadors are key people or organizations present in the country that possess the knowledge and experience to answer the above-mentioned questions. This is due to the fact that they have a lower barrier to obtain such information and the possibility of testing the

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4 Electrocardiogram
product in the market. Key is to identify ambassadors that can be trusted and that are progressive in their thinking. Ambassadors are also often necessary in order to avoid certain regulations and as well as to get insight into the practicalities of the country’s medical technology industry.

Despite its strategy document, Kiwok does not actively survey markets for potential introductions. Instead Kiwok has experienced that actors in foreign markets tend to reach out to Kiwok because they have an interest of bringing its products to their home market. For example, there have been individuals, export institutions and consultancies in China, India and Canada that have expressed their interest in introducing Kiwok’s products to their native market. Kiwok has visited all of these countries in order to test its offerings and identify actors that could potentially help introduce the product to the marketplace. Several of the markets have not been as promising as they seemed initially. For instance, when assessing the possibilities of establishing its business in India, Kiwok identified two issues. Firstly, national law dictates that a native company must own at least a 50% stake in Kiwok. The company Kiwok was currently working with was not suitable and so they broke the deal. The second issue was that some stakeholders described regulatory compliance as too complex. Through a delegation including the general director of the Swedish medical products agency (Läkemedelsverket), Kiwok came in contact with the corresponding organ in India. They informed Björlin that Kiwok only needed to comply with import regulations. The whole situation seemed complicated and Kiwok decided not to enter India.

Furthermore, Björlin explains that the size of the market is not necessarily important in the beginning of an expansion. For example, Kiwok would like to enter the Icelandic market despite it being very small in terms of its population size. If it is possible to find a small but homogenous market with actors that are trustworthy and with good networks then it is regarded as promising.

The data that is generated through the BodyKom EKG is transmitted via mobile networks (for testing purposes as the product has not yet been launched outside of Sweden). Kiwok receives this user data and stores it temporarily in Swedish data servers. Kiwok’s aim is to transmit data back to the country of origin as soon as possible. From Björlin’s experience, companies should avoid using cloud storage as it has a poor reputation in relation to recent developments and that a majority of countries want sensitive data to be stored domestically rather than abroad.

**Kiwok’s thoughts on future internationalization**

When asked about countries where the BodyKom EKG could potentially be introduced in the future and how Kiwok would evaluate them, Björlin touches upon several subjects.
When speaking about larger markets that also have a “mobile health buzz”, UK came up as a topic. However, Björlin suspects that it is a market that is hard to enter as a mHealth company. There are both regulatory and cultural barriers (e.g. strong conservatism and a national health projects and initiatives that exclude foreign actors). Nonetheless, it is a market that is rather progressive when it comes to mHealth. There are also other countries that have developed as potential markets for mHealth. Björlin tells us that the development is often fueled by insurance financed health care models (however, although Germany has a largely privately financed health care system, it is not as progressive, as it tends to be rather conservative when it comes to digital health).

Björlin explains that one of the major barriers for mHealth in Europe relates to the issue of who is paying for the service or product. There is currently no reimbursement system for patients that are heart monitored from a distance. In Kiwok’s case, it has been challenging to explain to health centers what the benefits of the BodyKom EKG are and why it should be financed with money that they (e.g. health centrals, hospitals) receive from the government. Only recently has this issue become a discussed topic in Sweden, and other parts of Europe are far behind.

Looking beyond the EU market, Björlin tells us that Kiwok would probably go through insurance companies if it were to enter the Canadian market as such companies pay a large portion of health care. Kiwok has not bothered examining the US market closer because of the time and resources that is required in order to sell a medical device in the country.

Regardless of which market Kiwok is looking at, Björlin believes that it is important that there is some sort of established competition or that other actors are doing similar things. He says that this is often one of the keys to performing well in the market. Furthermore, if there are other smart mHealth solutions on the market, then key institutions are more accustomed to the fact that change is happening and therefore more inclined to support the change.

Björlin finishes off by, yet again, emphasizing the importance of ambassadors and market knowledge as well as how players act in these markets.

"It is necessary to avoid any obstacle that is in the way. For instance, small companies should not focus on driving change in larger organizations and systems to avoid inertia.”
- Anders Björlin, CEO Kiwok Nordic - 2016-03-23
5.2. Parameters of the IMS model

In this section, we present the parameters that we have identified as critical in an IMS evaluation of EU countries in regards to the mHealth industry and the market for CMD start-ups, such as AdhereBox. The pre-study and literature review allowed us to construct an initial IMS model which we were able to test, discuss and develop with industry experts and mHealth firms with experience within digital health or internationalization. The qualitative empirical findings provided by the interviews help us to arrive at our final IMS model. We complement these findings by reading up on articles and papers on mHealth provided by the public domain. In addition, we align our findings with and receive feedback and input from AdhereBox. We do this by conducting a workshop with representatives from the company.

Our IMS model is created from our empirical research, which is mainly based on semi-structured interviews. Besides using insights from the interviews with the CEOs from the two mHealth firms NaturalCycles (Scherwitzl, 2016) and Kiwok (Björlin, 2016), presented in the previous section, we will also in this section refer to our interviews (for more information, we refer the reader back to Chapter 3. Methodology).

To gain general overview of digital health phenomenon and health care systems, we interviewed Karoline Beronius, the Assistant Manager at EIT Digital which is a European open innovation organization. To complement Beronius with insight on CMDs and start-ups, we also talked with Tobias Vahlne, Business Developer at the Stockholm office of EIT Digital. Besides working at EIT Digital, where he also is responsible for its sub-business Digital Health, Vahlne is an owner of two start-ups - one start-up being in the IoT and consumer goods sector.

We interviewed the manager of EHealth at SICS (Swedish ICT), Silas Olsson to receive insights into the development of digital health in the EU. Olsson has among other places worked at the EU Commission with questions concerning the adoption of digital technology in health care, e.g. eHealth. Interviewing Lars Iversen, the CEO of Frogleap - an innovation lab for start-ups within digital health - helped us to further understand the barriers and opportunities in the EU in regards to mHealth start-ups.

To increase our knowledge about data protection laws in the EU, the organization of health services and delivery as well as the mechanisms behind the procurement and reimbursement models in health care, we spoke to Jovan Stevovic, the CEO and co-founder of the Italian software and technology start-up Chino. To gain insights into internationalization and market selection of innovative firms seeking opportunities outside Sweden, we spoke to Adam Edström - Innovation Specialist at Swedish ICT.
We also interviewed one of the mentors to AdhereBox - Oliver Trepte. Trepte is Senior VP at a engineering consultancy firm specializing in life science technology. Trepte could with his years of experience in the field of medicine technology, as well as insight into AdhereBox, share great insights into consumer behavior when it comes to health care products and the health care system in general.

In addition we spoke to the CEO and COO of the Swedish mHealth firm Brighter, in order to gain further perspectives on the business environment of mHealth companies.

In addition we complement our primary data by including information identified in industry reports (e.g. Kanavos, Schurer and Vogler, 2011; Banga, Klein and Martelli, 2015)

Our specialized IMS model includes both qualitatively and quantitatively assessed factors and indicators. These are aimed to guide the strategic decision process behind the IMS of mHealth CMD start-ups such as AdhereBox. We propose the following model (see Figure 6), which includes parameters that we believe may influence the outcomes of a potential product launch for companies like AdhereBox. We arrive at these parameters, as they are recurring topics throughout the whole interview process. They can also be backed up by theories in existing literature. The model involves both the screening and identification stages of an IMS process. It accounts for two main categories into which we group the parameters, namely “Stakeholders” and “Barriers and Enablers”.

Recall that in the network perspective of internationalization, firms are engaged in networks of relationships with a number of different actors (competitors, suppliers, customers, government and others). These relationships are seen as the firm’s most important assets and source of foreign market knowledge and opportunities (Axelsson and Johanson, 1992). Therefore, we believe that our IMS model should include key stakeholders in the business ecosystem of mHealth consumer medical device start-ups. We have identified these as being consumers, payers, providers and distributors.

Barriers and Enablers is a term that we have given IMS parameters that we have identified as highly influential when it comes to the commercial success of an mHealth CMD firm. These factors can either constitute obstacles or facilitators depending on their readiness and maturity when it comes to mHealth innovation. These factors interplay with the stakeholders of our model, something that we will show in Chapter 6., which centers on the country evaluation stage of our research.
We believe that these parameters form the “ecosystem” that should be assessed in order to answer our main research question. Our research suggests that these are essential to assess in an IMS for mHealth CMD start-ups, especially AdhereBox. We propose that an initial evaluation can be done in two stages: (i) first, through an initial screening stage, in order to filter out low potential countries; and (ii) an identification stage. Our choice of the proposed parameters as well as the questions that need to be addressed in a country evaluation are explained and presented in the forthcoming sections of this chapter.

### 5.2.1. Screening stage

Researchers have found that the process of screening is often used by companies in order to more quickly and inexpensively filter interesting markets that require more in-depth research (Rahman, 2003; Russow, Lloyd and Solocha, 1993). In our model, the screening stage allows one to eliminate countries that do not meet certain requirements when it comes to factors
related to user demand and receptiveness. These include target population size, economic development and digital literacy of the country’s population. As portrayed in the case study of NaturalCycles, several of these factors were assessed when screening foreign markets in its IMS (Scherwitzl, 2016).

Furthermore, these parameters can be assessed quantitatively using readily available statistics from reliable sources. Leveraging existing data, one can easily apply weights to each indicator and rank countries according to their score, which was something NaturalCycles did in their IMS screening (Scherwitzl, 2015). This enables one to identify countries that should be filtered out and those that move on to the subsequent stage of assessment. In summary, the Consumer parameter assesses different aspects of the consumer population using quantitatively measurable indicators.

5.2.1.1. Consumers

mHealth is believed to contribute to a more consumer driven and patient centric health care (PwC, 2012). For AdhereBox, the consumers represent the end users of AdhereBox’s mHealth app and pillbox (Workshop, 2016). The end consumer and user of the mHealth product is thus an essential stakeholder in the business ecosystem of CMD firms. In order to assess the attractiveness and potential of a country’s consumers and market size in the screening stage of an IMS process, researchers recommend using macroeconomic indicators such as population size and economic development (Rahman, 2003). However, this approach does not directly measure market size but implicitly assumes that aggregate, general country indicators will reflect it (Sakarya, Eckman and Hyllegard, 2007). Hence, in addition to using macro level variables, it has been observed that firms also choose to combine such variables with product specific indicators in order to assess potential market demand. The parameters that will be presented below under the consumer parameter is market size, economic development and level of digitalization.

Market size

The size of the country population was something NaturalCycles used as an indicator to estimate the potential market size of the country. “In order to gain economies of scale and return on investment, a large potential user base is necessary” (Scherwitzl, 2016). As such, NaturalCycles valued this criterion as critical in their second international market selection analysis (ibid).

As mentioned in the case study of Kiwok, the size of the market is an important factor, but should not exclude countries with conditions that are suitable for the innovation (Björlin, 2016). Recall Iceland and its homogenous market but small population (ibid). In the situation that Kiwok is in, it may be difficult to convince stakeholders to enter smaller markets with low potential for scale.
The market potential of a certain country largely depends on the target group of the mHealth solution. AdhereBox identifies their most important target group to include (i) individuals (10 years and above) (or related persons to individuals) that (ii) take medication (in the form of pills) on (iii) a daily basis (Workshop, 2016). These could be individuals taking pills regularly for a wide range of purposes. For instance, individuals could be those taking pills due to chronic diseases requiring medication, cancer, mental illnesses, epilepsy, diabetes or high blood pressure (Workshop, 2016). The potential market size for AdhereBox’s product can be calculated as the whole age segment of the population that take medication on a daily basis and would therefore have incentives to use medication reminders or pill-organizers. However, bearing in mind that national data on medication usage or the volume of different patient groups is not easily accessible for each EU country, we believe that a country’s population size is a good enough proxy indicator of a country’s addressable market size. Mortality rates for certain chronic diseases can be accessed through Eurostat. However, these do not necessarily reflect the percentage of the population affected by such diseases or conditions.

**Economic development**

Besides estimating the volume of potential consumers in a country using macro level indicators, we know, from the theoretical review, that the level of economic development is also of great importance when assessing market potential (Cavusgil, 1985; Connolly, 1987; Young et al., 1989; Ball and McCulloch, 1993; Papadopoulos and Jansen, 1994; Daniels and Radebaugh, 1998; Rahman, 2001; cited in Rahman, 2003).

When asked about what parameters they looked at when identifying potential target markets for their product, Brighter AB (2016) says that they naturally needed to establish some sort of cut off point when it came to solvency in the country, in other words the financial strength of the country population. In their analysis of foreign markets, they saw a high correlation between certain diseases, such as diabetes, and a high median income. In AdhereBox’s case this would suggest that economic development to a certain degree implies a higher level of prescribed pills for chronic diseases. This relationship, together with a lack of medication adherence, could increase demand for smart pill organizers in a country. In another interview, Edström (2016) agrees that macroeconomic statistics is a good way of assessing the economic climate of a country. This coincides with previous research that shows that macroeconomic indicators are common variables assessed in IMS screening, where proxy variables are used to assess a country’s economic environment (Sakarya, Eckman and Hyllegard, 2007).

AdhereBox agrees that it is important that the country has an economic development that enables their consumers to purchase consumer medical devices in a certain price range (Workshop, 2016). Important to note is that if reimbursement models for mHealth are in place, then the disposable income level need not be as important (ibid). We also believe that a comparably good economic development serves as an indicator of consumers having the financial ability to buy and own a smartphone, which is needed to operate AdhereBox’s hardware.
Level of digitalization

The consumerization of digital health and increasing role of smartphones propelling the global health care accessory hardware market is largely driven by the availability of smartphone platforms (Barker, 2016). The expanding spread of smartphones and network technology, such as 3G and 4G networks, has boosted the use of mHealth services and products. In addition, the market for mobile apps has become a key driver of mHealth deployment facilitated by smartphone penetration (European Commission, 2014).

NaturalCycles assessed factors related to the level of digitalization of the country population in their market selection analysis (Scherwitzl, 2016). They assessed different indicators of digital literacy, such as smartphone coverage and credit card usage, as they are essential parts of the product offering. This suggests that an IMS model should include variables that measure certain characteristics of the country’s consumers that indicate some sort of familiarity with product features and functions similar that of the firm’s device.

Trepte (2016) emphasizes the importance of assessing aspects related to how accepting consumers are to new innovations and digital technology. “The sociological aspect is very important to assess when it comes to the product of AdhereBox” (Trepte, 2016). Furthermore, Trepte (2016) recommends looking at patterns on elderly people's digital literacy and technological maturity as he suspects it is an attractive segment because older adults have a higher tendency to have chronic diseases which requires regular medication.

Our findings show that a country’s customer receptiveness of mHealth is highly dependent on the level of digitalization of its consumers as mHealth leverages on the advancement of mobile device technology. This coincides with previous empirical research. In their study, Sakarya, Eckman and Hyllegard (2007) argued that customer receptiveness is a factor that should be considered when assessing foreign markets. Recall, that customer receptiveness covers the consumers’ attitudes toward new goods and services (ibid). In our model, we choose to evaluate customer receptiveness by assessing the ”digital literacy” of the country population as an indicator of the country’s consumers’ receptiveness to mHealth products. We use this as a product specific indicator that complements the macroeconomic variables when assessing country market potential.

Just as with NaturalCycles, the smartphone is a central piece of technology for AdhereBox, and an attractive country should have high smartphone penetration. Representatives of AdhereBox further suspect that a population with overall high level of digital skills and confidence are more receptive to new technology and hence more receptive to AdhereBox’s medical device. Suggestions on using proxy variables is put forward by representatives from AdhereBox to describe how well adapted the population is to using their phones and other mobile devices to perform certain actions. This would indicate how well consumers would
welcome AdhereBox’s product and using a smartphone for its intended functions. (Workshop, 2016)

Furthermore, as users share their personal data with AdhereBox when using the medical device, there is a secondary market for the Big Data generated. Consumers of some countries are suspected to be more willing to share such data than others. Consumer wariness may limit the uptake of the more sophisticated mHealth products (Monitor Deloitte, 2015). This suggests that the spread of digital wearables in the country would be a good indicator for measuring this aspect of customer receptiveness.

**Summary of Consumers**

In summary, macro- and micro-level variables such as population size, economic development and digital literacy, are useful screening indicators in the IMS of mHealth CMD firms. By combining macroeconomic indicators (population size and economic development) with product specific indicators (level of digitalization) we believe that we are able to assess the attractiveness of a country’s consumers and receptiveness to mHealth solutions. In Chapter 6.1, we will present the findings of the screening of EU member states using statistics from the sources presented in Chapter 3.2.

**Questions for the firm to consider in its IMS:**

1. Who are our target customer segments?
   a. What is the volume of potential users?
2. How economically developed is the population of the country?
3. What features does our mHealth solution have and what digital skills are required amongst our target consumers?

**5.2.2. Identification stage**

Researchers suggest that the focus of the identification stage should lie on industry and firm-specific information in order to highlight the market which best matches the company and its field. In the identification stage, industry specific information on market factors and entry barriers is often used to cull and name potential countries for market entry. (Rahman, 2003) As such, this stage focuses on industry related parameters and the characteristics of the health care system of the country.

**Stakeholders**

In our interview, Olsson (2016) stresses the importance of not only understanding the end-consumers of an mHealth product but also to consider the major intermediaries and players in the value chain of consumer mHealth. In the industry for mHealth and CMDs, these are identified as the providers, payers, distributors and collaborators of health related products and services (Olsson, 2016). Olsson further suggests that firms, especially smaller companies,
approaching a country’s health care market, need to make a prior analysis of who they would need to influence in order to gain access to the different stakeholders (Olsson, 2016).

5.2.2.1. Providers

Olsson (2016) points out that an important aspect and success factor in the health care market is making sure that all stakeholders of the health ecosystem are gaining from the product and solution that a firm is offering. Stakeholders, such as health care providers, are key to “understanding who you need to influence in order to access and reach the market” (Olsson, 2016) In this parameter we want to get an overview of the organizational structure and governance of the providers in the country’s health care system.

Healthcare providers are an integral part of the health care system (Moss et al., 2010). Providers encompass health professionals that “study, advise on or provide preventive, curative, rehabilitative and promotional health services based on an extensive body of theoretical and factual knowledge in diagnosis and treatment of disease and other health problems” (WHO, 2010, p 1). In addition, Trepte (2016) addresses the importance of understanding where the primary point of contact with a patient occurs with a health care provider, as this often acts as a gatekeeper to mHealth products.

Questions for the firm to consider in its IMS:

i. How is the health care system structured and who are the main providers?
ii. Who are, and where is, the main and first point of contact with the health care system?

5.2.2.2. Payers

A topic that is touched upon in all of our interviews is the impact and implications of health care financing. The different member states of the EU use a range of contribution mechanisms to finance health care. These can include both public and private financing. Public funding can come from taxes and social insurance contributions. Private funding can come from private health insurance and out-of-pocket (OOP) payments in the form of direct payments from the consumer, cost sharing and informal payments. (Foubister, Mossialos and Thomson, 2009)

In general health care expenditure in the EU is largely publicly financed, by taxes or social security funds (through a system of health insurance). In our interview, Björlin (2016) explains that one of the existing issues challenging the adoption of mHealth in Europe regards the question of who is paying for the services or solutions. Consumers in EU member states, with tax-financed public health care systems, tend to be very price sensitive when it comes to paying OOP for health related products and services (Levy, 2014). What has been noted in countries where individuals, to a higher degree, pay OOP is that they tend to be more willing...
to pay for mHealth, probably reflecting the higher proportion of all health care costs they pay out of their own pocket (ibid). This coincides with findings from our interviews. For instance, Scherwitzl (2016) informs us that publicly financed health care systems that are largely subsidized or have free medication affects the mentality of people and they tend to be less willing to pay for his or her own medical appliances.

Healthcare systems differ in the extent to which payers can apply certain incentives. For example, insurance-based systems tend to be more responsive to incentives, because consumers typically have greater visibility into and responsibility for paying their health care than do consumers covered by tax-based systems. (Dixon-Fyle and Kowallik, 2010)

When talking about the different financing agents in health care, Brighter AB (2016) views privately financed health care markets as more agile and forward thinking than publicly financed systems. As such, these markets are often more receptive to “smart” and innovative health care solutions (ibid). In addition, Edström (2016) tells us that insurance companies are becoming more influential and important when it comes to medtech, as these often mediate or distribute money in one way or another. Furthermore, they are also more inclined to support solutions that reduce costs in health care, which innovative mHealth solutions and services tend to do (Edström, 2015). This contradicts Olsson’s experience from his work for the European Commission in Brussels in the beginning of the millennia. Olsson (2016) suspected that health insurance companies would be very interested in applying financial incentives on their customers. That is, a customer could be rewarded with a lower premium given that they followed certain instructions or used certain products. However, from what Olsson recalls, this was not something that became widely adopted (Olsson, 2016).

The sources of health care funding have proven to be a factor that influences the entry of valuable types of innovation into the health care system (Herzlinger, 2006). The funding of health care and complex system of payments can come from several parties - both public and private. As such, it is important for firms to understand the organization and characteristics of health care payers and its implications. The mechanisms behind and structure of health care expenditures will most likely influence consumers willingness to pay for medical devices and mHealth innovations, which in turn will affect the distribution channels, a company chooses.

**Questions for the firm to consider in its IMS:**

i. What is the distribution between public and private health care expenditure and what are the sources of funding?

ii. How much do consumers pay out-of-pocket and for what services?

iii. What are the implications of the country’s structure and distribution of its health expenditure?
5.2.2.3. Distributors

As touched upon in the theoretical review, networks are an important aspect when evaluating a market (Axelsson and Johansson, 1992; Gadde and Håkansson, 2001; Barbosa, Fuller and Ferreira, 2005). Distributors are also included in the strategic network of an internationalizing company. Access to the end-customers is determined by the selection of distribution channels that best adapt to the characteristics of the firm’s offering and the market. The choice of distribution channel will in this sense determine the expansion of the company in the new market. Zahra, Ireland and Hitt (2000) suggest that start-up businesses should work diligently to establish distribution channels in order to position its products so that it can generate significant sales (Zahra, Ireland and Hitt, 2000). The availability and characteristics of possible distribution channels of a country is thus important to assess when evaluating global market opportunities.

Depending on the type and characteristics as well as purpose of an mHealth innovation, there are different ways to enter a market and reach the end-consumer. Unlike stand-alone software based products such as mobile applications, medical devices generally require physical delivery. The software part of the product (mobile application) is usually accessed through online application stores (e.g. iTunes App Store). Hardware medical devices can on the other hand, for instance, be distributed to consumers via pharmacies, hospitals and clinics, websites, physicians or partnering with mobile network operators. As such, there are different channels (specialist and mass-market channels) that are becoming credible means of distributing mHealth products.

When it comes to consumer-centric health care, the choice of distribution channel is particularly critical. From our findings from interviews and literature, it seems as if consumer medical device companies can distribute their products either via the (i) public health care system, (ii) private sector or (iii) directly to the end-customer. Historically, pharmacies have been the dominant consumer health channel, protected by several regulations and customer expectations on how health products should be sold. However, there is a trend for increasing deregulation of such channels and a growth in e-commerce and regular stores of health-related products (Thomas, Hembert and Anscombe, 2012). However, even though government procurement of health related products is a complicated process, traditional health care players are expected to become more relevant as distribution channels for mHealth products and apps in the near future (Research2guidance, 2014).

As mentioned above, there are challenges entering public health care systems. These could for instance relate to the amount of resources you must invest when entering the process of becoming subsidized by the health care system (Scherwitzl, 2016). Iversen (2016) also notes that choosing to distribute through the public sector is difficult as inclusion of mHealth innovation in countries’ health care procurement lists have not happened. However, Edström (2016) points out that the advantage of public procurement processes is that they usually result in very large contracts if they succeed. Edström (2016) adds that there is an advantage of
going through private channels as private channels tend to relatively quickly generate some type of cash flow.

Stevovic (2016) notes that although the public sector in many countries is the largest customer and thus payer of health care, it is often easier to approach private actors. According to Iversen (2016) a lot of medical technology firms choose to push their consumer products through the private markets, such as retail and pharmacies, as private actors tend to be more open to adopting innovation. Similarly, Olsson (2016) suggests, as going through the public health care system can be complex, that private distributors could be an alternative channel to market and distribute a firm’s health care product, especially if it is a consumer medical device. According to Beronius (2016) pharmacies seem to be the best alternative for fast and effective distribution, but that depends on the type of mHealth product.

In addition, firm capabilities and resources also play a role in how mHealth companies choose to enter foreign health care markets with their consumer product. For instance, Brighter AB (2016) partners with mobile network operator (MNO) Ericsson for distributing their products. Brighter AB (2016) suggests that it is better to partner with a distributor that already has routines and support systems in place (such as credit control, billing, etc.) instead of building such functions locally per market (Brighter AB, 2016).

However, distributing via private channels is not without its implications. For instance, the private sector is often more competitive and requires a lot of marketing efforts (Stevovic, 2016). It also implies that you know your target customer segments and adapt your marketing approach and distribution channel accordingly (Olsson, 2016). For example, Olsson (2016) and Trepte (2016) say that individuals with chronic diseases are often elderly that might prefer buying medical devices at pharmacies. As AdhereBox’s product addresses non-adherence, many of its target customers would perhaps often be older with chronic issues. As such, Trepte (2016) suggests pharmacies as being channels offering credibility as well as exposure.

Important to note is that different countries require different entry mode strategies and distribution channels. And different means of distribution have their different advantages and disadvantages. For instance, traditional health care channels such as pharmacies and hospitals increase the credibility of products, which is vital in countries that tend to be skeptical to medtech innovations. However, going through wholesalers and pharmacies also decreases margins that can be gained by the company. (Scherwitzl, 2016)

The choice of distribution channel needs to guarantee the efficient distribution of a company’s products for the intended markets and at reasonable cost (Kanavos, Schurer and Vogler, 2011). AdhereBox is looking for economies of scale. As such the company prefers markets that are dominated by a few, rather than many and fragmented actors. This is because more focus can be put on fewer stakeholders. Important to note is that AdhereBox is cautious of getting into the public sector as it suspect it to be fairly slow (Workshop, 2016). AdhereBox does not
want to get stuck in slow and non-progressive procurement processes - something that appears to be common in the public sector. Instead the firm wants to be flexible (ibid). Neither is direct-to-consumer marketing highly prioritized as it requires substantial upfront investments and adds to the complexity of its operations (ibid). As a start-up with limited resources, AdhereBox seeks to leverage the resources and capabilities of external distributors (ibid). This has much to do with AdhereBox's limited capabilities and resources from being a start-up. It cannot for instance afford multiple salespeople (ibid). Especially for smaller companies, such as start-ups, the choice of distribution channel requires resourcefulness and considerable strategic planning. As such, by assessing this parameter we want to understand the target distributors from the public and private sectors and evaluate them in terms of suitability for AdhereBox’s product.

Questions for the firm to consider in its IMS:

i. How are similar products being accessed by the consumers?
ii. How are these channels structured and how do we reach these?

5.2.2.4. Collaborators

As brought up in the theoretical review, the IMS of many small entrepreneurial firms is largely determined by the networks accessible and available in the foreign market (Moen, Gavlen and Endresen, 2004). Our empirical research seems to confirm this as several of our interviewees emphasize the importance of external network actors, or collaborators, as facilitating factors in internationalization.

Collaborators could for instance be key opinion leaders (e.g. individuals from medical universities and health care professionals) and patient organizations. Recall that Kiwok looks for “ambassadors” in foreign countries when analyzing international markets, meaning that these are key to obtaining market information and for field-testing (Björlin, 2016). Findings from previous research as well as from our interviews suggest that networking is often a crucial way of gaining access to a market (Johanson and Vahlne, 1990; Axelsson and Johansson, 1992). Networks often help mediate contact with distribution channels, as well as influence payers and providers of health care (Ohlsson, 2016; Trepte 2016). In addition, networking aspects are touched upon in internationalization literature as pull factors that influence market selection (Axelsson and Johanson, 1992; Porter, 1998; Moen, Gavlen and Endresen, 2004; Barbosa, Fuller and Ferreira, 2005; Sakarya, Eckman and Hyllegard, 2007; Laanti, Gabrielsson and Gabrielsson, 2007).

Edström (2016) introduces so-called patient organizations and associations of relatives as important collaborators, which also can work as a marketing channel to reach users. There are several such organizations - for different diseases and conditions. “These type of networks can act as ambassadors for a firm's products and do often have information channels through which you can market yourself” (Edström, 2016). In addition, Trepte (2016) tells us that key
opinion leaders (or champions) are important to identify as these can help promote a firm’s product. These are often notable researchers that have the position to influence politicians to implement changes in health care that could help the company’s innovation to roll out on the market. Olsson (2016) agrees with Trepte (2016) on the importance of identifying champions that can come from any level of an organizational hierarchy, but the closer to a decision-maker the better.

Beronius (2016) agrees that the network of agents and organizations has large impact on medical technology: “In regards to mHealth and medical devices that need CE marking, networks prove to be very important” (Beronius, 2016). External testing and validation of your product is beneficial and help increase credibility even if the product does not require labeling of any sort. Networks can also prove important for financial support in the development of a product” (Beronius, 2016). On financial agents, Edström (2016) says that these actors are not vital in a network as capital need not be in the same place as the foreign market. They could just as well be in the home market.

Networks and clusters can also be used in order to understand the foreign market and raise awareness (Scherwitzl, 2016). Networking with relevant influencers in mHealth is a vital part of NaturalCycles marketing efforts as it creates brand awareness and provides insights into the market (Scherwitzl, 2016). Findings from the Uppsala School Model and network theory on internationalization become apparent when analyzing NaturalCycle’s IMS approach. For instance, personal connections and networks in the country with market knowledge were seen as an important factor when deciding upon which market to enter.

Olsson (2016) emphasizes the importance of coming in contact with people and organizations that can influence decision makers within the health care system (Olsson, 2016). “The goal is to approach decision makers. If you want to be endorsed by and marketed through doctors and primary care, you may have to go approach them indirectly, e.g. through social managers or IT managers - people who can influence processes in health care” (ibid). It is the people that want to change or improve a behavior, in AdhereBox’s case medication adherence, which should be approached (ibid).

Edström (2016) speaks from experiences when he tells us that the international market selection of many firms tends to derive from the company having some sort of established connection to the country. “Companies tend to go to neighboring countries or to countries where there already is already is some sort of established contact” (Edström, 2016). This corresponds with the observations done by Barbosa, Fuller and Ferreira (2005) in the area of networking theory.

Edström (2016) adds to the discussion about start-ups entering markets, where they already have an established network, that “in this sense the choice is quite opportunistic as these sort of networks could be established at conferences or events”. He also points out that this type of
market selection need not be the best strategy. However, “born global or not - networks always play a large role in the internationalization of firms” (Edström, 2016).

When asked about indicators of a good network environment that firms should look for, Edström (2016) and Trepte (2016) mention Life Science and research clusters as well as universities. “Relevant universities are important as these can be good sources of future employees” (Edström, 2016). An additional indicator is the existence of activities such as events and conferences related to digital health (Edström, 2016; Trepte, 2016). “This usually says something about the market readiness for these types of innovations” (Edström, 2016). Beronius adds that indicators of relevant collaborators could also include the presence of medtech incubators, accelerators, and hubs. Edström (2016) points out that there should be a good entrepreneurial climate, and a lot of hospitals and medical centers. In the theoretical review, we mentioned that clusters could serve as indicators of a preferable business environment and that the presence of relevant clusters related to digital health could act as an indicator of accessibility and market readiness; technology clusters can generate many benefits for the companies involved, from cost savings to research collaboration (Banga, Klein and Martelli, 2015).

Representatives from AdhereBox also acknowledge that collaborators can help aid the entry, launch and adoption of its mHealth product. In addition organizational networks related to digital health can also indicate if a country is more welcoming in adopting mHealth innovation than others. In conclusion, supporting networks, or collaborators, are valuable indicators of market attractiveness when it comes to start-ups seeking to establish themselves in a foreign market and can facilitate a potential product launch by mediating contact with important people and organizations (such as distributors) in the country.

Questions for the firm to consider in its IMS:

i. Do we have relevant contacts in the country?
ii. How can we extend our network to the country?
iii. Are there any organizations that could facilitate the launch of our product?
iv. Is there a presence of clusters and/or events related to our field of business?
Barriers and enablers

In our interview, Iversen (2016) refers to the term “commercial disruption” and “disruptive innovation” when speaking about the health care market’s readiness for mHealth. He means that the health care systems of all countries are moving towards a complete decentralization and consumerization where technology will be enforced in health care without the control of authorities. Iversen (2016) believes that health care systems will become increasingly pushed by entrepreneurs, as well as consumers and patients, towards a more digitalized health care. Hence, Iversen (2016) suggests that an IMS model for mHealth should measure each country’s level of maturity as well as acceptance of mHealth in this so-called disruption process. Factors to be assessed should include barriers to and enablers of mHealth adoption and indications of maturity include the presence of regulatory, financial and technological systems that support mHealth innovation.

Similarly, Trepte (2016) believes that, sooner or later, “all EU countries will reach the maturity required in order to be attractive and suitable for mHealth innovations”. As such, this category of our IMS model aims to include parameters for assessing how far developed a country is in regards to mHealth. We label these parameters the “Barriers and Enablers” of the mHealth business ecosystem.

However, we acknowledge that this measurement of maturity and acceptance are destined to change overtime. This means that our country evaluation is an assessment of the countries’ current maturity in regards to mHealth innovation.

The Barriers and Enablers dimension summarizes the external forces, or macro environment factors, that we have identified, through both primary and secondary data, as particularly influential when it comes to mHealth CMD start-ups. Recall that there is, in previous research, a dominating interest in the external environment’s influence on the selection of international markets (Koch, 2001a). These surrounding forces influence a firm indirectly, be it economically, culturally, politically, legally or technologically (Gould, 2002). These factors can be assessed in their level of market readiness for and compatibility with mHealth.

5.2.2.5. Incentives

Trepte (2016) highlights that the acceptance of new technology and solutions is higher where there exists incentives to take in innovations that have desired outcomes. There are several incentives for stakeholders in the health care business ecosystem to endorse mHealth innovation. These could, for instance, relate to reducing costs in the health care system, solving public health issues or increasing efficiency and patient centricity. As our assessment is adapted to AdhereBox, we will consider incentives that relate to issues such as medication adherence, something AdhereBox aims to improve with its product.
The majority of EU countries are experiencing a demographic shift as the life expectancy of their citizens is increasing. The aging population is putting pressure on the health care systems, as today’s workforce is not equipped with staff to support this increase. As such, Olsson (2016) highlights the need for physical labor and technology to intertwine in order to meet tomorrow’s demand. mHealth medical devices are believed to automatize certain aspects of health care services, subsequently replacing many activities normally performed by physicians such as prescription and monitoring with sensors, data collection and analytics (Olsson, 2016). In a report by the European Commission, summarizing the views and actions suggested by stakeholders in regards to mHealth, it was suggested that the strongest case for providing funding for mHealth solutions (e.g. reimbursement schemes) is to demonstrate their savings to national health systems (European Commission, 2015f). This is not just in relation to the cost of health care services, but also in the improved health of the population (ibid).

In our interview, Olsson (2016) stressed that in order to successfully enter the health care market, providers and payers need to understand the purpose of your product. Björlin (2016) informs us that the issue lies in who is financing the innovation. Healthcare providers need to understand that an innovation that reduces complexity and resources spent on patients often saves money that surpasses the price of the innovation (Björlin, 2016).

Olsson (2016) points out that “medication non-adherence is a big issue across Europe, and is on the political agenda in nearly all European countries”. It is believed that mHealth technology can help ease this situation by for instance enabling remote monitoring, analysis and medication adherence. This suggests that an important incentive for health providers to endorse AdhereBox’s product would be that it addresses issues that cause and increase non-adherence (e.g. demographic aging and rising occurrence of chronic diseases).

As such, we believe that an important aspect of market readiness is if a country’s health care system has shown interest in the type of innovation a company offers. For AdhereBox, it would be preferable to assess whether or not a country has taken initiatives to increase medication adherence before. Assessing what type of interventions the country previously has done, or is doing, when it comes to medication non-adherence is one way of evaluating if the country actually has put, or is putting, money into solving this type of problem. As such, this parameter is also an indication of readiness for such innovations.

Knowing and understanding issues related to the health care system of a country makes it easier for companies to argue for reimbursement, knowing which collaborators to contact and modes of distribution. As such, understanding the potential of mHealth and how a firm’s solution can contribute to the health care system can facilitate discussions with key-decision makers as well as identify suitable entry strategies.
Questions for the firm to consider in its IMS:

i. What issues does our product address and solve?

ii. Are there any indications of the country having or addressing such issues, and would therefore have incentives to adopt our solution?

5.2.2.6. Reimbursement models

A major obstacle preventing mHealth solutions to reach the mainstream of health care provision within the EU has been suggested to stem from the lack of adequate reimbursement models (European Commission, 2015f). Currently, many national health services of the EU have no defined system for pricing and reimbursing mHealth initiatives, even though they are seen as key to the future of its adoption (ibid). Although the European Union’s medical device approval process applies uniformly across all member states, obtaining reimbursement for a medical device varies from country to country as it largely depends on the health care policies of the government (ibid).

As previously mentioned, health care expenditure in the EU is largely publicly financed. It has been observed that in developed health care markets, with governments or employers as the primary payer, adoption of mHealth is slower since consumers feel less inclined to pay for such products themselves (PwC, 2013). By including mHealth solutions in reimbursement schemes, providers can “incentivize” citizens to use cost-effective technologies, look after themselves better and take medication properly (A.T. Kearney, 2010).

The issue of identifying countries with reimbursement models for mHealth is addressed in several of our interviews. For example, Trepte (2016) emphasizes the importance of assessing the reimbursement aspect in the IMS for AdhereBox. This aspect, he says, is more complex than the regulatory aspect of mHealth (ibid). Factors that should be considered if one wants to be included in reimbursement models are if the innovation increases the quality in health care or if it lowers costs.

However, Scherwitzl (2016) notes that consumer medical product companies risk forgetting about the most important stakeholder in their value chain when spending too much effort in getting reimbursement for their products - namely the end-consumer. In this sense, it is sometimes better to be consumer-focused as it also makes regulations less of an issue.

In conclusion, reimbursement models for buying mHealth consumer medical devices can create economic incentives for consumers to pay for such products. As such, countries where mHealth is included into the nomenclature of reimbursable health care activities would be considered attractive markets to enter.
Questions for the firm to consider in its IMS:

i. Are there indications of mHealth being included in the reimbursement schemes of the health care system?

ii. Are there solutions similar to ours that are reimbursed?

5.2.2.7. Technological infrastructure

Stevovic (2016) notes that a big issue in mHealth is that concerning the public health care systems’ interoperability with new innovation. He adds that there is no single EU country with completely mature technological infrastructure for mHealth to date, and countries are for instance still struggling to build up Electronic Health Records (EHR) (ibid). Despite this, there are some countries showing more openness to innovative technology, but a large obstacle in mHealth is that these take time to develop interoperability with the health care system (ibid). Olsson (2016) stresses the importance of interoperability and the condition of the country’s health IT infrastructure, as mHealth often needs to integrate into a system. “Some countries are more ready than others when it comes to health IT infrastructure and improving health using technological innovations” (ibid). Ensuring interoperability in mHealth is complex and there is a wide heterogeneity of health information systems across the member states (European Commission, 2015f). Interoperability across the overall health system is also essential if an mHealth innovation is to achieve scale (BCG, 2012).

Previous research suggests that a nation’s market readiness in terms of infrastructural capacity to support new innovation is something that should be assessed when evaluating countries in an IMS (Rahman, 2003). An attractive market implies the existence of systems that support the firm’s products and services (ibid). It is therefore critical for mHealth firms, wanting to establish themselves in a country that systems, applications and functions that support their innovation are in place. The range for how digital health care technology is developed and adopted is very broad between the different EU member states (Stroetmann, Artmann and Stroetmann, 2011). This criterion is thus important to evaluate as it assesses the country’s technological systems and if its health care integrates ICT into its health services. As such, this criterion must include indicators that in some way measure the country’s adoption of digital health related infrastructure. Examples of technological infrastructure related to mHealth include electronic identification, authentication and authorization services as well as access to electronic health records, ePrescription, and e-dispensation.

Mobile health technologies require a robust technological infrastructure and key components in order to deliver their solutions. As previously outlined, AdhereBox requires certain technological systems in place for consumers to use all of its function. In the EU, several countries have implemented certain core eHealth and mHealth related technologies into their health care systems, but with varying level of deployment. This can create both barriers and opportunities for mHealth firms depending on the market’s mHealth technological maturity.
For AdhereBox, countries, with the following systems in place, are deemed as more attractive than those not having them (Head of Technology, 2016; Workshop, 2016).

i. **Electronic identification system**: A country should have a standardized way of easily identifying oneself online (via a smartphone). Electronic identification is a way for people to identify themselves when logging into mobile applications. A country having an established and developed infrastructure of online ID verification is an indicator of high attractiveness. A package that already is developed also implies little or zero development costs and secure set-up without AdhereBox needing to change its infrastructure. The log-in into AdhereBox’s mobile app needs to be of high security standard. Logging in using electronic signature is one way of ensuring safety and also facilitates if one wants to pay or order medication online using the app. Authentication (including eID) constitutes the process of verifying a person’s identity to be authentic.

ii. **Open APIs**: Open APIs are publicly available application programming interface/open architecture. Open application programming interfaces (APIs) enables an ecosystem of applications, data and processes working together (Monitor Deloitte, 2015). Open mHealth APIs allows developers to access and integrate data and functionality with other applications and to create new applications (ProgrammableWeb, 2016).

iii. **Electronic prescription**: Electronic prescription, or “ePrescription”, is an electronic system, or prescription depot, that can enable people to order subscriptions online. ePrescription is defined as the electronic prescribing of medicine with the use of software by a health professional to a pharmacy where the medicine can be dispensed (Health Information and Quality Authority, 2012).

Countries differ in their integration of these systems in their health care structure. Although they are not relevant for all mHealth business models, having access to Open APIs in health care and ePrescription service available in a country increases the options for mHealth companies significantly. With such systems in place, it would indicate higher market readiness and thus market attractiveness and potential for mHealth companies like AdhereBox.

Important to note is that, although mHealth strongly depends on high capacity and flexible networks, this parameter is less critical when assessing the EU market as countries of the EU in general have high-speed wireless communication networks. In addition, having high-speed and high-quality networks is less critical to AdhereBox, as its product’s software can communicate with its hardware using smartphone Bluetooth and simple 2G networks. This factor would be more critical if we were to assess emerging markets where local technological infrastructure is less common than within the EU.
Questions for the firm to consider in its IMS:

i. What technological infrastructure is necessary for our mHealth CMD?
ii. Does the country have these systems in place? If not, can our product be launched effortlessly without requiring too much modification?

5.2.2.8. Regulations

When asked about which parameters he would evaluate in the IMS of AdhereBox, Trepte (2016) highlights the importance of the regulatory aspect. “There are distinct regulatory requirements for medical devices in the EU” (ibid). In the EU, there is the Medical Device Directive that intends to harmonize laws related to medical devices within the EU (ibid). In general, the EU sets Directives that its member states are required to translate into practice (ibid).

Despite the EU’s efforts of harmonization, health care is viewed as a difficult market to enter as regulations and compliance can create large barriers for expansion (Iversen, 2016). “The health care system is still adapted to old ways of working and thinking” (ibid). Therefore, it can be challenging for start-ups to establish them in an area that has to do with medical technological products and innovations (ibid).

Vahlne (2016) agrees with the above statement; “electronics are often attached to a lot of approvals”. However, Vahlne (2016) also admits that the EU has to a great extent “increased the simplicity of going global as a start-up” as it is working towards “one regulatory framework”. Trade is already well integrated, but when it comes to certain rules, such as those related to data storage and medical and financial data, member states can differ widely (ibid).

As previously mentioned and touched upon in our interview with Vahlne (2016), regulatory authorities of the EU is putting effort in promoting digital health by creating a harmonized regulatory system that implies access to the EU market by medical device compliant manufacturers and distributors (DigitalEurope, 2015). However, EU member states also have their own specific requirements with regard to protecting the health and personal data of their citizens and are therefore able to exercise control over data laws and the quality of medical devices (ITU, 2014). As such, there can be differences between member states when it comes to the acceptance of medical data transfer and storage and other types of regulations that can relate to mHealth. When asked about EU’s efforts to harmonize legal requirements for digital health firms, Stevovic (2016) answers that it is a good strategy and vision, but that there is still a lot of work to do. It is difficult to uniform Europe, especially when it comes to health care (ibid). This is generally because member states tend to impose and set up additional requirements to EU regulations (Stevovic, 2016).

On the topic of personal data protection and storage, Stevovic (2016) says that if you are a company collecting personal health data in single countries, you can be subject to single
certifications. In some EU countries (e.g. France) you need to go through an additional certification process or venture with a French local company if you want to deliver or be present in the country. However, if you are able to anonymize the collected data then you are able to store data wherever you want in Europe (as long as it stays within the EU) (Stevovic, 2016).

The regulatory barriers depend on the kind of mHealth solution you are offering - if it needs to communicate with the public service’s systems or if it can be sold without the involvement of a public institution (Stevovic, 2016). Edström (2016) says that some medical devices are more strictly regulated than others (e.g. class III), but that diagnostic helping aids or measuring aids (class I) are usually not as regulated. Trepte (2016) notes that once a company fulfills the requirements of its specific risk class, it is quite hard to fail in this aspect in the EU. In addition, this would imply that the regulatory barriers are higher for some mHealth medical devices are lower than for others.

As such, we believe that this parameter is important to include in our IMS model. It aims to identify any laws or regulations that differ from the EU Directives related to data storage and transfer as well as medical devices and which might create barriers for AdhereBox. Recall that individual member states are allowed to shape rules to better suit the national health care culture. In this parameter we want to identify if are any additional rules you must be compliant in order to be present with a medical device such as that of AdhereBox - a class I medical device.

**Questions for the firm to consider in its IMS:**

i. Are there are any national restrictions or legislation on personal health data storage that would create barriers for us?

ii. Is there an acceptance of international health data transfer?

iii. Are their differing rules that apply to our medical device risk class?

### 5.2.2.9. Existing solutions

NaturalCycles evaluated market demand and customer receptiveness by assessing existing ways and habits for using contraceptives (Scherwitzl, 2016). Iversen (2016) points out that the level of customer receptiveness to a high degree is affected by the degree of competition and existence of similar products in a market place. Assessing how many similar products there are in the market, as well as identifying cases in the country where medical devices are connected to something digital is important. When assessing competition, Iversen (2016) points out that focus should lie on assessing if you are introducing a new behavior with your mHealth innovation or competing for the best solution. Furthermore, “existing competition could also be an indicator that a relevant consumer behavior already is in place and that you do not need to spend resources introducing a new behavior. It could also mean that buying power exists” (Iversen, 2016).
Björlin (2016) believes that it is important that there are established competitors on the market or other actors with similar solutions, and that it is often one of the keys to performing well. Furthermore, if there are other smart mHealth solutions on the market, then relevant institutions have “already gotten used to the fact that change is impending” which would lower the barriers for new entrants. (Björlin, 2016)

Several authors have touched upon the importance of analyzing the existence and implications of competitors and substitutes on a foreign market (Sakarya, Eckman and Hyllegard, 2007; Gould, 2002; Porter, 1998; Porter, 2008; Leonidou, 2004; cited in Serafica Hredzak and Zhang Yuhan, 2010). Important to note, and as our interviews imply, is that competition is not necessarily negative. Although rival players compete against each other for higher market share, the existence of competition also indicates that there is a market for the product or service and that consumers are receptive to such solutions.

Our interviews tell us that it may be attractive with existing solutions, that require a similar behavior, in the marketplace before introducing a mHealth product. As a small company it is essential that minimum focus is put on changing an apparent behavior to fit your product; if consumer already possess the behavior, then the barrier of ‘learning’, or need to “educate” the market, can be eliminated.

Thus, all major types of pill organizers (including direct rival solutions such as smart pillboxes) or medication reminders should be considered in our country evaluation of existing solutions. Alternative solutions to AdhereBox’s smart pillbox include both traditional (analogue) pill organizers, medication reminder apps that are solely software based and electronic and “smart” pill organizers. The main purpose of these products is to help individuals take their medication and improve adherence.

**Questions for the firm to consider in its IMS:**

i. Are we introducing a new behavior with our mHealth solution?
ii. What current alternative solutions and substitutes exist amongst the target users?
iii. Are there any mHealth versions of our product?

**5.3. Resulting IMS model**

The resulting IMS model is based on our empirical observations from interviews, supported by theory on internationalization and international market selection, as well as secondary data (such as industry reports). We argue that the opportunities for mHealth CMDs can be assessed by analyzing a market’s Stakeholders and Barriers and Enablers. These Stakeholders include the Consumers that are target users of the mHealth firm’s CMD, Payers that finance the health care system which to a large degree affects the funding of CMDs, Providers of health care that can work with the user and benefit from the CMD. Furthermore, there are
Distributors that act as channels for the product to reach the end consumer and Collaborators that could help facilitate the entry of the internationalizing firm. Beyond the Stakeholders are surrounding factors that could either act as Barriers or Enablers. These five factors that we have chosen to include in our IMS are: Incentives for mHealth innovation, Regulations that directly apply to mHealth innovation, the Technological infrastructure for mHealth that exist in the country, Existing Solutions for the issue that the firm is addressing and Reimbursement Models for related solutions and the country’s general attitude to mHealth solutions. These groups of parameters are interdependent of one another, which we will exemplify in Chapter 6. by adapting the model to AdhereBox in an assessment and evaluation of different EU countries.

Figure 7: Picture illustrating the proposed IMS model.
6. Country evaluation and discussion

In this section of the report, we aim to show how countries can be assessed in a two-step evaluation process using the IMS model presented in the previous chapter. In the screening stage, we will assess the 28 EU member states using quantitative criteria related to the country’s consumers. We suggest that the screening stage enables one to identify countries that qualify for a deeper assessment in the identification stage. The identification stage assesses the remaining parameters of our IMS model, which focuses on more industry-specific and qualitatively measurable factors. We include the country evaluation in this paper to answer and demonstrate our second research question:

RQ2: How can these parameters be assessed in order to identify opportunities in the EU for mHealth CMDs?

As our assessment is adapted to the client company AdhereBox, this market analysis will present an evaluation of the countries in terms of their market readiness and receptiveness towards AdhereBox’s product. Chapter 6.1. concerns the screening of the total set of EU markets and Chapter 6.2. concerns a deeper analysis of the UK market including a discussion of the observed linkages between the parameters of our IMS model.

![Figure 8: Visualization of the screening funnel that filters countries for further analysis.](image)

6.1. Screening

In the country evaluation of the EU market, we start by assessing the consumers, which is one of the stakeholders of the mHealth CMD ecosystem and our IMS model. Recall that the objective of a screening is “to identify potential markets quickly and inexpensively without regard to method of entry” (Russow, Lloyd and Solocha, 1993, p. 67). As such, in the screening stage of our IMS approach we apply different quantitative indicators from readily available statistical sources in order to assess the volume and economic development of the country population and how receptive their consumers would be towards AdhereBox’s CMD.
6.1.1. Consumers

Recall from Chapter 5.2.1. that the dimension Consumers evaluates the market size, economic development and level of digitalization of the country. We will in this section of the chapter discuss this parameter from the perspective of AdhereBox and present the resulting score from our screening of the EU market.

**Market size**

We have chosen to assess the country population by measuring the volume of the population in the age segment of the population aged 10 years and above. There are several reliable sources that provide statistics on certain population segments. In our evaluation we use macro-level statistics from Eurostat as it includes data for all EU countries. At the time of writing, the latest available data for population by age segment is from 2014. We choose to only gather data on the population size of the target age segment, as data on medication consumption is not readily available for all EU countries. This prevents us from estimating a more precise figure of the different country sizes of AdhereBox's target markets. However, we suggest that firms should include additional factors to include when estimating market size in order to obtain a more accurate figure for their target market. Nonetheless, we believe that this measure of demand will be captured in the identification stage, in which we assess other product- and industry related variables.

**Economic development**

To measure economic development we use statistics from Eurostat on Actual Individual Consumption (AIC) as an indicator of the economic environment of the individual different EU countries. While Gross Domestic Product (GDP) is a basic measure of a country’s overall economic health and level of economic activity (Eurostat, 2013), AIC is an alternative indicator adapted to describe the material welfare of households (Eurostat, 2016b). We chose volume indices of real expenditure per capita in Purchasing Power Standard (PPS) as units to measure these indicators. PPS is an artificial currency, which equalizes the purchasing power of different national currencies. This unit is desirable in international comparisons as it enables meaningful volume comparisons between countries as it expresses data in common currency and adjusts for price levels (Eurostat, 2016c). We use the latest available data from 2014 for these statistics.

**Level of digitalization**

The level of digitalization in a country can be measured using different proxy variables. For instance, smartphone penetration (that is, the number of smartphone users in the market) is one example of a recurring indicator mentioned in industry reports (Monitor Deloitte, 2015; BearingPoint, 2013). Monitor Deloitte (2015) states that smartphone penetration is a major consumer growth driver in mHealth. High smartphone penetration is further a good indicator of that necessary digital infrastructure is widely available, such as high bandwidth, which
provides access to advanced services, enabling advanced smartphones to act as medical devices (BCG, 2012).

We choose to measure the level of digitalization by using proxy variables that indicate digital literacy amongst the individuals of a country. The indicators also help us identify countries with citizens that are familiar with using their smartphones for different services and activities. This would indicate that the acceptance of mHealth is likely to be high (BCG, 2012). We use statistics from Google Consumer Barometer and Eurostat. The variables are chosen on the basis of their ability to measure relevant parameters of digitalization. These include smartphone and connected device usage, online activity and purchasing habits. Purchasing habits was a measurement indicator that NaturalCycles used in their market analysis (Scherwitzl, 2016). Some indicators also serve as proxies for measuring consumer willingness to share personal information (e.g. the percentage of individuals using smartphone to track health levels). All these indicators are quantitatively measured variables and are therefore easy to use for comparison between countries.

There are institutions that have created indices for measuring and comparing the evolution of different countries’ digitalization. For instance the EU “The Digital Economy and Society Index” (DESI) is a composite index that summarizes relevant indicators on Europe’s digital performance (Digital Single Market, 2016). However, this index includes several indicators that we deem as somewhat irrelevant for mHealth consumer goods firms such as AdhereBox. As such, one can see the indicators of this sub-dimension as a digital evolution index tailored for mHealth CMD firms that share similarities with AdhereBox.

In summary, this parameter is constructed around the following indicators (see table below).
## Screening parameters for Consumers

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Unit</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Market size</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Size of population in age segment +10 years old</td>
<td>Number of people</td>
<td>Eurostat</td>
</tr>
<tr>
<td><strong>Economic development</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actual Individual Consumption</td>
<td>Volume indices of real expenditure per capita in PPS</td>
<td>Eurostat</td>
</tr>
<tr>
<td><strong>Level of digitalization</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smartphone penetration</td>
<td>% of individuals using a smartphone device</td>
<td>Google Consumer Barometer</td>
</tr>
<tr>
<td>Wearable digital usage</td>
<td>% of individuals using a wearable digital</td>
<td>Google Consumer Barometer</td>
</tr>
<tr>
<td>Connected device usage</td>
<td>Average number of connected devices owned by individuals</td>
<td>Google Consumer Barometer</td>
</tr>
<tr>
<td>Individuals who have basic or above basic overall digital skills</td>
<td>% of individuals</td>
<td>Eurostat</td>
</tr>
<tr>
<td>Individuals using internet to seek health information</td>
<td>% of individuals</td>
<td>Eurostat</td>
</tr>
<tr>
<td>Individuals using smartphones to track health/diet/activity levels</td>
<td>% of individuals</td>
<td>Google Consumer Barometer</td>
</tr>
<tr>
<td>Individuals that use phones to make their purchases (out of store, phone,</td>
<td>% of individuals</td>
<td>Google Consumer Barometer</td>
</tr>
<tr>
<td>direct mail, online, email or other)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage of population that is of age +55 and uses a smartphone</td>
<td>% of population</td>
<td>Google Consumer Barometer &amp; Eurostat</td>
</tr>
</tbody>
</table>

Table 6: Table summarizing the indicators identified as important for the assessment of consumers.
The implementation of this stage depends largely on the availability and quality of the necessary data. We arrived at these indicators as they had statistics readily available for all countries. However, for some indicators in the level of digitalization sub-dimension, data was not available for Cyprus, Malta and Luxembourg. We suspect that this derives from the fact the three countries have very small populations and are therefore often excluded from being surveyed. Similarly, Cyprus, Malta and Luxembourg were discarded and filtered out from the set of countries after assessing their size of the target age segment, as they were considered too small to be interesting as a first international expansion.

We refer the reader back to Chapter 3. Methodology for an elaborate description of the methods used to score the countries in each dimension and indicator.

<table>
<thead>
<tr>
<th>Screening output including Sensitivity Analysis</th>
<th>Score - 20 % sensitivity</th>
<th>Score - 10% sensitive</th>
<th>Country Score</th>
<th>Score + 10% sensitive</th>
<th>Score + 20% sensitive</th>
</tr>
</thead>
<tbody>
<tr>
<td>United Kingdom</td>
<td>113,3</td>
<td>110,2</td>
<td>101,2</td>
<td>91,1</td>
<td>82,6</td>
</tr>
<tr>
<td>Sweden</td>
<td>102,1</td>
<td>101,5</td>
<td>99,5</td>
<td>86,4</td>
<td>77,9</td>
</tr>
<tr>
<td>Netherlands</td>
<td>96,1</td>
<td>96,1</td>
<td>91,6</td>
<td>80,3</td>
<td>77,5</td>
</tr>
<tr>
<td>Spain</td>
<td>100,9</td>
<td>96,3</td>
<td>91,5</td>
<td>76,2</td>
<td>69,0</td>
</tr>
<tr>
<td>Denmark</td>
<td>102,1</td>
<td>100,1</td>
<td>90,8</td>
<td>80,1</td>
<td>73,8</td>
</tr>
<tr>
<td>Germany</td>
<td>100,9</td>
<td>97,6</td>
<td>90,4</td>
<td>81,1</td>
<td>74,1</td>
</tr>
<tr>
<td>Finland</td>
<td>100,1</td>
<td>94,4</td>
<td>85,1</td>
<td>79,1</td>
<td>70,3</td>
</tr>
<tr>
<td>Austria</td>
<td>92,9</td>
<td>86,6</td>
<td>79,5</td>
<td>68,0</td>
<td>62,5</td>
</tr>
<tr>
<td>France</td>
<td>92,6</td>
<td>84,7</td>
<td>78,0</td>
<td>68,9</td>
<td>62,9</td>
</tr>
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<td>79,8</td>
<td>77,0</td>
<td>63,7</td>
<td>60,7</td>
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<td>74,0</td>
<td>68,5</td>
<td>60,0</td>
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<td>Belgium</td>
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<td>71,7</td>
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<td>82,3</td>
<td>69,9</td>
<td>69,3</td>
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<td>50,8</td>
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<td>Poland</td>
<td>89,8</td>
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<td>68,4</td>
<td>59,5</td>
<td>55,0</td>
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<td>Croatia</td>
<td>78,8</td>
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<td>65,8</td>
<td>52,7</td>
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<td>62,3</td>
<td>47,1</td>
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<td>61,7</td>
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<td>Hungary</td>
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<td>50,2</td>
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<td>59,5</td>
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<td>59,3</td>
<td>55,7</td>
<td>49,2</td>
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<td>Bulgaria</td>
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<td>51,2</td>
<td>50,4</td>
<td>45,2</td>
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<td>Romania</td>
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<td>48,2</td>
<td>45,2</td>
<td>45,2</td>
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<tr>
<td>Luxembourg</td>
<td>40,0</td>
<td>40,0</td>
<td>37,0</td>
<td>39,4</td>
<td>37,4</td>
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<tr>
<td>Malta</td>
<td>32,0</td>
<td>27,4</td>
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<tr>
<td>Cyprus</td>
<td>30,0</td>
<td>25,4</td>
<td>20,4</td>
<td>18,8</td>
<td>16,8</td>
</tr>
</tbody>
</table>

Table 7: Country scores and sensitivity analysis from the screening stage.

In the table, the results from the sensitivity analysis are also presented. From it we see that the rankings between countries only differs slightly if thresholds are changed. The only significant
change occurs when thresholds are decreased by 20%. In this instance, Slovakia’s ranking increases, making the country eighth place on the list. Naturally, a decrease in threshold generates a higher, or equal, score for each country.

We can see from the data in the below tables (see Table 8 and Table 9, also found in the Appendices), that the EU member states differ in how digitalized their societies are; the rate of smartphone penetration and compatible devices, as well as how internet is used amongst its citizens. The consumers of Eastern and Central European countries tend to be less developed and more analogue when it comes to technology usage. However, when asked which countries they believed have made particularly progress when it comes to adopting eHealth solutions in the health care system Olsson (2016) distinguished the Spanish regions Catalonia and the Basque Country as being fairly mature and more developed than other Spanish regions. Other states with relative high degree of mHealth adoption were Netherlands, Estonia, England, Scotland and the Nordic countries (Olsson, 2015).

<table>
<thead>
<tr>
<th>Country</th>
<th>Population size</th>
<th>Actual Individual Consumption</th>
<th>Smartphone usage</th>
<th>Wearable digital usage</th>
<th>High-tech connected devices as people use</th>
<th>Internet use seeking health information</th>
<th>Individuals using smartphone to track health or health accessibility</th>
<th>Percentage of individuals who use a smartphone</th>
<th>Digitalization of elderly population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albania</td>
<td>2,940,994</td>
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<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
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<td>100</td>
<td>100</td>
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<td>100</td>
</tr>
<tr>
<td>Belgium</td>
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<td>100</td>
<td>100</td>
<td>100</td>
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</tr>
<tr>
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<td>100</td>
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</tr>
<tr>
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</tr>
<tr>
<td>Malta</td>
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<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Netherlands</td>
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<td>100</td>
<td>100</td>
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<td>100</td>
<td>100</td>
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<tr>
<td>Portugal</td>
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</tr>
<tr>
<td>Spain</td>
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</tr>
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</tr>
</tbody>
</table>

Table 8: Table presenting the data used in the screening stage. Cyprus, Luxembourg and Malta are lacking data for some indicators due to missing data in our source databases. Find Appendix A for full sized figure.
As mentioned in the methodology chapter, a contribution analysis was conducted to assure that no sub-dimension contributes too much to the final score. The contribution of each group of indicators is depicted in the chart below. We see that the digital device ownership variable contributes the most to the overall score, followed by market size, digital skills and level of digital skills. Market size contributes to 17% of the overall score. This can explain the high scoring of the largest EU countries (in terms of their population size) - e.g. United Kingdom, Spain, France and Germany.

**Figure 9: Pie chart presenting the overall weights attributed to the different indicators reflecting AdhereBox’s priorities.**

**Table 9: Table presenting the weights and score for each country’s performance in the indicators assessed in the screening stage. Find Appendix B for full sized figure.**

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Population size</th>
<th>Actual Individual Consumption</th>
<th>Smartphone usage</th>
<th>Shareable digital range</th>
<th>How many connected devices as people use?</th>
<th>Scope of digital skills</th>
<th>Interest in new technologies</th>
<th>Digitalization of elderly population</th>
<th>Final Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case Company A</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Cyprus</td>
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<td></td>
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</tr>
<tr>
<td>Luxembou</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>93.4</td>
</tr>
<tr>
<td>Romania</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>90.4</td>
</tr>
<tr>
<td>Hungary</td>
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<td>Latvia</td>
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<td></td>
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<tr>
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<tr>
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<tr>
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<tr>
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<tr>
<td>Germany</td>
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<tr>
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<tr>
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<td></td>
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<td>42.8</td>
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<td>Set of EU countries (in terms their population size)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>40.0</td>
</tr>
</tbody>
</table>

**Weights and scores from screening stage**

- **Digitalization of elderly**
  - Market size: 17%
  - Economic development: 13%
  - Digital Device Usage: 17%
  - Digital Skill: 18%
  - Smartphone Activities: 9%
  - Purchase behaviour: 17%
- **Digital Device Usage**
  - Purchase behaviour: 9%
  - Smartphone Activities: 17%
  - Digital Skill: 18%
  - Economic development: 9%
- **Digital Skill**
  - Market size: 17%
  - Economic development: 13%
  - Digital Device Usage: 17%
  - Smartphone Activities: 9%
  - Purchase behaviour: 17%
- **Smartphone Activities**
  - Market size: 17%
  - Economic development: 13%
  - Digital Device Usage: 17%
  - Digital Skill: 18%
  - Purchase behaviour: 9%
  - Digitalization of elderly: 15%
- **Purchase behaviour**
  - Market size: 17%
  - Economic development: 13%
  - Digital Device Usage: 17%
  - Digital Skill: 18%
  - Smartphone Activities: 9%
  - Purchase behaviour: 17%

**Source:** Eurostat, Google Consumer Barometer; Note on population retrieved from Eurostat. Data on smartphone usage retrieved from Google Consumer Barometer. Resulting indicator is a multiplication between the two data sets.
6.2. Identification

In the identification stage we examine the remaining evaluation criteria of our proposed IMS model and the interdependencies between these. We believe that this market analysis can guide mHealth CMD firms in identifying opportunities, barriers and possible entry modes related to a potential launch of its product in a country. As in the screening, we analyze the parameters from AdhereBox’s perspective.

The purpose of the identification stage is to identify countries that could offer favorable market conditions for mHealth CMD start-ups. We demonstrate ways that companies can assess and analyze the remaining dimensions of the IMS model presented in Chapter 5.: Stakeholders (Providers, Payers, Distributors and Collaborators) and the Barriers and Enablers (Incentives, Reimbursement models, Technological infrastructure, Regulations and Existing solutions). Although being beyond the scope of our research purpose, the outcome of this analysis will also reveal potential entry modes.

In this report we have chosen to present our findings from the in-depth identification of one country. We will also discuss these findings in terms of the country’s level of suitability and readiness towards embracing AdhereBox’s product. The findings and analysis from the identification stage will be presented visually in a country profile as well as in text in a discussion. The country that we choose to present in order to show how an identification stage can be conducted is the United Kingdom.

Important to note, is that the conclusions made are based on our interpretation of the secondary sources that were used in order to assess the remaining dimensions of our IMS model. As such, we believe that further examination as well as field studies, are needed in order to support a final selection of countries for market entry. Nonetheless, we believe that the findings from this stage may guide AdhereBox and similar firms in finding possible ways of approaching countries with potential. We also believe that our findings will identify those areas that need to be further investigated in a final selection phase.

6.2.1. Country profile

The country evaluation of the identification stage, that we have to chosen to present in our report, is that of the United Kingdom (UK). This is due to the fact that the UK scored the highest in the screening stage. We note that a deeper evaluation should be performed of other countries as well, to enable comparison in the remaining parameters of our IMS model. However, we choose to present the country profile of one country, as our report would otherwise become too lengthy. The figure that follows summarizes aspects of each parameter from our deeper analysis of the state.
United Kingdom

Challenges to cope: aging population, meeting high patient expectations of latest technology, high bed occupancy & waiting times, expanding infrastructural capacity but with limited resources, need to reduce unnecessary hospitalizations & emergency services

Efforts to increase efficiency and reduce costs: number of hospitals declining, health services shifting from hospitals to community, innovative compensation models introduced (e.g. P4P in England)

Initiatives on improving medication adherence (e.g. New Medicine Service (NMS) and previous study by Improvement and Efficiency West Midlands (IEWM) and NHS)

No clear reimbursement model for CMDs despite high demand

However, NHS Choices provide recommendations on e.g. smartphone apps

All nations see development of eHealth crucial for future - Scotland

NHS in frontier of eHealth adoption

NHS in collaboration with tech specialist to create mHealth apps for citizens

Technological Infrastructure

Electronic Identification System

Open APIs

ePrescription

Analysis

UK offers favorable conditions for AdhereBox with several points of contact for market entry

However, mHealth adoption still immature in several areas (see right figure)

UK qualifies for final assessment stage of IMS process

Figure 10: Country profile for the UK.
6.2.2. Discussion

This discussion is a reflection based on our interpretation of the information gathered about the UK. With it, we demonstrate how an analysis in the identification stage may look like, and which conclusions can be made based on it. But before presenting our analysis of the UK, we begin by summarizing the information gathered on the remaining IMS parameters.

Stakeholders

Providers

The United Kingdom (UK) comprises four nations (England, Scotland, Wales and Northern Ireland), where 80% of the total population lives in England, followed in size by Scotland, Wales and Northern Ireland (Cylus et al., 2015). There is no unified health care system in the UK. Instead, England, Scotland, Wales and Northern Ireland encompass four distinct National Health Systems (NHS) (“Health and Care service” in the case of Northern Ireland), each with its own unique characteristics. (epSOS, 2010) From 1997, the health systems of the four nations have diverged in how services are organized and paid for (Cylus et al., 2015). Despite their differences, all nations have health services that provide a comprehensive package, mostly free of charge and with universal access (ibid).

The UK nations have somewhat different stated objectives of their health care systems. In England decentralization of decision-making, choice and competition in the commissioning (i.e. strategic purchasing) of care as well as meeting performance targets are stated goals. Scotland maintains a national approach and formally emphasizes cooperation, collaboration and partnership over competition. It also makes meeting performance targets a priority. Wales has a similar approach as Scotland, in that it is generally centralized and emphasizes cooperation over competition in commissioning. The Northern Ireland system seems to be, in some respects, most similar to what is in place in England, but lagging somewhat behind. (Cylus et al., 2015)

In the UK, patients can access primary care services through their local general practitioner (GP), generally free-of-charge, through the NHS. The GPs control the access to secondary care through referrals (Cylus et al., 2015). Private companies are the main providers of nursing care for older citizens, but there are also a number of private hospitals and clinics that provide services for patients that pay fees directly or those with private health insurance. Private providers can also be contracted to provide a wide range of services under NHS contracts in England. In Scotland private providers are generally only used by the NHS to ease waiting time pressures (Cylus et al. 2015).
**Payers**

Healthcare services in the UK are predominantly financed from general taxation, where 83.1% of total health expenditures came from public sources in 2014, with the remaining coming from private sources, these being private medical insurance (3.4%), out-of-pocket (OOP) payments (9.7%) and non-profit institutions (3.7%) (WHO, 2016). The proportion of public health funding is relatively high compared to other EU member states, which was on average 73.4% in 2014 (ibid). Although the different NHS:s of the UK generally provide comprehensive health services, in practice, coverage for specific services varies across the UK.

The NHS’s care is mostly free at the point of access, but there are cases where patients have to make co-payments (for goods and services covered by the NHS but requiring cost sharing) and direct payments (for services not covered by the NHS or for private treatment). Some citizen groups, such as children, pensioners over 65 and those on low income, have recourse to reimbursement or exemption for some co-payments. (Cylus et al., 2015)

About a tenth of the UK population has private health insurance of some kind, which is most often purchased by employers for their employees (Arora et al., 2013). Private insurance is usually used to finance services not offered by the NHS or to access NHS-covered services more quickly (Cylus et al., 2015). Healthcare funding from private insurance make up 3.4% of the total health expenditure (WHO, 2016).

**Distributors**

Although we acknowledge that there are several distribution channels that can be used by mHealth CMD firms in order to access its end-consumers, we have chosen to present our findings from examining the UK pharmacy market.

The UK offers one of the least restrictive government environments of pharmacies between member states; discounts from wholesalers to pharmacies are allowed, chains and non-pharmacy ownership are allowed, and no control of location exists. Furthermore, many pharmacies offer additional services such as blood glucose testing and emergency contraception, sometimes at no cost to the patient (Kanavos, Schurer and Vogler, 2011). In addition, the UK is a major producer of pharmaceuticals. Manufacturers of drugs distribute to wholesalers, who then sell these to pharmacies and dispensing doctors. Wholesalers and retail pharmacies are all commercial enterprises and retail pharmacy has managed market entry (Cylus et al., 2015). There are several pharmacy led chains in the UK, the majority of them having online outlets as well as online prescription services. Besides pharmacies, there are also supermarket chains with in-store pharmacies (see Appendix for a comprehensive list of pharmacies in the UK). In the UK, most prescription items are dispensed by community pharmacies (HSCIC, 2015). In England, ~62% of all the community pharmacies were owned by multiple contractors - that is, contractors owning 6 pharmacies or more (ibid).
Procurement by hospital trusts can be done in several ways in the UK. Hospital trusts are in charge of their own procurement. Nonetheless, there exists a governmental organization, the NHS Supply Chain, which operates central procurement for hospital trusts (NHS England, 2016). Through the NHS Supply Chain, hospital trusts can purchase some categories of products at consistent prices (e.g. devices for specialist services) (ibid). The NHS Supply Chain offers e-commerce to hospital trusts so that ordering, updates and billings can be readily available (NHS Supply Chain, 2016a). The NHS Supply chain offers access to roughly 386,000 articles through their suppliers (NHS Supply Chain, 2016b). As of 2015, records showed that 80% of all contracts were awarded to small or medium enterprises (SMEs) suppliers, which amounted to 30.2% of NHS Supply Chain's contract portfolio sales (NHS Supply Chain, 2016c).

There are several procurement hubs for NHS that have started under different circumstances but with the same goal of improving NHS procurement (NHS LPP, 2016). There are also commercial hubs that are not part of the NHS (ibid). NHS London Procurement Partnership is a not for profit membership body that hospitals pay an annual membership fee to be a part of (ibid). In order to become a supplier a company must (in the majority of cases) advance through frameworks or pre-tendered contracts (NHS LPP, 2016). Contract Notices are published in the Supplement to the Official Journal of the European Union (OJEU) (ibid). All tenders above the value of £113,000 are published in the supplement to the OJEU (ibid).

**Collaborators**

The digital technology industry is doing well across the UK, and is growing in terms of revenue, number and employees (Tech City UK, 2015). In addition, Tech City UK (2016) has identified 21 clusters in digital technology in the UK (Tech City UK, 2015). Recall from Chapter 5. that clusters can help build regional reputation, affordable property and attract inward investment. The cluster that we see as most suitable for mHealth innovation are the following:

i. **Leeds** has a high growth in data management, HealthTech and FinTech. (Tech City UK, 2015)

ii. **South Wales** is dominated by start-ups and small firms, with special focus evolving on HealthTech and data management and analytics. The government has launched several HealthTech funds in this region. (Tech City UK, 2015)

iii. **Oxford** has several centers of excellence, with growing expertise within HealthTech (Tech City UK, 2015). Oxford is also strong in app and software development (Tech City UK, 2016).

iv. **Cambridge** has notable competences within Internet-of-Things and connected devices as well as data management and analytics (Tech City UK, 2016) (For more information on Cambridge and why it has become a successful Life Science cluster, see Vasco Advisors (2015) [in Swedish])
v. **Reading and Bracknell** has a notable field in data management and analytics as well as good access to local networks. However, it is perceived by local companies as having a limited supply of talents. (Tech City UK, 2016)

Important to note is that networking is not bounded to the immediate surrounding as many UK digital tech businesses collaborate both across UK and internationally (Tech City UK, 2016).

In addition, we have identified the following organizations that could serve as suitable collaborators for AdhereBox.

i. Accelerators that have direct influence in the field of healthtech (Tech City UK, 2016);

ii. Governmental authorities with substantial knowledge about UK health care and the developments that they have gone through (e.g. Healthcare UK is part of the Department of Health and UK Trade and Investment (Healthcare UK, 2015);

iii. Agencies that provide guidance on the UK health care system (e.g. National Institute for health and Care Excellence (NICE) ([https://www.nice.org.uk/](https://www.nice.org.uk/)) (NICE, 2016); and

iv. Large patient organizations and foundations in the UK related to chronic diseases (MSD, 2013) (e.g. Diabetes UK [Diabetes UK, 2016]).

**Barriers and Enablers**

**Incentives**

Like several other EU countries, the UK faces several challenges going forward which are likely to affect the cost and quality of health care. These include:

i. coping with the needs of an ageing population;

ii. managing citizen groups with poor health behaviors and associated chronic conditions;

iii. meeting patient expectations of access to the latest available medicines and technologies; and

iv. the issue of expanding the infrastructural capacity of a health care system with limited resources so that it can rise to these challenges. (Cylus et al, 2015)

There are evident examples of efforts being made to increase efficiency and reduce costs. For example, the number of hospitals across the UK has declined as care has shifted from smaller hospitals to larger ones, and health services have shifted away from hospitals and into the community (Cylus, 2015).

Another example is the initiative to introduce new compensations models to the health care system, such as the Pay for Performance (P4P) in England (Cylus, 2015). P4P schemes have
been introduced in order to encourage improved quality of care (ibid). These are believed to give financial incentives to clinicians for better health outcomes, as it rewards GPs and other health care providers for meeting certain performance measures for quality and efficiency (ibid). P4P is believed to give payers of health care financial incentive to, for instance, encourage healthy behaviors and better monitor chronically ill patients to avoid costly hospitalizations (Ernst and Young, 2012).

Nonetheless there are still issues that need to be solved. One example is the long-standing issue of reducing waiting times in emergency care and for elective procedures (Cylus et al., 2015). Despite the fact that the average length of stay has been declining, the UK still has high bed occupancy rates (above the EU average), which suggests little spare capacity to deal with shocks of demand (ibid). Another issue relates to reducing the demand for emergency care services and unnecessary hospitalizations (ibid).

While the approaches to health care in each of the four nations of the UK has somewhat diverged, their health care systems all share the same objective of promoting public health and providing high-quality care, being efficient and cost–effective, and providing an integrated system of health and social care. (Cylus et al, 2015)

When it comes to initiatives on improving medication adherence, we have identified at least two initiatives in the UK the New Medicine Service7 (NMS) (Elliott et al, 2014; PSNC, 2016) and the Automated Pill Dispenser Project pilot by NHS West Midlands in England and Improvement and Efficiency West Midlands (IEWM) (IEWM and NHS, 2010). Both initiatives have received positive outcomes. For instance, the NMS service increased adherence by 10% (Elliott et al., 2014). The business case of the Automated Pill Dispenser Project automatic pill dispenser resulted in substantial health care savings during its six-month trial and reduced many burdens for the health care system as unnecessary visits and admissions could be avoided.

Reimbursement models

Despite the large demand for mHealth CMDs in the UK, it is difficult to commercialize these through the public health care system as there are no clear and central reimbursement models for mHealth apps and wearables (Monitor Deloitte, 2015). In a recent report that Deloitte carried out for the UK Office of Life Science (which is part of the governmental departments of Business, Innovation and Skills and Health), they identified the need for improving reimbursement policy for digital health solutions as an area of improvement in order to grow the UK health industry (Monitor Deloitte, 2015).

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7 Initiated 2011 and funded by the NHS, the NMS aims to provide support for people with long-term conditions who have been prescribed a new medicine to help improve their adherence. The service is provided by pharmacists and focuses initially on particular patient groups and conditions, for example those receiving medication for diabetes, hypertension, asthma and anticoagulant / antiplatelet medication. Patients are recruited at the point of dispensing, counselled on any relevant points about the new medication and provide consent to participate in the service. Within two weeks the pharmacist conducts an interview with the patient in order to identify any problems, side-effects, concerns or non-adherence to the new medication.
However, the NHS has listed recommended mHealth applications that can be accessed through their webpage NHS Choices (NHS Choices, 2016), and some of these may be subsidised by local authorities (Monitor Deloitte, 2015).

**Technological infrastructure**

As confirmed in the screening stage of our IMS model, the UK population has overall high digital literacy when it comes to the usage of smartphones and the Internet. The NHS collaborates with technological specialists to create mHealth applications that can be used by its citizens (UKTI, 2015). For instance, Handle my Health is a smartphone app that NHS has partially invested in, which helps people to manage their medication and improve overall quality of life (UKTI, 2015). In addition, England’s NHS is investing substantial amounts on an effort to go paperless and shift chronically ill people to remote patient monitoring (Versel, 2016).

Although they pursue somewhat distinct health care strategies, the nations of the UK all see the development of eHealth related services as crucial for the future. For instance, Scotland has seen improvements in telehealth and telemedicine, which are considered especially important in a country with large remote rural areas (ibid). Technology initiatives that Scotland has adopted include eHealth systems such as imaging storage, digital referral systems and the United Kingdom’s first electronic prescriptions transfer program. The government has also issued information about assuring the security of patient information as part of an overall eHealth strategy. Implementation of information technology development in Wales is led nationally, and shares similar objectives to Scotland. (Cylus et al., 2015)

When it comes to the systems that AdhereBox sees as valuable to have in place, we have identified both barriers and enablers. For instance, the UK does not have any electronic identification system in place (PBLQ, 2015). Neither do personal identification numbers exist (ibid). Instead, in England and Wales, a patient has its own unique NHS number, and Scotland also uses reference numbers in its NHS to identify people in their databases. This would create some complications for AdhereBox if its app would include functions that require the user to identify himself or herself electronically.

Regarding Open APIs in health care, the NHS England has expressed its wish to develop this type of technological architecture (Emis Health, 2015; NHS, 2014). Despite having addressed this in discussions on digital health efforts and with organizations that work with interoperability in health care (DHACA, 2016) there is no evidence of Open APIs currently in place.
The electronic prescription (ePrescription) service is the most adopted eHealth innovation among AdhereBox’s list of valuable technological systems. England has introduced an ePrescription service, which is supposed to expand gradually to encompass all potential prescribers, including walk-in clinics and dental practices in England (Milieu, 2014). However it is not nationally employed and implementation is relatively low. As previously mentioned Scotland has also ePrescription services in place, as part of its cohesive eHealth strategy.

**Regulations**

AdhereBox will design its software so that data automatically becomes anonymous. As a result, the start-up will not be as affected by national laws on data security and privacy, as perhaps other mHealth firms would be. There are no differing data security regulations to comply with as long as AdhereBox stores anonymous personal data within the EU. This is due to the fact that the majority of these regulations concern how companies should store personal data outside the borders of the country (Lead developer, 2016). As such, national laws on data storage have not been examined as rigorously as the other parameters in our country evaluation (Workshop, 2016). Recall that AdhereBox is also in the process of CE-marking its product as a class I medical device (Head of Technology, 2016).

**Existing solutions**

As we concluded in Chapter 5., we view the presence of competing or alternative solutions in a country as an enabler of mHealth adoption. After a closer examination of the competitive landscape of the UK, we note that there are several types of solutions addressing medication adherence. These include regular analogue pillboxes, electronic pill dispensers as well as alternative solutions aimed towards certain patient groups, such as the NHS-funded New Medicine Service. Also, we identify mHealth solutions - e.g. medication reminder apps and a yet to launch smart pill organizer (Tinylogics - Memo Health).

**Analysis and conclusion**

When analyzing the Incentives parameter for the UK market, we discover several macro environmental factors that could act as enablers for mHealth adoption. These include both demographic (such as an aging population) as well economic factors. The incentives for mHealth innovations in the UK are seemingly high, especially in England, which seems to be more cost-driven than the other UK nations. Furthermore, there is evidence of initiatives being made on improving medication adherence, which we deem as an opportunity for AdhereBox. The different incentives that the UK is carrying out, as a result of its expressed vision of cost control, is a sign of that increased efficiency will dictate the future development of its health care system. Knowing that the UK health care system is largely publicly financed and that initiatives on addressing medication non-adherence have shown to reduce health care costs, would suggest that the health care system would support products like AdhereBox’s. However, we also note that a health care system with more private actors (e.g. private insurance companies) would perhaps have more incentives to adopt such a product.
Furthermore, AdhereBox could learn from the outcomes of these previous initiatives in order to increase the success of a potential launch in the market.

Also, the receptiveness towards mHealth solutions by practitioners, such as doctors and other physicians, could be higher in the UK relative to other EU countries as financial and non-financial incentives have been deployed to reward increased efficiency and quality of care. These remuneration models (e.g. the P4P model) have proven to be efficient. Hence, the incentives to recommend patients using mHealth solutions (e.g. products like that of AdhereBox) might be higher in the UK relative to other countries where such incentives do not exist.

There are clear linkages in the health care system between its providers, payers and consumers and how these create incentives towards adopting mHealth solutions. For instance, there is a strong desire to reduce unnecessary health care expenditures (e.g. emergency care), and authorities are putting pressure on public providers of health services to become more efficient. In an effort to do this, remuneration models (e.g. P4P) have been introduced in order incentivize providers to become more efficient and increase the quality of health care outcomes. This will most likely affect the patients, or consumers of health care services, as they will need to become more responsible over their health. This in turn creates incentives for the health care system in adopting mHealth solutions.

Consumers have free access to universal care by the providers in the UK. As touched upon earlier, providers have incentives to reduce time spent with patients in order to become more efficient and reduce costs that the payers stand for. AdhereBox addresses this issue as its product could possibly reduce unnecessary hospital admissions due to e.g. double-dosing or other forms of medication non-adherence.

The UK has today a lower than average OOP expenditure by consumer payers. Its health care system is largely publicly financed through taxation, which makes incentives for consumers paying for medical devices OOP less likely. Adding to this is the fact that reimbursement models for mHealth CMDs are not yet widespread. Due to the high accessibility of the public health care system and low coverage by private insurance, the consumer’s incentives to purchase the medical device of AdhereBox might therefore be low. However, because of the incentives for adopting mHealth products, the future may open up for co-payments of mHealth products. Payment models for reimbursement of mHealth CMDs may arise as a result of the many financial and non-financial incentives to adopt such solutions.

We see the existence of reimbursement models for mHealth CMDs as an important enabler to increase customer receptiveness, as OOP payments of the UK are low. In terms of reimbursement models for mHealth, we currently see this aspect as a barrier for AdhereBox. However, despite not having any apparent reimbursement model for mHealth related
products in place, we see the UK’s acknowledgement of mHealth applications as an important step in their gradual progress towards becoming a more mature market for mHealth.

The structure of the UK pharmacy market offers opportunities for mHealth CMD companies like AdhereBox. This is due to the fact that its pharmacy industry is unregulated offering several large chains as well as online outlets. Considering its large and unregulated pharmacy market of big chains, it may be easier for companies to access a larger consumer market in the UK than in countries with a more regulated and fragmented pharmacy market. In addition, most prescription items are dispensed by community pharmacies, which to 62% are owned by multiple contractors (e.g. chains). Further IMS assessment should include a deeper examination of how these pharmacy chains handle their procurement and identify the intermediaries (e.g. wholesalers or cooperatives) and their characteristics (e.g. order volume, governance structure and margins). GPs, dispensing medication, could also serve as distribution or marketing channels of mHealth products.

When it comes to potential collaborators, the UK offers several aspects of this parameter. There are many clusters and organizations in the UK that offer suitable collaborators and networking opportunities for mHealth start-ups. The regions where these competences are headquartered can be used for both establishing a local office to work from, as well as gathering knowledge about the national market. These are spread out across the state, but with the majority being located in England. We suggest that these can be approached in order to find ambassadors and perform field studies in the country as well as identify key opinion leaders that can help promote AdhereBox’s product.

Key opinion leaders are examples of collaborators that could directly influence the consumer market through championing certain mHealth products. Several of our interviewees have indicated the need to identify such collaborators in order to efficiently gain access to important stakeholders in the market. Some collaborators (e.g. patient organizations) may have the power to influence policy making (regulations) in matters that concern the health of their members or the citizen groups they represent. This has been observed in other EU countries, e.g. the Netherlands and Denmark. Patient organizations could very well be suitable collaborators for AdhereBox. These could, for instance, help mediate contact with distributors in order for AdhereBox to access its consumers.

Furthermore, the prospering health tech scene in the UK might create incentives for public authorities to facilitate the adoption of digital health initiatives. As governments become aware of the growing presence of digital health firms - as an employer and source of tax revenue - they might also increase the ease of doing business for such companies.

Regulations may affect the development of mHealth related technological infrastructure negatively as national laws on, for instance, data security create barriers. However, from our
market analysis, we have not identified any apparent barriers for class I compliant CMDs or restrictions on handling data that would be applicable to AdhereBox.

The technological infrastructure and systems in place clearly affect the consumers in the way they can access the full spectra of functions that AdhereBox’s pillbox has to offer. For instance, the UK currently lacks a unified and secure electronic identification system that can be accessed through a smartphone (e.g. the Mobilt BankID in Sweden or NemID in Denmark). This could create barriers for AdhereBox, as it would need to reconfigure some of its functions in order to adapt to this. Although there are some technological systems on AdhereBox’s list that the UK has not yet implemented, we judge the market as fairly mature in its readiness for mHealth with its comprehensive and broad eHealth strategy. Some nations have come further in the deployment of single systems, where Scotland has been the early adopter in many cases. We do however see issues with the adoption of mHealth solutions by consumers due to the lack of online identification methods that we deem necessary to access full the functionality of this type of innovation.

Our findings imply that other actors have identified a need for products in the UK market, addressing medication adherence. This suggests that there would be no need to introduce a new behavior or educate the market in using medical aids to help adhere to one’s medication regimen. Hence, we regard the UK as mature in this aspect. We have observed that public providers (NHS) have helped finance and cooperate with consumers and collaborators to create existing solutions aimed towards increasing medication adherence (e.g. the NMS and the Automated Dispenser Project). We believe that this indicates a certain acceptance towards solving health issues through new innovative products or services. Furthermore, there are linkages between existing solutions and the consumers as the presence and characteristics of available options on the market addressing medication adherence reflect the behaviors of its consumers. In the case of the UK, there are several different products for this.

As we intend to show how start-ups, usually with limited time and resources allocated for market analyzes, we acknowledge that certain aspects of our IMS model may require too much effort in assessing. Hence, we also show that parameters, such as regulation and technological infrastructure, can be identified by studying the existing solutions already on the market. As we already have mentioned, there are signs of mHealth CMDs probably handling medical data and using Open health APIs.

After examining the UK in terms of its “business ecosystem” for mHealth CMD start-ups, we notice several examples that could imply preferable market conditions for companies like AdhereBox. We can conclude that these include both suitable stakeholders and other enabling factors. Nonetheless, we also find evidence of barriers, which could challenge the receptiveness of mHealth CMDs.
Bearing in mind the national division between the four UK countries, we believe that companies, such as AdhereBox, should see England, Scotland, Wales and Northern Ireland as different markets, but not as entirely isolated silos. It is important to note that the NHS addresses some issues on an aggregated scale. Entering one of its nations could therefore be considered a springboard to the larger UK market.

Based on our analysis using our constructed IMS model, we believe that the UK market has several favorable conditions for mHealth CMD start-ups, with several points of contact to enter the market. However, its health care system is not entirely mature when it comes to mHealth adoption; in several areas, mHealth adoption has not been fully executed. Furthermore, the health care industry is complex for start-ups to enter and there are several linkages between parameters that start-ups need to reflect on before choosing a suitable business model and entry mode. The complexity of the mHealth ecosystem is visualized in the below figure (see Figure 11). It depicts the many linkages between the parameters of our IMS model. Based on the analysis, we qualify the UK market for the third and final stage of the three-stage IMS process (see Chapter 4.2.1.).

Figure 11: Illustration of the linkages between the different IMS parameters in our country evaluation of the UK.
7. Concluding remarks and further research

This concluding chapter is dedicated to summarizing our study and discuss questions that have arisen during the research process, as well as concluding remarks about our study. In Chapter 5, we answered our main research question regarding what parameters should be evaluated in an IMS model for mHealth CMD start-ups, by conducting interviews with mHealth firms and industry experts. We supported our empirical findings with existing research on internationalization and IMS theory. In Chapter 6, we demonstrated how our choice of parameters could be evaluated in order to identify opportunities for mHealth CMDs by performing a screening of the EU as well as an identification evaluation of the UK. Through this analysis we answered second research question. Furthermore, we identified several linkages between the parameters in the two categories Stakeholders and Barriers and Enablers to illustrate the complexity of a health care system and the industry in which mHealth CMD start-ups operate.

7.1. Fulfilling the purpose of the research

The purpose of our research was to identify critical factors that should be considered in an IMS model for mHealth CMD start-ups, when evaluating the EU market in an IMS. By applying our IMS model on AdhereBox, we hoped to illustrate how the model can be used and its parameters assessed. In addition, we believed that our research would illustrate how existing theories in international market selection can be applied and used in the emerging field of mHealth and international market selection.

7.1.1. Research question 1

In order to serve the purpose of our research two questions were to be addressed. The first, and main, research question was:

RQ1: What parameters should be assessed in an international market selection model for mHealth consumer medical device (CMD) start-ups, in order to identify attractive countries in the EU to launch their products in?

By conducting a literature review in combination with unstructured and semi-structured interviews, it was possible to identify factors that should be considered by mHealth CMD start-ups in an IMS. The pre-study and literature review led to the identification of aspects that required further examination in the subsequent stage of our research process regarding the gathering of primary data. Our empirical observations later resulted in an IMS framework consisting of macro and micro factors, which together captured the structure of the business ecosystem of mHealth CMD start-ups.
From our study we find that the networking aspect of internationalization is particularly prevalent. In previous research, Moen, Gavlen and Endresen (2004) observed, from analyzing the entry forms and market selection of born globals, that a firm’s selection of market (as well as entry mode) is highly dependent on the available networks in the country. The findings from our interviews support previous empirical research on internationalization theory; throughout our gathering of primary data, the networking aspect of internationalization was a recurring topic of discussion. In our research, interviewees proposed several actors that could help facilitate the entry for mHealth firms. Because of the complex system of stakeholders in health care market we find this an especially critical factor in the IMS of mHealth start-ups. These could for instance be key opinion leaders or patient organizations and be indicated by the presence of life science and digital health clusters or events. Recall from our case study of Kiwok, that its IMS strategy centers a lot on identifying collaborators, or “ambassadors”, that can help facilitate market entry into the respective country. As such, different collaborators can be used to acquire market knowledge, mediate contact with distributors as well as influence decision makers in the health care system.

Besides collaborators, we also identified distributors as an important factor for accessing and reaching the end consumers. Besides analyzing the country’s consumers, NaturalCycles analyzed other stakeholders on the market in their IMS analysis, such as its potential distributors. Factors that were examined in this parameter were related to criteria concerning profitability and access to the end-consumer. In our model this parameter assesses ways of distributing consumer mHealth medical devices to see how optimal they are in regards to the firm and access to its target consumers. This parameter should assess the main sales channels for accessing the end-consumer. Although this is a factor mainly assessed in a country’s entry mode strategy (post market selection), we showed that it largely affects the attractiveness of a country. The choice of distribution channel is influenced by the structure and funding of the country’s health care system, which we showed through their interdependencies in the identification stage of the UK. In this country evaluation, we focused on understanding the structure of retail pharmacies, as they constitute an important channel out to the end-consumer when it comes to health care. However, we suggest that further research should examine the potential of more alternative means of distribution, e.g. direct sales through ecommerce channels or partnering with larger companies e.g. MNOs and pharmaceutical companies.

When carrying out our study, we did not make use of any established IMS framework, when analyzing the market for mHealth CMDs in our investigation for RQ1. This was a conscious decision from our side, as we did not want our exploration of empirical data to be bound to a pre-established structure, and because we found that our research phenomenon required additional criteria for its market analysis. Traditional IMS frameworks, presented in existing literature, focus largely on macro economic variables, whereas our model incorporates other dimensions as well. Our choice of creating a more industry and firm-specific framework is further supported by literature (Sakaraya, Eckman and Hyllegard, 2007). As there is no
previous framework developed for mHealth CMD start-ups, wanting to perform an IMS analysis, it is difficult to place our model in comparison with others. However, our model does incorporate theories from existing literature on IMS theory, such as internationalization of born globals (e.g. Moen, Gavlen and Endresen, 2004; Oviatt and McDougall, 1994) and customer receptiveness (Sakaraya, Eckman and Hyllegard, 2007)

7.1.2. Research question 2

By applying our developed model on the client company AdhereBox, we wanted to answer the second follow-up question to RQ1, namely:

RQ2: How can these parameters [of the IMS model] be assessed in order to identify opportunities in the EU for mHealth CMDs?

Using the parameters, we had identified when answering RQ1, we showed how the developed model could be used to assess the EU countries in an IMS of a mHealth CMD start-up. We did so by using our model in the screening and identification stages of an IMS process. In the screening stage we assessed the first parameter our model, namely the consumers. We measured each country’s level of attractiveness using different quantitative indicators. We showed how weightings could be applied to produce a final score for each member state.

As part of our screening, we planned to calculate the market size of AdhereBox’s product based on the population size that suffers from chronic diseases or other conditions and that require a daily medication regimen. Some of these were mentioned in Chapter 5.2.1.1. However, the data that we identified as accessible, in a resourceful manner, to start-ups was of mortality rates for some diseases and conditions. Therefore, estimating a more accurate value for AdhereBox’s addressable market was experienced as difficult.

In the identification stage we showcased our model by analyzing the UK in the remaining parameters. In the discussion of our findings, in the identification stage of the UK, we identified different linkages between the parameters of our IMS model. One could see from our findings that macro and micro environmental factors interplay with each other and that these interdependencies further affect the level of potential a country offers for mHealth CMD start-ups. The interdependencies between the parameters of our IMS model were visualized in Figure 11. It illustrated the complexity of the macro and micro business environment of mHealth CMDs, with the UK as an example. Although the existence of linkages can seem trivial, this empirical finding suggests that the attractiveness and suitability of the Stakeholders included in our framework are highly dependent on external forces, which could either constitute barriers or enablers for mHealth deployment. This complexity of the business environment further supports the need for a systematic approach to IMS for a mHealth CMD start-up seeking to internationalize its offering. Despite this, one key insight from our research is that it is important to gather market information from within the
country, by for example conducting field studies. As Scherwitzl (2016) highlighted in our interview: "You need to be present in the country in order to understand the market". This further supports our choice to not include a final selection phase in our country evaluation. In this sense, despite being resource-constrained, start-ups seeking to internationalize should put effort in gaining access to information about a potential country, or collaborate with actors in the market, with more capabilities to do so.

7.2. Future research

This section presents recommendations on future work, resulting both from findings in the research process and from limitations in this research that offers opportunities for additional investigating studies.

Being a relatively new phenomenon, with little or no empirical data in regards to IMS theory, we acknowledge the need for further studies on mHealth and internationalization. This research is certainly only the first step in exploring mHealth in the context of internationalization theory. However, we believe that our study has narrowed the gap in existing theory on the IMS of mHealth CMD start-ups. Nonetheless, there are areas that we have identified as interesting for further research in order to complement our findings. Further research could for example analyze the cultural aspects of IMS. This type of factors characterizes the Uppsala School Model, in which firm’s choice of market to enter follows a sequential entry pattern into successive culturally-close markets where companies select foreign markets that exhibit similar economic, cultural, and political systems (Johanson and Wiedersheim-Paul, 1975; Johanson and Vahlne, 1977). For instance the impact of language in a linguistically heterogeneous market as the European Union could be further examined.

An interesting empirical observation from our interviews was that regarding disruption and disruptive innovation. Recall that Iversen (2016) referred to these terms when speaking about health care systems’ readiness for mHealth. He meant that the health care systems of all countries are moving towards a complete decentralization and consumerization where technology will be enforced in health care without the control of authorities. We suggest that this topic could offer potential for further research areas within mHealth and market analysis. Such research could for instance investigate if, or how, mHealth innovation is creating a new market and value network.
9. References

9.1. Interviews

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Björlin, Anders (2016-03-23) Skype, Stockholm
Brighter AB, (2016-02-03) Kista, Stockholm
Edström, Adam (2016-04-04) Skype, Stockholm
Iversen, Lars (2016-03-21) Stockholm
Lead Developer (at AdhereBox) (2016-02-23) Stockholm
Olsson, Silas (2016-04-15) Stockholm
Scherwitzl, Raoul (2016-03-22) Stockholm
Stevovic, Jovan (2016-03-22) Skype, Stockholm
Trepte, Oliver (2016-04-06) Kista, Stockholm
Vahlne, Tobias (2016-02-03) Kista, Stockholm
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9.2. Publications


**Internet publications and websites**


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Ernst and Young (2012) *mHealth: Mobile technology poised to enable a new era in health care*. Ernst and Young. Available at http://www.ictliteracy.info/rf.pdf/mHealth%20Report_Final.pdf (Accessed 2016-04-20)


# Appendix A: Collected screening data

## Collected data for screening stage

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Population size</th>
<th>Smartphone usage</th>
<th>Wearable digital usage</th>
<th>Perceived digital skills</th>
<th>Internet use: seeking health information</th>
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- **Source:** Eurostat and Google Consumer Barometer
- **Note:** Data on population retrieved from Eurostat. Data on smartphone usage retrieved from Google Consumer Barometer. Resulting indicator is a multiplication between the two data sets.
## Appendix B: Weighted screening score

### Weights and scores from screening stage

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<th>Indicator</th>
<th>Market Size</th>
<th>Economic Development</th>
<th>Digital Device Usage</th>
<th>Digital Skills</th>
<th>Smartwatch Activities</th>
<th>Purchase Behaviour</th>
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### Weighting

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<th>Digital Device Usage</th>
<th>Digital Skills</th>
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<th>Purchase Behaviour</th>
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<th>Final Score</th>
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### Explanations:

- **Average Number of Devices**: a value based on Google Consumer Barometer that presents the number of connected devices (0-5+) that the interview sample owns.
- **Combination of population size age 55+ retrieved from Eurostat and Smartphone usage per population age 55+ retrieved from Google Consumer Barometer.
- **Data on population retrieved from Eurostat. Data on smartphone usage retrieved from Google Consumer Barometer. Resulting indicator is a multiplication between the two data sets.**
## Appendix C: List of UK pharmacies

### UK retail pharmacy chains

<table>
<thead>
<tr>
<th>Pharmacy</th>
<th>Description</th>
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<tbody>
<tr>
<td>Boots UK</td>
<td>A pharmacy chain that offers an extensive range of health related products both in stores and online. It is a pharmacy chain in the UK and Ireland owned by Walgreens Boots Alliance. On website also sells analoge medical dispensers.</td>
</tr>
<tr>
<td>Chemist-4-U</td>
<td>An online pharmacy which also has pharmacy stores throughout the UK.</td>
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<tr>
<td>Well Pharmacy</td>
<td>The largest independent pharmacy business and third largest overall pharmacy chain after Boots and Lloyds Pharmacy in UK, with 782 branches in the UK.</td>
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<tr>
<td>Lloyds Pharmacy</td>
<td>Has over 1,600 pharmacies in the UK and an online shop where it among other items sells electrical health appliances (such as electronic pill box reminders).</td>
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<tr>
<td>Numark</td>
<td>A buying group of over 2,000 independently owned pharmacies in the UK.</td>
</tr>
<tr>
<td>Gordons Chemist</td>
<td>Has 60 branches in the UK and an online store.</td>
</tr>
<tr>
<td>Rowlands Pharmacy</td>
<td>A chain of over 500 branches throughout the UK. It is a NHS Service Provider, offering dispensing service aiming towards offering high-quality patient-centred service.</td>
</tr>
<tr>
<td>Superdrug</td>
<td>Has over 225 in-store pharmacies in the UK as well as online outlet.</td>
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<tr>
<td>Weldricks</td>
<td>A chain of 61 pharmacies based mainly in South Yorkshire.</td>
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</tbody>
</table>

Besides pharmacies, there are also supermarket chains with in-store pharmacies: Asda, Morrisons, Sainsbury's, Tesco.