When Mobile Applications can be Considered to be Medical Devices?

The case of Natural Cycles

Master Thesis in M.Sc. Business Administration and Information Systems / E-Business

Viktorija Terebaite
Student id: 660347
vite15ac@student.cbs.dk

Supervisor: Till J. Winkler
Characters: 108.158
Normal pages: 57

July 25, 2018
Copenhagen Business School

Abstract

There is growing evidence that fast advancing technology can positively affect the healthcare industry which has resulted in an increasing number of sophisticated digital medical devices brought into the consumers market. Whilst there are legislations in place to regulate the determination and classification of digital medical devices, the effects of such certification on our health are not clear. This paper provides an analysis of the existing regulations that apply to software as a medical device and identifies technology trends reshaping the healthcare industry. Further, my survey and interview data reveal the effects medical device certification has on customers and businesses and suggests a set of guidelines for the medical device determination process.

Keywords: digital health, digital contraception, digital medical device, software as a medical device

1. Introduction

1.1. Motivation

During the first 10 years of its existence, Facebook's corporate motto was "Move fast and break things" (Taplin, 2017). Mark Zuckerberg's social media behemoth won the battle for social media dominans by tolerating flaws and errors in its software, in order to enjoy the benefits of rapid innovation. "Unless you are breaking stuff, you are not moving fast enough," the quote famously continues (Taplin, 2017). Another innovator in the Information and Communication Technology (ICT) industry, LinkedIn founder Reid Hoffman, is aligned with Mr Zuckerberg: He is quoted for stating that "If you are not embarrassed by the first version of your product, you've launched too late" (Hoffman, 2017).

The low barriers to innovative breakthroughs in ICT attract the attention of today's young entrepreneurs. There's easy access to all the tools one may need: Computers, digital infrastructure, skilled labor available globally, scalable hosting, even the construction of physical devices is now achievable through mature hardware ecosystems like the one in Shenzhen, China (Economist, 2017).

When everybody can do it, it easily follows that a lot will try, thus, this world of breakneck innovation is now spreading into the healthcare industry. The opportunities are easy to spot: More than 2 billion consumers (Statista, 2018) already have a powerful computer in their pockets (the smartphone), fully connected to a global information sharing network (the Internet). And the smartphone is already packed with useful sensors, collecting vast amounts of health data. Harnessing this data into useful and actionable insights for the consumer is the immediate opportunity. Adding a layer through more advanced and dedicated biometric sensors represents another layer of opportunity. And the power of centralized analysis of vast amounts of quantified

health data, through Artificial Intelligence and Machine Learning technologies, promises yet another level of opportunity.

Therefore, technology like sensors, Big Data and Machine Learning are bringing huge advancements to the existing healthcare system and disrupt medical fields that were never thought to be digitized. One of the examples of such digitization is a medical field of reproductive health, which is in the center of my research. Today we have technologies that can help women to have control of their reproductive health without any physical contraception. There are many mobile applications in the market that claim to be able to help women avoid pregnancy by tracking their fertility. While the application of advanced technologies, such as Big Data and Machine Learning in healthcare, and especially reproductive health, are still in their infancy (Schaw, 2016), the products that can provide proof of being efficient in giving accurate predictions, are being certified as medical devices and exist in the consumers marker as such.

The attitude of the biggest tech innovators to move fast and break things together with the fact that technology is advancing at such a speed that the limitations faced are rarely technical, but often legal, regulatory and ethical raise many concerns (Schwab, 2016). Innovation and advances within eHealth should be an unequivocal good for society. But major questions arise when fast-paced risk-taking, outdated regulations and our health meet. Therefore, it is my motivation for this study to understand what benefits and disadvantages a classification of a software as a medical device may have to our health. While we may have been perfectly ready to accept the many failures of Mr. Zuckerberg while he was building out his social network, not so much if what might be missed is a pregnancy aborted. More is simply at risk.

In my study I lie down the existing regulations and laws that apply to software as a medical device in order to understand what it takes to get a medical device certification. I focus on Natural Cycles, the world's first certified digital contraception, from both the company and user perspective, to understand the effect the medical device certification has for both sides. Thus, the aim of the study is to understand the effects mobile applications certified as medical device have

to our health, and suggest when such applications can be considered as medical devices.

1.2. Problem Statement

In order to carry out a well-grounded research, it is highly important to define a problem statement, which can be referred to when analysing the digital medical device industry. Hence, the objective of this study is to discuss when mobile applications can be considered as medical devices and what implications they have on our health, by identifying relevant legal documents, success factors that make mobile devices contribute to our healthcare system, and risks exposed to the end user and its health. After having conducted an intensive literature review in the field of digital health, I was able to derive the following research questions:

1. Drawing on the research on regulations that apply to medical devices, what are the existing regulations for software as a medical device in the European Union?

2. Drawing on the literature review, what are the main challenges and opportunities for products and services in the eHealth industry?

3. Then, how the above identified regulations on software as a medical device apply to Natural Cycles - world's first mobile application to be certified as a digital contraception? What implications does a medical device certificate has on our health and to the product?

4. When mobile applications can be considered to be medical devices?

1.3. Case company

Natural Cycles (NC) is a mobile application that is used in combination with a basal thermometer to track ovulation and identify the fertile window. The use of NC sounds simple - a woman should measure her temperature first thing in the morning with a basal thermometer and enter the temperature reading into the app. Then the underlying technology (algorithm) takes the reading and other parameters and their uncertainties such as ovulation day, luteal phase, follicular phase, cycle irregularities and temperature fluctuations, and detects ovulation and fertility. The algorithm then assigns green and red days which are meant to indicate when the use of protection is needed or not. It takes a couple of weeks till the algorithm gets enough data and can learn the woman's cycle. Eventually, the algorithm learns from previous cycle recordings and can predict fertility status and upcoming ovulation.

The NC application uses data visualisation such as status bars, calendar view and temperature graph, which allows women to make more sense out of the recorded data and learn about their bodies. It is very important to enter every days recordings, so the application sends reminders to measure temperature. In addition, an additional notification is being sent on red days to warn the user to use protection on fertile days.

What makes fertility tracking and Natural Cycles interesting is that it can be used in two scenarios: as a contraception to prevent unwanted pregnancy and as a form of family planning to plan pregnancy. In the 'profile' section of the application a user can chose/switch between *'prevent pregnancy'* and *'plan pregnancy'*. While planning pregnancy does not introduce any risks and does not give any impressions that the use of Natural Cycles will definitely be effective, the contraception use case is a bit more tricky. The founders of Natural Cycles (Elina Berglund Scherwitzl and Raoul Scherwitzl) has conducted a study that was the first study ever to study the effectiveness of the application as a contraceptive method. The goal of the study was to determine the number of pregnancies in a group of participants. The pregnancies were identified through users entering data of their pregnancy test, through an algorithm detecting a possibility

of a pregnancy, and through an additional questionnaire. The results of the study revealed that the failure rate (green day given within the fertile day) is only 0.05%, which means that Natural Cycle's perfect use efficacy is 99% (Berglund Scherwitzl et al. 2016).

While there are many mobile applications that help women track their menstrual cycles and fertility windows, they are difficult to use, are powered by basic mathematical algorithms and are not evidence based (Berglund Scherwitzl et al. 2016; Duane et al. 2015). What makes Natural Cycles unique is that due to its scientific research and implementation of regulatory processes Natural Cycles is the first and only quality assured and certified digital contraception in Europe. NC is in compliance with Medical Device and other relevant directives and therefore was classified as a IIb medical device.

The unique algorithm and the fact that Natural Cycles has been certified as a medical device has received a lot of media attention. According to the available articles online (Ong 2017) the goal of the company was to become a certified contraception in every country of the world. Therefore, a natural next step for NC is to get the FDA's approval. By the end of 2017 the company has received a $30 million investment which it will spend on clinical research, product development and global expansion.

Victoria Jenning, director of the Institute for Reproductive Health at Georgetown University calls attention to a significant amount of missing data and high drop-out rates, hence, making the study not meet the efficacy trial standards (Lomas, 2017). What is more, in the beginning of 2018, a major hospital in Sweden, reported to the swedish medical device authorities that 37 out of 668 women who were seeking abortion claimed to be using Natural Cycles as their primary contraception (Bederoff 2018). Even though 37 unwanted pregnancies account for only 5 percent of total users in Sweden (133,000 users) which meets the companies promise to the users and regulators (93 percent efficacy rate), the company is now under investigation by Swedish Medicines Agency.

2. Literature Review and Regulatory Background

2.1. Technology trends in the eHealth industry

Technology holds the promise of making healthcare more accessible while reducing costs - a promise that is much needed: Healthcare expenditure is rising year by year, putting financial pressure on both the public and private health systems. In 2014, the healthcare expenditure in the European Union reached €1.5 trillion, meanwhile, in the United States the amount has reached a total of $3.2 trillion in 2015 (Sonnier 2017). The increasing demand for healthcare, infrastructure upgrades, rising labor costs and (paradoxically) technology advancements are growing costs ever higher (Deloitte, 2017).

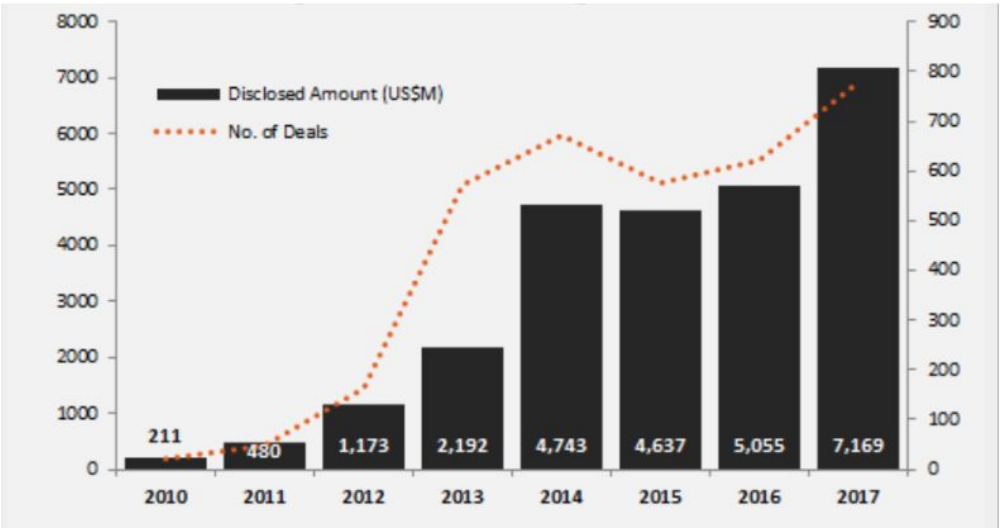
While the healthcare costs keep increasing, WHO has estimated that 400 million people worldwide are lacking access to some of the fundamental health services (pregnancy care, clean water). For example, in some developing countries total health spending per year per person is only $12 (Eritrea), with government covering only $2 (Myanmar) per person per year (World Health Organization 2012). Often, the costs of medical help will fall on the patients, resulting in an out-of-pocket payments, which in extreme cases can account for the entire amount of the household's annual income.

2.1.1 Innovation incentives

The need to change the current healthcare system with unbearable costs for the patients, and a lack of access to fundamental healthcare services for many, has attracted a lot of entrepreneurs and scientists attention. The world's biggest technology companies like Google, IBM, Facebook are all investing in technologies and R&D to reduce costs, increase access, and improve existing health care.

But not only the biggest, most influential companies are trying to reshape the current market. Many small, unknown, startup companies are building products designed to disrupt healthcare. 2017 was a record year for digital health venture capital (VC) funding. There were 778 deals made with nearly $7.2 billion raised, which was a 42 percent increase from the previous year which accounted for a total of $5.1 billion and 662 deals (Figure 1).

Figure 1: Digital Health VC Funding 2010-2017



Source: Mercom Capital Group, 2018

According to the report by IQVIA, over 318,000 health apps and 340 consumer wearable devices were available worldwide in November of 2017. Every day there are 200 new health apps being added to the app stores, with general wellness apps accounting for the majority of the health apps available. However, the number of more advanced applications, with a focus on health condition management is also growing and accounts for 40% (IQVIA, 2017).

Even though the amount of health apps available might look overwhelming, only 41 mobile applications account for half of all health app downloads. These most dominant apps each have at least a few of the following criteria: high ratings, frequent app updates, are connected to sensors, are connected with healthcare institutions, have endorsements and a promising clinical evidence (IQVIA, 2017).

2.1.2 Sensors

One of the technologies that is significantly changing the healthcare industry is wearable technology (wearables). The wearable device market is growing steadily year by year and over 55% of the most downloaded health apps use sensor data (IQVIA, 2017). Mary Meeker, in the Internet Trends Report (Staff 2018), states that 25 percent of Americans own a wearable device - a device that can be worn and can closely monitor an individual's activities, without interrupting or limiting the user's motions (Gao et al. 2016). What makes these devices special is that they can have an accelerometer, heart rate sensor, GPS, gyroscope, compass, microphone, light, barometer, altimeter, camera, temperature and other sensors integrated into textile, fashionable clothes, smartwatches or glasses. Through these sensors, physical activity, body and emission data is registered, processed and visualised through apps or computers.

The most popular wearables among the consumers are small size devices, measuring vital signals and sending the collected data to a smartphone device (Haghi et al. 2017). Therefore, some of the most popular wearable, sensor-powered product categories are health, sports and fitness tracking devices such as Fitbit and Apple Watch. Activity trackers provide immediate feedback on the user's activity levels and motivate the user to keep moving/exercising. One of the examples of such existing products in the market is Apple Watch, which sends hourly notifications reminding the user to stand up and move.

The user generated data about activity levels can be sent to electronic health records systems, which can then be monitored by doctors. Having this data on hand prior to the arrival of the patient will allow health practitioners to spend more time with a patient.

In the recent years self-tracking has gained a lot of popularity. Two Wired editors, Gary Wolf and Kevin Kelly, started a movement called the Quantified Self (Tanamachi 2007) whose motto is "self knowledge through numbers". The movement relates to wearable devices and sensors because it is the focus of the movement to collect data of one's daily habits and activities, such

as food consumed, quality of air, mood, skin, mental and physical performance. The examples of the most popular devices to collect such personal data include Fitbit, Jawbone UP, Nike+Fuel, Runtastic, Apple Watch.

The self-tracking phenomena has become popular not only among the wearable device owners - it has also received an increased attention from scholars during the last few years. Btihaj Ajana (2017) in her research paper "Digital health and the biopolitics of the Quantified Self" is concerned that such an increased concentration on analysing the everydays data is affecting our health in a negative way. Ajana points out that even though tracking one's own health is believed to have a positive impact, because it allows the user to set daily goals and monitor health habits, it does not necessarily lead to the improvement of exercise ability or better physical condition. Wachter (2015) writes that Quantified Self movement is likely to affect those who have too much time and money.

Pantzar and Ruckenstein (2017) suggest that self-tracking devices fail to improve user's physical health not because the self-tracking idea doesn't work, but because, often, digital health promoters set user goals that just can't materealize. One of the common examples is a recommendation made by World Health Organisation, that was applied by many pedometer focused apps, to walk 10,000 steps per day. While this WHO recommendation of a daily target is used for gamifying incentives, not many know that the original source of this recommendation comes from Japan: In 1960s a researcher Yoshiro Hatano estimated that making 10,000 steps per day would possibly be enough to burn 20 percent of the days calorie intake (Cooper 2013). Today, most apps use the 10,000 step goal as a baseline as it is easily achievable and set the users realistic goals, however, this amount of steps does not make a significant difference to a person's health.

Robert Wachter (2015) looks at the use of sensors to integrate patients with the healthcare system in a cost-efficient manner. By using sensors on patients with chronic diseases, the healthcare systems could cut hospitalisation costs by being able to monitor the patient from

home. For instance, a patient with a heart failure, diabetes, and other chronic diseases could be monitored through sensors embedded in watches, wristbands or stick-on devices. Sentrian, a California based remote patient intelligence company, is using sensors and artificial intelligence to detect illnesses and reduce preventable hospitalization. The company identifies patients who are at high risk to become hospitalized, monitor these patients and collect data such as body temperature, oxygen saturation of the blood and heart rate, uses machine learning algorithms to analyze patient data to detect patterns signaling hospitalization and, finally, if such a pattern is found, the computer notifies the relevant healthcare resource. Not only has the company proven that sensors and wearable devices can lower the costs of hospitalization, the technology also improved the experience of patients with chronic disease.

2.1.3 Telehealth

Today, a clinical process that can be performed at a distance is called telehealth. There are different existing definitions of telehealth. The U.S. Department of Health and Human Services describes telehealth as the use of electronic information and telecommunications technologies to support and promote long-distance clinical healthcare, patient and professional health related education, public health, and health administration. Eren and Webster (2015) define telemedicine as the tasks that the clinician carries out (such as observing, consulting, interpreting), assisted by information and communication technologies, in circumstances where there is physical distance between the patient and a healthcare provider. Both definitions mention the physical distance factor as the key to telehealth, while the technology is just the enabler. Eren and Webster (2015) even concludes that a modern telehealth is simply medicine at a distance.

Many articles speak of the benefits of telehealth, especially for patients in remote and rural areas. In many cases, existing telehealth services cancel out the need to travel to the medical institution, which not only gives a faster access to healthcare services, but also reduces costs undertaken by patient. Morrissey (1998) points out that telehealth is especially beneficial when there is a lack of

specialty expertise in the area. Telehealth enables to link patients to physicians with the expertise the patient is in need of. Morrissey also adds that the benefit is not solely for the patient, as telehealth enables new referrals to find their patients and help the ones that are in underserviced areas. Scott and Mars (2015) specifically focus on the developing world countries that have merely 1 percent of world health expenditure and are facing severe shortages of health workers. In their article they point out that in South Africa, approximately 43 percent of population live in rural areas and only have 1 general physician to 7,700 people. While this is one of the biggest global issues, many scholars agree that, if implemented correctly, telehealth could make the healthcare situation in developing countries better. Sadly, high costs due to undeveloped infrastructure and lack of technology in developing countries are scaring the businesses away.

Other studies that focus more on the specific cases rather than broad aspects of the potentials and challenges of telehealth, show that telehealth can make a difference serving the patients with mental illness (Sonnier 2018; El-Miedany 2017). According to the numbers published by National Alliance on Mental Illness in the United States, approximately one fifth (44.7 million) of population in the U.S. experience a mental illness (mental, behavioral, or emotional disorder). In 2016 alone, 19.2 million of the adults received mental health treatment (National Institute of Mental Health 2017). This leaves half of the population with a mental illness without a treatment. While the statistics do not involve any context as to why such a big part is left without treatment, Perle and Nierenberg (2013) point out why so many people lack the care they need. According to the authors, limitations such as geographical location, financial support, lack of transportation, lack of insurance, or, simply, time constraints, stop individuals from receiving treatment. Even though Perle and Nierenberg (2013) focus solely on the access to mental health treatment, their findings align with the ones of Scott and Mars (2015). Furthermore, the authors also reveal that many mental health specialists are unwilling to move to rural areas, which was also pointed out by Scott and Marts (2015)

"Nowhere is the need for mental health services more prevalent than in rural locations."
(Perle and Nierenberg 2013)

Some earlier research made by Calam et al. (2000) showed that a fear of shame of going to a mental health specialist is also one of the factors that holds back individuals with mental illness from receiving treatment. In their study, Perle and Nierenberg (2013), acknowledge that studies have shown that patients interacting with mental health doctors over telemedicine technologies, disclose more and open up easier. Meanwhile, A CEO of MDLIVE (treats patients with certain medical, dermatological and behavioral problems) - one of the most successful telehealth providers in the U.S., states that there are more and more patients who choose telehealth solutions as a way to receive treatment:

"It could be as big as our core business over time, and it probably fits our model even better than basic physician office visit. A virtual visit can take away the stigma that has been associated with behavior health issues."

Scott Decker, CEO of MDLIVE (Dahlberg 2017)

Telehealth sounds like a problem solver to many of the healthcare problems, however, it is not widely available. Scott and Mars (2015) address some challenges for why telehealth is not not so widely spread, even though many admit it to be beneficial. Firstly, the authors call attention to the technical issues in regards to current medical systems. Some hospitals/physician centers are using hundreds of different systems, which are often outdated, its vendors don't exist anymore or have been acquired. Hence, it becomes costly to merge new telehealth technologies with the existing healthcare systems. Secondly, governments tend to build on the existing investments and therefore areas where telehealth would be the key, are left without financing. Finally, another study conducted in the United States has found out that the said telehealth benefits are not necessarily reflected in reality. The study claims that the benefit of avoiding unnecessary office visits and phone calls of patients that do not in need to see a doctor in reality trigger about 6-7% additional patient calls. Another commonly discussed benefit of telehealth is said to be an increased doctor's capacity by not having that many patient visits in person, thus allowing the doctor to treat more patients. According to the study by Bavafa et al. (2017), it was found that

digital doctor visits in fact reduce the number of patients that a doctor can see per month by 15%. Additionally, it was found that digital doctor visits result in additional 2.16 face to face patient visits, which is equivalent to approximately 44 minutes per day.

2.1.4 Big data analytics in healthcare industry

As a relatively new technology, the definition of the term "big data" (BD) varies in different science sources. According to Fisher et al (2012), big data means data that is of a size of at least 1 million data points and therefore cannot be handled and processed in a straightforward way. However, Boyd and Crawford (2012) argue that big data is less about data that is big than it is about a capacity to search, aggregate, and cross-reference large data sets. Boyd and Crawford look into big data not only from the technological point of view, but from the cultural angle as well. They define Big Data as *a cultural, technological and scholarly phenomenon that rests on the interplay of:*

1. *Technology - maximizing computation power and algorithmic accuracy to gather, analyze, link, and compare large data sets.*
2. *Analysis: drawing on large data sets to identify patterns in order to make economic, social, technical, and legal claims.*
3. *Mythology: the widespread belief that large data sets offer a higher form of intelligence and knowledge that can generate insights that were previously impossible, with the aura of truth, objectivity, and accuracy.*

Big data can come in real time and in very large scale from sensors, devices, video/audio, networks, web and social media (IBM). Analysing this kind of data by using analytics techniques such as text analytics, machine learning, predictive analytics, natural language processing, analysts can now get new insights and make a better informed and faster decisions. The existing research in the Big Data Analytics (BDA) field focuses on the benefits (Baesens 2014),

implementation (Heitmueller et al. 2014; Wang et al. 2015) and challenges (Kshetri, 2014) of BDA.

While there are many examples of Big Data being used in different industries (predicting a movie one might like, suggesting music or type of news), the main use case of BD in the healthcare industry is to build better health profiles and better predictive models around individual healthcare seekers, so that the better diagnosis can be made and better treatment can be assigned (McKinsey 2015). Big data allows to accumulate information from different sources such as DNA, proteins, tissues, organs, organisms and ecosystems. That information then allows to build models that can predict outcome and find trends. The accuracy of these models depend on the amount of data. In order to get high accuracy of the predicted models, trends and patterns, the training data set needs high amounts of data. The most common information sources for health data come from web and social media data (Facebook, Twitter), sensors, transaction data (billing records, healthcare claims), biometric data, Electronic Medical Records.

The existing research in the healthcare sector in regards to Big Data and Big Data Analytics is mainly focused on two factors - challenges and benefits.

2.1.4.1 Challenges

When performing the literature research around BD challenges, the vast majority of articles address the issues of data structure (Raghupathi et al. 2014; Fernandes et al. 2012). Fernandes and his co-authors in their study on big data in healthcare, address an issue of huge amounts of medical data being collected every day. While that sounds like a good thing, authors claim that the medical data is mostly unstructured, fragmented, dispersed and not standardized and thus needs considerable effort in cleaning and standardizing. As an example, IBM's chief science officer claims that even though Watson can read an equivalent of million of books per second, 90 percent of data that is available for some patients is missing for others, while the rest of the data is "noisy".

Another factor that is brought up as a disadvantage of BD is cost. The costs for storage and protection of generated data are high and increase firm's expenditures. Jee K. and Kim GH (2013) in their study on big data in the medical sector found that the healthcare workers often lack skills to work with a new technology that is being integrated in medical institutions. In addition, it was found that firms and organisations implementing big data analytics into their systems, face regulatory issues which make the implementation process longer and more costly (Schilsky et al. 2014).

A third commonly addressed issue is security and data privacy. Healthcare data, by law, is considered to be sensitive data. By means of mobile technology and sensors, health related individual data is being collected, stored, processed, analyzed and sometimes shared between machines and companies. Therefore, there are several studies that focus on the firm's' strategy in regards to consumer data privacy and consumers perception of how eHealth companies treat their personal data. Some companies collect and process our genetic data, and while that can help to make a better treatment decision, personal data is at risk. Even though individual's data is stored without any identifiable information, the identity can be detected through blood test results and fingerprints (Wachter, 2015).

2.1.4.2. Opportunities

Even though critics seem to be fairly concerned about the issues and challenges that big data analytics bring to the healthcare industry, the same studies have found that integration of BDA into the health care systems will bring huge opportunities for both patients and health care providers. The biggest impact is seen in general improvement of the quality of health care (Fernandes et al. 2012; Sonnier 2018; Wu et al. 2017). The studies focus on BDA being able to analyse historical patients data and existing research, and then find patterns, predict outcome, detect the disease early or even prevent it (Fernandes et al. 2012; Jee K. et al. 2013; Raghupathi et al. 2014). Literature on medicine currently includes approximately 24 million records with

2,100 medical articles being added every day. Patients with a long and difficult medical history can have thousand of pages of Electronic Health Records. No doctor could ever read and study such a massive amount of literature and patient history. Computers, by performing big data analytics, can process and analyse this information and give a summary and prediction to the doctor, while the doctor can focus on the patient.

As for the costs, critics agree that even though using big data analytics is costly for the company, it has the potential to significantly cut down healthcare expenses. BDA provides with several ways to reduce healthcare costs, one of them being within the field of radiology. According to Wachter R. (2015), computers are very good looking into x-rays and finding patterns of cancer, tuberculosis and pneumonia. This means that radiologists who earn $400, 000 per year on average could be changed by computers that can perform big data analysis.

Finally, Wachter (2015) points out that even though Big Data is disrupting the healthcare industry, the application of it is still at its infancy. The author sees the big data as a crucial area for research and development:

"A wise person once observed that we usually overestimate what can be done in a year and underestimate what can be done in a decade. To me, big data in healthcare meets that descriptor perfectly."
(Robert Wachter)

2.1.5 Technology and Female Health

The promise of technology's disruptive potential to the healthcare sector is especially potent when considering female health.

"Female health has been an underserved sector although it concerns half of the global population."
Walter Masalin, NGP Capital (Heathman 2018)

2.1.5.1 Family Planning, Technology and Women Rights

The history of family planning as it relates to medicine and contraception technology dates back to at least 1795, when the economist Thomas Malthus raised the idea of modern population control, and opposed new artificial methods of fertility control. Malthus argued that a growing population would naturally diminish the world's ability to feed itself, and was of opinion that the society should simply let the nature take its course and allow the poor to die (BBC 2014).

In the 19th century, the gender ideologies defined maternity as "women's primary social function and moral purpose" (Weisman, C.S. 1997). In order to protect women's health and reproductive functions, the legislation of the 19th century was prohibiting contraception and abortion (Weisman, C.S. 1997).

In the early twentieth century, when socialists and feminists in the United States started promoting birth control as a woman's right and as a means to sexual freedom (McCann 1999), women were given some influence over family planning for the first time. However, when contraception was legalized in the United States, it wasn't done to strengthen women's rights: Protection of the maternal and infant health, limiting family size and especially, limiting the ethnic diversity of the population were the main reasons for legalizing contraception, according

to McCann.

"The most far reaching social development of modern times is the revolt of woman against sex servitude. The most important force in the remaking of the world is a free motherhood."
Margaret Sanger (Keetley 2005)

It wasn't until the 1990s when women's health received a more intense public attention in the United States and women demands for a gender specific healthcare were heard. In 1995, The Fourth World Conference on Women held in Beijing, 189 countries adopted a declaration that "the right of all women to control all aspects of their health, in particular their own fertility, is basic to their empowerment" (United Nations 2005).

Today, women are significant stakeholders in healthcare. According to Rock Health (2017) report on women in healthcare, women make up 80% of healthcare workers, 84% of bachelor's degrees in the health professions, 58% of bachelor's degrees in biological and biomedical sciences, 85% of bachelor's degrees in nursing, and now represent half of all medical students. However, women make up only one third of hospital executive teams with the most common position of Chief Nursing Officer.

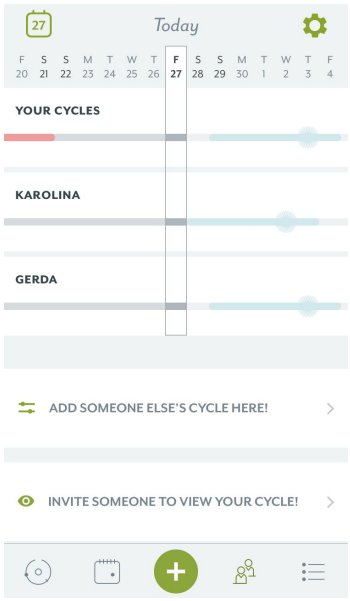
"Women are well represented in the healthcare workforce—just not at the top."
(Rock Health 2017)

2.1.5.2 eHealth Innovation and Women

Even though women do not have a major share of executive positions in healthcare, as of 2014, there has been a huge increase in women CEOs leading eHealth companies (24.1% in 2016 compared to 8.9% in 2014) (Rock Health 2017). One of the reasons of such an increase is a boom of startup companies focused on women's healthcare and sexual wellness.

Today, there are many digital health products empowering women to understand and manage their own menstrual cycles with a help of period and fertility apps. Two of the most popular ones on the app store today - Clue and Natural Cycles - are co-founded and managed by female entrepreneurs. Clue was launched in 2013 and by now has 5 million users. The app helps women to track way more than just the period days. It allows users to input data such as pain, mood, sleep, sexual activity, so that women can better understand their body. What is more, the application allows women to share information on their cycle with anyone whom they feel should be able to follow their cycle (Figure 2).

Figure 2: Clue app screen



Another app founded and led by a female executive is Natural Cycles - the case company of this study. As already mentioned in the introduction of the company, NC allows women to track their fertile days no matter whether they are trying to get pregnant or avoid pregnancy.

The existence of mobile applications that allow women to better manage their fertility cycles and better understand their bodies is a big empowerment for women. According to the data from the Center for Reproductive Rights (Worldabortionlaws.com 2018):

- 22 percent of countries in the world prohibit abortion unless woman's life is in danger
- 21 percent of countries prohibit abortion unless woman's health is in risk
- 23 percent of countries allow abortion without restriction as to reason

To summarize, 43 percent of countries in the world do not support women's rights to reproductive health and do not allow a free choice regarding family planning. In some of these countries, not only the abortion is not legal, but oral contraception is available only with a doctor's prescription (e.g. Ireland, Poland). In countries, where women's reproductive rights are underrepresented, digital contraceptive solutions can disrupt the female health market.

2.1.5.3 Contraception and eHealth

Today there are many types of contraception for both men and women. I found that the existing literature on family planning and contraception technology mainly focuses on four areas:

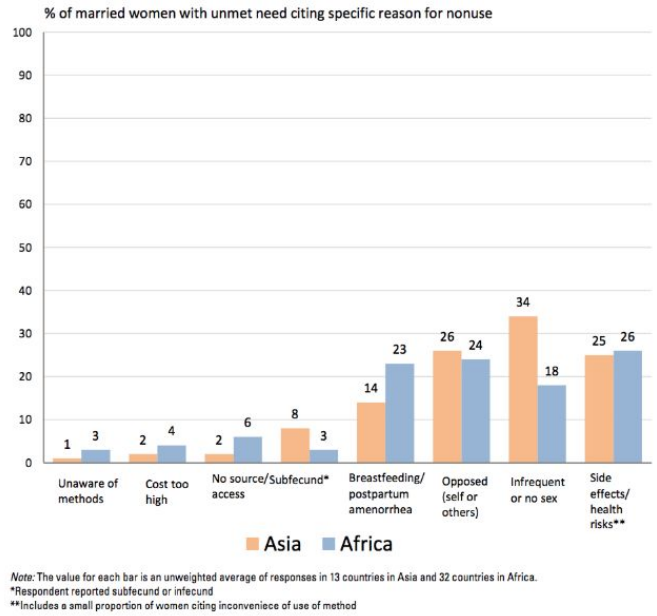
- Contraception in developing countries (Guttmacher Institute 2016)
- Side-effects of hormonal contraception (Berglund et al. 2016; Duane et al. 2016)
- Abortion (Gelman et al. 2017)
- Effectiveness of fertility awareness based mobile applications (Duane et al. 2016).

Even though women can take measures to prevent pregnancies and control the size of their families, studies on family size in developing countries reveal that women have more children than they would prefer to have (Guttmacher Institute 2016).

One of the reasons is the public opposition to contraception and abortions. Gelman et al. (2017) bring attention that abortion is still highly stigmatized. The study found that women who had or were considering an abortion received anti-abortion attitudes from their partners and family members. Abortion is perceived to be immoral, rejecting the right of motherhood and

irresponsible as it affects future fertility. A report made by Guttmacher Institute (2016) further reveals opposition to contraception and its side effects are one of the major reasons why married women in developing countries don't use contraception.

Figure 3: Women's reasons for not using contraception in Asia and Africa



Source: Guttmatcher.com (2016)

Studies show that side effects of contraception are one of the major factors for why women have negative feelings towards contraception. (Berglund et al. 2016; Duane et al. 2016).

The idea of Self-Tracking and fertility awareness methods is to keep track of ovulation in order to find the most and the least fertile days, without hormonal side-effects. Thus, there are many mobile applications that allow to self-track fertility and menstrual cycles.

Duane and co-authors (2016), with a help of many physicians and researchers, have looked into 95 of such apps available on app stores. They concluded that the majority of fertility applications are not designed to avoid pregnancy and are not based on fertility awareness methods, and

therefore relying entirely on such applications may not be enough to prevent pregnancy. As such, not all fertility focused mobile applications can be considered as means of contraception.

2.2. Regulatory background

2.2.1. Processing medical data

The core function of most digital health applications is collecting and processing user data. This often includes information linked to an identifiable user which is legally known as personal data. This type of data is protected by laws in all highly developed countries. The two most important legal sources that are the pillars of the data protection legal framework in the European Union are the ePrivacy Directive (Directive 2002/58/EC 2002) and as of May 2018, General Data Protection Regulation (Regulation 2016/679).

The aim of both legal documents is to ensure that all communications over public networks maintain respect for fundamental rights and freedoms of natural persons, ensure that personal data can only be gathered under certain strict conditions, while also allowing the free movement of personal data within the European Union in order to support the prospering of the Internal Market.

The Directives apply when personal data is processed by a controller (natural or legal person, public authority or any other body that determines the means of the processing of personal data) or processor in the European Union, indifferent of whether the processing takes place within the European Union or not. Personal data is defined as any information that can identify a natural person, while processing of personal data is defined as an operation performed upon personal data, such as collecting, storing, retrieving, publishing, distributing or deleting data (Art. 2, ePrivacy directive). Any freely given specific and informed indication of a person's wishes by which data subject indicates his agreement to personal data relating to him being processed is

called ‘the data subject’s consent’. The rules for a request for consent had tightened in the previous years and it now must be given in an easily accessible form that clearly states that the user data will be processed. It must be possible to easily withdraw the consent (art. 4).

There are a number of data subject rights introduced in the General Data Protection Regulation that empower the data subject and increase data transparency. The rights are:

- The right to get breach notification - when data breach (‘accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, personal data transmitted, stored or otherwise processed’, art.4) is likely to “result in a risk for the rights and freedoms of individuals”. The notification must be sent in within 72 hours after the processor becomes aware of the breach.
- Right to access - gives data subjects the right to get confirmation whether personal data concerning them are being processed and if it is, where and for what purpose. Additionally, data subjects have the right to ask the data controller to provide a copy of the personal data collected on the data subject. This request must be fulfilled free of charge and in the electronic format.
- Right to be forgotten - article 17 states that data subject has the right to require the data controller to erase his/her personal data, if the data is no longer being relevant to the original purpose for processing, or if data subject withdraws his/her consent. However, this right might be trumped by the right of “the public interest in the availability of the data”.
- Data portability - enables the data subject to transmit data collected on them from one data controller to the other.
- Privacy by design - addressing data privacy issues when designing the system/software, instead of introducing it as an additional feature. “The controller shall <...> implement appropriate technical and organizational measures <...> in order to meet the requirements of this Regulation and protect the rights of data subjects”.

The GDPR also directly touches upon rules regarding health data. It classifies genetic, biometric data, data concerning health or a person's sex life, as a 'special category' data. The processing of personal data that falls under this category is prohibited (art. 9) unless an explicit consent is given. However, the Union or Member State law can decide that the prohibition of processing such data may be lifted. Dyke et al (2016) argue that health data should be categorized into different levels of sensitivity as sharing of sensitive data raises both ethical and legal issues. They suggest that data categorized as 'sensitive' or 'special' in GDPR should be categorized in different sensitivity levels and therefore should have different levels of protection. Information on data subjects ethnicity, genetics, mental health, addictions and substance abuse, sexually-transmitted disease, disability, reproductive care, palliative care, geolocation and sex life should be treated as a higher risk data and should have the highest level of protection.

2.2.2. Selling and Buying eHealth products and services - Consumer goods legislation

Even though eHealth tools and services are focusing on disrupting the healthcare industry by reducing healthcare costs and making us live longer, they are products and services existing in the consumers market. This means that the consumer using the product is protected from any harm or poor quality of the good or service. However, it is important to get the reader's attention, that there is no specific legislation regulating the sales of eHealth products in the European Union. Both traditional health and eHealth products and services are covered by the standard Consumer Goods legislation. Just like with any goods, if the eHealth product fails to arrive or arrives late, the standard contract will apply, which will allow the customer to pay less or even return the product. Anyone selling digital health products have to comply with general sale of goods rules, and of course, anyone purchasing a digital health product will be protected by this legislation.

It is also important to introduce the Directive 93/42 on Medical devices which requires that medical devices be designed and manufactured in such a way that the use of such devices does

not compromise the health and safety of the ones using it (if the device is used for its purpose and according the instructions). It is the responsibility of the Member State to make sure a failing, compromising safety and health product is taken off the market.

2.2.3. Determination and classification of a software as a medical device

In order for a software to be certified as a medical device, a regulatory approval process must take place. The process is the same in the United States of America and European Union and consists of five main steps (Mihaylov et al. 2016) listed below:

1. Determination whether the software meets the definition of a "medical device"
2. Classification of the software as a medical device
3. Preparation of technical documents, development and implementation of quality management systems
4. Fulfilment of premarket requirements and application for assessment
5. Maintenance of quality management system and post-market surveillance

2.2.3.1 Regulation on medical devices (European Union)

There is no piece of legislation in Europe that would focus solely on digital medical devices, therefore the Regulation on Medical Devices is applied to software. The Regulation on Medical Devices (5 April 2017) aims to ensure smooth functioning of the internal market, set high standards of quality and safety for medical devices and harmonise the rules for placing such devices on the market and putting them into service. It is then a responsibility of the Member States to decide on a case-by-case basis whether or not a product falls within the scope of the Regulation on medical devices (Recital 8).

In order to follow the steps of the regulatory approval process for medical devices that were introduced in the beginning of this chapter, the definition of the medical device shall be introduced.

'Medical device' *is any instrument, apparatus, appliance, software, implant <...> or other article intended to be used for:*

- *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease*
- *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability*
- *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state*

As the aim of this study is to discuss when a mobile application can be considered as a medical device, it is important to look into what does the regulation say about the software as a medical device. The first mention of a software can be found in recital 19. It states that when a manufacturer intends to use the product for one or more of the purposes laid down in the definition of medical device, the product qualifies as a medical device. If the software is intended to be used for general purposes, for lifestyle or wellbeing, it can not be classified as a medical device. Also, Article 2 (2) classifies software as an active device (operation of such device depends on a source of energy). Later on, in Annex 1, on requirements regarding design and manufacture of medical devices states that software medical devices shall be designed in a way that ensures reliability and the intended performance and should be developed in accordance to the principles of risk management, including information security, verification and validation. Finally, it is also stated under the Annex 1 that software intended to be used with mobile devices shall be designed and manufactured taking into account the features of the mobile platform (size, level of light, noise).

2.2.3.1.1 Classification

The classification of medical devices in the European Union follows international practise and divides products into four main categories - Class I, Class IIa, Class IIb and Class III which includes the highest risk products. The rules for classification are based on the risk for the human

body, how long the device is intended to be in continuous use and whether or not the device in invasive, implantable or active. There are not many rules that apply for software, and the ones included in the Regulation do not cover the wide spectrum of software as medical device products. The classification rules only state that a software that is intended to provide information that is later used to take decisions with diagnosis or therapeutic purposes and monitor physiological process is classified as IIa. And only when such software has a serious deterioration of a person's health it is classified as IIb. All other software is classified as class I.

The Regulation on Medical devices also touches upon contraception, stating that all devices used for contraception are classified as class IIb.

2.2.3.2. Federal Food, Drug, and Cosmetic act (USA)

Federal Food, Drug, and Cosmetic Act define the term "device" as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease (chapter II, section 201 (h)). The Act classifies medical devices into three groups: group I, II and group III (Chapter 5, section 513).

If general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, the device falls under class I. If general controls by themselves are not sufficient to to guarantee the safety and effectiveness of the device, but the device is not meant to support or sustain a human life, prevent impairment of human health, and does not introduce any potential risk of illness or injury - the device still falls under classification I. If special controls are sufficient to provide reasonable insurance of safety and effectiveness the device belongs to Class II, and if insufficient - Class III.

Besides the Federal Food, Drug and Cosmetics Act that defines what is a medical device, the administration has also released legal documents, that address innovative medical devices in the

healthcare industry. One of such legal documents is a non binding guidance document on mobile medical applications for Industry and Food and Drug Administration staff. This document defines Mobile Medical Application (Mobile Medical App) as a mobile app that meets the definition of 'device' under the Food, Drugs and Cosmetic Act (section 210 (h), and is either intended to be used as an accessory to a regulated medical device, or transform a mobile platform into a regulated medical device. The document also explains and gives examples of cases when a mobile app is not a medical device (does not meet the definition of medical device); when a mobile app meets the definition, but because it does not pose any risk, or pose very low risk to the public, FDA does not enforce the requirements under the Federal Food, Drug, and Cosmetic act.

One of the examples of when a mobile app becomes a regulated medical device is when a mobile app performs a patient specific analysis and provides patient specific diagnosis or treatment recommendations. However, if a mobile app helps its users to self manage their disease or condition, but does not provide treatment suggestions; provides users with tools to manage and track their health information, the app is not enforced to comply with the requirements under the Food, Drugs and Cosmetic Act.

Both regulations decision on whether software is a medical device is based on the "intended use" of the software.

3. Methodology

3.1. Research Philosophy

In order to design a coherent research, I chose a mix of philosophies - positivism and interpretivism - that will help to develop the knowledge needed to address the set of my research questions that all lead to my main problem question of when mobile applications can be considered to be medical devices. Positivism, in the words of Saunders et al. (2016) , focuses on

"strictly scientific empiricist methods designed to yield pure data and facts uninfluenced by human interpretations and bias", is followed to lie down regulations that apply to digital medical devices. Interpretivism, which developed as a critique of positivism, aims to create new, deep understandings and interpretations of social worlds and contexts (Saunders et al. 2016). The interpretivism philosophy is, therefore, followed to better understand the use of digital medical devices and the people that use them.

3.2. Research Design and Methods

The study was conducted by using a mixed method research design approach. While working on the research I found that the first chosen method led to new insights that needed elaboration and clarifications, thus, required for another research method to be introduced. Therefore, the mixed method research design approach, which according to Saunders and co-authors (2016) , *"combines quantitative and qualitative data collection techniques"*, *"help to establish the credibility of study"* and *"produce more complete knowledge"* was chosen to produce a coherent research study. The methods are sequential and consist of four stages. In stage 1, a case study method was applied in order to conduct a focused in-depth research on a digital medical device. The case study company, Natural Cycles, is the first certified digital contraception, thus, has a unique service that hasn't been explored in many research studies yet. The case study method is widely used among researchers as it allows to get insights from intensive and in-depth research, which helps to identify what is happening and why, understand the effects of the situation and implications for action (Saunders et al. 2016). As the study focuses on analysing the case of NC and whether products like it should be certified as medical devices, the case study has the dominant role, while other methods hold a supporting role.

In order to get primary data about the case company and its views, in the stage 2, an individual structured interview was held with an employee of Natural Cycles (list of questions available under Appedix A). The interview data was analysed qualitatively. The aim of the interview was three-fold: 1. To understand the process and regulatory challenges that NC had to undergo in order to get a medical device certification; 2. NC liability towards its users; 3. The implications

of certification to the company and its product. The findings of the interview combined with the findings of the literature review helped to develop a stage 3 method - user survey.

User survey allows to collect quantitative data which according to Saunders et al (2016), can help to *"suggest possible reasons for particular relationships between variables and to produce models of these relationships"*. The survey was presented only to the users of Natural Cycles, who were recruited on an official Natural Cycle's Facebook page. In total, 23 respondents participated in the survey and were presented with 22 questions (list of question available under Appendix B). Even though, one of the factors that any researcher has to bear in mind when applying a survey method is the *"limit to the number of questions that any questionnaire can contain if the goodwill of the respondent is not to be presumed on too much"* (Saunders et al. 2016), the completion rate of the survey was as high as 62 percent.

Finally, at stage 4 another research method was introduced - archival and documentary research. The app reviews written by NC users available on Apple app store and Android Play store were used in order to get a bigger size of data to test whether the survey findings are in line with the general user feedback. Even though the reviews are not actual documents, they do document user feedback about the product. Such data, just as traditional form of documents, should be considered as secondary type of data because they were originally created for another purpose than to be analyzed and generalized for my research (Saunders et al. 2016). However, app reviews analysed using text analytics techniques, provide with rich and unbiased data for my analysis. In order to perform text analysis I processed publicly available NC app reviews on two major app stores - Apple App Store and Google Play. In order to perform the text analysis I extracted all available reviews from the two main english speaking markets - United States and United Kingdom. I then split the data into positive reviews and critical reviews based on the rating given (1 to 5) and performed text analysis to find key characteristics of these data sets. Finally, I visualized the results so it is easier for the reader to understand the data. The list of words and their count is available in the Appendix C.

Date	Data Source	Type	Participants	Purpose
22 March, 2018	Individual interview	Structured, open-ended questions	Natural Cycles	1. Understand challenges and opportunities of getting a medical device certification for a digital product/service. 2. Understand whether NC sees itself liable towards its customers.
1 - 31 May, 2018	User survey	Structured, combination of multiple choice and open-ended questions	User of NC application	1. Understand why women are using NC. 2. How much do they understand about the product/service. 3. What do they expect from the product/service 4. Do they see the company liable
25 June, 2018	App reviews	English	Users of NC application	Understand the key characteristics of the user experience and perception.

Table 1: *Summary of research methods*

The study has both deductive and abductive approaches. I start my research with a deductive approach by laying down laws found in the literature review and using them to analyze the case company. I continue following the deductive reasoning approach as I build a questionnaire for a user survey based on the findings from the literature review, interview with NC analysis, and case study. However, I later use an abductive approach as I use the survey results and the rest of the findings to identify emerging themes and patterns, as well as I test them through additional data analysis (text analysis of app reviews).

The paper is organized into 6 chapters. In Chapter 1 the reader will find the motivation for this research study, problem questions and introduction to the case company. Chapter 2 is split into two subchapters as it provides with a literature review on technology trends in the digital health industry, as well as regulatory background that applies to medical devices that use the identified technologies. Chapter 3 explains the design of the research study, while Chapter 4 presents with

an analysis with Natural Cycles in the center of it. The analysis has a two-fold approach (2 subchapters) - first NC is being analysed in the regulatory light based on the literature review and the interview with NC data, then, the focus shifts to the user of the product in order to understand the user perception. Finally, Chapter 5 provides with a discussion where the findings of the literature review and analysis are organized into themes. The study finishes with Chapter 6 where I provide my conclusions.

3.3. Measurement model

To process the data collected from the interview with Natural Cycles, I used a qualitative, mixed open coding analysis approach. Which means that I looked for relevant words, phrases, sentences and sections in order to assign them to different relevant categories/labels, such as, opinions, experiences, differences, etc. Later on, I connected these labels with the main findings derived from the theoretical background and empirical literature review. Finally, I used the mapping of labels and literature review findings to build a strategy for other research methods I perform in my study and to produce the results of this thesis.

The summary of the processed user reviews retrieved from the app stores is available in the Appendices section (Appendix C), as well as the survey questions (Appendix B). However, the interview with NC was made upon an agreement that the raw interview data will not be shared. Therefore, I will only include extracts in Chapter 4 to provide validity to my statements, while interview questions can be found in Appendix A.

3.4. Validity and reliability assessment

Research validation is a process verifying that the means of research data measurement are accurate and whether they are actually measuring what they are intended to measure (Golafshani 2003). In my study, this process helps to evaluate whether the choice of methods, analysis and interpretation of data can be considered to be credible when answering my research question.

There are two popular validation techniques that can be used in order to conduct a quality research - triangulation and participant or member validation.

Triangulation is a technique that involves application of more than one data source and collection method to confirm the validity of the study (Saunders et al. 2016). The use of triangulation technique allows to cross-validate the results from different methods and check whether the data findings are consistent. In my study four different data collection methods were used, thus, findings were constantly cross-validated not only with the findings of each of the data sources, but with findings from the existing research and legislation. The triangulation method has provided my study with the value of adding depth and richness to my study, as well as helping to make valid interpretations of the analysed data.

Participant and member validation technique is applied by allowing the study participants to confirm the accuracy of the data they have provided by allowing them to correct it in order to validate it (Saunders et al. 2016). In order to validate the structure of my survey and to be sure that the survey questions are not ambiguous, I discussed it with 2 survey respondents after they have submitted their answers. The results of the participant and member validation technique have shown that the structure of the survey had a logically evolving flow and that the questions were not ambiguous, however, when discussing the answer of the question "Do you think Natural Cycles is a medical device?" one of the two respondents reported that a definition of what is a medical device would have been helpful when answering the question. While I considered the feedback to be valid, it was the aim of my study to understand the user perception about NC without influencing it by providing additional information about the product or it's nature, thus I did not make any changes in my questionnaire.

The application of the two techniques to my study have helped to identify consistent findings and, thus, arrive at conclusions provided in the final chapter. While I consider the findings of this study to be highly valid, it is important to evaluate the reliability and, thus, my role as a researcher for this study. One of the threats to reliability of any research is the researcher bias.

This threat becomes even higher when the research is performed by just one researcher, as for example, a researcher may "allow her or his own subjective view or disposition to get in the way of fairly and accurately recording and interpreting participant's responses" (Saunders et al. 2016). Thus, I find it important to inform my reader that I have never used Natural Cycles and, therefore, I have no personal experiences that would make me form a strong view about the product. However, I did download the application in order to understand its features and perform the necessary analysis.

4. Analysis

4.1. Natural Cycles regulatory analysis

It was found in the Literature Review and Regulatory Background chapter that, when a software is determined and classified as a medical device, medical data processing, selling and trading laws apply and must be met. Natural Cycles has been approved and classified as a medical device by the EU authorities based on the rules lied down in the Regulation of Medical Devices, hence, the company is now not only a unique player in the women's health market, but is also subject to the above identified laws. This chapter serves as an analysis of Natural Cycles in the context of EU and US regulations and, thus, brings in legal factors to the discussion on when can mobile applications can be considered as medical devices.

4.1.1. Medical device

It was identified in chapter 2 that both Federal Food, Drug, and Cosmetic Act and Regulation of Medical Devices decide whether software is a medical device, based on the "intended use" of the software. For instance, according to 'medical device' description and use cases provided in the Regulation of Medical Devices, Natural Cycles is a medical device because it is a software intended to be used for diagnosis, prevention, monitoring or prediction of a physiological state. Table 2 provides with an overview of medical functions and physiological states that NC is able to perform.

	Pregnancy	**Fertility**
Diagnosis	yes	yes
Prevention	yes	no
Monitoring	no	yes
Prediction	yes	yes

Table 2: *Summary of medical functions Natural Cycles can perform*

Not only does the intended use of Natural Cycles meets one of the purposes laid down in the definition of a medical device, it also meets the requirements for designing and manufacturing medical devices. According to the company's website (naturalcycles.com): "Natural Cycles is designed in a way that ensures reliability and the intended performance and is developed in accordance to the principles of risk management. The product is certified with EN ISO 13485:2012, which is the biggest international standard for medical devices" .

Due to NC meeting the requirements set by the Regulation of Medical Devices and having a potential serious deterioration of a person's health/physiological state (falsely assigned green day, thus, possible unwanted pregnancy) the product is classified as IIb. The regulation, though, specifically points out that devices used as/for contraception shall be classified as IIb.

NC is not certified as a contraceptive in the United States of America, however it is the aim of the company to receive such certification in the states. Therefore, it is worth looking at NC from the legislation in the United States perspective. According to Federal Food, Drug, and Cosmetics act, a mobile application becomes a regulated medical device when the application performs a patient specific analysis and provides a patient specific diagnosis. Natural Cycles does analyse a user specific body temperature as well as other user provided parameters, and provide a user specific diagnosis (whether the woman is on her fertile day or not), therefore, the application

could be regulated as a medical device in the United States. Additionally, Natural Cycles has done the necessary research and provided authorities with scientific proof that their software can predict the woman's fertility at 93% accuracy.

4.1.2. GDPR and processing of sensitive data

In order to predict woman's fertile days, Natural Cycles collects and processes data on women's reproductive health. According to General Data Protection Regulation, all data concerning health or a person's sex life is a 'special category' type of data, which requires protection and can only be processed with an explicit data subject's consent. While the general laws in regards of data protection were laid down in chapter 2.2.1, a table below (table 3) provides with an overview of identifiable data that is being collected by NC, as well as how it is being used and what are the data subject's rights.

Data subject rights	**Identifiable data being collected by NC**	**NC Use of personal data**
- Right to ask what personal data is being held - Right to request to delete collected data - Right to request to update personal data. - Right to restrict processing personal data -Right to data portability	Email address First and last name Height and weight Date of birth Reproductive health: - planing or avoiding pregnancy - use of hormonal contraceptives - body temperature - menstruation cycle - **intercourse history**	NC does not share their users personal data to third parties without permission, except in the following cases: - personal data can be shared with NC affiliates, agents, business partners - in order to comply with a legal or regulatory obligation - personal data may be transferred and processed in the United States or any other country. By creating a User

	- ovulation test results - pregnancy test results - phone sensor collected data	Account, the user automatically consents to its data being transferred outside the EEA. - in the event if NC is sold (including merger or acquisition)

Table 3: Summary of Natural Cycles Data Privacy Policy (naturalcycles.com 2018)

Since GDPR took effect, NC is informing its users about the data that will be collected. A user is asked for consent to the use of their health, pregnancy test and intercourse data before they start using the application. Thus, a user is now informed about the types of sensitive data that will be collected and can make a choice of either agreeing to the processing of such information, or stopping using the application. Even though a consent for processing sensitive data is required in order to use the application, entering pregnancy test or intercourse data is optional. Such data serves the purpose of measuring the effectiveness of the application, not a woman's fertility cycle.

4.1.3. Liability in the consumers market

In the section 2.2.2 on regulations that apply on selling and buying digital health product and services, I drew my reader's attention to the fact that there is no specific legislation regulating the sales of eHealth products in the European Union. Both traditional and digital health products and services are covered by the standard Consumer Goods legislation.

In order to get accurate predictions on the NC application, a special, basal thermometer is needed. The thermometer is available for purchase on the NC official website and through the mobile application at any time. The Terms of Use section provides with the customer rights in regards of returning physical products (the thermometer), however, the company declares that it "shall not be liable for any injury, loss, claim, or any direct, indirect, incidental, punitive, special,

or consequential damages of any kind, including, without limitation lost <...> loss of data, replacement costs, or any similar damages, <...> arising from your use of any of the Service or any Products procured using the Webshop, or for any other claim related in any way to your use of the Services or any Products, including, but not limited to, any errors or omissions in any content, or any loss or damage of any kind incurred as a result of the use of the Service or Products, transmitted, or otherwise made available via the Service, even if advised of their possibility."

The fact that NC does not claim itself liable for any damages and data loss, again, raises some legal and ethical questions that will be discussed in chapter 5 of this paper.

"You use the Services and the Products at your sole risk."

Natural Cycles, Terms for Use (2018)

4.1.4. Natural Cycles and the process of getting a medical device certification

"The market is currently flooding with apps for health, but noone is getting the certification because it's very hard to get and it demands so much effort to maintain"

Own interview with Natural Cycles, 2018

My thesis has a high focus on regulation around medical devices, therefore, the natural direction of the interview was to learn about the Natural Cycles journey to getting the digital contraception certificate and its experience with the governmental authorities. According to the interviewee, the process of getting the certificate took 2 years, required getting consultants and was highly funded by the investment money. During those two years of trying to get the certification, Natural Cycles experienced quite a few obstacles. To begin with, according to the interviewee, during the entire process there was a constant lack of clarity about proof the authorities were looking for. Another obstacle was preparing the necessary documents in the legal language - the employees involved in the process had to learn to express themselves in regulatory terms in order to provide the necessary documentation. Finally, NC experienced and is still experiencing

resistance due to the misconception about the company's nature - Natural cycles is "not an app company but rather a medical device with patients, not users <...>" (Own interview with Natural Cycles).

While there are many mobile applications helping women track their health, NC is the first application that was certified as a medical device in the European Union. This not only gives the company a strong competitive advantage but serves as marketing campaign, as it received a lot of media coverage. According to the interviewee, the main effect of getting the certification was that "it made Natural Cycles look trustworthy, it has also attracted a lot of media attention, both good and bad".

4.2. Natural Cycles user perception analysis

It is not that often that mobile applications available on app stores have been certified as medical devices. Natural Cycles state that being a certified medical device has a marketing value for the company as it brings consumer trust; something that is essential to a new brand and a new way of preventing pregnancies.

My study on when mobile application can be considered to be medical devices is motivated by understanding what benefits and disadvantages that such classification may have to our health. As such, while the user experience of a product by itself does not define whether that product is a medical device or not, it is within the scope of this thesis to understand the actual user perception and experience of the product, and how the certification impacts user perception and trust.

4.2.1. App review analysis

App reviews on the app stores serve as a primary source of information to get user insights about the application and learn about the experience of its existing users. Natural Cycles is available on app stores since 2013. The majority of users seem to be satisfied with the product: The

application has an average rating of 4.8 out of 5 on the Apple App Store (AppFollow 2018) with almost 3,000 ratings.

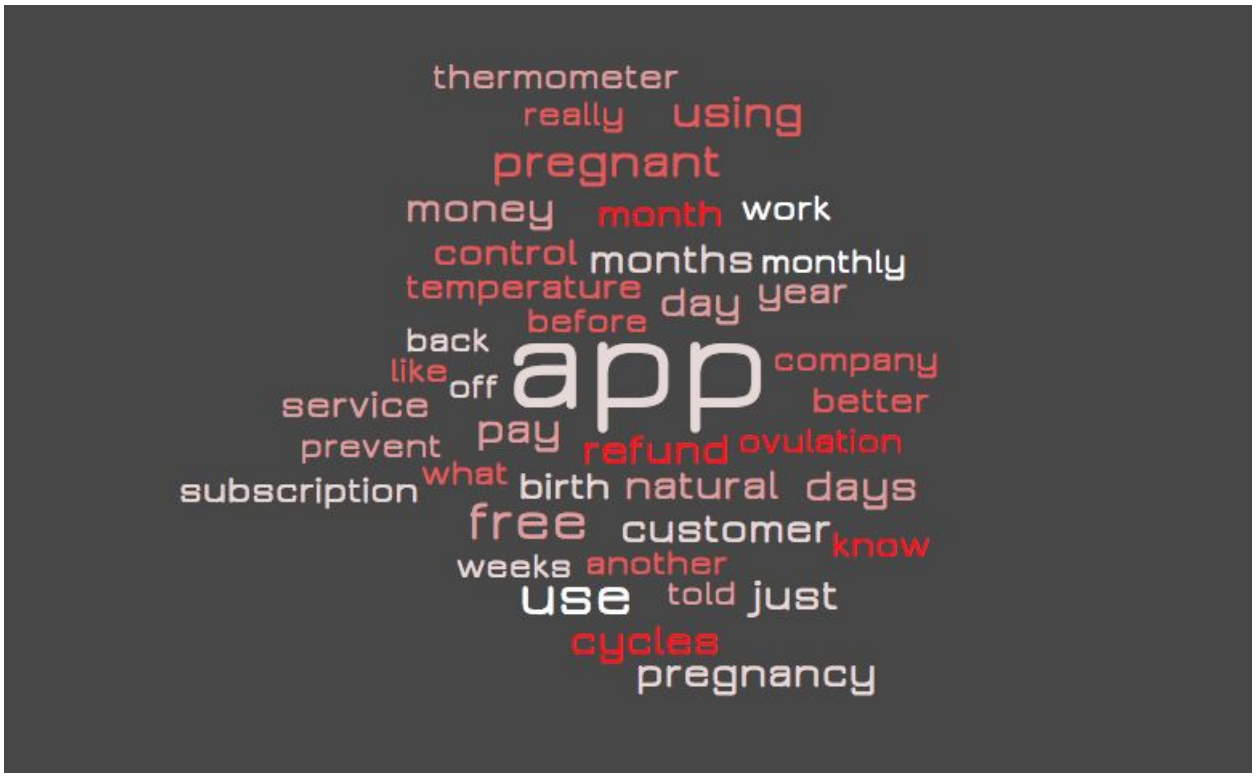
Looking at the positive user reviews (4 or 5 stars) in the Figure 4 below, the most frequently used words (highlighted) are “app”, “body”, “using”, “control”, “know”, “natural” and “easy”. This could suggest that women like using Natural Cycles as it empowers them to have a better control of their body while avoiding hormonal contraception.

Figure 4: Positive app reviews

Source: Own graph made by using AppFollow.io data

However, not all NC users seem to have a satisfactory experience. Figure 5 represents the sentiment of those NC users who rated the app with 1 star. The most frequently used words are “use” “app”, “free”, “pregnant”, “pregnancy” and “pay”. When looking into the reviews that contain these words, it can be seen that users are mainly reporting to have fallen pregnant within the first few months of using Natural Cycles, and asking for refund/pay back.

Figure 5: Negative app reviews



Source: Own graph made by using AppFollow.io data

4.2.2. Survey analysis

4.2.2.1 Reasons for use

The user survey of Natural Cycle users found that the side-effects of hormonal contraception is the biggest reason why women choose to not use any contraception: 77% of women who participated in the survey have been using contraception regularly, but were not happy with it due to many side-effect such as depression, low libido, infections, pain, allergic reactions, gained weight and even anaemia and nausea. According to the respondents, the side-effects of the contraception they were using made them look for other, more natural ways of protecting themselves from unwanted pregnancy.

Most of the women first heard of Natural Cycles from their friends (37%), researched hormonal contraception alternatives online (32%), saw ads on social media platforms such as Facebook and Instagram (32%), or read about it in the news articles (17%).

"I was researching natural contraception methods <...> and found a handful of news articles about Elina Berglund and Natural Cycles. I was impressed with her credentials and excited about the possibility of an effective and noninvasive birth control option."

Anonymous survey respondent, 2018

Due to Natural Cycles being simply a fertility tracking type of contraception, using only a basal thermometer, it does not have any side effects and is accessible, as well as fairly cheap mean of contraception. The idea of using a measured body temperature to calculate a fertile window meets the idea of the Quantified Self movement as Natural Cycles help women to learn about their bodies through numbers. 5 out of 22 women who participated in the survey mentioned that NC helped them to become more knowledgeable, therefore, better understand their bodies, trace patterns and be more in control. One respondent claimed that NC has helped her to realize she is having health problems.

"It has been great! Opened my eyes to the patterns of my cycle. Making me feel in control. "

Anonymous survey respondent, 2018

4.2.2.2 Trust and Efficiency

Asked about how much they trust the output of the Natural Cycles algorithm on a scale from 1 to 10, the vast majority of the respondents skewed towards the "trust" variable resulting in an average rating of 8. Furthermore, 82% of respondents indicate they highly trust the outcome of the NC algorithm.

Even though the general feedback about the idea and the use of product is mainly positive, some of the women had negative experiences to share. 2 out of 23 participants of the survey claimed to

fall pregnant while using Natural Cycles as their primary means of contraception. One of the women declares that NC had errors resulting in the application assigning the outcome of the algorithm to the wrong color which indicates whether the woman is fertile or not. The other woman admitted entering body temperature data only 5 times per week, which resulted in the algorithm being not as accurate.

4.2.2.3 Perception of liability

According to the study conducted by Natural Cycles (Berglund et al 2016) "1 out of 100 women <...> may become pregnant, <...> due to method failure i.e. the app wrongly attributing <...>". Additionally, the study shows that "7 women out of 100 may get pregnant during one year of use due to all possible reasons".

This leaves the product having the efficacy rate for a typical use of 93% according to the study.

As discussed in the theoretical background section in chapter 2, any digital health product or service existing in the consumers market in the EU must comply with the Sales of Goods legislation. This means that the consumer is protected from any harm or poor quality of the product or service. Looking into the Natural Cycles mobile application, the efficacy rate of the algorithm must not be lower than 93%, otherwise the product can be considered of a poor quality and may cause the user damages. Even though the algorithm can not make any direct damage to the customer, the failure of the algorithm may missinform the user about the need for protection, which can lead to an unwanted pregnancy. Even though the legislations in the EU make the company subject to the Consumer Goods act in order to protect the customer rights, the website of the legal terms of the company state the following: "Natural Cycles in no way guarantees the accuracy of the Products' measurement outputs". Additionally, by agreeing to Terms and Conditions (2018) upon the registration, the user agrees that Natural Cycles will incur no legal liabilities: "All information provided to the User through the Services is provided for informational purposes only and shall in no way be interpreted as medical practice or medical advice".

In the survey, only 91% of the participants at the time of completing the survey were not pregnant. Even though this number can not be considered to be statistically valid due to a too small sample size, it does support the need for investigation by the authorities.

The results of the survey, show that 70% of the respondents think that Natural Cycles should not be liable when the app showed a green (non-fertile) day, but the woman got pregnant. Only 9% of respondent think that NC should be liable. However, when asked whether the NC should be liable for misinforming the user about her fertile days **due to an algorithm error**, only 34% respondents thought that NC should not be liable, while 26% of women said the company should be liable for providing with an information that cannot be trusted. The remainder of the respondents were not sure or thought that NC should be partly responsible (40%).

"No, I do not feel they should be liable. While I trust them to get my algorithm correct, at the end of the day it really is just an app on my phone."

Anonymous survey respondent, 2018

"It's no different to being prescribed a pill that didn't have the correct chemicals in it. The app has to be giving you accurate information else it cannot be trusted."

Anonymous survey respondent, 2018

However, the results of the interview with Natural Cycles are contradictory to both the legal terms of the company, and the general user perception in regards of NC liability to its users. The interviewee from the Natural Cycles has stated that the company considers to be responsible for their users not getting pregnant. The results of the interview bring up inconsistencies between the companies official and unofficial statements, while the legal terms of the company do not seem to represent the existing laws that apply to medical devices.

"We are responsible for patients who are using NC not to get pregnant. We have to prove that we can live up to our claims that NC is 93% efficient as a birth control option."

From the interview with Natural Cycles, 2018

4.2.2.4 Perception of certification

Even though Natural Cycles is certified as a medical device by the European authorities, only 61 percent of the survey participants think that NC is a medical device. The explanations on why NC is, or, is not a medical device, differ not only between the categories (medical device, not medical device), but also within the categories themselves. This indicates a different user understanding of the product and what is a medical device. Looking more in depth, the breakdown of the user perceptions on why NC is a medical device can be grouped into these subcategories:

1. Scientific proof - research proving the 93% efficacy rate.
2. Legally certified - medical device approval in the EU.
3. Contraceptive - all contraceptives are medical devices
4. Supporting technologies - thermometer is a medical device
5. Effect - allows women to understand their bodies, offers a natural and personalized way to avoid pregnancy.

The remaining 39 percent of respondents don't think that NC cycles is a medical device. The argumentation can be grouped in the following three categories:

1. The nature of the product - it is just a mobile application;
2. Personal experience - NC failed to accurately monitor fertility;
3. Medical knowledge - individual knowledge on what is a medical device and medical data.

While the majority of the arguments why NC is a medical device are actually correct, the argumentation for "not medical device" category, invites for a further analysis (see Table 4). The first subcategory introduces a user perception that a mobile application can not be perceived as a medical device. It was found in the literature review and regulations on digital health products, that software can be a medical device when the intended use is to monitor, predict or prevent a disease. Furthermore, the mobile health industry is growing at a fast pace and is proved to be effective in many medical areas. These findings allow to conclude that the opinion of NC being just a mobile application and, thus, not a medical device is faulty.

The second subcategory introduces the user experience variable - the application did not manage to give accurate predictions, therefore, it is not a medical device. While the user experience with the product by itself does not define whether that product is a medical device or not, it supports the idea that if a consumer has a negative experience with a certified device, this damages the trust of not only the device but of the concept of certification. As such, the statistical strong performance of a certified device must be a strong factor for the authorities when investigating whether a product/service should be certified as a medical device or not.

Finally, the third subcategory offers insights into a segment of users who do not consider contraceptives to be a medical device or menstrual cycle to be a medical matter, which results in a group of users who don't think that NC is processing medical data.

Medical device	**Not medical device**
● Offers a natural alternative way to protect against getting pregnant. Removes any change of any side effects from other forms of contraception. ● It is 93% effective. It gathers months of medical data. ● It's scientifically backed ● It has received approval in the EU ● Piece of technology used to assist in the understanding and control of fertility	● It is a "contraceptive device" ● Failed to monitor my fertility accurately ● It can never be a substitute for a medical professional ● There's no medical involved ● The menstrual cycle is not a medical matter ● It's an app

• Has enough proving research • Allowing me to get to know my body, and in doing so preventing me from an unwanted pregnancy • Thermometer is a medical equipment which data is used to predict fertility. • It's personalized and natural. • Contraceptives are medical devices	

Table 4: *Survey summary: arguments for and against NC being a medical device*

The above findings show that even though 39 percent of respondents do not think that NC is, or can be a medical device, 70 percent of respondents would use Natural Cycles as their primary means of contraception in order to avoid pregnancy.

4.2.2.5 Perception of Personal Data

When looking into the Natural Cycles privacy terms and communication about the use of personal data, it appears that the company is compliant with the new GDPR regulations. However, user perception is not clearly aligned with what actually could happen with their data. According to the survey results, 83 percent of survey respondents said they trust Natural Cycles to not share their data with third parties - but as shown in chapter 4.1.2, this can happen.

86 percent of respondents would not like the data being collected on them to be identifiable, meaning that a company collecting it, or a third party company getting access to this data, can identify the data subject.

Almost all respondents believe that their data is being adequately protected (96%), so it is not surprising that 74 percent of participants said to be sharing sexual intercourse data with NC or other fertility tracking applications. Slightly more than half of them consider it a sensitive type of data, which they would not like to be shared with the third parties.

As it can be seen in chapter 4.1.2 above, Natural Cycles do collect personal and sensitive data on their users, and do share this data with NC affiliates, agents and business partners or universities. Even though the company says the shared data is not identifiable, in case of a merger or acquisition, all personal and sensitive data would be shared without a user permission.

5. Discussion

My study on when mobile application can be considered to be medical devices was motivated by understanding what benefits and disadvantages that such classification may have to our health.

Technology such as mobile applications and sensors has enabled us to monitor our health habits and better understand our bodies. By allowing sensors to surreptitiously collect our health data and by reporting it on mobile applications, we enable algorithms to perform big data analysis in order to find patterns, predict outcome, detect or even prevent a disease or critical condition coming. Based on the findings in literature review and survey analysis, such information allows us to better understand our body and enables us to take more informed decisions about our health.

The literature review has also clearly shown that innovative technologies such as inexpensive sensors and easy-to-access, connected mobile applications bring many potential advantages to the healthcare systems in the developing world. Digitised healthcare has proven to be reducing healthcare costs as well as being able to to provide healthcare services in the world's rural, underserved areas (Scott et al. 2015).

However, when medical devices are easy to access, and require no training or certification to operate, the responsibility to use them correctly will fall on the consumer. And when the purpose of the medical device is female contraception, the negative consequence of a misunderstanding, wrong use or a faulty device is dramatic.

The following findings from the literature review and analysis all invite for discussion whether Natural Cycles (NC) is an efficient enough product to be used as a primary means of female contraception - and if not, what are the true benefits and disadvantages of classifying and marketing it as a medical device:

- 43 percent of countries do not allow women to get an abortion (Worldabortionlaws.com 2018).
- The existence of anti-abortion attitudes in countries that do allow abortion and its impact on women's ability to manage their reproductive health (Gelman et al. 2017).
- Aborted or unwanted pregnancy as a potential permanent damage to the female body.
- 70% of NC users say they would use NC as primary protection against pregnancy, and the algorithm scores 8 of 10, when users are asked how much they trust its predictions.
- Hospitals and women reporting unwanted pregnancies when the primary contraception used was NC: 2 of 23 respondents in my survey, 37 pregnancies reported from the Swedish hospital (Wong 2018), and user reviews from app stores.
- The accuracy of NC depends fully on the accuracy of manually entered data by the consumer.
- NC declaring not to have any legal liability towards its users, while at the same time marketing their product as a certified and thus trustworthy medical device to be used for contraceptive measures.
- NC providing information for informational purposes only, which should not be interpreted as medical advice, while again marketing their product as a certified medical device.
- 40 percent of survey respondents not considering NC to be a medical device, but still trusting it's predictions.
- 83 percent of survey respondents trusting NC not to share their data with 3rd parties, even though it is indeed being shared with 3rd parties.

Benefits of Natural Cycles versus Unwanted pregnancies

Natural Cycles is certified as a digital contraception, therefore a medical device, and claims to be 93 percent effective. This means that the application has proven to be as effective as other popular contraceptives (pill, condom) (naturalcycles.com 2018). The survey findings are consistent with the literature review finding: Women using hormonal and implantable contraception are suffering heavy side-effects and thus often chose not to use any. While some women get to make the choice whether to use contraception or not, others don't have an easy access to contraception and need a doctor's prescription. What is worse, women in 43 percent of countries in the world don't have the freedom to make decisions regarding their reproductive health. In the light of such findings, NC can be considered to be a disruptive technology that allows women in rural, underserved areas, and countries where women have little or no rights to their reproductive health, to better understand their bodies and be more in charge of their health. In addition, NC also gives a hormone free contraception alternative, which is especially appreciated by women who are suffering from exhausting side-effects caused by hormonal or implantable contraceptives.

At the same time, hospital reports, NC app reviews and survey responses show that women using NC as their primary means of contraception are falling pregnant and seeking abortion. 2 out of 23 survey respondents reported to be pregnant after using NC for 5 months. While one of the 2 respondents was seeking an abortion, another one could not do it due to the religious beliefs that her family holds. This finding, again, aligns with the findings in the literature review - one of the major reasons why women have more children than they would like to have is the anti-abortion attitudes from their partners, family and society (Gelman et al 2016).

These findings combined with the fact that all data must be entered manually raise concerns whether a method that is highly prone to errors can be used for medical devices. One mistake in reporting body temperature will lead to inaccurate prediction for that day or even the rest of the cycle. Even if NC, when used exactly as intended, is as effective as other means of highly

effective contraception, the application depends on many factors that can make the product ineffective or faulty.

Certification benefits versus dangers

As shown in the interview with NC and in the review of NC publications regarding their certification as a medical device, the certification wields important benefits to the business: Being able to market their product as a certified contraceptive device brings consumer trust and thus increased sales.

"It makes us look trustworthy, it has attracted a lot of media attention"
From the interview with Natural Cycles, 2018

However, the two women who became pregnant while using NC now score the product 1 of 10 in trust and no longer consider it a medical device. Those respondents that do consider NC to be a medical device scores the product 8.5 in trust.

This highlights the importance of perception and trust when it comes to contraception, and how important certification is from a marketing and sales perspective. When medical devices are meant to be purchased and used directly by consumers, certification is no longer only a matter of whether the device is allowed to be purchased and used in professional medical settings such as hospitals, but holds marketing value towards consumers.

At the same time, software requires precious little initial investment to get to market, which is why we're seeing an influx of eHealth applications and services. As these products seek and potentially receive certification, it is fair to question what impact this may have on consumer trust in such certifications.

Certification Process versus Evolving algorithms

It was found in the regulatory background overview that it is the responsibility of a Member State to define whether a product/service falls within the scope of the Regulation on Medical Devices (Recital 8). In a case of certifying a product like NC, where a product in question is a software, a lack of in-depth understanding of technology and its implications, together with a lack of detailed regulations on software as a medical device, can result in a relaxed medical device determination process.

There are fundamental and important differences between devices that mainly rely on hardware versus software, and even further differences between static software and automatically evolving algorithms based on Big Data and Machine Learning.

The algorithm that powers NC and its ability to correctly predict the female fertility cycle is not static, and it is not universal for all women. In fact, its main claim to effectiveness is its ability to adjust to the individual, while benefiting from constant automated learning from the incoming data from all its users (Berglund 2016). While this method is ground-breaking and potentially much more efficient than static methods, it is extremely hard to control and understand from a regulatory and certification perspective.

- The algorithm can change after certification is granted
- The complexity and individual nature of the predictions makes quality assurance considerably more complicated and test-results harder to reproduce
- An human engineering mistake can lead to an algorithm providing the wrong output
- A downtime of the service can result in losing that day's data or a product not operating at all

There is no piece of legislation in European Union that focus on medical devices that mainly rely on software using automatic and evolving algorithms. This raises the concern that Member States are certifying products based on outdated definitions and laws.

Data Sharing versus Privacy

From data perspective, in order to be able to use the NC application, a user is asked to consent to the processing of sensitive (sexual intercourse) data. This type of data, however, is not crucial for the application to work.

It was found in the survey analysis, that 74 percent of respondents are sharing such data, but half of them would not like NC to share it with 3rd parties. 83 percent of survey respondents trusting NC not to share their data with 3rd parties. At the same time, NC states in their Terms & Conditions that data will indeed be shared with 3rd parties.

The introduction of the new GDPR laws, especially those improving clarity of user consent, withdrawal of consent and the right to have personal data deleted, has set a clear framework to address these issues. And indeed, following May 25 2018, when the GDPR directive came into effect, NC has updated their Privacy Policy to reflect the changes. However, the above mentioned survey results show a significant gap between existing customer perception and actual reality, when it comes to the use of the data provided by NC customers.

Further, even though the rules for processing sensitive data have tightened with the new GDPR laws, Member States have the power to allow the processing of such data. It can be argued that the Member States and Unions should not have the ability of lifting this regulation because of the two following reasons:

1. Even though both digital and health industries are being highly regulated, the technology is advancing at such a speed that the legal regulations can’t address it right away.

High-level technical understanding is needed to comprehend the implications of new technology.

2. According to Dyke et al. (2016), health data should be categorized into different levels of sensitivity. Information on data subjects reproductive care and sex life should be treated as a higher risk data and should have the highest level of protection.

Therefore, the policies should take into account that the technologies are advancing at an enormous speed, leaving an average citizen no understanding of how it works and what effects it has on our daily lives. A choice to lift the prohibition of sensitive data processing made by a Member State without considering the implications of rapidly developing technologies, might result in an unethical accessing and processing of sensitive data by 3rd parties.

Consumer Empowerment versus Liability

NC makes it clear in its Terms & Conditions that it is not liable for any damages or data loss. As with the issue of Data Sharing, the results of the survey show that customer perception on this issue is hazy.

A clear majority of 70% think that Natural Cycles should **not** be liable when the app showed a green (non-fertile) day, but the woman got pregnant. However, when asked whether the NC should be liable for misinforming the user about her fertile days **due to an algorithm error**, only 34% respondents thought that NC should not be liable, while 26% of women said the company should be liable for providing with an information that cannot be trusted. The remainder of the respondents were not sure or thought that NC should be party responsible (40%).

The nature of the NC product makes it hard to pin-point responsibility. One mistake in reporting body temperature will lead to inaccurate prediction for that day or even the rest of the cycle. A mistake in an update to the algorithm could lead to temporary faulty results for some customers,

while other might be unaffected. A simple graphical error in an app update could have a radical impact, but be quickly fixed with another update.

As it is extremely hard to reproduce the individual and changing nature of the NC algorithm, or to check for input errors done by the consumer, liability for this type of medical device is hard to pin down. The application depends on many factors that can make the product ineffective or faulty - some owned by the company, others by the untrained consumer.

While NC promises to empower consumers with an non-intrusive way to impact reproductive health, this empowerment clearly comes with increased responsibility.

6. Conclusion

The healthcare expenditure is increasing every year, while many regions in the world do not have access to the fundamental healthcare services (World Health Organization 2012). Advancing technologies have the potential of radically reducing the size of these problems, as well as create many opportunities for improving human health. Unfortunately, while the technology is advancing at an enormous speed, regulations and ethics on what role technology should have in our lives, are falling behind.

It was proven that digital health devices can help us improve our health (Wachter 2015,\; Morrissey 1998; Sonnier 2017), as well as access to healthcare services (Scott & Mars 2015). In fact, the potential of these findings has encouraged not only scientists, but also entrepreneurs, to build products and services that aim to help us better track and manage our health condition. One of the most popular types of digital health products available in the consumers market are mobile applications. While the vast majority of applications are not approved by any authorities, there are a few that have performed a scientific research to prove it’s efficiency and to receive a digital medical device certification.

Natural Cycles, a mobile application that is freely accessible on app stores, is a unique and disruptive product, as in the end of 2017 it got a medical device certification and now is the world's first certified digital contraceptive. After receiving the certificate, the company has received a lot of media's attention: Some congratulate the innovative thinking and addressing a field such as reproductive health (Sonnier 2017), others raise questions whether such technological approach can be efficiently applied in the reproductive health area as there are numerous reports of women falling pregnant while using Natural Cycles as their primary means of contraception.

Thus, this research project set out to investigate when mobile applications can be considered to be medical and what implications such certifications can have on our health, by (1) looking into the existing regulations that apply to products that are aiming to get a medical device certification, (2) interviewing Natural Cycles that has received such certification, and (3) conducting a survey with NC customers - users of a mobile application that has been certified as a medical device. The study was driven by the motivation to understand the effects that such certificate may have on customers (users) and companies (products/services).

My analysis revealed that contraception allowing women to manage their reproductive health is not satisfying and causing side-effects, thus, many women are looking for more natural, hormone free alternatives. When reading about the alternative methods of hormonal or implantable contraception, women come across media articles and consequently, Facebook and Instagram ads promoting a side-effect free contraceptive - Natural Cycles. Thus, my study reveals that medical device certification plays a big role in the marketing and sales strategy of NC. The survey results have shown that user's who realize or have the knowledge about NC being a certified medical device trust the NC predictions better and use it as a primary means of contraception. However, both media and my survey results revealed that women are falling

pregnant, which invites to question whether the product is effective enough to be certified and whether unwanted pregnancy is an acceptable damage.

In my study I have identified 5 areas that I suggest should be considered when assessing whether a software is a medical device.

1. **Benefits versus consequences for human health**: Can a device that is prone to errors, relies on the customer's manually entered data and, most importantly, has severe consequences on human health or human life, be certified as medical device and be freely accessible in the consumers market.
2. **Certification benefits versus dangers**: Will the certification give the company a competitive advantage and help establish dominance in the market? If so, should there be higher acceptance standards for such companies? How will failure of such products impact consumer trust in such certifications?
3. **Certification process versus evolving algorithms**: How and who and will monitor that each update in the algorithm can produce results of the same effectiveness and whether the effect is still enough to keep the medical device certification.
4. **Data sharing versus privacy**: Can sensitive/medical data be collected and shared with 3rd parties without the consumers understanding the power that data holds against them.
5. **Consumer empowerment versus liability**: Can a company that is charging customers for a use of their medical device be not liable for any damages and data loss? Should there be special regulations for medical devices designed for significant health impact, while being operated by untrained consumers?

While the regulations and ethics are not fully reflecting on the implications that technology can have on our health, and the society does not understand the power of highly advanced technologies, following my suggested 5 step assessment guide, could help the authorities to manage the existence questionable quality products and risks introduced in the digital health market. Further, it is important that our governments take a more agile approach to making laws.

The regulatory processes are beyond the scope of my thesis, however, it may serve as a suggestion for the future work investigating the topic.

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Appendices

A. Natural Cycles Interview Questions
B. Natural Cycles User Survey Questions
C. Natural Cycles App Review Keywords Summary

A. Natural Cycles Interview Questions

1. I would like to understand your journey to getting Natural Cycles certified. In particular, I'm interested in understanding what advantages and disadvantages you experienced as a provider of an innovative digital solution when working with the governmental authorities.

a. Why did you consider it important to achieve certification?

b. How long did the process take?

c. What resources did you use (financial and personnel) to get the certification?

d. What were the obstacles experienced?

e. Did you experience resistance? If yes, what and why?

f. Why is Natural Cycles the first to get the certification? Do many try and fail? Or is the field small?

g. What were your considerations regarding achieving certification in EU versus US?

h. What has been the effect so far from getting the certification?

i. Do you expect further positive effects from the certification in the long term?

j. How did you handle wanted changes and further innovation to your product, while the certification was underway?

2. I'm interested in the question of liability of producers of medical devices

a. What kind of liability do you consider Natural Cycles to be responsible for?

b. How does Natural Cycles handle customer service when it comes to liability

claims?

c. How does the certification of your product impact your liability?

3. For Natural Cycles to work optimally, steady user interaction is required (sleep pattern, regularity of temperature measuring, skip on sick days etc.).

a. What steps are you taking to ensure that customers understand and adhere to these guidelines?

b. What are your guidelines for including such information in marketing materials?

c. Do you have a product strategy and/or goal to decrease the reliance on manual user input?

4. Natural Cycles is dealing with sensitive private data. I'm interested in understanding your approach to data privacy and to the economic potential that this data may hold for your company

a. Will Natural Cycles be GDPR certified by the time the regulation goes into Effect?

b. Would you consider changing your End User License Agreements at some point in the future to allow for 3rd party access to your data?

5. Beyond Natural Cycles, The future of digital medical devices

a. How do you see the future of digital medical devices?

b. What benefits and dangers do you see for consumers in this field - now and in the future?

B. Natural Cycles User Survey Questions

1. What is the age group you belong to?
    a. 18-25
    b. 26-35
    c. 36-45
    d. 45+
2. Have you been using contraception regularly?
    a. Yes
    b. No
3. What types of contraception have you used?
    a. The Male Condom
    b. The Pill
    c. Natural Family Planning (fertility tracking based methods)
    d. Emergency Contraception
    e. The Contraceptive Implant
    f. The Contraceptive Patch
    g. The Intrauterine Device (IUD)
    h. The Vaginal Ring
    i. The Female Condom
    j. The Cervical Cap - Femcap
4. Were you happy with the contraception you used? Could you share any of your positive or negative experiences?
5. How did you get to know about Natural Cycles?

6. What do you use the application for?
    a. Avoid pregnancy
    b. Plan pregnancy
7. On a scale from 1 to 10 - how much do you trust the output of the Natural Cycles algorithm?
8. How would you describe your experience with Natural Cycles so far? How long have you been using the product by now?
9. Could you describe in your own words how does Natural Cycles work?
10. Do you think Natural Cycles is a medical device?
    a. Yes
    b. No
11. Why?
12. If you were to avoid pregnancy, would you use Natural Cycles as a primary protection?
    a. Yes
    b. No
13. Imagine a situation where you use Natural Cycles as a form of contraception. The application assigns you a green day, meaning you are on your non-fertile day. You don't use any other protection and get pregnant. How would you feel about the situation? Do you think Natural Cycles is/should be liable for your pregnancy?
14. Imagine a situation where you use Natural Cycles as a form of contraception. **Due to a an algorithm error** the application assigns you a green day, meaning you are on your non-fertile day. You don't use any other protection and get pregnant. How would you feel about the situation? Do you think Natural Cycles is/should be liable for misinforming you about your fertile days?
15. Imagine a situation where you use Natural Cycles as a form of contraception. **Due to a mistake you made** when entering your body temperature manually, the application assigned you a green day, meaning you are on your non-fertile day. You don't use any other protection and get pregnant. How would you feel about the situation?
16. Do you use any other fertility tracking applications? Can you name them?

17. Usually fertility tracking applications ask to share sexual intercourse data. Do you share such data?
    a. Yes
    b. No
18. Would you categorize it as a sensitive type of data that you would not enclose to any other application/company than the fertility tracking application that you are using?
    a. Yes
    b. No
19. Do you, as a user of Natural Cycles or any other similar type of digital application, feel that your data is adequately protected?
    a. Yes
    b. No
20. Do you, as a user of Natural Cycles or any other similar type of digital application, trust that your data will not be shared with 3rd parties?
    a. Yes
    b. No
21. Is it important to you that your data is not identifiable, meaning, any data you provide, which is then stored by the company you provided it to, or any 3rd party that received your data, can't be traced back to you?
    a. Yes
    b. No
22. How likely are you to recommend Natural Cycles to your friend? (Scale 1-10)

C. Natural Cycles App Review Keywords Summary

Table 1: Top 20 most frequently used words in positive (4-5 star) Natural Cycles app reviews

Words	**Occurrences**
app	611
body	342
natural	319
you	315
cycles	267
control	259
cycle	238
using	231
use	230
your	226
birth	222
love	204
pill	181
easy	159
know	153
get	146
now	144
really	136
years	133
just	133

Table 2: Top 20 most frequently used words in negative 1 star Natural Cycles app reviews

Words	**Occurrences**
app	113
you	76
use	32
free	29
your	26
pregnant	22
using	19
pay	18
just	18
natural	17
days	17
cycles	16
money	16
even	16
months	16
did	15
pregnancy	15
get	14
day	14
refund	14