DEVELOPING AN INTEGRATED SYSTEM SOLUTION FOR EARLY STAGE COLORECTAL CANCER DIAGNOSTICS IN A HOME SETTING

Master of Science thesis
Industrial Design Engineering
Management of Product Development
University of Twente
Faculty of Engineering Technology
PO Box 217
7500AE Enschede
The Netherlands

Author
R. R. H. Dommerholt
S1298348

University of Twente supervisor and professor
Prof. Dr. Ir. J. Henseler (Jörg)

Company supervisor
Ing. P. Spackler (Pim)

Commission
Ir. M. E. Toxopeus (Marten)
Dr. Ir. G. D. S. Ludden (Geke)

Publication Date
11-07-2019

Number of pages
167

Appendix pages
21

Publication ID
DPM-1593

ACKNOWLEDGEMENTS

First and foremost, I would like to thank the following people for their support and contribution to this thesis.
Marten, thank you for starting this process with me and thank you for ending it as well.
Jörg, I would like to thank you for guiding and advicing me through the better of six months that we worked together. I am especially grateful for the fact that you, without questioning, took over the tutorship and that you are able to ask the rights questions to ease my mind.
Pim, thank you for the opportunity and the support during the entire operation. You and I have been working on, thinking about, and developing this concept for over a year now and I hope you are happy with this manifestation that lies before you.
Daan, Mats, and Mick, thank you for listening to my ramblings and thanks for teasing me. I think I figured out the business case for our company.
Eeke, Rianne, Vera, and Matthijs, thank you for taking the time to listen to my test-drive of the colloquium. I think that my colloquium will be significantly better and that is all thanks to you.
Luuk, Fenna, Thijs, Leendert, Mauricy, Sjoerd, Remco, Gijs, Martijn, Marian, Patrick, Mike, Semme, and Iris, thank you for providing me with the information and knowledge that I needed to progress.
Esther, thank you for providing me with so much information and thank you for opening your network to me. That brought me in incredibly useful conversations with the vast majority of experts I talked to (and thanks for replying to my emails when I sometimes forgot to).
Evelien, thank you for teaching me everything about CRC.
Frans, thank you for taking the time to talk with about almost anything, from tuberculose, GP's, the 'maffia', the health council, to the train to Berlin.
Tara, thank you for providing more support than I think you realise.
Mijke, thank you for your loving support, advice, and a hearing ear. I am grateful we found each other again.
Last, I would like to thank my parents and my little bigger brother. Thank you for helping me grow up and thank you for giving me the chance and the freedom to screw up from time to time.

PREFACE

More than 7 years ago,
Henk lost his life to colon cancer. The difficulty of certain types of colon cancer is not necessarily the treatment, but rather the diagnostics and the treatment time. This type of colon cancer has a relative short period of time, between being able to diagnose the cancer and being able to treat this disease.
Once Henk got to the hospital, as something wrong had been discovered, he got to hear that there was not much that could be done. The time in which a treatment would have been possible had passed, making any efforts futile.
This made Pim, Henk's friend, think about possible solutions to this problem. They didn't exist.

SAMENVATTING

Ten eerste, voor dit onderzoek is er een ontwerp en implementatie plan voor een systeem ontwikkeld dat in staat is om ontlasting te analyseren en op basis daarvan een indicatie te kunnen geven van de gezondheid van zijn gebruikers. Voor het ontwikkelen van dit systeem zijn meerdere academische papers en theorieën gebruikt in combinatie met bronnen buiten de academica en interviews met experts uit het veld. Het onderzoek van Kroneman et al. (2016) beschrijft de Nederlandse gezondheidszorg vanuit meerdere facetten, welke zijn toegevoegd door bronnen van de NZa, het ministerie en de Europese wetgeving IVDR. De stakeholder theorie van Mitchell et al. (1997) bood een kader waarin alle belanghebbende, met betrekking tot de ontwikkeling en implementatie van de oplossing, geanalyseerd konden worden. **Ten tweede**, er gerealiseerd dat dit onderzoek valt onder Design Research (Simon, 1996; Van Aken et al., 2017) dat op zoek is naar een generiek ontwerp als antwoord op een vraagstuk dat ook toegepast kan worden in andere (onderzoeks-)velden. Om zo'n generiek ontwerp te ontwikkelen was een methodiek nodig die deze ontwikkeling kon sturen. De User-Centred Design methodology (Norman, 1986; Rahimi & Ibarra, 2014), de Design Thinking methodology (Gordon, 1961; Osborn 1963; Brown, 2008), en de Stage-Gate Approach (Cooper, 1986) zijn meegenomen in de overweging, alleen geen van de drie voldeden aan de gestelde eisen. Daarom is er een nieuwe, cyclische en iteratieve methodiek ontwikkeld die de beste elementen van de drie andere methodieken combineert. Hoe het resultaat van deze methodiek, het generieke ontwerp, uiteindelijk waardevol voor de gespecificeerde doelgroepen kon zijn is toegelicht via de Hybrid Offerings theorie (Ulaga and Reinartz, 2011).Deze theorie beschrijft hoe een ontwerp waardevol kan zijn in een complex netwerk bestaande uit meerdere belanghebbenden (Mitchell et al., 1997) die samen moeten werken om het systeem te laten functioneren als behoren. **Ten derde**, zijn er drie cluster van groepen gevonden die mogelijkerwijs de doelgroep kunnen worden van een systeem zoals ontworpen is in dit onderzoek. Deze drie groepen bestaan uit mensen die van nature angstig zijn aangelegd wat betreft hun gezondheid, mensen die boven mate geïnteresseerd zijn in hun gezondheid, en mensen die op basis van demografische gegevens het meest zouden kunnen profiteren van zo'n systeem. **Ten vierde**, zijn er vier toegangen tot de Nederlandse markt gedefinieerd op basis van onderzoek (Janssen et al., 2014) en interviews met experts. De eerste route is de consumenten route die het meest haalbaar lijkt voor de start-up, doordat er minder investeringen nodig zijn en er minder regel- en wetgeving mee gemoeid is. De tweede route is de zorg professional route die probeert de markt te betreden door zorg professionals ambassadeur te laten spelen voor het product. De derde route probeert toegang te verschaffen door de verzekeraar te overtuigen van het nut en de kostenbesparende kwaliteiten van de oplossing. De laatste route probeert via de overheid toegang te krijgen tot de markt en mogelijkerwijs een alternatief te bieden voor het huidige darmkanker bevolkingsonderzoek. **Ten vijfde**, door de methodiek is er een conceptuele oplossing ontworpen die in staat is om de gezondheid conditie van zijn gebruikers te bepalen door het analyseren van de stoelgang. Meerdere diagrammen in dit verslag tonen hoe dit systeem moet functioneren in coöperatie met de relevante stakeholders. Op basis van de eerder gespecificeerde routes is er een implementatie plan ontwikkeld om deze oplossing daadwerkelijk te implementeren in het Nederlands gezondheidszorg. Het Capital Model werd ontwikkeld om het ontwerp van het implementatie plan te structuren. Door zes perspectieven (sociaal, HR, intellectueel eigendom, organisatorisch, middelen en activa, en financieel) werd er een plan ontwikkeld, bestaande uit vier fases, dat het best inspeelde op de gelimiteerde kwaliteiten van het bedrijf. De eerste fase beschreef de ontwikkeling van het prototype om bewijslast te creëren van het concept. De tweede fase beschreef de ontwikkeling van een configuratie van het systeem dat verkocht mag worden aan consumenten. De derde fase beschrijft hoe het concept klinisch gevalideerd kan worden om zo ook medisch gebruikt te mogen. De laatste fase beschrijft hoe de oplossing een eventueel alternatief zou kunnen zijn voor het huidig bevolkingsonderzoek. Ten slot, is het gehele proces gevalideerd door ofwel literatuur ofwel interviews and discussies met experts uit de relevante (onderzoeks-)velden: van hoogleraren gastroentologie, tot business developers in de zorg, een lid van de Gezondheidsraad, twee huisartsen, en onderzoekers betrokken bij klinische validatie projecten en kosteneffectiviteit calculaties.
Gezamenlijk komend tot een passende oplossing voor het probleem van dit onderzoek.

SUMMARY

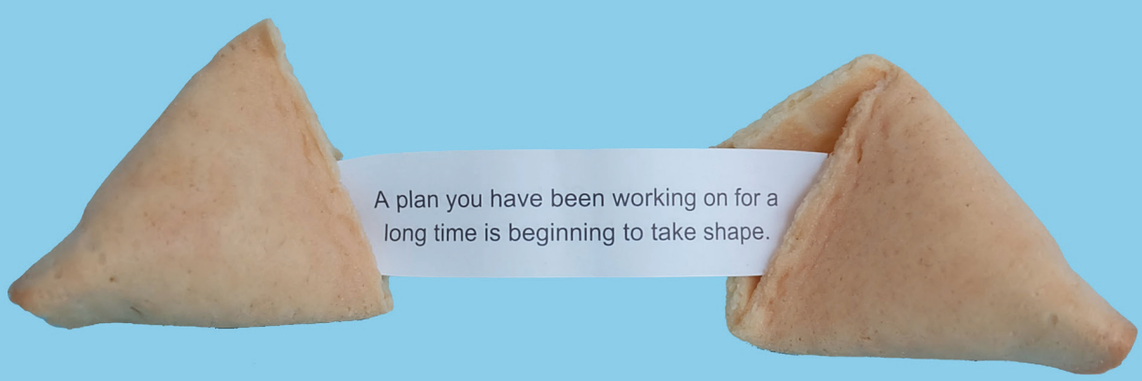
First, what has been developed during this assignment is a design and an implementation plan of a system capable of measuring and analysing stool to provide users with an indication of their health condition. To develop such a solution, multiple academic papers, non-academic sources, and expert interviews were used. Kroneman et al. (2016) described the Dutch healthcare system, which was added upon with knowledge and detailed information from the IVDR and sources from the NZa and the MVWS. The stakeholder theory from Mitchell et al. (1997; with additional knowledge from Hillebrand et al., 2015) was used to define stakeholders and their relationships based on research from Kroneman et al. (2016). **Second**, it was identified that this assignment should be considered as Design Research (Simon, 1996; Van Aken et al., 2017) aiming for a generic design and a new body of knowledge applicable in multiple contexts. For the development of such a generic design, a methodology was needed. Three methodologies were considered, from the User-Centred Design methodology (Norman, 1986; Rahimi & Ibarra, 2014), the Design Thinking methodology (Gordon, 1961; Osborn 1963; Brown, 2008), and the Stage-Gate Approach (Cooper, 1986). However, due to their limitations, neither was used. Therefore, a new methodology was developed combining the best elements of the three methodologies: iterative, cyclical, and consisting of two stages. How this solution can provide value was described through the Hybrid Offerings theory (Ulaga and Reinartz, 2011) providing insight into how value is delivered to multiple stakeholders in a complex network. Identifying the stakeholders (Mitchell et al., 1997) was crucial for the development of such a network. **Third**, when designing the target group, information from the CBS as well as non-academic sources showed that three clusters of people exist: those who are worried about developing CRC, those who are interested in knowing more about their health and body, and those who based on statistics should be profiting most from such a solution. **Fourth**, Janssen et al. (2014) described the four entry points how this market can be approached, which has been validated with insiders and experts. The first route being the consumer approach which is more feasible from a start-up perspective, as less is demanded of the company in terms of legislative requirements and resources. The second approach is through care professionals, which can become ambassadors of the new solution in negotiations with insurers. The third route directly targets the insurers, which requires a solid business case and clear cost-effective or cost-saving capabilities of the solution. The last approach targets the government through the Ministry and the NZa, which is thought to be bureaucratic and demanding. **Fifth**, through the methodology, the solution had been developed: a conceptual system architecture with functions capable of measuring, analysing, and reporting the results to its users. Multiple diagrams showed how the system as a whole is structured and how it functions with relevant stakeholders in the context. After the design and validation of the design by experts, the implementation of that solution into the Dutch market had to be developed. From a broad collection of over 20 literature papers, the Capital Model was developed able to structure the multiple phases of implementation. The Capital Model consists of 6 perspectives: the social, human, intellectual, organization, resource, and financial capital perspective. This model was also used to scope the assignment and in doing so, provided cohesion between research and practice. The entry points to the market, as specified before, were analysed in cooperation with an assessment of the capabilities of the company. In doing so, a four phased implementation trajectory had been developed moving from the less resource-demanding prototype phase, to a phase in which a consumer product configuration will be developed, to the use of this product as a medical device and therefore needing a clinical validation, and the possible application of the device as an alternative to the current national CRC screening in the Netherlands. **Last**, the result of this entire project has been validated throughout the project as at the end of the development process. Representatives of a large collection of relevant stakeholders were requested to provide advice and guidance in the development of both solution and implementation. From a professor gastroentology, to business developers in the medical industry, a former member of the Health Council as well as general practitioners, to researchers involved in the establishment of clinical trials and the cost-effectiveness calculations of screening methods.
Resulting in a fitting solution to the defined problem and goals of this research.

CONTENTS

PART 0

INTRODUCTION

This part will provide insight into the reasoning and demand for this design research project. A look is given into colorectal cancer, from both an individual as from a societal perspective. Additionally, it is discussed why the current solution is insufficient in solving the problem and how a solution used in a home setting could be the answer.


A plan you have been working on for a
long time is beginning to take shape.

1. INTRODUCTION

1.1 COLORECTAL CANCER – AN INDIVIDUAL'S PERSPECTIVE

Being diagnosed with colorectal cancer is too often a death penalty. In most cases, the possibility for successful treatment has passed before the patient is even aware of having the disease. Colorectal cancer (a collection of cancers in the small intestines, colon and rectum, CRC) is a malignant (=*kwaadaardig*) neoplasm (=*nieuwvorming*) growing on the epithelium (=protective tissue) of the inside of the colon. The disruption of normal behaviour of cells causes the process of neoplasia: disrupted cells get the ability of autonomous growth, invasion and destruction of surrounding tissue, and the spreading to other parts of the body (=metastasis, *uitzaaïngen*) (Maag Lever Darm Stichting, 2019a). CRC is commonly found in older people (90% of the patients are 50 years or older (Maag Lever Darm Stichting, 2019b)) as the process of developing CRC takes several years (between 10 and 15 (Maag Lever Darm Stichting, 2019c). Due to this long development time, health complaints often occur in later stages of the development. These health complaints include blood in the stool, abdominal pain and cramps, decreased appetite, altered stool pattern, and weight loss (Maag Lever Darm Stichting, 2019a). The survival chance[1] of CRC is heavily dependent on the stage in which the cancer is found. In 2017, the average 5-year-survival-rate, for men and women, is 66% (RIVM, 2018). Since the 80's, the 5-year-survival-rates have been increasing (RIVM, 2018), which is accredited to better therapy, pre-operative radiation and improved surgery procedures. Compared to other Western countries, the Dutch 5-year-survival-rate is good . Therefore, the absolute number of CRC deaths is lower than the incidence numbers would presume [45].
In most cases, a patient[2] experiences symptoms related to CRC and decides to visit the General Practitioner (GP). Or, the patient gets picked out because of the national screening. The patient describes his/her medical history (=*anamnese* (Radboud UMC, n.d.)) and a preliminary (physical) analysis by the GP or an outpatient clinic is performed. If enough evidence is present to suspect the presence of CRC or advanced adenomas, the patient is referred to the hospital for a colonoscopy (or sigmoscopy). The results of the diagnostic test are discussed in a multidisciplinary council (MDC = *Multidisciplinair overleg* (iNKL, n.d.)) consisting of a surgeon, gastroentologist, internist, radiologist, radiotherapist, pathologist, case manager and nurses. When it is decided to treat the patient, the council will establish a treatment plan. After the diagnosis, the colon cancer or rectum cancer is treated (within 6 weeks after the first visit to the outpatient clinic) by removing the adenomas through surgery and a chemotherapeutic is pumped into the abdomen to treat any left-over metastasis (HIPEC (Antoni van Leeuwenhoek, n.d.)). After the surgery, another MDC is being held that will discuss the results of the surgery and based on that, determine what after-care is necessary for the patient. After the treatment, the patient will have to check in every half year for the first 2 to 3 years, and every year up until 5 years after surgery, for examinations. Either the GP or the case manager can become responsible for the check-ups, this will be decided in the after-care plan. If the case that it becomes clear that the disease cannot be treated anymore, the patient becomes a responsibility for the GP which develops an appropriate plan to assist the patient and his/her beloved ones in the final moments.

1.2 COLORECTAL CANCER – A NATIONAL PERSPECTIVE

In 2017, 13.739 people got diagnosed with colorectal cancer (14.076 if cancer in the small intestine is included) in the Netherlands (iKNL, 2019). 1 in 20 people will acquire CRC in their lifetime and in 2017, 5.103 persons died from colorectal cancer (iKNL, 2019). Every year, a general practice has at least one new patient with CRC and, in total, 9 living patients with CRC, on average. In 2015, 575.5 million Euros was spent on CRC (RIVM, 2018b), which is €34 per Dutch citizen. 86,6% of that amount was spent on hospital care, the rest on prevention, medication, elderly care and other related activities. In other words, the majority of money spent on CRC is in treating and trying to cure the patient. And in 35% of the cases, the patient doesn't survive for more than 5 years (iKNL, 2018).

[1] The survival chance is almost always depicted as the 5-year-survival-rate. In other words, how many patients live 5 years after the diagnosis (National Cancer Institute, 2019).
[2] In this case, that person is not yet a patient as no disease has been diagnosed. However, to improve the readability of this report, undiagnosed people are also called patients.

Table 1. Stages, incidence and survival rates (iKNL, 2018).

Stage	Description	Incidence[a] (%)	Incidence[b] (%)	5ysr[b] (%)	Treatment steps	People deceased[b]
I	Carcinoma found in colon	26	17	95	Surgery	207
II	Carcinoma penetrated gut	28	23	88	Surgery, radiotherapy, and possible chemotherapy	534
III	Carcinoma spread to lymph	25	35	69	Surgery, radiotherapy, and chemotherapy	1231
IV	Carcinoma spread to organs	21	26	11	Surgery, radiotherapy, and chemotherapy	2967

[a] 2015
[b] 2017

1.3 THE NATIONAL SCREENING – THE GOOD

The incidence[3] of CRC has been growing steadily over the years due to increased medical expertise, increased general health as people become older increasing the chance of getting cancer. Additionally, the costs for treating late-stage CRC have been increasing significantly (due to costly pharmaceuticals, Lansdorp-Vogelaar et al., 2009). Therefore, the Health Council, in 2009, advised a national screening program based on the iFOBT (27% sensitivity and 65% specificity (Gezondheidsraad, 2009; RIVM, 2014)), which tests a population of 2 million people every two years: men and women of the age of 55 to 75 (Gezondheidsraad, 2009). This screening should be able to save at least 1.400 lives a year. And so, the population screening was introduced by the Dutch government in 2013 (RIVM, 2018)[4].The participant receives an announcement through the mail (this is only true for participating the first time). Two weeks later, the participation package is delivered containing an invitational letter, a folder explaining CRC and the procedure, the actual test, a manual, a bag in which the samples can be placed, and a self-addressed envelope. Contracted laboratories analyse the sample, three outcomes are defined: positive, negative, and insusceptible (at which a new invite is sent to the participant). Two weeks after sending the sample to the laboratories, the results will be communicated to the participant through another letter. A letter indicating a positive test result will be combined with an invite for an intake at a colonoscopy centre. Additionally, the letter also advises the positively-tested participant to seek out the GP and discuss what is necessary to figure out before the intake. The intake occurs within 10 work days after sending the letter bearing the result, the colonoscopy within 15 work days. The results of the intake and colonoscopy are sent to the GP, which in their turn contacts the participant (RIVM, 2013). After this procedure, the established care path is followed. This screening program was able to prevent an estimated 2.400 lives from ending needlessly early due to CRC.

1.4 THE NATIONAL SCREENING – THE BAD

The screening process has been developed to outweigh the cons. However, the Dutch screening process is not without shortcomings (Van Dam, F., & Stalpers, L., 2012). In 2014, 14,5% of CRC was not found with the population screening. This is due the relatively low sensitivity of the test for cancers (NOS, 2017). As can be imagined, this is one of the most prominent risks of the screening: people will be told that everything is fine, yet this is most definitely not the case. In this case, the situation can only worsen as the health complaints that are present can be wrongfully ignored as the false promise tells those that they're okay. Additionally, because of the high number of false negatives (people tested negative for the test but did have CRC or advanced adenomas), a new thing occurred called 'interval carcinomas. Which are people that got a negative test result (and thus were told that they did not show signs

[3] The incidence of cancer concerns the number of new cases that are diagnosed in a certain period (usually 1 year).
[4] This should not give the impression that the introduction of such a screening is without debate, politics, and public opinion. For an example of how complicated this process can be, see 'Het bevolkingsonderzoek op tuberculose: een virus tot maatschappelijk debat?' M. Dijkstra & F.J. Meijman (2002).

of CRC) which did actually had CRC. These people, unjustly, got their chances on curing the disease decreased. Because now, if these people got health complaints related to CRC, they will think that they do not have CRC as they were tested negative. Additionally, most of the criticism is directed towards the effectiveness and the burdening on the Dutch population. Six out of 1.000 participants were tested positive for CRC (and 30 for advanced adenomas) and referred to a colonoscopy. Of 1.000 colonoscopies, 67 carcinomas and 335 advanced adenomas were found. Which results in 15 colonoscopies necessary to find one person with CRC (Rozendaal, 2016). And thus, 14 people have to undergo a colonoscopy with all complications considered completely pointless. Even though the quality of colonoscopies is high in the Netherlands, in 2017, 1 person passed away because complications of a colonoscopy and 39 had serious complications but stayed alive (RIVM, 2018). Or in the other case, something could be found which did not have to be found. An example, such as a dilation of the large body artery has not proven to be essential for early diagnostics. In other words, because of intensive screening the number of diagnostics is dubbled [247,262] which increases the pressure on the entire healthcare system. Another issue with screening has not necessarily to do with the treatment possibilities, but more with the unjust estimated performance of the test. The lead-time bias explains the phenomenon where a person has a supposedly longer 5-year-survival-rate as the cancer is found earlier. However, the actual situation is that the person only knows earlier that he/she is going to die. This is often the case for lung cancer, as for the moment that a lung tumour is visible on a lung scan, that tumour has already spread to other organs (Van Dam, F., & Stalpers, L., 2012).
Recently, physicians have been sued because of alleged diagnostic mistakes in population screening targeted at cancer (something that has been happening with other screenings in the past (Wilson, 2000; The Lancet, 1999)). Dutch Pathology and Radiology associations have also indicated an increase in civil procedures; however, no data is available yet (Giard, 2001). Liability is a complex issue in population screening, as every test will deliver false positives and negatives, regardless of quality. Especially in the case of population screening, the difficulty is in understanding who is liable for wrongful diagnoses as the test is only an indication. The actual diagnosis has to be determined through a follow-up test (Schouten et al., 1998). A false positive is not a diagnosis of a disease, and a false negative can cause an unnecessary death as the participator is under the wrongful impression that he/she is free from the targeted disease. Essentially, a national screening will increase wrongful diagnostics.
The population screening in 2017, cost €14,22 per participating citizen (RIVM, 2018) (excluding the intake and the colonoscopy, the most expensive procedures in diagnosing CRC) which accumulates to just a bit more than €20 million growing to €27 million when the screening is fully implemented, paid for by the government. Over-treatment, unnecessarily treating someone which does not improve the well-being of that individual, will also add up to the costs of the screening. This could be by treating something that could grow out to cancer, but is not cancer at the moment, or by unnecessarily let people undergo a diagnostic test (like a colonoscopy, Bonneux, 2011) to determine CRC which is 14 times out of 15. All these over-treatment procedures only add to the cost and do not result in a better well-being or better health. The test is covered through subsidies and insurance. However, the following colonoscopy and intake are not covered. Therefore, in cases where no indication of CRC is found people are spending unnecessary money (between €300 and €425 for a colonoscopy) on these procedures (De Visser, 2014).

1.5 DUTCH CONSUMER MEDICAL DEVICE MARKET AND DEVELOPMENT

Developing new medical systems and solutions is becoming increasingly expensive every year. Research and development of new solutions are becoming more complex and take longer to deliver results, and thus become more expensive, yet the payback of such development trajectories cannot be guaranteed (think of drug development with lead times of 12 years, after which clinical trials have to prove its effectiveness, effectively flipping a coin on the fate of the return on investment). Most efforts to improve the system, like specialized medicine or treatments, only add to the expenditure. However, the incumbents of the industry are most likely not the organizations willing and capable of providing the necessary change[5]. It is often stated that change in healthcare must come from entrepreneurs and intrapreneurs, doctors, patients, and start-ups as disruption and change should not be expected form incumbents (Christensen, Waldeck, & Fogg, 2017). Even more so, for many incumbents in the healthcare

[5] Medical device developers, business developers, see **Appendix 2**.

industry it is currently more cost-effective to purchase and takeover a start-up with a proven concept or new innovation, that has done a lot of necessary R&D and market research, than to develop products themselves (Morgan Stanley, 2015). Buying another firm is currently the most cost-effective way to broaden the product portfolio of an incumbent and decrease the risks of investing in new tech. Reducing risk is an essential part of these incumbents as many solutions perish before reaching the market due to the many barriers involved in medical device development. From a limited access to funds and other resources due to a lack of proof, to heavy and demanding regulations (Deloitte Center for the Edge & Deloitte Center for Health Solutions, 2014), and conservative and sceptical stakeholders often unwilling to adopt new tech ("not invented here") .

The Netherlands is increasingly becoming older, greyer and more urban. The growth of children is decreasing steadily since the 1980s, whereas the growth of seniors is increasing (Kroneman et al., 2016), meaning that more and more pressure is put on systems that provide care to older people. Even more so, because of the growing life expectancy (CBS, 2018, which is essentially a favourable trend) and the improvements in diagnostics, chronic diseases are becoming more and more prevalent in the population. Thus, people will increasingly have "multi-morbidity", which is two or more chronic conditions. Socio-economic differences in life expectancy are large in the Netherlands and are expected to grow. Currently, the life expectancy for people with lower education is six years shorter than those with higher education (Kroneman et al., 2016). Malignant neoplasms and diseases of the circulatory system are most predominantly the cause of death for many Dutch men and women (Kroneman et al., 2016). The five-year survival ratios for people diagnosed with breast, cervical or colorectal cancer have increased mildly between 2000 and 2011. Dutch survival ratios are middle range compared to other countries (Van den Berg et al., 2014a; OECD, 2013; Kroneman et al., 2016), which is surprising in light of healthcare expenditure, as the Dutch healthcare systems is one of the most expensive. However, because of improvement in treatment options cancer is becoming "more and more a chronic disease instead of a lethal illness" (Kroneman et al., 2016). The growing prevalence of cancer (iKNL, 2019), and especially colorectal cancer, sparked the initiative to launch additional screening programmes in the Netherlands. And even though the standardized rates for groups with malignant neoplasms as the main cause of death have been decreasing, the absolute numbers have been growing due to the aging population (Kroneman et al., 2016). Despite the flattening growth of healthcare expenditure since 2013, the Dutch healthcare system remains one of the most expensive one in the world. Quality indicators, like the prescription of generics and length of stay indicate improvements in the efficiency in the system. Additionally, healthcare investments and related profits have been growing to almost pre-crisis levels. Nevertheless, as healthcare expenditure keeps increasing (from 8% of GDP in 1995 to almost 13% in 2013 (van den Berg et al., 2014a)), the "pressure to contain healthcare costs" become only stronger (Kroneman et al., 2016). The most conventional claim is the lack of efficiency (Ahli, 2019) in healthcare provision because of the lack of proper cost-reduction tools, lack of meaningful data and the complex relations between insurers and providers. Causing frequent overspending of forecast budgets by almost all healthcare professionals (Kroneman et al., 2016).

The consumer medical device market is blooming and more solutions become available for consumers to use at home. From systems capable of monitoring the prevalence of a progressive eye disease (ForseeHome, n.d.), and a device that can placed over the chest of a women to measure the presence of breast cancer (Braster S.A., n.d.), to the first FDA approved home test for CRC (Philippidis, 2019). As has been mentioned, treating a patient is currently more expensive than maintaining a patients' good health. This train of thought is slowly becoming more established among leaders and professionals in the healthcare industry, allowing the introduction of new treatments, business models, and methods of improving the system while making revenue. Therefore, it is not strange to see that most innovative solutions are centred around preventive and primary care[6] issues and service delivery[7] (Govindarajan & Ramamurti, 2018). As consumer spend more money 'out-of-pocket' (not covered by insurance) for medical treatments, solutions, and devices, they begin to expect the same quality of experience as with regular consumer products. A new paradigm shift is occurring in which 'patients' are becoming 'consumers'. Companies capable for adapting to this change and treating these consumers properly will most likely profit most (Citrin, 2018).

[6] Iora Health developed a new business model that 'doubled down' on primary care expenditure by maintaining good health in patients with the help of coaches. Since the start, seven years ago, Iora Health reduced hospitalizations by 35-40%, lowered costs by 15-20%, all while improving patients' health.

[7] The University of Mississippi Medical Center developed a telehealth system where they could share their medical expertise with physicians in rural hospitals which decreased the unnecessary flow of patients to the UMMC (the only top tier hospital in the Mississippi state).

1.6 THE PROPOSED SOLUTION – FOR AT HOME

To gather information for this design research project, multiple sources were employed. The main source of information are academic papers (see all Bibliographies and **Appendix 1**), and discussions with experts (**Appendix 2**). I had discussions with founders and management of other medical device companies, with an expert in brand management, experts in business models and customer value, a professor gastroentology, multiple business developers, a data sharing and communication expert of the national association for GPs, a former GP and now member of the Health Council, the head of the patient association for CRC patients, and a healthcare reimbursement calculations researcher. Additionally, I participated in 11 events. From an event focussed on philosophizing where healthcare will be in the future, the biggest European medical device trade fair, a panel discussion about the future of cancer data management, a panel discussion on business models and market acceptance in the Dutch healthcare market, a panel discussion on start-up funding and venture capital, and an event discussing the health tech innovations in the East of the Netherlands. I also participated in 7 workshops. From multiple workshops on different ISO standards (e.g. risk management (ISO 14971:2007), quality management system (ISO 13485:2016), etc.), on intellectual property rights and protection methods, on business models and business model innovation, production of medical devices and specifically on the production of low quantities, and on how to involve users in the development of a medical device. I had 6 meetings with the total company during the progress of this project. Last, I read 118 pieces of grey literature (e.g. blog posts, news articles, opinion pieces, etc.) and saw 5 lengthy YouTube (panel) discussions that further aided my understanding of the subject matter while also provide insight in how the related subjects are seen by healthcare professionals and other interested/involved people. Generally speaking, the papers[8] formed the scientific backbone of this research. Discussions with experts were used to validate my understanding of the papers, as well as discuss my ideas and answer any remaining questions. The events and workshops were chances to further my understanding of the subject and at the same time, offer the chance to meet new people and make useful connections. Specifically, because of participating in 1 workshop was I able to contact a gastroentology professor who's network was so grand that I could make contact with others more easily as well. As said before, the grey literature explained subjects in a simplified way, making it easier to understand, as well as offer insight into the perspective of the interested and involved healthcare professionals and researchers. The tutor meetings, of which there were 47, were most predominantly used to show progress and discuss new findings. Brainstorming and thinking about the concept was mostly done with my company supervisor, whilst solving problems and safeguarding the process was mostly done with my university supervisor. In the opinion of the company, the solution provided by the government does not solve the issue adequately. The idea exists that this screening can be more efficient when it's performed at home and on a daily basis. Doing so, there is no more room for error as false positives or negatives get filtered out by other measurements. Currently, there are over 200,000 medical devices on the European market (Fraser et al., 2011), yet not one solved this issue in a home setting. Therefore, the following solution is proposed: a scanning device is introduced that will be mounted at the back of the individual's toilet that will be able to analyses the faeces in a similar manner to the national screening. However, the scanning device will analyses every time the individual visits the toilet. Therefore, being a better tool to use than the one-time screening as performed in the Dutch screening. This device will analyse the faeces and the results will be presented in such a way that the individual can be monitored. At first, this monitoring will be done by the user self and the device will only alert the user, based on statistical deviations, of any possible dangers. In the future, the solution might be an alternative to the national screening program. However, implementing the solution in such a way is far from easy. As because of the influence and involvement of the medical industry might pose significant risks for successful implementation. From regulatory and liability issues, to difficulty in financing the development process as well as the actual solution itself. This report will provide an overview of how these issues can be solved. I think that the development of such a product that can solve issues with diagnosing colon cancer can be a very interesting case for a management of product development student. As this situation is quite complex: the medical world is a demanding place to develop a product for, and as a start-up there is a clear limitation in terms of resources, capital, and employment. The designed solution will be presented as well as the implementation of this solution in the Dutch consumer medical device market, which is structured with the Capital Model, a framework consisting of 6 perspectives regarding business and development. Afterwards, this process will be evaluated to show the academic merits and prove its academic value.

[8] In product development literature, papers used are often only included if published in the last five years. In the medical industry, however, papers that exceed this are still used (the Health Council report on the national screening uses several sources older than 2000). When the content allows it, older papers are included in this research as well.

“IT’S INCREDIBLE TO THINK EACH TEASPOON OF YOUR STOOL CONTAINS MORE DATA IN THE DNA OF THOSE MICROBES THAN IT WOULD TAKE LITERALLY A TONNE OF DVDS TO STORE. AT THE MOMENT EVERY TIME YOU’RE TAKING ONE OF THOSE DATA DUMPS AS IT WERE, YOU’RE JUST FLUSHING THAT INFORMATION AWAY. PART OF OUR VISION IS, IN THE NOT TOO DISTANT FUTURE, WHERE AS SOON AS YOU FLUSH IT’LL DO SOME KIND OF INSTANT READ-OUT AND TELLS YOU ARE YOU GOING IN A GOOD DIRECTION OR A BAD DIRECTION. THAT I THINK IS GOING TO BE REALLY TRANSFORMATIVE”

PROF. ROB KNIGHT, 2018

1.7 GLOSSARY

Colorectal cancer (CRC)	Cancer development in the colon or rectum (*darmkanker*).
Gastroentology	A branch of medicine focussed on the digestive system and medical conditions regarding the digestive system.
Biomarker	A measurable indicator of a biological state or condition.
5-year-survival-rate	The percentage of people that survived a disease 5 years after its diagnosis.
Incidence	The occurrence of a medical condition among the population over a given time period.
GP	General Practitioner (*Huisarts*)
Curative care	Care focused on curing the patient [0021]
Colonoscopy	An endoscopic (= looking inside) examination of the large and small intestine with a camera. A sigmoscopy only examines the first part of the large intestine.
iFOBT/FIT	*Immunochemische fecaaloccultbloedtest*, the stool test used by the Dutch government in the national screening. The iFOBT tests for remnants of faecal (old) blood in the excrement of the participant. Also called fecaal immunochemische test (FIT).
FOB	Faecal Occult Blood, old blood remains present in human stool.
IVDR	In Vitro Diagnostica Regulation, European legislation on in vitro diagnostica regarding validation, market entry, surveillance, production methods, and more.
MDR	Medical Device Regulation, European legislation on medical devices regarding validation, market entry, surveillance, production methods, and more.
RCT	Randomized Controlled Trials, a type of scientific research to determine the effectiveness of a treatment.
Reimbursement	The act wherein an insurer pays for the services of a healthcare provider to a patient (*Vergoeding*). If a product/service is reimbursable, that indicates that the insurer is willing to pay for this product/service if the patient desires/needs it.
GDPR	General Data Protection Regulation (*Algemene Verordening Gegevensbescherming , AVG*), European legislation on privacy and data protection.
Notified Body	An entity that has been accredited to assess whether a product meets predefined standards.
Methodology	A research-based framework with analysis tools and proposed actions that try to improve and/or guide a process. In this case, the process of product development.
Solution design	Conceptual design of a product, a service, or a combination of both that answers a specific users need.
Implementation design	Conceptual roadmap/framework describing the processes necessary to implement the solution design into the real world.
Concept	A first iteration of a design.
MVP	Minimal viable product, a product with minimal features and functions that still satisfies the needs of early users and which can be used to gather feedback for the development of future products.
DSR	Design Science Research. DSR is the academic conceptualization of the rather natural design process:
Generic design	A conceptual design that is able to solve the problem it was developed for, which is also translatable to other contexts.
Black-box	A theory in which the inner mechanisms of a product/process are unclear. In other words, it assumes that a process delivers output B with input A, unknowing how that happens.
UCD	User-Centred Design, a design methodology to develop products with a strong user focus. A collection of methods.
SGA	Stage-Gate Approach, a development methodology that divides a development process in separate phases that need to be executed and completed consecutively. Each phase is completed with a phase describing certain criteria, which must be upheld, before a new phase is started.
Financial Capital	A collection of practices, processes, competencies, and goals related to the financial management of a firm. Think of accounting, business model, investments, etc.
Social Capital	A collection of practices, processes, competencies, and goals related to the alliance and stakeholder management of a firm. Think of, stakeholders, alliances, cooperation, marketing, etc.
Human Capital	A collection of practices, processes, competencies, and goals related to the human resource management of a firm. Think of employees, contracts, scouting, etc.

Intellectual Capital	A collection of practices, processes, competencies, and goals related to the intellectual property management of a firm. Think of patents, trademarks, protection methods, etc.
Organizational Capital	A collection of practices, processes, competencies, and goals related to the organizational management of a firm. Think of legal entities, business architecture, shares, etc.
Resource Capital	A collection of practices, processes, competencies, and goals related to the resource capital management of a firm. Think of machinery, procurement, maintenance, sustainability, etc.
Super-system	The context in which a system operates.
Subsystem	A subdivision of a system.
System	A description of a product, service, or both detailing components, functions, and processes.

1.8 READING GUIDE

This reading guide is supplied to help the reader effectively through this thesis. Therefore, I am going to give suggestions on how to approach this report given certain foreknowledge, expertise, or interests. In doing so, I hope to not scare people away from the massive amount of pages at first glance. **For a medical industry expert**, it is possible to skip the analysis part as this describes, most predominantly, the context of the Dutch healthcare system. When working in this industry, most of the information provided should be already be known. Especially when knowledgeable about medical device development, this part may be skipped. Therefore, Part III and IV will be most interesting as they describe the solution and its implementation into the Dutch healthcare system. **For a hasty reader**, it is possible to only read the summary and the summary of Part III and IV describing the solution and the implementation of that solution. In these parts, the main value of my work can be read. Only when some aspects remain unclear, or when referred to the previous parts and chapters, can one scroll back and read more. **For the academical reader**, the most interesting parts are Part II and V. These describe the goals, approach, methods, and process of this design research project as well as a discussion and reflection on the presented results. These parts contain the used methodology to design the solution and structure the implementation, as well as the scope of this research.

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PART I

ANALYSIS AND CONTEXT

This chapter describes value proposition of the solution, the relevant stakeholders in the Dutch healthcare system and their relationships, and the conditions in which a medical device is allowed on the market. Most prominent are the In Vitro Diagnostic Regulation regarding medical devices and the four routes to enter the market in the Netherlands. Additionally, an assessment of the company, that must develop and implement the solution, is provided according to a newly developed method.

2. VALUE PROPOSITION

As treating a patient is currently more expensive than maintaining a patients' good health due to increased costs of treatment (Hart & NU.nl, 2019; Emery, 2017; DutchNews.nl & Pascoe, 2019). Even more so, diseases that used to have a high mortality are now turning into chronic diseases (NU.nl & den Elt, 2015). As a countermeasure, more emphasis is being place on preventive methods and treatment options. Technology can aid this process and so, smart technologies are becoming increasingly more prevalent in the modern medical industry. The introduction of these new technologies also allow for the development and implementation of new treatments, business models, and methods of improving the system, while making revenue. Therefore, it is not strange to see that most innovative solutions are centred around preventive and primary care issues and service delivery (Govindarajan & Ramamurti, 2018).The best context for preventive care is where the patient is not a patient: at home. Therefore, more and more preventive care solutions find their way into the homes of healthy individuals that want to remain healthy. From well-known example heart rate monitors that are increasingly more often built in smart watches (Tweakers, 2015), to the fitness trackers (21,6 million units sold in Q2 of 2017 (Bright. nl, 2017)), and even Amazon's Alexa that is becoming used for medical applications (Chen, 2019). Even more so, patients are the fastest-growing user group for electronic medical records (Gawande, 2018). This solution will also be used in a home context and can therefore be seen as a consumer medical device. Due to this consumer approach to medical innovations, it is important to define the value proposition of the solution first to be able to design the architecture, functions, business model, and implementation roadmap. Therefore, a look is taken at the value that this solution can provide to its users, the company, as well as any relevant stakeholders (for an in depth analysis of stakeholders, see **Chapter 3** and **5**).

2.1 VALUE

In stakeholder theory, value is the entity that is conjoined and created thought the complex relationships and co-operations between stakeholders. To view the value creation process as something that only the company has under control, depicts an "imperfect understanding" of how value is created (Hillebrand et al. 2015). Value in from this solution is created through relationships and cooperation with the relevant stakeholders from the medical industry. **First**, value for the user can be found in the capability of the system to enable the user to maintain good health. As has been mentioned in the introduction (**Chapter 1**), this solution enables users to monitor their health more closely by measuring and analysing the user's stool. A part of the value is created when the user is able to monitor his/her health through the interpretation of the test results. The rest of the value is created when healthcare professionals recognize and acknowledge the test results of the solution. Only then can the user use the output of the system to actively restore their health. In doing so, the solution does not pose as an alternative to other health management systems and PSS's but as an entirely new category of products. If the system is capable of predicting CRC, then the issues regarding the national screening can be solved. **Second**, value for the system can be found in the capability of the solution to lower the expenditure by reducing the amount of (unnecessary) treatments due to better maintained health and subsequently further the understanding of CRC, stool, and good health through data and pattern recognition. The system is able to monitor users and all the output combined can be used to establish a database. The database can be analysed to identify new insights in CRC development and health condition.

Table 2. Value proposition for the user and the system.

	User	**System**	
Goal	Monitor and maintain good health	Reduce costs	Further the understanding of CRC and good health
By	Measuring valuable information from the stool	Reducing (unnecessary) treatments and diagnostics	Gathering more information and data
Trough	Sensors and pattern recognition	Better data and understanding	Smart technologies

2.2 PREDICTIVE VALUE OF THE HUMAN STOOL

2.2.1 Measuring for?

To be able to provide value for the users of this system, the system must be able to measure biomarkers that can indicate the healthiness of an individual. However, there lies the first major problem. The medical industry and medical research fields are currently undivided or unaware of biomarkers in faecal matter capable of indicating or assisting in the indication someone's health condition[9]. For the same reason, the Health Council advised the Dutch government to use a testing method capable of detecting old blood in faecal matter, as FOB is capable of predicting CRC. Other biomarkers, are either unable to predict CRC or too expensive to be used successfully (**Appendix 3**).

What can be measured is blood in faeces and the relief pattern as these are able to provide an assessment of health of the user. Faecal occult blood in faeces is the best non-invasive method to detect possible CRC and measuring relief pattern is the only technically feasible and cost-effective option available. DNA tests are effective predictors, but too expensive to be used in a consumer product. The microbiome (i.e. the bacterial biomass responsible for the digestion and establishment of the immune system (Rose et al., 2015)) also has its clinical application[10], yet no proven measuring method exists yet. Other biomarkers have not been found or are hampered by to other problems (e.g., massive differences in genomics between individuals (Health Council, 2009).

2.2.2 Measuring blood

Faecal (=in the faeces, ***fecaal***) occult blood (=old blood) can be a resultant of bleeding carcinomas in the colon. Faecal occult blood (FOB) is often dark-brown of colour, and difficult to spot in human excrements (you can probably guess why). The downside of using occult blood, is the possibility that blood exists in the faeces because of other reasons. For instance, haemorrhoids can also cause bleeding which can in turn, create a false positive for an FOB test. Faecal (=in the faeces, ***fecaal***) occult blood (=old blood) can be a resultant of bleeding carcinomas in the colon. Faecal occult blood (FOB) is often dark-brown of colour, and difficult to spot in human excrements (you can probably guess why). Faecal occult blood is still the only biomarker known that is able to identify people that possibly have CRC. A biomarker is "A defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes or responses to an exposure or intervention" (FDA-NIH Biomarker Working Group, 2016; Califf, 2018). In this case, the biomarker is used as a predictor of CRC. A "predictive biomarker" is able to find changes in the health condition of an individual that might indicate a favourable or unfavourable effect occurring in the user (FDA-NIH Biomarker Working Group, 2016). The biomarker on its own does not indicate much, it is the interpretation of healthcare professionals that can apply medical knowledge, context and understanding to a biomarker. To be able to prove that a biomarker can predict diseases in persons, requires considerable effort, time, and money. This assessment is always done through randomised controlled trials (RCT), a rigorous clinical study that compares two or more populations to evaluate the capabilities of a biomarker (Califf, 2018). Biomarker development for CRC is to this day a subject of healthcare that is heavily researched. Researchers are always looking for new clues that can help in diagnosing CRC and especially in finding these people earlier than current methods are able to do. Several other biomarkers have been identified over the years, but none has been able to demonstrate an improved sensitivity or specificity to CRC compared to FOB (**Appendix 3**). Even more so, advanced adenomas (i.e., the 'things' that grow into CRC have shown to be bad predictors as well (Majumdar et al., 2014)). Other methods have tried to combine methods with FOB, yet the main issue in those cases is the cost-effectiveness of the measurement. Additionally, the research field is also prone to too many failures, where improvements can include the introduction of "stringent" research methodologies, researching in large collaborative efforts, and more rigorous systematic reviews of biomarkers (Ioannidis & Bossuyt, 2017). The downside of using occult blood, is the possibility that blood exists in the faeces because of other reasons. For instance, haemorrhoids can also cause bleeding which can in turn, create a false positive for an FOB test.

[9] In conversation with a professor gastroentology, as well as Rose et al. (2015).

[10] In literature, a change in the microbiome (i.e., *dysbiosis*) has been linked to obesity (Turnbaugh et al., 2006), type two diabetes (Qin et al., 2012), high blood pressure (Yang et al., 2015), inflammatory bowel disease (Frank et al., 2007), autoimmune disorders (Proal et al., 2013) and mental health problems (Cryan and Dinan, 2012). Recent research has shown that the microbes are also related to modulation in the actions of chemotherapeutic drugs used in cancer treatment (Alexander et al., 2017).

All things considered, to this day, FOB is the most reliable and proven biomarker being able to identify people with CRC. So, this solution will focus on identifying FOB. Several methods exist, yet in most cases it comes to down to adding a reagent (a substance that reacts to blood) and measuring the reaction to determine the amount of FOB in the faeces.

2.2.3 Measuring relief pattern

Changes or complaints in the relief pattern can be a reason for a healthcare professional to examine a patient and perform diagnostic tests[11]. Therefore, due to a lack of knowledge of biomarkers and other possible indicators of CRC, relief pattern will be the second focus point to analyse faeces. Relief pattern constitutes to the characteristics of one's pooping behaviour. This pattern has some characteristics focussed on how the faeces is (consistency, colour, pH, weight, and type on the Bristol stool chart (Lewis and Heaton, 1997)) and how often it is 'laid' (frequency).

2.2.4 Longitudinal measuring

As would seem logical, increasing the number of tests will increase the sensitivity (.e.g., the sensitivity of the iFOBT improved from 65% to as much as 80 to 90% sensitivity (Nakama et al., 1999). For the national screening, however, the Health Council (2009) pointed out that screening every year, instead of every two, will only roughly double the screening costs as the iFOBT used is a disposable. So, it was decided that screening once every two years is the most cost-effective method. For this solution, the value can be found in measuring over longer periods of time, instead of just once. Doing so, it becomes possible to notice subtle differences in the faecal output of the user. This is a radically different approach than what is available now.

2.2.5 What must be measured to provide value

Table 3. Measuring methods.

What	How	Preparation of the faeces	Effect on the faeces
FOB	With a reagent	The reagent should be able to reach the faeces	Reagent remains in the faeces and can distort other measurements
Consistency	Calculation based on weight and volume	Weight and volume have to be measured first	-
Frequency	Calculation based on time and number of visits per user	No preparation needed	No effect
pH	Measured with a sensor	Sensor should be able to reach faeces	No effect
Weight	Measured with a scale	The faeces should fit the measuring container of the weight scale	No effect
Bristol stool chart	Image-recognition through camera	No preparation needed	No effect
Colour	Image-recognition through camera and colour sensor	No preparation needed	No effect
Volume	?	?	?

Table 3. summarizes all possible options. Behind every biomarker it is indicated how it can be measured. Providing this information will clarify that it should be taken into account how the faeces is treated, manipulated, and modified and how this can (negatively) affect the test. To ensure that the tests are performed correctly, the sensors used for measuring the biomarkers must be validated before every testing. It is important to test with a known variable if the sensor is able to perform the test accurately. For instance, the colour sensor could first measure a colour of which the variables are known to see if the sensor outputs the same variable. Measuring faeces can also leave some dirtiness obstructing the sensors efficiency and therefore, the sensors should be cleaned after every visit. Additionally, as some biomarkers can only be measured by manipulating the faeces or adding substances to the faeces, it is

[11] In conversations with experts, see **Appendix 2**

important to test on multiple samples as to avoid impurities. What must be guaranteed to provide the value is the validity of the measuring methods and the guarantee of valid results. Otherwise, the user cannot trust the device and will not use the results provided by the solution, deeming it obsolete.

2.3 VALUE FOR THE COMPANY

Selling the solution obviously provides value for the company, however, in this chapter other types of value will be discussed. The company can find value in the usage data of the system and the subsequent database. As new products are increasingly more equipped with communication and information technologies, usage data or strategic customer data (Rijsdijk, Hultink, and Diamantopoulos, 2007) becomes a new asset manufacturers have access to. New networks are formed from these products where manufacturers have remote control over these technologies (i.e., the installed base (Wise and Baumgartner, 1999)), capturing data on its usage, the use process, and its user (Allmendinger and Lombreglia, 2005; Shugan, 2004). This information is a powerful resource for a multitude of applications: from predictive maintenance process, to monitoring user experiences, improving design parameters, and developing new knowledge. Closely monitoring the users of the system also allow for the establishment of a database containing health data of the installed base. Assuming that the privacy and safety of its users can be guaranteed and the users have allowed for data-sharing, such information could provide tremendous amounts of value for the healthcare system. That database can provide health information of a large set of individuals over longer time periods than ever has been recorded before. This is inherit value for care professionals and researchers, as they can use this information to improve their understanding of CRC and CRC development, as well as stool in relation to health. Data analytics and statistical analyses can provide inside in the behaviour of the digestive system from a perspective that has not been researched in such detail before. Possessing such a database is therefore incredibly valuable, for the company[12] as well as the academia[13].

2.4 COST-SAVING CAPABILITIES OF SMART TECH

Table 4. Costs of cancer treatment for the stages of CRC (Lansdorp-Vogelaar et al., 2018).

CRC treatment costs (€), per patient per year	Stage I	Stage II	Stage III	Stage IV
Initial treatment	17,219	22,177	26,585	30,992
Continuous care	685	685	685	685
Terminal care, death CRC	23,786	23,786	24,888	32,050
Terminal care, death other causes	9,352	8,912	10,234	19,930

CRC treatments were divided into 3 clinically relevant phases: initial, continuous, and terminal care. Initial phase was defined as first 12 months after diagnosis, terminal phase was defined as final 12 months of life, and continuous phase was defined as all months between the initial and terminal phases. For patients surviving less than 24 months, the final 12 months were allocated to the terminal phase. The remaining months of observation were allocated to the initial phase.

Last, the new product could also be capable of saving costs for the healthcare industry through two means: keeping people healthier longer and reducing the amount of processes necessary. Maintaining health is more affordable than treating a disease. Even more so for CRC, as cancer medication is expensive, as has been mentioned before. Table 4. has been used to calculate the cost-effectiveness[14] of new biomarkers vs. the current iFOBT for non-invasive cancer screening, and shows us the costs of treating cancer for each of the four stages. As this table shows, is that finding an individual that has CRC earlier saves tremendous costs for the healthcare system. For example, an individual was found with stage I CRC, after the initial treatment that individual lived for another 4 years (i.e. , 5 years from the diagnosis) before dying due to other causes. Another individual was found with stage III CRC and after the initial treatment lived for another 4 years (i.e. 5 in total) before dying of CRC. The treatment of the first individual costs €51,231, whereas the treatment of the second individual costs €76,133. A significant difference due to treatment options, medicine types and use, the need for specialists, and more.

[12] Founder and CFO of a medical device company possessing such a database, see **Appendix 2**.
[13] Professor gastroentology, see **Appendix 2**.
[14] Calculating the cost-effectiveness of treatments in healthcare might seem odd from an ethical standpoint. However, these calculations are necessary to make most use of the financial resources of the industry and keep expenditure as low as possible so that saved money can be spent on other treatments and improvements of the system, as well as keep the taxes low.

When calculating simulations of these numbers of different scenarios while keeping variables the same, it becomes clear that most money can be saved on the ineffective treatment of late stage CRC patients. As the 5-year-survival-rate of these individuals is low (69% for stage III and 11% for stage IV (NKR, 2019)), a significant portion of the treatments does not reach its goal and thus the investment can be regarded as one without return[15]. To make most use of the financial means, it is better to identify CRC patients in earlier stages, not just for the return on investment but also for the improved survival chances and more effective treatments (by some this is called 'value-based healthcare'[16]).

2.5 EXTENDING THE BODY OF KNOWLEDGE

As has been mentioned, a database filled with health condition information on a multitude of users over longer periods of time can have significant value for care professionals and researchers. Such a database does not exist (publicly) yet, so there is no say in how much value this will bring. Nevertheless, it is safe to assume that this amount of knowledge will inevitably extend the body of knowledge regarding CRC, cancer development, and the health condition derived from human stool. To make use of such a database, some preparations are needed. **First**, the safety and privacy of all users in the system (assuming they agreed to share data) must be guaranteed and clearly communicated as not to push away any potential buyers of the system. **Second**, a platform through which the data becomes available must be built, safe from cybersecurity threads. **Third**, payment structures must be developed to allow researchers to access the data after payment. **Last**, the responsibility of the company regarding the data must be established. In other words, it must be clear to all participants in this process that the company strives for the best data possible and does not alter the data without permission or to deliberately change research outcomes.

The system could also be designed in such a way that the database and the operating system located in research hospitals and institutes are linked. Such a system could avoid administrative efforts for the researchers as the data is automatically transposed to the operating system of its new user. However,the administrative benefits are questioned among researchers and healthcare professionals (Bell et al., 2017; Wolff et al., 2016). It has been found that American physicians already spent two hours doing computer work for every hour spent with a patient (Sinsky et al., 2016). The fastest-growing occupation in healthcare in the United States has been the role of medical scribe: assistants trained to perform the computer tasks for doctors, so that doctors can make more time for patients (Gawande, 2018). Even more so, the Massachusetts General Hospital has introduced "virtual scribes" : India-based doctors hired to perform the documentation based on digitally recorded patient visits (Leventhal, 2018). The time that is freed up by these scribes, however, is not used to lighten the doctor's workload. Rather, it just shifted. Additionally, linking these systems could potentially crash them, a risk that must be avoided or at least mitigated. New initiatives have sparked to allowed users to access their own medical records and make changes. However, due to a fear of loss of control and revenue, most electronic-medical-record companies are hesitant (at best) about opening up their systems. This is however changing (Gawande, 2018).

In addition, such a system could also aid the process of 'shared decision making', in which the opinion of the patient is included more thoroughly. (Dees, 2017; Sanders et al., 2016; Meijers et al, 2018) All things considered, the design of such a system and its process are outside the scope of this assignment as for such a project, other research fields must be addressed (e.g., cybersecurity, data transformation and analytics, health processes, health expenditure calculations, ethics, etc.).

[15] This is perhaps an unethical standpoint, but I tried to approach it from a business perspective. Not to disregard the necessity of trying to treat patients regardless of survival chances, but to indicate the cost-effectiveness that can be improved from finding and identifying CRC patients earlier.

[16] Future of cancer data management, 26-11-2018, Jaarbeurs, Utrecht.

3. IDENTIFYING STAKEHOLDERS

In medical device development projects, it is essential to have a clear understanding of all stakeholders involved in the development and implementation of the device, as will be mentioned in **Chapter 5**, stakeholders in the medical device industry are crucial for achieving compliance, acceptance, and funding. Additionally, with many product-service systems, stakeholders are necessary for the successful execution and operating of the system. As an example, Amazon's e-reader alone without content would not provide the value that the solution was capable of providing for the customers. Therefore, Amazon quickly realized that publishers must be involved in the marketing of the solution and actively sought out publishers that were willing to supply content. Even going so far as to limit certain user functionalities to improve the value for the publishers. In other words, cooperation between product-service systems and stakeholders are common, also in the medical device industry. To better understand these stakeholders, a look is taken at relevant literature. The goal of this chapter is to identify relevant stakeholders and establish an understanding of the complexity and interrelatedness of the system in order to define a business model for the solution that is capable of working.
For the identification of stakeholders, the most well-known method is identification through the stakeholder power grid by Mitchell et al. (1997). Placing stakeholders on multidimensional grid along the axes of legitimacy, power, and urgency. This method will be used in this chapter. Identifying the links between stakeholders can be done through social network analysis (Wasserman and Faust, 1994), value blueprints (Adner, 2012), or agent-based modelling (Gilbert, 2008). However, for this project, a look will be taken at payment structures, the role of different stakeholders in the acceptance process of new technology, the role of stakeholders in the compliance process, and their roles in the managed competition system. These topics will be discussed in the following chapter, **Chapter 4.3**.

3.1 COMPLEX NETWORKS AND CAPABILITIES

3.2.1 What are stakeholders and why should attention be paid to them?

Stakeholders are defined as "any group or individual who can affect or is affected by the achievement of the organization's objectives" (Freeman 1984, p. 46). An organization should balance the difference in interests between stakeholders, rather than focus exclusively on maximizing the benefits of one (Clarkson 1995). To improve this balance, stakeholder theory has been put forward pushing for "simultaneous attention to the legitimate interests of all appropriate stakeholders" (Donaldson and Preston 1995, p. 67) and providing an understanding how the "ethical principles" of stakeholder management can lead to economic advantage in the long term (Hillebrand et al, 2015; Jones 1995). Often referred to as stakeholder marketing (Bhattacharya and Korschun 2008; Frow and Payne 2011; Hult et al. 2011; Gummesson, 2008; Gundlach and Wilkie, 2009; Smith et al. 2010), these activities to facilitate and maintain value through exchange with stakeholders (Hult et al. 2011), can be managed. Even more so, several studies have empirically shown that managing multiple stakeholders and balance their interests results to an organization performing better (Homburg et al. 2013; Koll et al. 2005; Luo and Bhattacharya 2009; Sisodia et al. 2007). Back in the days, relationships with stakeholders was often dyadic (Hillebrand et al. 2015). In other words, the company supplied something to the stakeholder and received money in return, or vice versa. Even more so, often the view on the marketing process of this was that the company provided value for the customer and the customer paid for that value. However, due to major industry shift from goods to services (most predominantly seen in other industries than the medical), Vargo and Lusch (2004) introduced the "service-dominant logic". This logic argues that value is co-created by the firm and its customers, and by its stakeholders (Vargo and Lusch 2008; Vargo 2011; Lusch and Webster 2011). Even more so, in service industries it is almost impossible for one firm to deliver all components necessary for value-creation and delivery. Collaboration and a network of firms and organizations that work together to create value are therefore essential, yet this goes accompanied by an increased interrelatedness between stakeholders (Edvardsson et al. 2011; Tax et al. 2013) and a multitude of other, new issues and problems. Therefore, attention should be paid to all stakeholders involved in the creation and delivery of value. Even more so, relationships with stakeholders offer other benefits and competitive advantages (Surroca et al. 2010), like protection against (competitor) hostility or contribution to firm survival chances (Choi and Wang 2009). Firms with a strong network

of stakeholders "are likely to have employees that are willing to work harder, have customers that are willing to pay premium prices, obtain endorsements from NGOs, and receive knowledge from suppliers" (Choi and Wang 2009). Strong relationships "reflect a willingness" of the stakeholders to contribute and support the firm with resources (Maignan and Ferrell 2004).
To understand complex relationships with multiple stakeholders, one must view such a network as continuous and multiple. As Hillebrand et al. (2015) note, in complex relationships with multiple stakeholders it is wrongful to assume that the interests of stakeholders are not interrelated. Understanding this interrelatedness, starts with understanding that such a network is continuous and multiple.

3.1.2 Capabilities necessary for creating and sustaining a stakeholder network

First, to understand the transition from a dyadic view on stakeholders' network and management to a more complex perspective ridden with interrelatedness and indirect value creation, systems thinking as a capability is essential. Considering all stakeholders and the relations "helps ... to better understand how to deal with complex value exchange" (Bhattacharya and Korschun 2008; Frow and Payne 2011; Layton 2007). System thinking starts with identifying all stakeholders and how they are linked. For the identification of stakeholders, the most well-known method is identification through the stakeholder power grid by Mitchell et al. (1997). The stakeholders will be placed on a multidimensional grid along the axes of legitimacy, power, and urgency, which can be seen at **Chapter 5**. This method will be used in this chapter. Identifying the links between stakeholders can be done through social network analysis (Wasserman and Faust, 1994), value blueprints (Adner, 2012), or agent-based modelling (Gilbert, 2008). However, for this project, a look will be taken at payment structures, the role of different stakeholders in the acceptance process of new technology, the role of stakeholders in the compliance process, and their roles in the managed competition system. These topics will be discussed in the following **Chapter 5**. **Second**, paradoxical thinking is an alternative approach to understanding why conflicting interests exists and how an organization can attend them (Poole and Van de Ven 1989; Lewis 2000; Smith and Lewis 2011). "Paradox theory suggests that the interests of various stakeholders and resulting tension between them should be accepted, meaning that a firm must acknowledge multiple "truths" and that there is not necessarily a simple solution (Westenholz 1993; Smith and Lewis 2011)" (Hillebrand et al. 2015). Paradox theory even suggests that this tension is an opportunity to learn and explore (Lewis 2000, p. 764). In stakeholder marketing, paradoxical theory can be used to understand and explore perspectives of stakeholders to develop new solution and new exchanges (Vince and Broussine 1996, p. 4) and improve the process (Eisenhardt et al. 1997; Norman et al. 2004).Due to the more open attitude to tension, conflict and other people's ideas, literature suggests that firms become more receptive to new ideas (Hillebrand et al. 2015) which is also a positive development from a strategy perspective (Amason, 1996). Even more so, in order to resolve conflict communication is vital and therefore, this capability can also be improved significantly by negotiating with stakeholders (Hillebrand et al. 2015). **Third**, as value-creation has become a process involving multiple stakeholders, control over this process is automatically delegated among the stakeholders (= "dispersed control" (Hillebrand et al. 2015)). In other words, when one stakeholder does not agree and halts his/her part of the process, the entire operation will not succeed. Therefore, the last capability proposed by Hillebrand et al (2015), is the capability of democratic thinking. In such a network it is essential to be able to come to decisions together. Firms that can do so and can do so quick, have significant competitive advantage over others that lack these skills. The authors suggest that "through trial and error" firms develop a sense of stakeholder democracy and how much is needed for it to operate successfully and effectively (Hillebrand et al. 2015), as "too much democracy may not be appropriate" (Harrison and Freeman 2004).

3.1.3 Implications for this research project

Three capabilities have been defined that must be present in a company to make successful use of such complex networks. As the solution will have a business model existing of a complex network, it is important to employ as many of the defined capabilities as possible. Systems thinking will be used as the relevant stakeholders must be identified as well as the links between them. The Dutch healthcare system will be analysed to define the relevant stakeholders. Paradoxical thinking is a capability that must be used when dealing with paradoxical situations in relationships with stakeholders. I.e., this

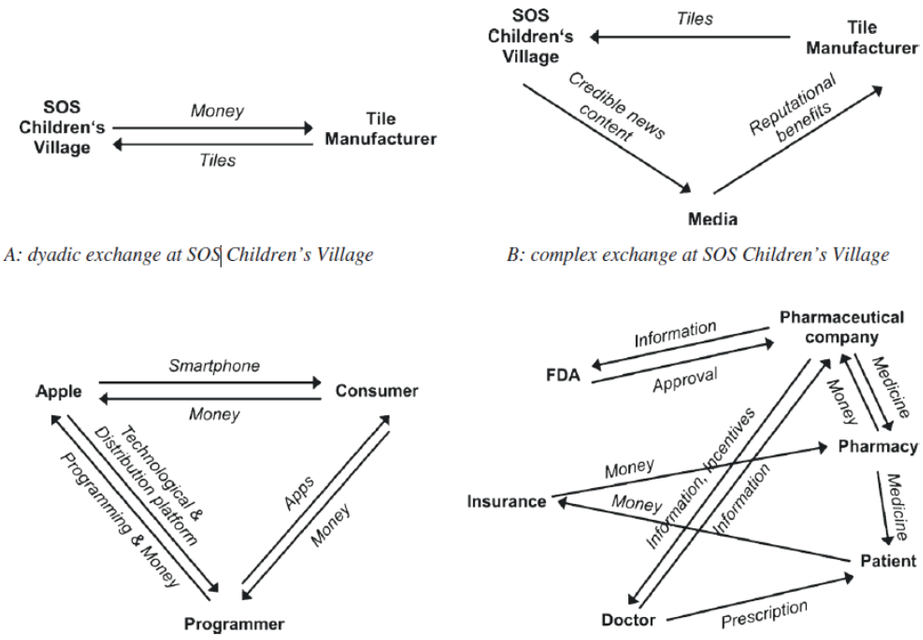

Figure 1. Examples of dyadic and complex exchange (Hillebrand et al. 2015). See especially example D., similar to the solution of this case.

capability is needed when problems occur. However, during this project no formal relationships with relevant stakeholders will be established. Therefore, no problems can occur and so, paradoxical thinking is a capability which will not be used in this project. Democratic thinking is similar in the way that, as a capability, it is needed most when establishing and formalizing relationships. Therefore, it can be argued that this capability is unnecessary during this process. However, a start in democratic and paradoxical thinking can be made by having multiple conversations with multiple relevant stakeholders during this project, to pre-emptively identify potential issues and improve the business model and system design.

3.2 THE DUTCH HEALTHCARE SYSTEM

In 2006, a major reform has been implemented that changed the Dutch healthcare system quite rigorously (Kroneman et al., 2016). This reform combined public and private insurance into one universal social health insurance and "introduced managed competition as a driving mechanism in the healthcare system" (Kroneman et al., 2016). Managed competition aimed to "promote efficiency, to reduce central governance and to improve access at acceptable societal costs". As this reform is implemented in a stepwise manner, continuous changes to the healthcare system are still made to this day, even though the implementation was more than a decade ago. As this reform changed the healthcare system drastically, there is no point in reviewing how the system used to be before the reform. Therefore, the information this chapter is based on is information developed and defined after the 2006 reform[17]. The 2006 reform changed the roles of all actors in Dutch healthcare. The government took on a more distant and supervising role, healthcare users, providers, and insurers now had to compete on healthcare and the civilian was becoming more and more (financially) responsible for his own health. Because of this

[17] It is important to notice, that after 2006 several other reforms have been implemented in the Dutch healthcare system. However, these reforms focus on specific parts of the healthcare system that are not relevant for this thesis. Topics like long-term care, mental health and well-being, and psychosocial youth care.

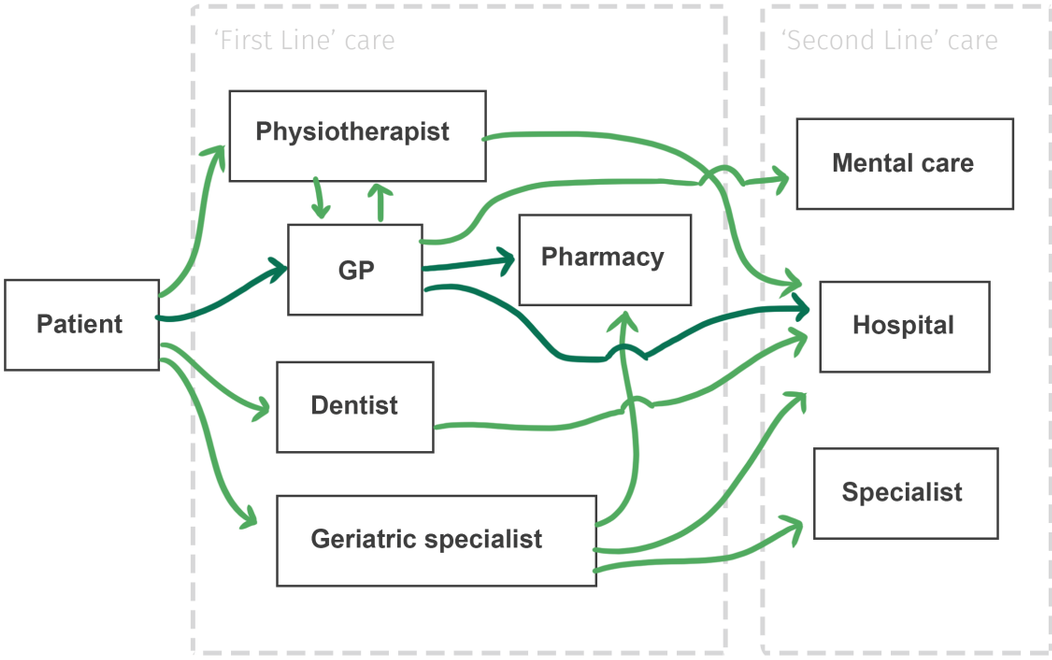

Figure 2. Flow chart for patient pathways in regular, non-emergency curative care (Kroneman et al., 2016). Curative care is care focused on curing a patient. It should be noted, that the product will be functioning in a non-emergency situation. This pathway is different from the pathway in an emergency situation. Important is to realise the importance of the role of GP in this system. The GP acts as the 'gatekeeper' of patient flow.

competition, multiple actors combined forces and consolidated to form a stronger negotiation position and thus, improve their competitive position. This is especially true for insurers, trying to compete with healthcare providers (van der Lee, 2000). Additionally, the reform aimed to strengthen the position of the general practitioner (GP)s, as this role is essential in the Dutch healthcare system. An overview of the total system and the relevant stakeholders is provided. In combination with the patient journey, it should be clear why certain stakeholders are important for the successful implementation of the system.

The goals for the healthcare system are defined and monitored by the Dutch government, as the government is responsible for the healthcare system. The government has stated three main goals for the healthcare system: "quality of care (effective, safe and patient-centred), accessibility to care (reasonable costs for individuals, travel distance and waiting times) and affordability of care (overall cost control)" (Kroneman et al., 2016). Additionally, "self-regulation has always been an important characteristic of the Dutch healthcare system" and thus, self-regulation is promoted by the government.

The ambition of the Dutch Ministry of Health, Welfare and Sport is "to keep everyone healthy as long as possible and to restore the sick to health as quickly as possible" (Kroneman et al., 2016).

3.3 ACTORS AND STAKEHOLDERS

The Dutch healthcare system is one with numerous actors with numerous tasks, goals, and responsibilities. In this chapter, an overview is presented after which the most relevant actors are discussed in detail. The Dutch healthcare system consists of numerous interdependent actors. **First**, it consists, obviously, of healthcare consumers that demand good healthcare for maintaining good health and curing

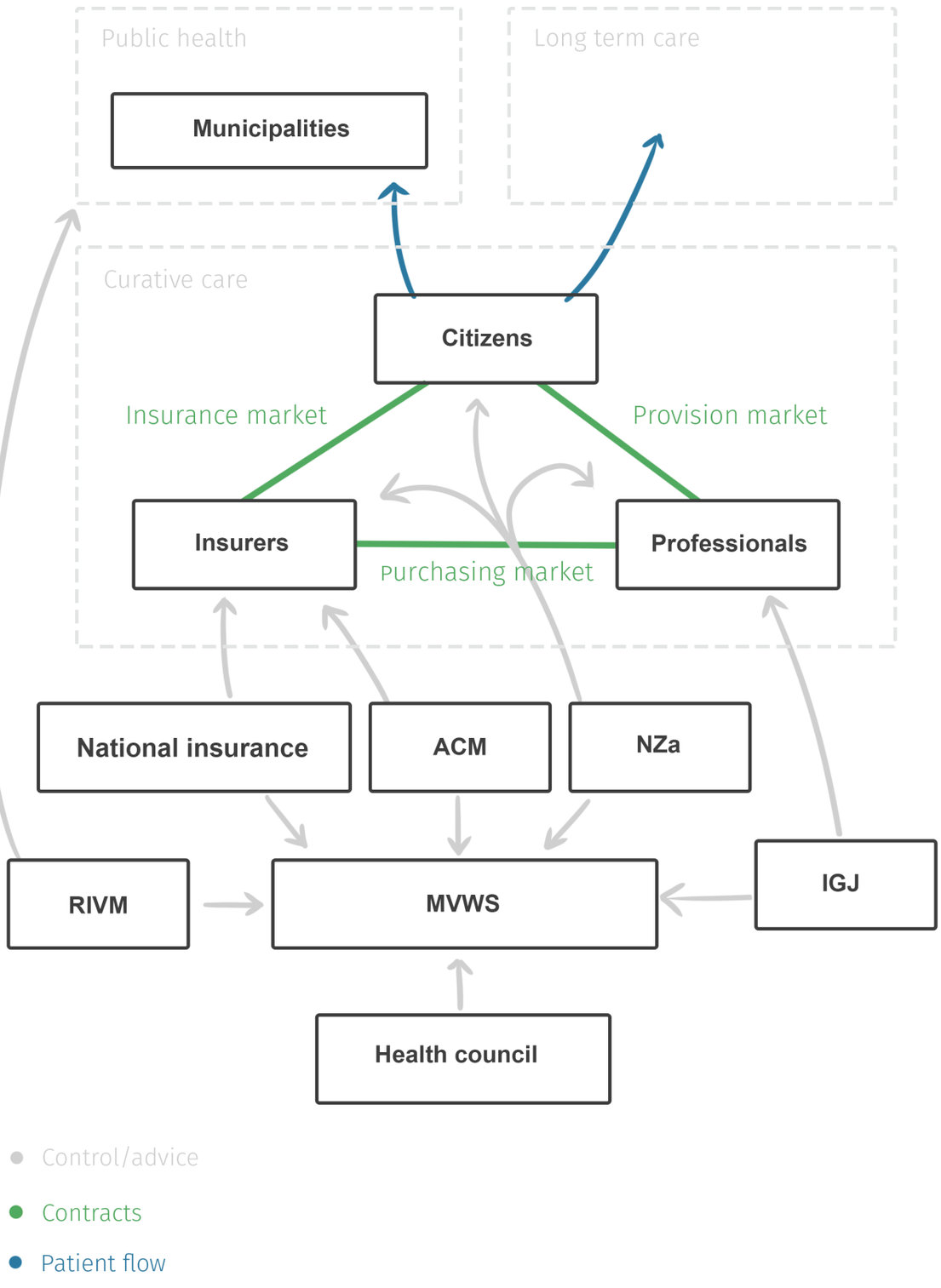

Figure 3. Simplified diagram of the organizational bodies of the Dutch healthcare system as compiled by the authors of (Kroneman et al., 2016). What these bodies do, and what they represent and try to achieve will be discussed in the Social Capital part.

unwanted health conditions. **Second**, the actors that actually cure are the healthcare providers. **Third**, healthcare insurers are the one's paying for the work that the healthcare professionals do. **Fourth**, the government plays an important role in the Dutch healthcare system as well, providing funding for the insurers and overseeing the market through its many advisory bodies. As **last**, multiple public bodies exist that have different responsibilities. Some oversee specific aspects of the healthcare system, like the basic health insurance package, while others oversee the health care markets. Other bodies are involved in research and informing and advising the public (Kroneman et al., 2016). The 2006 reform "shifted the focus to the demand side, introducing three managed markets for a defined universal health insurance package, plus healthcare purchasing and provision". The role of almost all actors changed, because of this managed competition (Kroneman et al., 2016). Generally speaking, advisory bodies provide expert advice and evidence-based experiences for the decision-making process of the government and governmental bodies. Insurers and providers are dependent on the policy decisions and regulatory practices, yet focus more on the market dynamics.

3.3.1 Healthcare supervisors

First, a look is taken at the guardians of the Dutch healthcare system: the bodies responsible for safeguarding the quality and delivery of healthcare. **First**, the government (*de overheid*). As mentioned before, the government, and specifically the minister of health bears the 'system responsibility' and is thus, "primarily responsible for the good functioning of the system as a whole, including the conditions for high-quality care, accessibility for all and the efficient use of resources" (Kroneman et al., 2016). However, its opportunities to "act autonomously on the basis of this responsibility" is limited. The government still has the major role in policy development and implementation. The government is the actor that can establish new health policy agendas. These policy agendas are based on four-yearly reports (VTV) on the state of the public health of the Netherlands, informing the government on the effect of previous policies as well as provide the necessary information to establish the new policies. Additionally, the government provides information to the other actors in the healthcare system, therefore fulfilling part of the system responsibility. This information is gained through the Health Inspectorate (IGJ) as well as the advisory bodies and research institutes. These actors can also commission reports "either on the state of knowledge in certain policy areas or to clarify the consequences of different policy options" (Kroneman et al., 2016). This information can be used in debates involving the many stakeholders, not only to improve the quality of proposed policies, but also to gain support in the decision-making and implementation of policies. Even though it seems like information, and thus evidence, drives policy decisions, it should be stressed that health policy decisions are not fully evidence-based (Kroneman et al., 2016). Financial motives are usually the most important determinant of health policy decisions. The actionable parts of this responsibility are heavily evidence-based. The Dutch government relies predominantly on scientific research, usually in the form of health forecasting studies (Volksgezondheid en Toekomst Verkenning[18], VTV) as provided by its advisory bodies (e.g. the VTV is from the RIVM). Furthermore, the government is backed by several independent organizations that provide intelligence, one of which is the Health Inspectorate (Inspectie Gezondheidszorg en Jeugd (IGJ)) which provides needed information on the state of healthcare. Since the 2006 reform, the government stopped administering direct control on the volumes and pricing of medical equipment, treatments, medicine, human capital, and other elements of healthcare. Instead, the government's role is now more distant as a supervisor of these markets as well as the provider of regulatory frameworks, "the specifics of which are carried out by local agencies, or by self-regulation". The government is also responsible to provide healthcare users with information to help them make better decisions concerning health, some independent websites makes this available. However, it should be noted that the options to make decisions in the Dutch healthcare system are quite limited. Even more so, the "extent to which patients exercise their notional choice" is also limited (Kroneman et al., 2016). At last, the government is responsible for determining which type of care is applicable for reimbursement by insurers. In other words, the government decides on the content of the care (the 'what') and the insurers are free to determine the delivery of the care (the 'how'). Developing a solution that offers the same type of care (the same 'what') through a different delivery (a different 'how'), might be a useful strategy for a new innovation to enter the market and apply for reimbursement. However, in this case it is still up to the insurers to decide if this new innovation will be purchased and implemented. **Second**,

[18] Four challenges were formulated: keep people healthy as long as possible and cure the ill, support vulnerable people and promote participation, stimulate autonomy and free choice, and maintain affordable healthcare.

the Ministry of Health, Welfare and Sport (Ministerie van Volksgezondheid, Welvaart en Sport, MVWS). The MVWS is the operating organization of the government and implements the policies devised by the government. Furthermore, the Ministry safeguards the access to high-quality healthcare (den Exter et al., 2004). **Third**, the municipalities (*De gemeentes*). Municipalities are responsible for the implementation of the targets set and measures defined in the Public Health Act (Wet Publieke Gezondheid, WPg) regarding the prevention programme. Since the reforms, more responsibilities have been decentralized to municipalities as well, including youth care, social protection, self care, social participation, and sheltered living. Through their municipal health services offices (Gemeentelijke Gezondheidsdienst, GGD) municipalities provide these services.

3.3.2 Healthcare consumers: patients (Patiënten)

Since 2006, patients are a "major health market party" allowed "to make independent and rational choices" (Grit, van de Bovenkamp & Bal, 2008). An important right that healthcare users in the Dutch system have, is the freedom of choice among all health care providers. Government policies, enforcing that patients be provided with vital information, decreased any barriers patients experienced in self-managing their health. The government enforced that the health care providers should inform the patient of "the state of their health and expected health developments, the impact and risks of treatment, and possible alternative approaches" (Kroneman et al., 2016).

3.3.3 Healthcare providers

"Healthcare providers are independent non-profit entrepreneurs" (Kroneman et al., 2016). Since the reform, healthcare providers have become responsible for aligning their business and practices to the patients' needs. Managing their business in an entrepreneurial manner is encouraged. For instance, since 2009, healthcare providers are responsible for investing in their functional resources, like work space and equipment (Kroneman et al., 2016). **First**, hospitals are the hubs where many of the specialists reside to offer their services to the public. Since the 1960s, hospitals have been merging "for market strategic reasons and to create more countervailing power against health insurers" (Kroneman et al., 2016). Additionally, governmental policies provided another reason to merge as the budget for a merged hospital is larger than the sum of the separate hospitals (van der Lee, 2000). The number of hospital organizations has been declining, from 172 in 1982 to 95 in 2005 (Van der Lee, 2000; MacGillavry & Zwakhals, 2005). **Second**, the general practitioner (GP) is (almost always) the first point of contact for anyone with a health complaint. General practitioners belong to primary care (also called: first line), as well as midwives and dentists. The referral to specialists either in or outside the hospital, is called the secondary care (also called: second line. This gate-keeping function is characterizing for the Dutch healthcare system. The solution tries to increase the possibility for a person with a health problem to recognize this problem on time and go through the appropriate health process. In other words, because of the product, people with health problems know in an earlier stage that the problem exists and thus, have the possibility to go to the general practitioner. Therefore, the general practitioner is the most relevant actor in direct relation with the product. In 'normal situations' (i.e. non-emergency situations), hospital or specialist care require a referral from a GP[19]. Because of this gate-keeping principle, the amount of services a GP can provide are quite broad: care for common chronic conditions, "such as diabetes, COPD, asthma and cardiovascular risk management, and mental care" are under coordination of a GP (Kroneman et al., 2016). This amount of services is especially broad in comparison with other European countries (Kroneman et al., 2016). As most minor health problems are treated by the GP, only 2,8% of all patients were given a referral to secondary care providers like hospitals or specialist in 2014 (and 27% of these referrals were not followed up. Meaning: people did not visit a medical specialist as recommended by their GP. This number has been increasing since 2009 (Van Esch et al., 2015). This means that the remaining 97,2% of all contacts are treated within primary care (predominantly by prescribing medication[20]), and thus by services provided by the GP (Verberne & Verheij, 2015). To put this in perspective, on average a Dutch citizen contacts his/her GP four times a year (Kroneman et al., 2016). The way general practitioners are organised is becoming increasingly professional and grand. As since the 1970s, general practitioners have been partnering up to form groups of professionals

[19] Additionally, other primary care givers, like midwives or dentists, can provide the necessary referral. However, for this research these actors are not relevant.

[20] 70% of registered patients received a prescription for medication in 2014 (Hek et al., 2015).

Table 5. (Relevant) actors in the Dutch healthcare system.

Category	Actor	Goal[a]	Influence & control
Patients	Patients[b]	Remain healthy	Significant
	Associations[b]	Represent the patients	Collectively significant
Providers	General practitioner[c]	Care for patients and keep them healthy, gate-keep the system	Modest
	Secondary care professionals[b]	Care for and cure patients	Significant
	Associations[b]	Represent the primary care professionals	Collectively significant
	Pharmacy	Aid primary care professionals and advise patients	Low
Insurers	Insurers[b]	Redistribute taxpayers money (and earn a profit)	Dominant
	Associations[b]	Represent the insurers	Collectively significant
Governmental[d]	Ministry of Public health, well-being, and sport *(Ministerie voor Volksgezondheid, Welzijn en Sport, MVWS)*	Maintain and improve public health	Significant
	Netherlands National Institute for Public Health and the Environment *(Rijksinstituut voor Volksgezondgeid en Milieu, RIVM)*	Aid the ministry and implement/ execute governmental policies	Significant
	Health council (*Gezondheidsraad, GR*)	Advise the government	Dominant
	Healthcare autority *(Nederlandse Zorgautoriteit, NZa)*	Determine the costs of care	Dominant
	Healthcare inspectorate *(Inspectie Gezondheidszorg en Jeugd, IGJ)*	Control and inspect care	Significant
	The Netherlands Organization for Health Research and Development *(ZonMw)*	Fund research	Significant
	Authority for Consumers and Markets *(Autoriteit Consument en Markt, ACM)*	Control and inspect the consumers market of healthcare	Modest

Important to notice, this table only shows relevant actors of the Dutch healthcare system. Actors involved in long term, youth or elderly care are not relevant for this project and therefore not included in the table.
[a] Heavily simplified to remain easily understandable.
[b] A collection of multiple different actors.
[c] More primary care professionals exist (e.g. dentists, physiotherapist, etc.), but are not relevant for this project.
[d] Includes governmentally funded.

and practices and combine them into multidisciplinary centres. Until the late 2000s, the same has been happening for out-of-hours primary care, as out-of-hours GP centres (*huisartsenposten*) have been introduced throughout the Netherlands. The ease of access of a GP in the Netherlands is impressive, as "less than 0.1% of Dutch residents live more than a 10-minute car journey from the nearest GP practice" (van den Berg et al., 2014a; Deuning, 2013). Even more so, in international comparison, it was found that the Dutch population is satisfied with GP care and their involvement in decision making (Kroneman et al., 2016). This is also very important for the system, as the GP determines the patient pathway as the first point of contact. This can also be seen in the reason why a GP visit is not excluded from the compulsory deductible. Additionally, new initiatives like telemonitoring allow for even more easy communication of patient and GP. **Last**, the healthcare specialist which in this case are the gastroentologists, surgeons, internist, radiologist, and radiotherapist of which the gastroentologist is of main concern. Specialists are the main party involved in research and exploring new theories and bodies of knowledge in the medical field (in combination with researchers from other academic fields) and therefore, are the leading coalition in establishing guidelines and methods in care as well as determining what is proper

and just. Doing so, the specialists are the most influential party as other organizations, like the NZa and the MVWS, base their decisions on the judgement of specialists. Even more so, the members of the Health Council are all specialists from various fields of medicine.

3.3.4 Healthcare insurers

To strengthen the positions of the insurers, they started consolidating just before the reform and currently, four insurer groups have between 13 and 32% share of the insurance market as well as cover 90% of the insured (Dutch Healthcare Authority, 2014b). Because of the reform, insurers now operate under private law, allowing them to make profit (but not pay shareholders as this is currently prohibited) (Kroneman et al., 2016). Insurers exist in two types: public limited companies, which are private for-profit organizations "with the shareholder meeting being the highest decision-making structure" and "daily management delegated to a board of administrators" (Kroneman et al., 2016). Mutuals are non-profit organizations where the insured people are also members of the organization. A board of members controls the management of such an organization (Kroneman et al., 2016).

3.3.5 (Semi-)Independent advisory boards and organizations

The Dutch healthcare can be characterized by the sheer amount of advisory and overseer bodies. Since the 1990s, "the government has started to reduce the strong proliferation of advisory bodies" (Kroneman et al., 2016). Despite this reduction, many bodies still exist. **First**, the Dutch Health Care Authority (Nederlandse Zorgautoriteit, NZa) is an independent supervisory organization, funded by the VWS. The NZa supervises the "core principles" of the Health Care Market Regulation Act (Wet marktordening gezondheidszorg, Wmg) as well as compliance with the Health Insurance Act (Zorgverzekeringswet, Zvw). More specifically, the NZa supervises the obligation of insurers to accept any application and to oblige the ban on insurance premiums differentiations. In addition, the NZa supervises the three healthcare markets and the NZa can impose tariffs and performance regulations (Kroneman et al., 2016). The NZa can impose obligations on players that obtained "significant market power" as well as set rules for healthcare providers and insurers to increase their price and transparency (Ministry of Health, Welfare and Sport, 2005). Additionally, the NZa can employ methods like: "inspection visits, enforcement and disciplinary measures, including closing of services, phased supervision, investigation of incidents and general monitoring based on indicators" (Kroneman et al., 2016). Because of this powerful combination of regulatory and supervisory roles, the relation between NZa and the Ministry is complicated[21]. **Second**, the National Healthcare Institute (Zorginsituut Nederland, ZiNL) is responsible for advising the Ministry on the basic care package. Therefore a close relation exists between the NZa and the ZiNL on insured care. Additionally, the ZiNL is also responsible for the "quality, accessibility and affordability" of the healthcare system. **Third**, the Consumers and Markets Authority (Autoriteit Consument & Markt, ACM) enforces fair competition, prevents cartels, and protects the position of the customer in all sectors of the Dutch economy, and thus, also in the Dutch healthcare markets. The responsibilities of the ACM relate with the NZa and so, these organizations collaborate often (this collaboration has been structured in a protocol). If the case of overlap, the NZa exerts "sector-specific authority" (Kroneman et al., 2016). **Last**, the Health Council (Gezondheidsraad) "advises the government, both on request and on its own initiative, on the scientific state of the art in medicine, healthcare, public health and environmental protection" (Kroneman et al., 2016). The government funds the council. Additionally, the Council consists of around 170 members "from different disciplines that cover the six focus areas of the council: optimal healthcare, disease prevention, healthy eating, healthy living, healthy working conditions, and innovation and knowledge infrastructure" (Kroneman et al., 2016). The advice from the Health Council bears considerable influence on policy development and health-policy decisions by the government. For instance, the 2013 population screening for intestinal cancer was employed because of a report from the Council (Kroneman et al., 2016).

[21] This has been discussed in the Parliament, see 'Kamerbrief van minister Schippers (VWS) aan de Tweede Kamer over de voortgangsrapportage NZa. 18 December 2015' (Kroneman et al., 2016).

3.3.6 Third sector organizations

Third sector organizations in healthcare consist often of health-profession specific organizations, associations, colleges, or societies that "advocate for professional interests as well as to contribute to scientific development and quality" [0021]. **First**, for GP's two organizations exist: the National Association of General Practitioners (Landelijke Huisartsen Vereniging, LHV) and the Dutch College of General Practitioners (Nederlands Huisartsen Genootschap, NHG), the latter focussing predominantly on scientific research and developing guidelines. **Second**, for patients, numerous organizations exist in the Netherlands. Two types can be distinguished: type-specific, focussing on a specific patient with a specific health condition, or general organizations, focussing on the general interests of users of healthcare services. **Third**, for healthcare professionals, the same two similar types of associations exist. However, for professionals, the type specific associations tend to be more predominant and bear more influence.

3.3.7 Research institutes

Actors in the Dutch healthcare system (private and non-profit) base their healthcare decisions on research and evidence-based knowledge and, therefore, healthcare research is well developed. Research institutes, delivering these insights, are often government-funded or have clear relations with universities (Kroneman et al., 2016). The two most important are discussed. **First**, The Netherlands Organization for Health Research and Development (ZonMw). ZonMw funds research and promotes "the application of knowledge for the benefit of health and healthcare" and therefore, ZonMw holds a unique intermediary position in the Dutch healthcare system (Kroneman et al., 2016). ZonMw offers grants for research into nine domains: "efficiency; mental health; pharmaceutics; youth; quality of care; elderly people; palliative care; prevention; and translational research" (Kroneman et al., 2016). The Ministry of Health, Welfare and Sport and the Dutch Organization for Scientific Research (Nederlandse Organisatie voor Wetenschappelijk Onderzoek, NWO) are the main commissioners for the ZonMw. **Second**, the National Institute for Public Health and the Environment (Rijksinstituut voor de Volksgezondheid en Milieuhygiëne, RIVM). The RIVM is one of the most influential institutes in the Dutch healthcare system. Besides focussing on infectious diseases, surveillance and control, the institute also manages National Immunisation Programme (Rijksvaccinatieprogramma, RVP). In addition, the institute is actively assessing food quality and consumer safety, informing the general public about disease prevention, as well as research pharmaceuticals for the admission and introduction of new pharmaceuticals, as the RIVM plays a role in this process. Every four years the RIVM publishes a report on the state of public health (Volksgezondheid Toekomst Verkenning, VTV). These reports are established with input from many other institutes and research groups and therefore, bear significant influence in healthcare decisions and policy. Apart from healthcare, the RIVM also focusses on environmental issues.

3.3.8 Notified bodies

A Notified Body[22] is an organization that has been accredited by the EU Member State to assess conformity of the product to (applicable) EU regulations (**Article 2 Paragraph 42,** IVDR)[23]. The Notified Body will be monitored, evaluated and adjusted (when necessary) by a Competent Authority, which in the Netherlands is the Healthcare inspectorate (IGJ (IGJ, 2018)). Interesting to consider, is that with the introduction of the new legislation in 2022, all current NB's have to reapply for the accreditation. However, at the moment of writing it remains unclear how this accreditation process will be organized as that has not been defined in the new legislation. Therefore, current NB's are unable to prepare for the new accreditation process which could, in theory, result in a situation where not a single organization is accredited to be an NB preventing all device development companies to achieve compliance and enter the market.

[22] Currently, the BSI Group has been declared the NB of the IVDR from 2018 for a period of 5 years (BSI, 2018).
[23] Much more about the regulation and the conformity process will be discussed in the next chapter, **Chapter 4**. Specific articles and paragraphs will be referred to, however the regulation starts with a summation of points structured in parentheses, which will be referred to as such.

4. MARKET & REGULATIONS

This chapter describes the Dutch (consumer) healthcare market from a business perspective. The Dutch healthcare market has always been focused on the private provision of services and the financing of the system through social insurance (Kroneman et al., 2016). Which "created a healthcare sector that is dominated by many mutually dependent actors with different backgrounds" as well as different aims for participating in the healthcare system (Kroneman et al., 2016). As we know all involved stakeholders, it is now necessary to specify to possible entries and what is necessary to be allowed onto the medical device market. **First**, the 'managed competition' system is described and analysed. Managed competition should reduce the costs of the DHCS and was introduced after the 2006 reform. However, this system is not without its shortcomings. **Second**, a look is taken at relevant payment streams to understand how stakeholders receive payment and thus, how the financial dependency is organized. So, an analysis is possible to assess if the solution will become a threat to any of the relevant stakeholders. **Third**, a look is taken at the acceptance that must be generated among stakeholders for a solution to be allowed onto the market. More specifically, the 'acceptance hierarchy' is determined and so it can be assessed which stakeholder is essential in becoming accepted and thus must be convinced. **Fourth**, a description is provided on the regulations concerning the (consumer) medical device market. The conditions to which the solution must oblige are described which are essential for the upcoming implementation of the solution. **Last**, the possible entry routes to the market are described and discussed. In the implementation part (Part IV), the chosen route is described. Which is a combination of the presented possibilities.

4.1 MANAGED COMPETITION

First, in the Dutch healthcare system three markets exist. The market between the insured and insurers called the health insurance market, the market between the insured and the healthcare providers called the healthcare provision market, and the market between insurers and providers, which is called the health purchasing market (Kroneman et al., 2016). These three markets (for insurance, provision, purchasing) have become the core of the in 2006 reformed system. Furthermore, this bond between these three actors has only been strengthened since the government took on a more distant and supervising role (Van der Grinten, 2006). Managed competition occurs on all three markets. On each of the three markets, negotiations take place on the volume, quality, and price of the provided care. Health insurers negotiate with healthcare providers on the delivery of care of their insured. The insured pay a premium as an addition to their basic health package and in doing so, the provided healthcare is financed. Care for which negotiation is not feasible (around 30% of hospital care), "such as emergency care (not planable) or organ transplantation (too few providers)" is the responsibility of the Dutch Healthcare Authority which establishes maximum prices. Important to notice is, that quality is not yet the "leading principle" in the purchasing process (Kroneman et al., 2016). Price and volume are the most predominant factors leading a negotiation on care. Quality is becoming more and more important, yet proper quality indicators for each type of care do not exist yet but are in development.

Second, the aim of managed competition and the negotiating of healthcare is that this may lead to more "demand-driven care and care that is tailored to the needs of the target group of the collective" (Groenewegen & de Jong, 2007). However, not every actor in the Dutch healthcare system has the same negotiating power. In 2015, 69% of insured negotiated through participation in a collective insurance policy (Vektis, 2015). The main four insurers (representing 90% of the insured (Dutch Healthcare Authority, 2014b)) have to negotiate with individual healthcare providers. Hospitals started to merge after the reform to increase their negotiating power, however, smaller healthcare providers (including GPs) where prohibited by the ACM to combine forces and have the GP associations negotiate on their behalf (Van der Bom, 2014). The ACM argued that GPs should compete with each other. Since 2015 cooperation among smaller healthcare providers is allowed in the negotiations on the condition that it is in the benefit of the healthcare user (Consumers and Markets Authority, 2015). However, the question remains if this has strengthened the position of, predominantly, GPs. Currently, GPs agree on a contract with the preferred health insurer and ask other insurers to use the same contract [0021]. These contracts include fee-for-service and capitation elements and as of 2015, pay-per-performance elements have been included. However, these financial elements are still new and thus not fully developed (Consumers and Markets Authority, 2015). Insurers may contract specific healthcare providers (= selective contracting) to compete with other insurers. However, that should always oblige to the duty to offer adequate care (Kroneman et al., 2016).

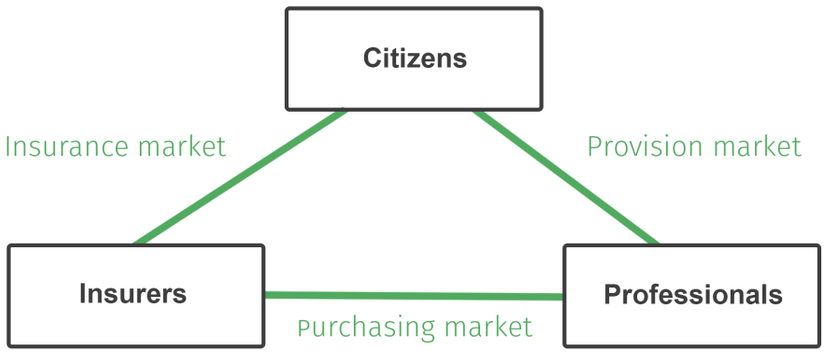

Figure 4. Actors and markets in the Dutch healthcare system since 2006 (Kroneman et al., 2016).

4.2 FINANCIAL MANAGEMENT AND PAYMENT STRUCTURES

Every actor in the healthcare system receives payment in a different way. To understand the differences, two systems must be explained: the DBC system and the insurance package system.

4.2.1 The DBC-system

In the healthcare purchasing market, the Diagnose-Treatment Combination-system (*Diagnose-Behandeling Combinatie, DBC*) is used to negotiate and communicate on provided care. This system attaches codes and a price to medical treatments. The prices are established by the NZa. The codes are communicated between insurers and providers, so that it is clear which medical treatment at what price has been executed. The DBC-system should increase the efficiency of the hospital care sector. The Ministry of Health, Welfare and Sport together with insurers, hospitals and relevant medical specialists have established this system and defined the treatment options with the associated costs (Kroneman et al., 2016). Since 2012, the DBC's have been changed to DOT's (DBC *onder weg naar transparantie*), reducing the total number of combinations from well over 30,000 to just 4,400 (Kroneman et al., 2016). Hospital care providers have an obligation to provide their DBC data to the DBC system. Healthcare specialists (under departments of hospitals) receive payment through this system.

4.2.2 Basic health insurance package, voluntary health insurance

In 2015 about half (48%) of Dutch citizens had an in-kind policy, approximately a quarter (23%) had a restitution policy, about a fifth (21%) had a combination policy and 7% had a selective policy (Kroneman et al., 2016).

In 2006, the Health Insurance Act (Zvw) was introduced, changing the health system drastically as well as introduce the basic healthcare insurance package (Kroneman et al., 2016). This basic package covers "GP care, maternity care, hospital care, home nursing care, pharmaceutical care and mental healthcare". The first €385 (in 2016) should be payed out-of-the-pocket (OOP, *eigen risico*), additional expenditures are covered by the insurance. GP consultations, maternity care, home nursing care and care for children under the age of 18 are excluded from the OOP. The contents of the basic health insurance package are fixed through government legislation, but insurers can compete and negotiate on the price and quality of the provided care. It is not allowed by insurers to vary the premium based on health risks of their insured. Additionally, it is also not allowed to refuse specific people based on their health risks, which is monitored by the NZa.

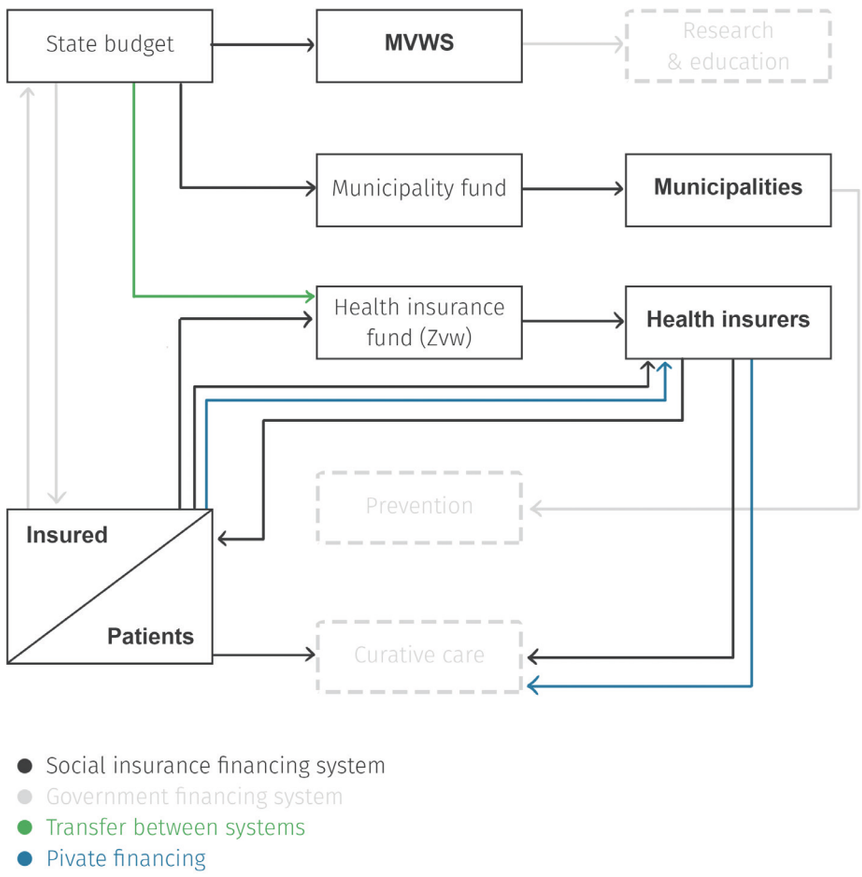

Figure 5. (Simplified) Financial flowchart of the Dutch healthcare system (Kroneman et al., 2016).

Insurers are free to define the content and the risks they cover, and the volume and price of the complementary voluntary health insurance (VHI). The VHI is a complementary package which provides coverage for health services that are excluded or not fully covered by the basic package and the Zvw. Adults pay a community-rated premium directly to their insurer as well as an income-dependent premium to a central fund, which redistributes this amongst insurers based on risk-adjustment (Kroneman et al., 2016). Most insurers deliberately make it unattractive to have a VHI without a basic insurance by increasing the price of a VHI if not purchased in combination with the basic healthcare insurance package (Kroneman et al., 2016). In 2015, 84% of insured people purchased the complementary VHI. The VHI coverage is decreasing over the years, as 93% of the insured purchased a VHI in 2006 [0043,23]. Children are offered a free VHI by most insurers.

4.3 REGULATORY CHALLENGES

4.3.1 The regulation

In 2017, Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices was appealed. This directive repealed the previous Directive 98/79/EC and the Commission Decision 2010/227/EU. The IVDR is a comprehensive (although substantial: 113 articles over 477 pages) guide to aid the legal manufacturer of the product with achieving mandatory compliance. The IVDR describes how an in vitro diagnostic medical device can achieve conformity and enter the European market. The main goal of these medical device regulations is to ensure that the device does not compromise the clinical condition or safety of patients and its users (healthcare professionals or

lay persons (**Article 2 Paragraph 30 & 31**). Medical device developers need to eliminate or reduce as much as possible the risk associate with the device [7]. The product (or product-service system) and the development process must be evaluated to determine if health, safety, and environmental standards have been met (Whitmore, 2004; Zenios et al., 2010; Ogrodnik, 2013; Privitera et al., 2017).

> "This Regulation aims to ensure the smooth functioning of the internal market as regards in vitro diagnostic medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for in vitro diagnostic medical devices in order to meet common safety concerns as regards such products. [...] As regards Article 168(4)(c) TFEU, this Regulation sets high standards of quality and safety for in vitro diagnostic medical devices by ensuring, among other things, that data generated in performance studies are reliable and robust and that the safety of subjects participating in performance studies is protected" (IVDR).

When the evaluation shows conformity, the manufacturer of the product is allowed to sell it on the extended Single Market of the European Economic Area (EEA). Additionally, a mark (Conformité Européenne, CE mark) is affixed to the product to signify the conformity. The legal manufacturer (LM) declares, through affixing the mark, that all legal requirements have been met. Important to notice is, that products can be manufactured outside of the EU, but have to meet EU regulation before they can be sold in the EEA (European Commission, 2017). The CE marking offers two benefits. First, businesses know that products bearing the CE mark can be traded in the EEA without restrictions. Second, consumers know that all products with the CE mark are deemed safe[24] to use through the evaluation of safety, health, and environmental protection standards.

4.3.2 The effect of the regulatory process on new innovations

In light of the development process, however, these regulations might be hinder-some (Pietzsch et al., 2009). These regulations, standards and guidelines are able to speed up the development process for incremental innovations (devices and systems that improve slightly from previous versions), as well as prevent unnecessary design mistakes as the Regulation can be seen as design support. Yet they can obstruct radical innovations (revolutionary product development): devices that are new and try to be something completely new. Therefore, Pietzsch et al. (2009) stress that a perfect balance must be found between organizational efficiency and regulated processes, and creative freedom and innovative ideas. From a business perspective, it has been found that in a highly regulated sector companies can only compete on development process effectiveness. This is caused by the fact that the product concept effectiveness is predetermined by the set regulations, to a great extent (Pullen et al., 2010). Therefore, understanding the conformity process is vital the success of the solution and the company.

4.3.3 The general process

In order to obtain CE certification, the following has to be defined/performed: (1) The intended use of the product must be described which can help identify the user of the system (de Ana et al., 2013; Privitera et al., 2017) (3) The Primary Mode of Action (= the means by which a product achieves its intended effect or action (Amor, 2016)) must be described as well as (4) what the product claims to do. (5) The appropriate risk category must be classified[25] and (6) the Conformity Assessment route must be defined describing which party must perform which test to determine if the product complies to the regulation. When that has been done, (7) the Declaration of Conformity must be published, (8) Technical Documentation must be supplied to the database and stored at the company, and (9) a Quality Management System (QMS) must be implemented.

[24] The EU stresses that a product with CE marking does not mean that the product is inherently safe, but that the product meets the safety, health, and environmental protection standards applicable to that product.
[25] In the case of products that feature apps or other linked software, then that software must also prove compliance.

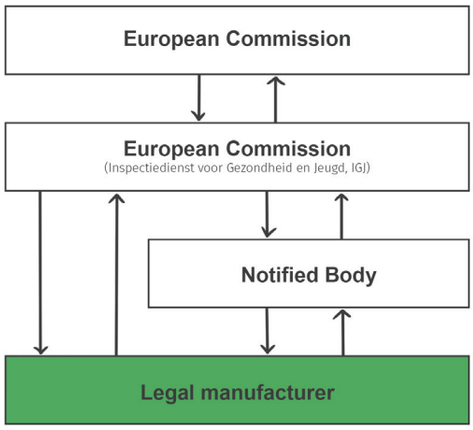

Figure 6. Hierarchy of the EC marking.

The Notified Body is the representative organization responsible for monitoring this process. The legal Manufacturer is the organization that is responsible for the design, manufacturing, and packaging of the product as well as selling the product, whether it fulfils those tasks or subcontracts them (**Article 2 Paragraph 23**); Obelis European Authorized Representative Center, 2011). The legal manufacturer is also the accountable party for EU compliance and possible damages done by the product due to malfunctioning or not achieving the desired performance. In the case where an organization is buying separate components and combines them to make a new product which is packaged and shipped to the EU, then that party is accountable for compliance and liabilities. After entering the market, a post-marketing surveillance system should be implemented as well to monitor their products (Cohen & Billingsley, 2011; Tarricone et al., 2017a)

4.3.4 Classification

Generally speaking, the higher the potential risk of the product, the more control will be applied to the product and development process. As can be imagined, a device that will be implanted into a person may pose more risk than a device that does not come in direct contact with a person or influences a vital health process, like surgical glasses for instance. To figure out how much control is needed, the classification rules must be followed to determine the class of the device. Important to notice, the 'intended use' of the device will be the defining characteristic in the classification process. The intended use means "the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements or as specified by the manufacturer in the performance evaluation" (**Article 2 Paragraph 12**). The intended use can include information on "(1) what is to be detected and/or measured; (2) its function such as screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction, companion diagnostic; (3)the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate; (4) whether it is automated or not; (5) whether it is qualitative, semi-quantitative or quantitative; (6) the type of specimen(s) required; (7) where applicable, the testing population; and (8) the intended user" (**Annex II Article 1 Paragraph 1, under c**). The intended for this device is dependent on its phase of implementation. In other words, the solution starts as a prototype and develops into a consumer product, which is later transformed into a medical device. More on this can be read in Part IV.

4.3.5 Clinical trials

"The purpose of clinical performance studies is to establish or confirm aspects of device performance which cannot be determined by analytical performance studies, literature and/or previous experience gained by routine diagnostic testing" (**Annex XIII Article 2 Paragraph 1**). These studies are measures to gather and source clinical evidence that can attest the performance of the device (**(62)**) as well as demonstrate its general safety. The gathered data shall be used in the evaluation process in which the NB

researches if the device demonstrates compliance. Clinical trials for in vitro diagnostics are significantly different from trials for other devices or pharmaceuticals, as the clinical benefit of an IVD is the ability to provide accurate medical information on patients usable for deciding on treatments and/or other diagnostic tests (**(63)**). The design of a clinical trial should be in line with international harmonised standards (specifically ISO 14155:2011, see also **Appendix 11**) It is the responsibility of the LM to specify and justify "the level of the clinical evidence necessary to demonstrate conformity with the relevant general safety (**Article 57** and **Annex I**) and performance requirements. The performance of the device means "the ability of a device to achieve its intended purpose as claimed by the manufacturer"(**Article 2 Paragraph 39**) and can consist of (1) the diagnostic sensitivity and (2) diagnostic specificity, (3) positive and (4) negative predictive value, (5) the likelihood ratio, and/or (6) the expected values in normal and affected populations (**Annex I Article 9 Paragraph 1, under b**). The level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose" (**Article 56 Paragraph1**).

Clinical trials can best be described through their general process (Rodriguez, 2007; Genesis Research Services, 2018)). **First**, the process starts with an early research phase in which the type, protocol, and design of the clinical validation study is determined. This phase generally uses between 10 and 30 subjects and requires reasonable investments and effort. **Second**, a larger study is performed with 20 to 30 subjects, which are patients, that uses a (near-)final version of the device. The goal of this phase is to guide the study design of the pivotal study which will determine the efficiency and validity of the system. **Third**, the pivotal study must be performed which is a large study containing at least 100 subjects that must confirm the efficacy, safety, and risks concerning the device. Such a study is characterized by its dependence on statistics to confirm the claims of the LM. **Last**, the post market surveillance studies are included in the conformity process which monitor the long term effectiveness of the device on thousands of subjects.

The clinical trial should be sponsored according to the regulation (**(71)**). A sponsor can be both the manufacturer or another natural or legal person (**(62)**). The sponsor is also responsible for publishing the results of the clinical trial(s) in a way that is understandable for the intended user (**(71)**; **Article 68 Paragraph 3**). During the process of clinical validation, the LM is also responsible for performing a systematic scientific literature review in which the device, its intended use, intended users, and more are investigated. The LM must also identify "unaddressed issues or gaps in the data" and, when necessary, generate new or additional data to address these issues (**Annex XIII Article 1 Paragraph 2**). This review shall contain relevant information on the scientific validity of other devices that measure the same biomarker, (peer-reviewed) literature, interviews and positions of experts and related associations, results from proof of concept studies, and available results from clinical performance studies (**Annex XIII Article 12 Paragraph 2**). When the device contains novel markers or markers of which no literature is available, the LM is allowed to employ different approaches that can demonstrate the scientific validity (**Annex XIII Article 12 Paragraph 2**). The benefits of performing such a clinical validation can be reduced to the argument of developing proof. Such a trial confirms the effectiveness and reliability of the system and allows the LM to sell the device on the market. Convincing stakeholders has become easier as proof can be shown that the system delivers what has been promised. Additionally, venture capital firms are more likely to fund start-up companies that have clinical data (pre-pilot data) and a clearly defined regulatory path (Huryn, 2013).

4.3.6 Quality Management system

A Quality Management System (QMS) is a system designed by the company itself or purchased from a retailer that is capable of collecting and processing all information related to the development of a medical device. E.g., to make the link with well-known product development systems: a QMS could be part of, or a combined system with, a PLM or ERP system. Additionally, the manufacturer must provide authorisation to the NB to execute yearly (on-site) audits regarding the functioning of the system (**Annex IX Article 3 Paragraph 2 & 3**). During such audits, the system will be tested for its performance, proper functioning, and if information is stored correctly. Therefore, the QMS should be updated frequently (**(75)**) Even more so, the NB is allowed to audit the manufacturer's supplier(s) and subcontractor(s), if appropriate (**Annex IX Article 3 Paragraph 3**).

Table 6. Minimal requirements for a QMS (taken from **Article 10**).

	Requirements
a	A strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system.
b	Identification of applicable general safety and performance requirements and exploration of options to address those requirements.
c	Responsibility of the management.
d	Resource management, including selection and control of suppliers and sub-contractors.
e	Risk management as set out in **Annex I**.
f	Performance evaluation, in accordance with **Article 56** and **Annex XIII**, including post-market performance follow-up (PMPF).
g	Product realisation, including planning, design, development, production and service provision.
h	Verification of the UDI assignments made in accordance with **Article 24 Paragraph 3** to all relevant devices and ensuring consistency and validity of information provided in accordance with **Article 26**.
i	Setting-up, implementation and maintenance of a post-market surveillance system, in accordance with **Article 78**.
j	Handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders.
k	Processes for reporting of serious incidents and field safety corrective actions in the context of vigilance.
l	Management of corrective and preventive actions and verification of their effectiveness.
m	Processes for monitoring and measurement of output, data analysis and product improvement.

4.3.7 Post-market surveillance system (PMSS)

Post-market surveillance is the practice of monitoring the devices which are in use by “actively and systematically gathering, recording and analysing relevant data on the quality, performance and safety of a device throughout its entire lifetime, and to drawing the necessary conclusions and to determining, implementing and monitoring any preventive and corrective actions” (**Article 78 Paragraph 2**) in a manner that is proportionate to the device risk class. The overall goal of such a system is to ensure the safety of its users and guarantee its performance (**(63)**). Such a system should be part of the QMS and its data used be to improve the risk management and its mitigation strategies (Annex I), update design, manufacturing, and performance evaluation information, and, if possible, contribute to the post-market surveillance of other systems.

4.3.8 Traceability

Traceability is very important in the medical device industry, as can be deducted from both the QMS and PMSS. Even more so, in a situation in which the system harmed a user, the manufacturer is required to deliver all information regarding the system within reasonable time (within 2, 10, or 15 days, **Article 82**). In the theoretical case that a supplier has delivered a faulty product, then the manufacturer should be able to explain to the NB where the wrongdoing has occurred, which processes where used, which employees were connected to the process and above-all, whose fault it actually was. It is in the best interest of the manufacturer to pinpoint in any case who is responsible, as a supplier can also be sued for damages based on liability. To improve the traceability across Europe, a database will be[26] established containing unique codes of all medical devices; the Unique Device Identification system (UDI system) (**(38)**). Additionally, another database will be created that should be able to integrate different electronic systems that collect information about the conformity and post-market surveillance processes; the European database on medical devices (Eudamed) (**(41)**). Even more so, the legal manufacturer also needs to register as a company to the CIBG[27] when it places an IVD on the Dutch market for the first time, regardless of geographical location of its headquarters.

[26] Bear in mind that this Regulation will become active in 2022.
[27] The executive organization of the Ministry VWS.

4.3.9 Responsible person

To be sure that the regulation will be followed, the Regulation states that all manufacturers must have at least one person available in their organisation that is responsible for regulatory compliance (**Article 15 Paragraph 1**). Additionally, this person must possess the "requisite expertise in the field of in vitro diagnostic medical devices". One exception to the rule is available to micro and small enterprises (within the definitions as stated in Commission Recommendation 2003/361/EC (1)); they shall not be required to have such a person available in their organisation "but shall have such person permanently and continuously at their disposal" (**Article 15 Paragraph 2**).

4.4 ISO STANDARDS

International, harmonised standards are often to use to structure processes in the development and validation of medical devices (**Article 8**). The Regulation allows for other standards to be used, but for a company it saves a lot of money and effort to use the internationally appraised standards. As said, these standards structure the process but, above-all, they can prevent unnecessary mistakes and can serve as 'checklists' for the development of new products. Additionally, the IVDR Regulation makes suggestions (which are highly advisable) for which standards to use for which process. I.e., ISO 14155:2011 defines how a clinical validation study must be designed and executed, ISO 14971:2012 which describes how a risk management system should be structured and implemented, or ISO 13485:2016 depicting the functioning and capabilities of a QMS.

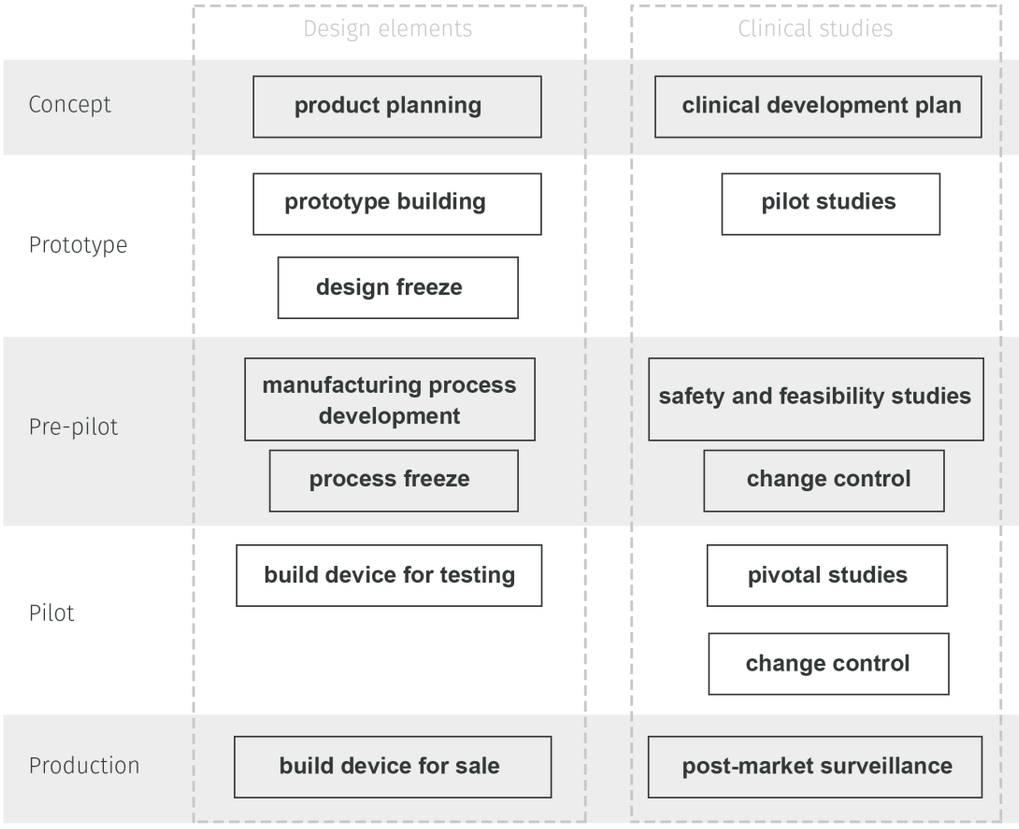

Figure 7. Schematic overview of clinical research combined with the product development cycle (Pietzsch, Shluzas, Paté-Cornell, Yock, & Linehan, 2009).

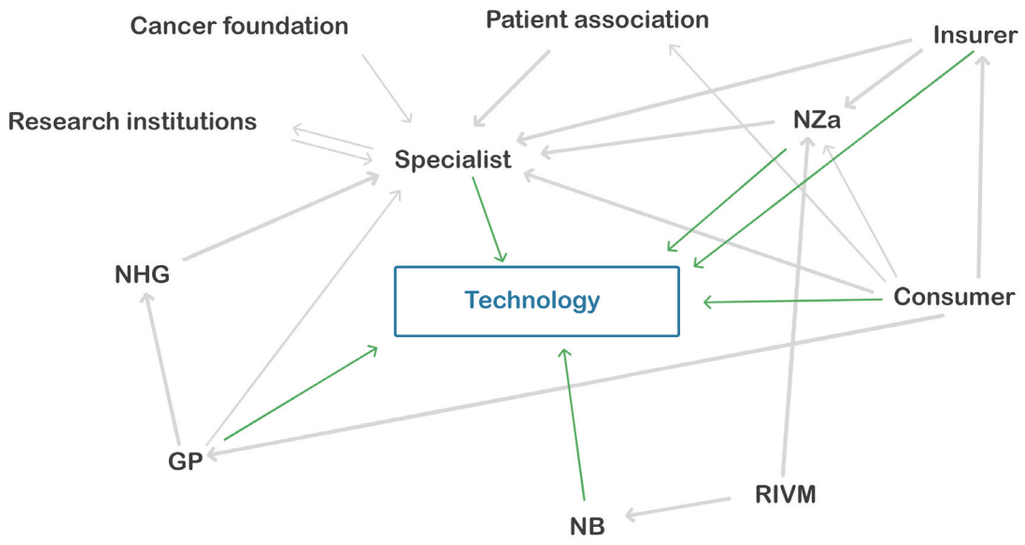

Figure 8. Technology acceptance.

4.5 TECHNOLOGY ACCEPTANCE

When looking at how these stakeholders react to each other and how they look at the opinions of others, what stands out is the important role of the specialist. When consulting GPs, it is often mentioned that there are two stakeholders that can shape the opinion of a general practitioner: the NHG, the scientific GP organization that develops the guidelines and advises on the newest technologies, and the specialist. The NHG itself also consults experts before approving any new technology and communicating this to all connected member GPs. Therefore, from the GP perspective, the specialist is the stakeholder with the most influence in the acceptance of the technology. This can also be seen in the initial start of the screening as in 2004 a questionnaire among GPs from Amsterdam (response rate 32%) showed that only half of them were of the opinion that a national screening was necessary, while 92% of gastroentologist were in favour of the screening (Terhaar sive Droste et al., 2006), essentially pushing the decision. From a governmental perspective, the NZa always employs and consults experts before developing or advising any new medical technology or innovation. When looking through the perspective of the insurer, it became clear that an insurer will only cooperate with a company in the development of a new solution, when that solution has already proven its functional validity and when a care professional "ambassador" is connected to the project[28]. Even more so, an insurer will only listen to the plea for the value of a new solution when this plea is coming for a care professional, a company won't be listened to. In addition, to acquire the necessary scientific proof of the practical validity of the solution, specialists must be involved to establish and guide the (clinical) validation study.
Another key issue, is a concept known as 'not invented here'[29]. This concept entails that sometimes care professionals are not willing to accept a new innovation, even though it has proven its effectiveness, solely because of the reason that they specifically were not included in the development of the solution. This has been mentioned in multiple workshops and conversations with experts (See **Appendix 2**). In other words, without a specialist, it is a near impossible feat to get the solution accepted by the relevant stakeholders in the system. Which is essential for the successful implementation of the solution, as literature has shown that "the resistance and low level acceptance by healthcare providers are among the main factors for failure" (Haslina Mohd et. al., 2005).

[28] Workshop Risk management & ISO 14971, 25-10-2018, TechMed Centre, Enschede. 'Wie gaat dat betalen?', 26-11-2018, Hotel theater Figi, Zeist.
[29] Workshop Risk management & ISO 14971, 25-10-2018, TechMed Centre, Enschede.

5. POWER GRID

As has been mentioned in the introduction of this chapter, the most well-known method for the identification of stakeholders is a stakeholder power grid (Mitchell et al., 1997). This grid places stakeholders on multidimensional grid along the axes of legitimacy, power, and urgency. Power is the stakeholder's power to influence the firm and gain access to means to impose its will in the relationship. Important to notice is that this power is transitory; it can be acquired and lost. Legitimacy can be described as "a generalized perception or assumption that the actions of an entity are desirable, proper, or appropriate within some socially constructed system of norms, values, beliefs, and definitions" (Suchman , 1995: 574). Power combined with legitimacy establish authority, with which is stakeholder has the power to impose its will and the legitimacy to do so. Urgency can be defined as the "degree to which stakeholder claims call for immediate attention" (Mitchell et al., 1997, p.876).

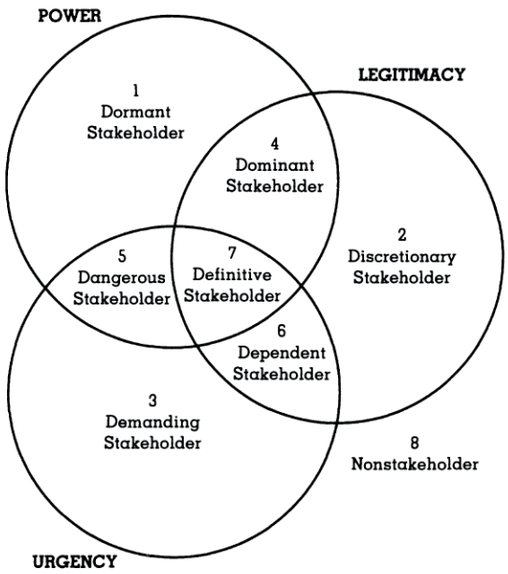

Figure 9. Stakeholder typology (Mitchell et al., 1997).

These stakeholder attributes are variable and dynamic: they can (and will) change over time). The most common shift will be from dominant stakeholders moving to the definitive category (Mitchell et al., 1997). Additionally, these attributes are "socially constructed", i.e. perceived and not objective (Mitchell et al., 1997, p. 868) and the stakeholder might not even beware of possessing one or more of these attributes. The most common stakeholders that hold two or more attributes should be closely monitored during the lifetime of the system. **First**, the dominant stakeholders. These posses both the power and legitimacy attribute which ensures their influence on the company. Generally, it can be expected that formal mechanisms will be in place that operate this power and legitimacy, acknowledging the relationship between the stakeholder and the firm (Mitchell et al., 1997). **Second**, the dependent stakeholders. These can be characterized by their lack of power whilst having legitimacy and which claims are urgent. Their dependency can therefore be explained as they will need other stakeholders to actualize their claims. To satisfy these stakeholders, the company must either by willing to cooperate and act on their claims or be subject to powerful other stakeholders, responding to the claim. **Third**, the dangerous stakeholders. These stakeholders combine power with urgency but lack the legitimacy for their claims, and pose therefore a threat to the organisation. Mitchell et al. (1997) would like to add that the depicting these stakeholders as 'dangerous' developed some discomfort, however, the authors were more concerned with the "failure to identify" these stakeholders as that would "result in missed opportunities for mitigating the dangers". **Last**, the definitive stakeholders which posses all three attributes and their claims, therefore, should be prioritized above all others. Managers of a company are obligated to closely monitor these stakeholders and act appropriately.

Two power grids will be defined: one for the development process and one for the implementation process, as the processes differ significantly in which stakeholders are involved and how their relationships are established. The stakeholders that were considered are all parties mentioned in the analysis of the Dutch medical system and the regulatory process. To estimate their position on the grid, a short analysis of the three attributes for (almost) all stakeholders will be discussed. The overall goal of this research project is to find a strategy that will allow for the successful development and implementation of the system. Therefore, the goal of this exercise is to estimate the influence of stakeholders on that development and implementation process. To define the level of power a look will be taken at how much influence the stakeholder can impose on either the development or implementation process. To define the level of legitimacy, an assessment will be made based on previously gained knowledge that will describe the desirability and properness of the stakeholders claim. The level of urgency will be analysed based on previously gained knowledge and can best be depicted as the amount of trouble the company will get in to when not acting on a claim immediately (e.g., sanctions, fines, disqualifications, etc.). Using this method, it shall become clear which stakeholders pose a threat to the development of the system and which relationships must be established. Additionally, this understanding will be the basis of determining the road of implementation of the system (Part IV) of which the options will be discussed in the next chapter. In both the development and implementation grid, the user as a stakeholder is excluded. This is due to the fact that the user is the only stakeholder which is undefined as well as 'moving': susceptible to significant changes. As has been mentioned before and will be discussed in Part III Chapter 11, no current target group exists: a target group must be designed for this solution. Therefore, providing a detailed analysis of the target group during this research project will not provide any more insight as this group might change significantly.

5.1 THE DEVELOPMENT POWER GRID

First, the discretionary stakeholders will be discussed. These stakeholders have the legitimacy to influence the process but are unable to do so, due to lack of power. Additionally, these stakeholders have no urgency for their claim in the process, and will therefore not be prioritized over other stakeholders. These stakeholders include the Health Council, the general practitioner as well the LHV and NHG, the research institutes ZiNL, Nivel, and ZonMw, the care professional association, and the universities. All these organizations are capable of evaluating the validation process and some are partly capable of evaluating the product development process. However, these organizations have no measures to influence the process and their claims are not urgent. **Second**, the dominant stakeholders will be discussed: the EU, the MVWS, and the RIVM. The EU has a significant power and influence on the entire medical device industry (E.g., the MDR and IVDR). However, these regulations will take considerable amounts of time before being introduced to the industry: the IVDR was appealed in 2017 and will become valid in 2022. Similarly, the Ministry has the power and influence to impose rules, regulations, mandates, or other measures that might effect the development or implementation project significantly (Privitera et al., 2017), especially for products wanting that are ought to be introduced to the Dutch market. The RIVM can also have a significant influence on the development of medical devices. However, what characterizes all these stakeholders is that the implementation time of any measures often take a considerable amount of time. As has been mentioned with the IVDR, the same goes for measures of the Ministry or the RIVM. In both cases, the notion that a new measure will be introduced is often way before the actual introduction of that measure, allowing medical device companies sufficient time to adapt to these new measures. Even more so, before the measure will be implemented and enforced, it will have passed numerous organizations before reaching the company and its processes Additionally, other organizations are most likely employed to act on the behalf of the EU and the Ministry and enforce their regulations and mandates. Both have other organizations acting on their behalf, the NZa and the Competent Authority, IGJ, respectively. **Third**, the dangerous stakeholder: the insurer. The insurer is capable of influencing the process without a justified and legitimate claim. As has been made clear during this research project, the insurer can impose certain demands to the development and validation process without having the legal justification. Rather, the insurer can demand in the first place, because of their role in the managed competition market. The insurer is the organization that will have the final decision on whether or not a new technology will be reimbursed. The insurer might claim that the NZa is responsible for determining what can and cannot be reimbursed, but in practice, the insurer must interpret these rules. In the worst case, the insurer might disregard or reject a the validation

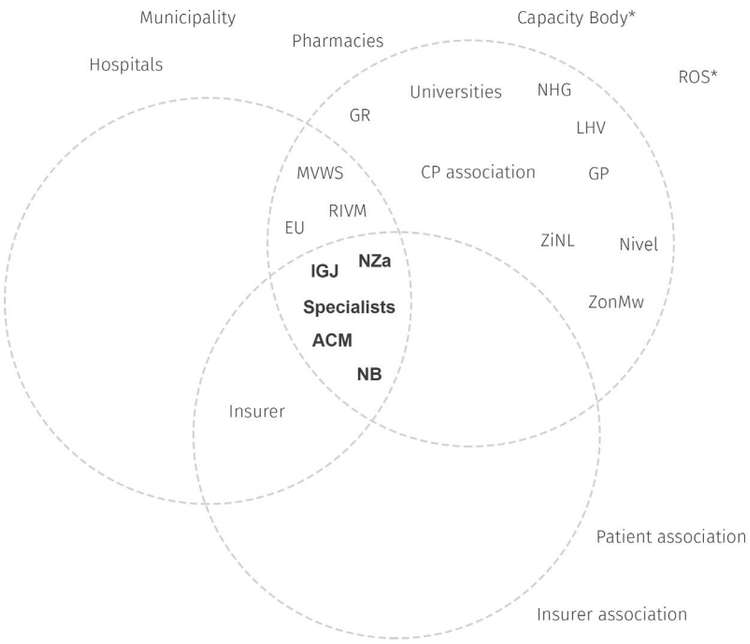

Figure 10. Development power grid.
What not is included are 'common' business related stakeholders (e.g., the tax authority and the Chamber of Commerce). As these stakeholders do not have relevant influence on the development of either the solution or the implementation.

methods of the new technology as either the insurer is unwilling to understand the tech or get involved in the development process of the tech, or because no care professional is willing to represent (i.e., play an ambassador role for) the tech and indirectly the company. Therefore, the insurer should be involved in the process to avoid such issues and the relation with the insurer should be closely monitored. **Fourth**, in this process no dependent stakeholders are present. **Fifth**, the definitive stakeholders during this process are the NZa, the IGJ, the ACM, the NB and the specialist. All five parties can influence the process, make justified and legitimate claims which should be acted upon immediately. Even more so, the first four organizations have the capability to stop and interrupt the process to investigate and evaluate its functioning. Additionally, these organizations can impose measures that significantly impact the future of the firm and its system, from sanctions and fines to disbanding the conformity. The specialist is perhaps the most definitive stakeholder, as the other organizations depend on the specialist to determine the entire validation process. **Last**, some organizations are not a stakeholder in this process. They might have some to say about the results of the process, yet lack the power and legitimacy to do so.

5.2 THE IMPLEMENTATION POWER GRID

First, the discretionary stakeholders. Which include the research institutes ZiNL, Nivel, and ZonMw, as well as the universities and hospitals. These stakeholders can have legitimate concerns with the implementation process of the solution. However unlikely that they will become involved in the implementation, it could occur that an investigation is started on the justification and outcome of the process. When something inappropriate is found, then these stakeholders will move to the dependent category and demand the powerful stakeholders to act, adding urgency to their claim. However, for now it is assumed that neither of these organisations will be bothered to research the implementation. **Second**, the dominant stakeholders which include the same group as can be seen in the development power grid (figure 10). For similar reasons, these stakeholders have the legitimacy and the capability to claim and impose regulations and mandates that will influence the implementation process. Similarly, however, it is unlikely that such actions will have the urgency to be acted upon immediately. Additionally, also with this process, it is more likely that these organisations will employ other organizations to act on their behalf (which are all located in the definitive category). The only new entry, is the ZiNL. This organization is responsible to decide on the contents of the basic care package in cooperation with

the NZa. Therefore, in the implementation phase, this organisation has significant influence when the company wants the solution included in insured care. **Third**, the dangerous stakeholder: the insurer. Also in this case, the insurer might disregard or reject a technology that has proven its validity and effectiveness due to an unwillingness to include the tech in the insurance packages or because no care professional is willing to represent the tech and indirectly the company. It can be argued that the role of the insurer in the medical device industry is questionable, as they act like for-profit companies while running on governmental funds (.i.e., tax). The behaviour of the insurer can best be described as an unwillingness to become involved in the development and implementation of new tech, unless a significant portion of care professionals support the technology, it has proven its scientific validity and clinical effectiveness, it does not need more investments then three years of use can repay, and not too much risk is involved. In other words, an insurer will never support unproven, high risk tech, which is usually the output of a start-up company, while demanding the most. Therefore, also in this case, the insurer should be involved in the project as soon as clinical data (data from the smaller studies of the validation process could suffice) is present and relationships with care professionals have been established. **Fourth**, in this process multiple dependent stakeholders are present: the Health Council, the NHG and LHV, and the patient and care professional associations. During the implementation, these parties might alert their powerful allies of any wrongdoings of either the product, its use, or the process. Although these organizations are dependent on others to act upon any issues, their relationships with these organisations is close and strong. **Fifth**, the definitive stakeholders during this process are the familiar NZa, the IGJ, the NB, and the ACM, as well as the GP and the specialist. For similar reasons as with the establishment of the development power grid, these stakeholders have a powerful and legitimate influence on the process that is urgent and should be addressed immediately. Additionally, the general practitioner turned to a definitive stakeholder in this process as the power attribute establishes in accepting the use of the system or not. If a patient turns up with the test results in a report constructed by the solution, then the GP must be convinced of their use and the scientific and diagnostic validity. Otherwise, the patient will experience a rude awakening when the GP does not take the report seriously and does not act on the patients concerns. This situation must be prevented at all cost as the value of the system will be obsolete without GP approval and acceptance. Additionally, the specialist is also in this process important due to their advising and defining role of what devices have been validated properly. **Sixth**, the insurer association is a demanding type of stakeholder as this organization has no power or influence over the process and has no legitimate claim to do so, but can pressure the insurer to act upon their demands. **Last**, some organizations are not a stakeholder in this process. They might have opinions on the system and its use and effectiveness, but they have no influence, no legitimacy, and no urgency.

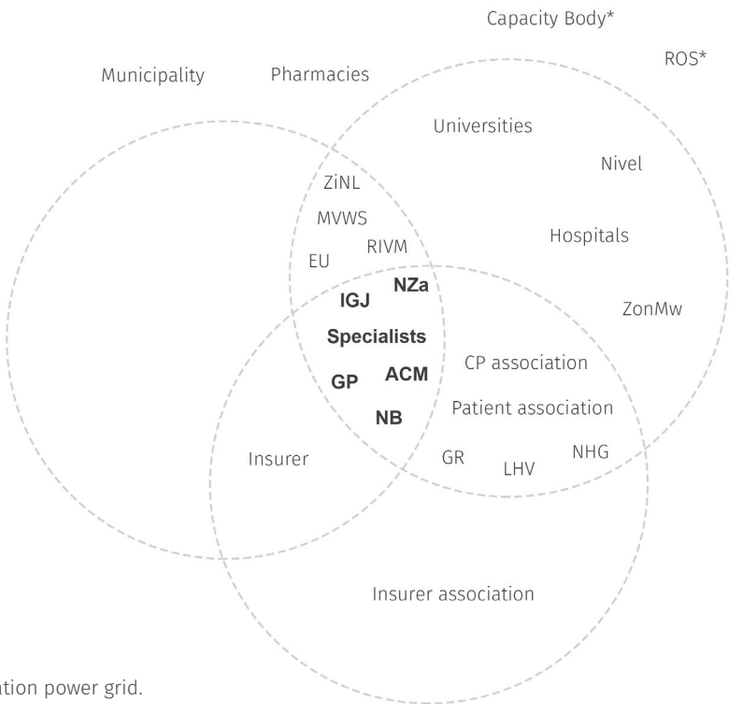

Figure 11. Implementation power grid.

6. APPROACHING THE MARKET

The relevant stakeholders of the industry have been described and analysed and the implementation challenges have been identified. Therefore, it is now time to define possible entry points for new technology to enter the Dutch medical (device) market. These entry points are often described as routes, as they signify a certain order and amount of steps that must be taken to complete the route and enter the market. Four routes have been identified: the consumer route, the care professional route, the insurer route, and the governmental route. Each of these routes demand a certain preparation, specific investments in time, money, and resources, as well as an involvement of stakeholders. Which are all discussed in this chapter. Additionally, a short summary is provided detailing the preparations necessary before attempting one of these routes. In Part IV, the routes are incorporated in the implementation design of this research project. Using them to achieve different results with the same technology.

6.1 PREPARATIONS AND ENTRY POINTS

Generally speaking, some preparations have to be made before an implementation route can be chosen and attempted. The details of these preparations can be found in Part IV. Before entering the market, the logical **first** step is to formalize the company. The start-up must become a formal company as otherwise attracting funding and talent is near impossible due to practical reasons (e.g., no formal company means no formal and trustworthy bank account), as well as the sense of legitimacy necessary to persuade investors and future employees. After the formalization, the **second** step should be to analyse and evaluate the power grid and confirm the positions of the stakeholders through conversations with said stakeholders or representative experts. **Third**, when these positions have been confirmed, the necessary relationships can be started as to prepare for the different routes. **Fourth**, the goal of the product, in line with capabilities of the company (will be discussed in Chapter 8), should be established as to prioritize and define the appropriate route for the appropriate time **Last**, a roadmap should be established (as has been done in Part IV) and acted upon, after this research project.
What will be discussed in this chapter are the four possible entry points to the medical device market in the Netherlands. These four routes are discussed in light of the stakeholders involved and their interest in the specific implementation route, the necessary proof that must be gathered to convince these stakeholders, the possible pitfalls during this route, and the criteria that must be evaluated to decide if this route is the appropriate one. Important to notice, is that the actual decisions regarding these four routes will be discussed in Part IV, as there actualisation of this knowledge can be found. The four routes ('zorginnovatieroutes', Janssen et al., 2014) consist of the consumer route, the care professional route, the insurer route, and the governmental route. They have been named in this way to signify the stakeholder that will be approached first to implement the solution. These routes have been established through research (Janssen et al., 2014) and have been confirmed with expert validation (**Appendix 2**)

6.2 CONSUMER ROUTE

First, it is important to realise that the intended use of the product must change when attempting the consumer route. As soon as the manufacturer claims that the product has a medical application, then the product will be subject to the IVDR (or MDR) and its related processes and demands. Therefore, the product must have the intended use to measure but not to assess, and no medical or diagnostic related claims can be made. Doing so, the process of entering the market through the consumer is significantly less complicated compared to the other three routes. In this route a NB (i.e., a different NB than those from the medical industry) is involved in the development and safety assessment of the product, but the demands and obligations are assumed[30] to be significantly less resource demanding. Additionally, the ACM is also involved from through its regular supervision role, intervening when necessary. **Second**, due to the changed intended use of the product, its medical application is negated. Additionally, because of this the consumer product version of the solution will not need a validation study and subsequently will not be reimbursed by the insurer. Therefore, the consumer must be willing

[30] The Regulation regarding measuring instruments (i.e., Directive 2014/32/EU, deemed the most likely alternative to the IVDR) is a notably less exhaustive piece of literature with fewer resource intensive demands and requirements.

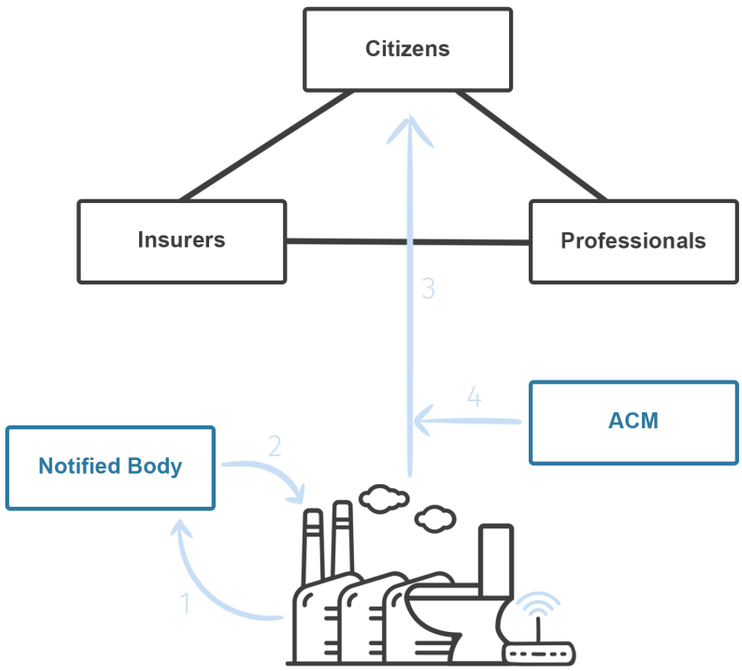

Figure 12. The consumer route.

to pay for the solution out of its pocket. The interest of the consumer can therefore be best described as a combination of value perception and cost price: the solution must offer a clear value for a fitting price as otherwise, the system will not be purchased. Negating the need for a validation process will definitely reduce the development costs and thus the cost price of the solution (Citrin, 2018). **Third**, When trying to convince the consumer from adopting and using a healthcare innovation, personal experience should be considered. The innovation should be user friendly and improve the health condition of the consumer's life. Some consumers are heavily influenced by what online forums say and others rely more on a care providers or patient associations (however, that number is decreasing every year (o'Connor Vos, 2016)). Thus, promoting a healthcare innovation to consumers can often look like marketing with an educational approach. Strong relationships with healthcare experts and patient associations can significantly improve the opinion of the general public. Especially the patient association is quite useful, as this organisation is knowledgeable of the patients, has relations with other organisations that can provide help during development, and offer a place where small-scale tests can be performed. Such an association can be of great help when determining the added value of the innovation, even in early stages. Other consumer' related options can also provide the necessary proof to convince a consumer. A specific website can showcase the innovation through (bought) expert reviews[31], online forums for people that suffer similar conditions[32] where new innovations can be discussed. Consumers often desire 'simplified' (i.e. made more readable for the average consumer) summaries of research reports showing the reliability of an innovation. Additionally, the product should be certified by a reliable, independent organization which shows that the innovation can be trusted. Linking these to goals of patient associations can be helpful as well. **Fourth**, this path is especially suited for innovations that do not require big investments in research and development (Citrin, 2018), which holds true for a solution without medical application and the consequent validation trajectory. Choosing this route will decrease the investments and need for resources, whilst also decrease the complexity and amount of stakeholders involved. The consumer, the NB, and the ACM will be the most relevant stakeholders in this process, but informal caregivers, family, and friends, and the personal GP should not be overlooked. **Last**, a possible pitfall of approaching the market like this, is the difficulty in reaching the consumer; patient associations can be of great help. Additionally, finding reliable partners

[31] De Digitale ZorgGids. (2019, May 20). De Digitale ZorgGids. Retrieved May 27, 2019, from https://www.digitalezorggids.nl/
[32] Stichting Diagnose Kanker (n.d.).

that are necessary for production and distribution can be difficult to find and attract. It should be considered that the healthcare consumer behaves in similar ways to a regular consumer and therefore, similar tactics can be applied to convince. Product demonstrations and a professional looking website can aid in a positive and reliable perception.

> "As people pay more money out of pocket for their healthcare, they begin to expect the quality of experience they find in other great consumer companies. The power dynamic is evolving as people who were previously "patients" are now becoming "consumers." Companies who treat them as such will be rewarded" (Citrin, 2018).

6.3 CARE PROFESSIONAL ROUTE

The care provider is in many cases the user of the product (think of surgical products), but not often pays for the innovation (as insurers provide the budget for care providers). **First**, care providers can be interested in different benefits that the innovation can provide. The care provider is interested if the innovation improves quality and delivery of care, increases the efficiency of care processes, decreases the amount of labour hours not spent on providing care and improves the (financial) position and image of the provider (Janssen et al., 2014; **Appendix 2**). **Second**, it is important to realise that a 'care provider' often consists of numerous stakeholders. Hospitals (and general practices for some) have physicians, nurses, IT-departments and (financial) management. Important to figure out is which of these stakeholders is going to invest in the innovation, who is going to use the innovation and who is responsible of maintaining the operability of the innovation. Finding people that belong to these three groups that support your innovation can greatly improve the chances of successful adaptation and implementation. Care providers can be convinced by showing that their problems are recognised and providing a solid and substantiated business case (Scott et al., 2007; Janssen et al., 2014) showing results from pilot studies and clinical studies[33]. This analysis should consider changes to the process too and what these mean for the quality, efficiency, costs and time of care directed to that specific healthcare provider. This might ask for information that is not publicly available and thus, developing the business case together with the care provider might be necessary and very useful. Even more so, performing a pilot study with the intended care provider might improve the desire to apply the innovation as the innovation has been seen in the real-life context (i.e. 'To see is to believe'). This route is suitable for innovations that provide direct benefits for healthcare providers. **Third**, when attempting this route, the management board (often the stakeholder that will make the final decision on investing) and the IT-department (often the stakeholder responsible for maintaining the innovation) should not be forgotten. Even though the healthcare provider itself is able to invest in the implementation of an innovation, management must allow the purchase and IT must implement it. Similarly to the consumer route, the provider target group can be accessed through professional associations too. These associations are responsible for developing medical guidelines and guard the interests of the professionals. Due to their scientific expertise and knowledge of the profession, the association can provide guidance in assessing the added value of the innovation. Therefore, as well as with the patient organization, it can be beneficial to include the appropriate professional association early in the development of the innovation. **Last**, it is very important that the innovation can be implemented with existing care provider processes. Otherwise, other systems must change to accommodate to the innovation, which is a difficult process that is almost never approved upon. In addition, the care provider should be enthusiastic about the innovation. Not that this is not relevant for any other path, but especially in this case the innovation spreads through a care provider's organization through word of mouth. Another major pitfall is the execution of a validation study and providing the wrong results. As mentioned before, the stakeholders should be asked what results they expect to see before performing a study. Another pitfall is the hesitation of the manufacturer to co-develop the innovation with the healthcare provider. Doing so, the developer might cast aside useful expertise and experiences. A good example of such an innovation is the 'COPD In Beeld' allowing patients to measure their condition at home to reduce the amount of emergency and re-admissions, reducing costs (Benschop, 2018).

[33] Important to consider, is that the care provider should be asked what results should be delivered from the different studies, before attempting these studies.

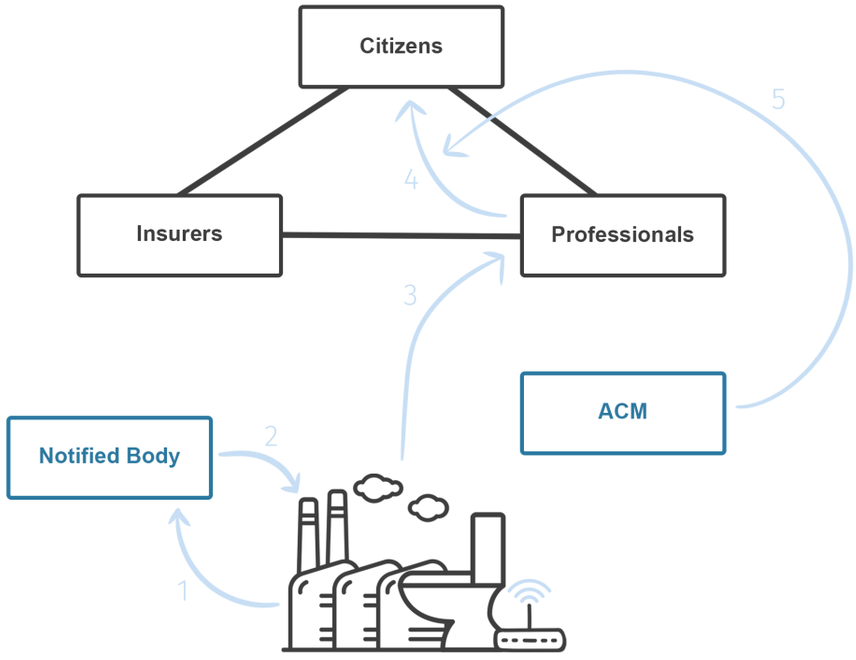

Figure 13. The care professional route.

6.4 INSURER ROUTE

In many cases, the insurer is the organization paying for the use of new healthcare innovations. To reduce costs, the insurer is always on the lookout for innovations that can provide quality care for a lower price or in a more efficient way. Scalability and the ability of an innovation to completely substitute an existing solution are two important aspects for consideration by the insurer. **First**, an innovation is interesting for an insurer if it can deliver the same quality care of an existing solution for a lower price. The innovation is also more desirable if it can reduce sickness of patients, either through prevention or by reducing the time a patient is sick. In addition, the insurer is also looking for innovations that can attract new customers, as this is part of the managed competition. **Second**, as with the provider, the insurer should also be divided in different stakeholders. An insurer consists of an innovation department, selecting and assessing new innovations, an investment fund, financially supporting new innovations, a purchasing department, negotiating with care providers, and a commercial department, developing additional insurance plans[34]. These departments negotiate with care providers on the delivery and quality of care. Therefore, the innovation should have support from care providers that are going to use the innovation. Even more so, the insurer wishes for the care providers to negotiate and convince the insurer. It is also important to think about the effect of the innovation to assess which department should be contacted first. As example, if the innovation can be used to attract new customers than the financial department should be contacted first. **Third**, insurers use medical advisors with expertise in specific fields to assess the added value of an innovation. The insurers demand a substantiated business case with results form a pilot or a clinical study. These results can be used to determine the consequences for the claims by the insured, by extrapolating the data and combining it with scientific literature and healthcare expenditure. Therefore, it is very important to determine what results the pilot or trial should deliver beforehand. This is also true for the research method. At the end of the line, the insurer wants to see a 'schadelast reductie' (= a decrease in health claims) which can be achieved through substituting an existing care process with innovation, or through self-management and prevention. This substitution will provide a cost reduction on the short-term, however, this substitution should also take into account the implementation costs and the possibility to reduce labour hours and increase the efficiency of care processes. Prevention and self-management can lead

[34] Important: these departments might not always agree with each other.

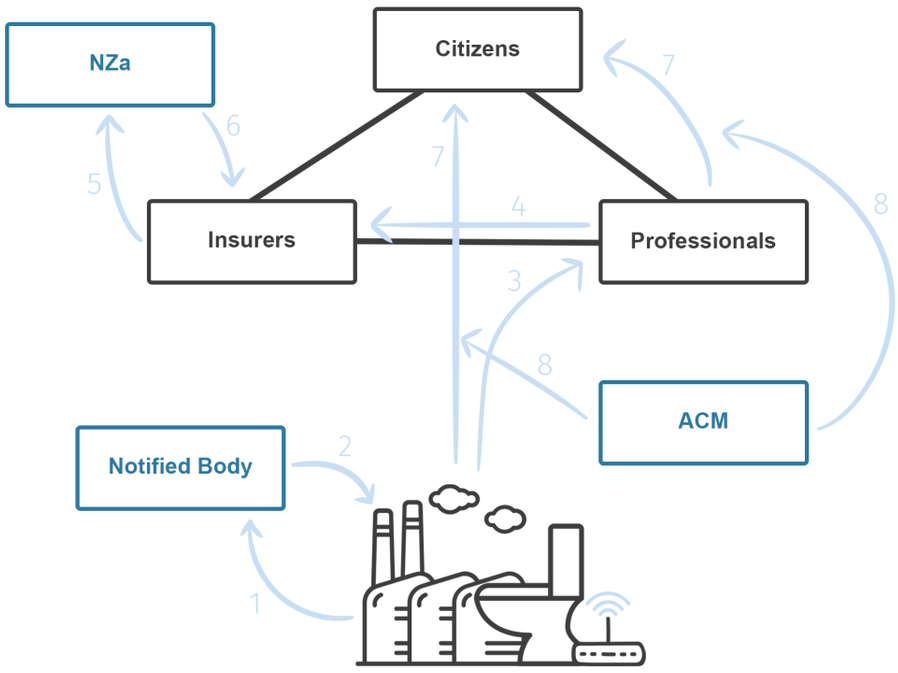

Figure 14. The insurer route.
Which step 7 and 8 occur, dependent on which stakeholder delivers the innovation to the consumer/patient. Either the company provides the solution, and the ACM monitors that delivery, or the professional provides the solution, and the ACM monitors that delivery. When the innovation is delivered by the professional, it will most likely be used in a hospital or specialists centre. When the company delivers the situation, most likely a more complex cooperation will be in place.

to less healthcare consumption. This is a less solid claim and therefore, the insurer demands that the payback period should not exceed three years. The reduction of care consumption should be proven in a threefold analysis: first, a trial aimed at the efficiency of the innovation and process measure (i.e. adherence to therapy). Second, the translation of this efficiency to final process measure (i.e. decrease in complications) proven with scientific research. Last, the use of own data to calculate the expected cost reduction. Facts and figures carry more weight than opinions and experiences and it is important to be careful with estimations. In the case that an innovation is beneficial for multiple conditions, focus on the one that delivers the most cost reduction in the shortest amount of time ('pick your battles'). **Fourth**, this route is suitable for innovations that change the delivery of care, but not the contents or quality. As the insurer believes that the negotiations should be between insurer and provider, it is very important to include the providers as soon as possible in the development of the innovation. This will create the necessary support and enthusiasm needed to convince the insurer. When the content of care is changed because of the innovation, then additional negotiations have to be held with the NZa. The care provider and insurer can file a motion at the NZa. This organisation will determine if the innovation will become reimbursable. If approved, the innovation gets time to prove its performance. **Last**, the biggest pitfall is the lack of support among healthcare providers and experts. Another problem is forgetting the substitution of existing care. It is also possible to surpass the insurer if the innovation has proven to lead to cost reduction for at least a similar quality of care. If the initial costs of the innovation are more expensive, but lead to a better quality of care, than the insurer should be involved and the support for this innovation should be bigger.

6.5 GOVERNMENTAL ROUTE

The NZa is the organisation that is responsible for most of the governmental tasks concerning healthcare. Therefore, when taking the governmental route, the NZa is the main stakeholder to take in account. **First**, the NZa is responsible for guarding the managed competition market of the Dutch healthcare

system. The NZa is also the responsible organisation that can decide if an innovation is applicable for reimbursement and thus, if the insurer can reimburse this care product. The ZiNL (*Zorginstituut Nederland*) supervises and manages the basic insurance packages. This organisation determines what belongs to the basic package[35] and so, if the innovation has the potential to be used for the entire Dutch population, then the ZiNL should be contacted as well. **Second**, the NZa is only interested in innovations with broad support from both providers and insurers, as those two are the only stakeholders that can request a new care product. To convince the ZiNL, two criteria must be met (Janssen et al., 2014): (1) the medical experts must accept this type of innovation and it should conform to established guidelines (ZiNL, 2018) for effective and quality care, and (2) the innovation must be clinically validated to provide supporting scientific evidence of its performance. This evidence should be 'fitting': the evidence should fit the type of care related to the innovation. The proof does not always have to be delivered through a clinical trial (ZiNL, 2015). The ZiNL has provided guidelines to determine which type of evidence collecting is suitable (Heymans, Kleijnen , & Verstijnen, 2013). **Third**, this route is applicable if the innovation delivers a new type of care in both content and delivery. Therefore, the solution should be analysed to figure out if both aspects of care change because of the solution design. To speed up the innovation research and development, the government has instituted two regulations: through the 'beleidsregels innovatie' regulation it is possible to define a temporary care product so that an innovation can be tested in the proper medical context on small scale for a few years. Through the 'facultatieve prestaties' it becomes possible for providers and insurers to file a motion for a new care product at the NZa. **Last**, this route is similar to the insurer route, and therefore, the same pitfalls exist. However, it is often underestimated how much time and effort this route asks. Most importantly, if the innovation is not used in practice and reimbursable, then no revenue is made from the innovation. Which requires a lot of external financing to gap the years of development and the reimbursement trajectory. Therefore, it is advised to contact the ZiNL early on in development to assess if this route is applicable.
Usually, these types of innovation are developed by medical specialists in combination with companies and researchers.

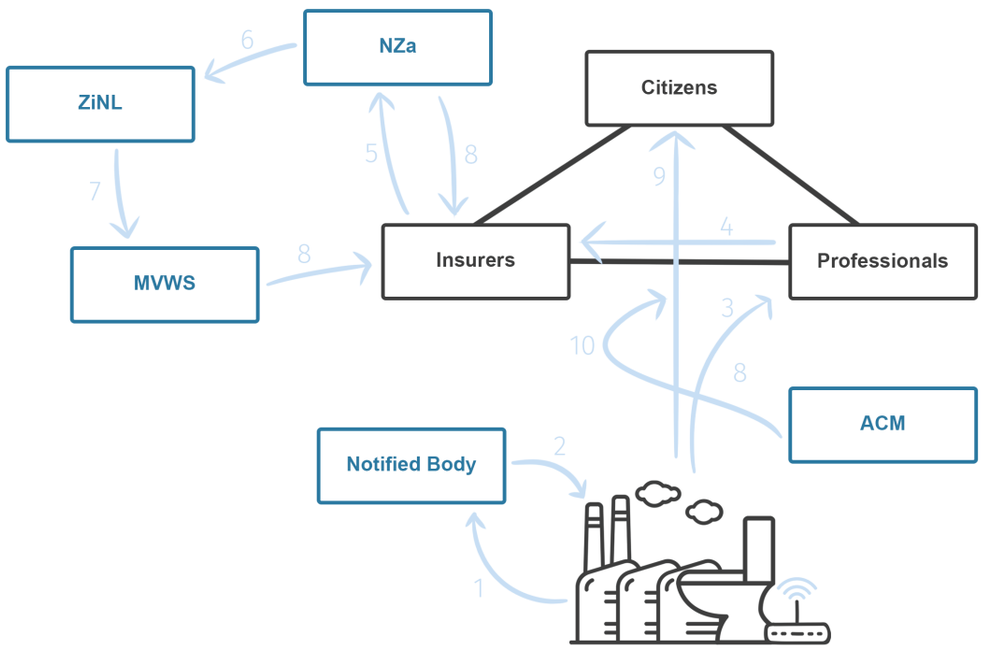

Figure 15. The governmental route.

[35] This is determined based on four principles: necessity (do enough people in the Dutch population benefit from this innovation?), effectiveness (does this innovation make care more effective?), cost-effectiveness (does this innovation deliver better care for less costs?), implementability (can this innovation be included in the basic package and will this be included for the coming years?).

7. COMPANY CHARACTERISTICS

The Capital Model is used to structure the phases the company assessment as well as the implementation design. Through the six perspectives of the Capital Model, it becomes possible to analyse the capabilities of the company. In the implementation design the model can be used to define the actions that must be taken, the knowledge that must be gained, the alliances that must be established and more are discussed. So that the company is well aware of what must be done to successfully execute one of the phases. In other words, each of the phases will be divided into the six capital perspectives and so, each phase will contain the same six chapters. In doing so (aside from the structuring argument), it becomes easier to describe, understand, and evaluate the changes between multiple (or two) phases. The order in which the capitals are explained (Social, Human, Intellectual, Organizational, Resource, Financial) follow a similar order to the Business Model Canvas. Doing so, the first three perspectives explain the interesting aspects of this business case. Whereas the following two focus on the business structures and architectures necessary for successfully completing this development process. The last capital perspective gives an impression of the business case and thus, the viability of this project.

7.1 SOCIAL CAPITAL

Social capital is “an asset available to individual or collective actors that draws on these actors’ positions in a social network and/or the content of these actors’ social relations” (Gabbay and Leenders, 1999). The social network of a founder is part of the social capital of a firm, consisting of actors and relationships with these actors (Hansen et al., 2000; Rothschild and Darr, 2005; Schwartz and Hornych, 2010; Tötterman and Sten, 2005). Commonly, a network can be divided into nodes and ties. Nodes can be defined along different organisational levels, like firms (Powell et al., 1996), divisions (Tsai, 2002), projects (Van Rijnsoever et al., 2015), or individuals (Cantner and Graf, 2006). The type of actor can also be used to categorise nodes: large firms, small firms, universities and government. The type of tie varies mainly along four dimensions (Eveleens, C. P., et al., 2017): the content (= what is exchanged), the formality (=how is it exchanged), the strength of the relationships (=how reliable is the exchange), and the form of the relationship’s communication (=how is the exchange discussed) (Eveleens, C. P., et al., 2017). So, ties represent some sort of relational characteristic, like “friendship, cooperation, power, and exchange of advice, assets or information” (Hoang and Antoncic, 2003; Slotte-Kock and Coviello, 2010; Witt, 2007). In addition, the position of the node is also a dimension that should be accounted for in describing social capital (Nahapiet and Ghoshal, 1998). As well as the level of homogeneity in the network (Ahuja, 2000; Ruef et al., 2003): are nodes completely different or similar? “This dimension refers to how similar the two actors are in terms of what they know, have and think” (Stam et al., 2014). The potential value of social capital lies “ in the opportunity for actors to access information and resources in their social network” (Maurer, I. and M. Ebers, 2006). Strong ties can provide many benefits because of trust and induced favours, and include “friendship, gratitude, and respect (Granovetter, 1973). However, these ties are costly to maintain (Eveleens, C. P., et al., 2017). Weaker ties can be valuable as they are “relatively cheap to maintain and they usually connect actors in different contexts holding different information” (Eveleens, C. P., et al., 2017), and therefore, offer access to to new pieces of information (Cantner and Graf, 2006; Granovetter, 1973). Because research suggests benefits from both types of relationships, it is advised for start-ups to develop a mixed balance between strong and weak ties (Stam et al., 2014; Uzzi, 1997). Additionally, these ties can also serve “as external endorsements by suggesting that the start-up has earned positive evaluations from other knowledgeable actor” (Baum and Silverman, 2004). In more detail, (Baum et al., 2000) has found that start-ups able to establish upstream alliances with universities and other knowledge expertise institutions, as well as downstream alliances with pharmaceutical, chemical, or marketing companies at the time of founding “exhibit significantly higher performance growth during their early years”.

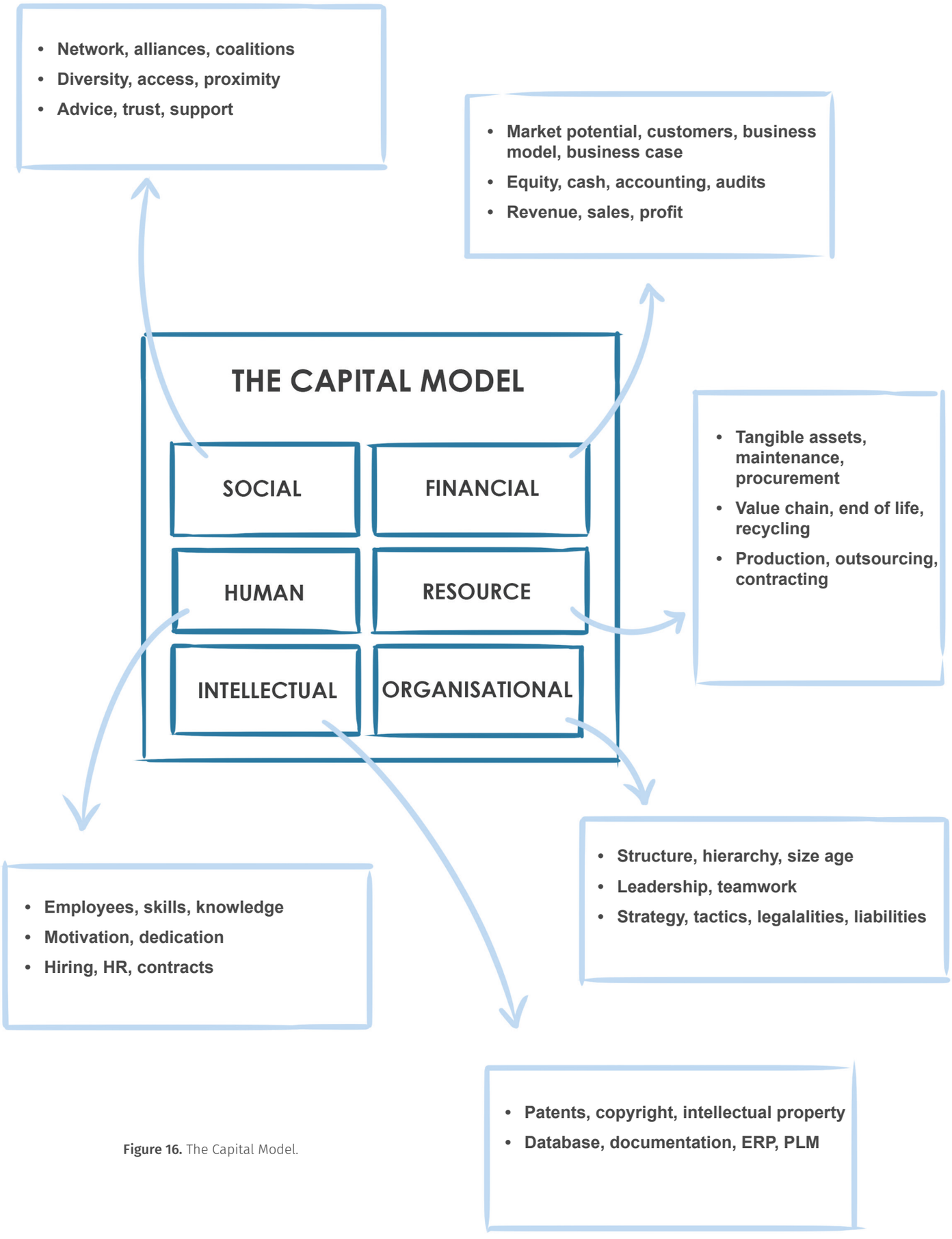

Figure 16. The Capital Model.

First, in these chapters the social network necessary to execute a specific phase is discussed. More specifically, it is indicated which stakeholders are relevant to the successful development in that phase and what kind of relationship with these stakeholders should be established. **Second**, these relationships are detailed in such a way that it becomes clear what the trade-off is for all actors in the relationship. **Third**, specific parties will not be suggested to fulfil the necessary stakeholder roles. Rather, generic descriptions are provided that should be used as guidelines to find the suiting real-life party that can fulfil the specified role description. What will not be discussed is how these actors are targeted, attracted, and secured. Neither will systems that manage stakeholders and actors in a business network be discussed. As these do not fit specified research goals.

7.2 HUMAN CAPITAL

"Human capital can be defined as the accumulation of personal attributes (i.e. knowledge, abilities, personality, health etc.) that allow human beings to function" (Peña, I., 2002). This accumulation is "throughout [the] cognitive development" of people (Jayawarna, D., et al., 2014). Additionally, education, business experience, level of motivation, and attitude are also part of human capital (Peña, I., 2002). As well as skills (Becker, 1964) and learning behaviours (Roberts, 2001). Firms are more likely to succeed when entrepreneurs have occupied a management position in a former company (Cooper et al., 1989; Stuart and Abetti, 1990; Doutriaux and Simyar, 1987). Human capital "begins to shape entrepreneurial potential years before individuals consider setting up a business venture" (Jayawarna, D., et al., 2014) and therefore, parents have a significant influence on future entrepreneurs (Athayde, 2009; Zellweger et al., 2011). Nowadays, human capital is seen as an important factor in achieving success as a firm (Peña, I., 2002). However, the question remains as to what kind of and how much human capital should be acquired to create a successful firm.
In these chapters, the human capital analysis will cover one aspect: the team necessary to fulfil the suggested actions. The necessary members, competencies, and experiences are described that will be beneficial for a successful execution of each of the phases. What will not be discussed is how these team members and these competencies should be attracted. I feel that this is a better assignment for someone educated in Human Resource Management. Additionally, I will not go into detail into employee contracts, past employment benefits, or how to assess a team member for the same reason. In my opinion, a description of the necessary competencies is sufficient to provide enough guidance for the company to successfully execute a phase.

7.3 INTELLECTUAL CAPITAL

Intellectual capital is "the sum of everything everybody in a company knows that gives it a competitive edge" and "create wealth" (Stewart, 1997). Intellectual capital can be divided into two categories: "codified" (Cowan, David and Foray, 2000; Kogut and Zander, 1992) which is knowledge structured in rules and relationships which makes it easier to document and communicate, and "tacit" knowledge (Cowan, David and Foray, 2000) which is knowledge that is not codified and resides in people, routines, and institutions, and is therefore more difficult to transfer and communicate (Kogut and Zander, 1992; Levitt and March, 1988). Especially in high-tech companies, intellectual capital is used to great advantage. Either by defending and capitalizing on what is known (i.e. through patents and intellectual property rights) or by keeping highly-priced information a secret to secure a monopoly. Intellectual property protection for newly developed products and processes can offer significant benefits: a firm with a patent is in a favourable position to obtain complementary assets and skills (Pisano, 1990), is more likely to obtain VC financing and willing partners to support

commercialization activities (Kenney, 1986; Lerner, 1994), and Silverman and Baum (2002) find a positive relationship between the number of pending patent applications that a biotechnology firm possesses and its survival chances (Baum, J. A. C. and B. S. Silverman, 2004). The exhaustive literature review of Centobelli, P., et al. (2017) conclude that "the process of knowledge management can have a positive impact on seven different start-up's performances: (1) economic and financial performance; (2) environmental performance; (3) human performance; (4) market performance; (5) organizational performance; (6) relational performance; and (7) technical and technological performance" (Centobelli, P., et al., 2017; Peña, I., 2002).

First, the intellectual capital analysis focusses only on codified knowledge, as tacit knowledge is near impossible to define let alone analyse. **Second**, this chapter describes the "mix"[36] of different types of intellectual property protection (**Appendix 4**), when these different types are relevant. Their relevancy is based on the possible use of such a protection method. Not all methods are applicable to this case, and are so, not included in the IP Mix. Which types exist and what their functionality is can be found in Chapter 14.5. What will not be discussed is how and which Knowledge Management System ("information system and/or a managerial practice adopted to support companies in creating, storing, transferring, sharing or applying knowledge." (Cerchione, Esposito, 2017) should be used. Additionally, specific intellectual property defending mechanisms, like patents or trademarks, and how to acquire them are not discussed, as enough information can be obtained by looking online or by consulting experts.

7.4 ORGANIZATIONAL CAPITAL

Organizational capital is that what indicates how a firm is organized: structurally, hierarchically, strategically, legally, and culturally[37]. When the organizational capacity of a company is at its best, the company has the "capacity to adapt quickly to changes and the ability to implement successful strategies" (Peña, I., 2002). Additionally, common business elements like a business model canvas, vision and mission statement, and strategy objectives are included in the organizational capital as well. As these elements define how a firm behaves. Other characteristics, like age, size, and maturity should also be seen as aspects of organizational capital. These characteristics can be laced in three, distinctive periods: ex-ante, gestation, and consolidation (Peña, I., 2002). First, the ex-ante period is defined as the moment in time where the entrepreneur develops an idea and decides to create a company. Second, the gestation period is defined as the period in which a company is started. Third, the consolidation period is entered when things calm down in comparison to the gestation period.

First, in each of the phases a suggestion is provided that shows the company structure of departments and teams. It should be taken into account, that an overlap between information can occur between the human, social, and organizational capital chapters due to their linked character. In human capital the competencies needed to execute the phases is discussed, which are placed in context by the organizational chapter. Additionally, the social capital chapter describes the necessary stakeholders that should be involved in the development process, whereas the organizational capital chapter places them in structural context. **Second**, a perspective is provided on the suggested strategic and tactical goals that the company should attain to. Bear in mind that strategy and tactics are in fact intellectual capital goods, yet are described in and belong to the organizational capital chapter. **Third**, a description is provided on the age and maturity necessary for each of the specific phases. What will not be discussed is the legal form of the company during any of the three phases. Additionally, legal measures (i.e. company by-laws, etc.) are not included as these do not fit the goal of this assignment.

[36] "IE-mix" (Intellectual Property mix): a concept borrowed from a patent advisor of the Netherlands Enterprise Agency (Rijksdienst voor Ondernemend Nederland, RVO) as discussed in a workshop (Basis van het Intellectueel Eigendom, 6-11-2018, RVO, Utrecht.

[37] Personal definition, as definitions found in literature did not suit the objective of the Capital Model.

7.5 RESOURCE CAPITAL

Resource capital is the collection of assets, asset management, product life-cycle management practices and systems, and sustainability policies and processes[38]. Whereas organizational capital focusses predominantly on intangible assets, like structure and culture, resource capital focusses on tangible assets (as well as the accompanying intangible processes). Especially in high-tech companies, assets can become costly investments to obtain, maintain, and repair. Think of airplanes for an airline company.
In this case, certain assets are necessary to execute the phases and therefore, these assets are discussed as the only aspect. What will not be discussed is how these assets are obtained, maintained, and repaired. Additionally, no focus will be laid upon the sustainability of the company or its processes. First, the goals of the first phase should be achieved and the viability of the company should be at least somewhat guaranteed before sustainability can become a major topic. Additionally, it is in my personal belief that in the case of sustainability, it is far more important to do than to talk. If the company is of the opinion that sustainability is important, also in earlier phases, then my suggestion would be to act upon this feeling of importance.

7.6 FINANCIAL CAPITAL

Financial capital is one of the most dominant resources. Higher financial capitalization increases the possibilities to pursue a wider choice of strategies, positively influencing the performance of a company (Duchesneau and Gartner, 1990; Cooper et al., 1989). Big, financial investments allow the company to open doors needed to progress the start-up and increase its performance (Megginson and Weiss, 1991). However, most start-ups do not possess such financial resources and thus, Venture Capital firms (VCs) can aid in providing the necessary financial (and even managerial and social) resources (Baum and Silverman, 2004). Even more so, start-ups that are backed by VCs "generally tend to be more successful than those that do not receive VC support" (Gompers and Lerner, 2004; Chemmanur et al., 2008; Bertoni et al., 2011)
First, financial capital is used to describe the necessary investments needed for the execution of the suggested actions. **Second**, through the financial capital perspective, a look will be taken to the business model (i.e. the application) of the solution and describe the corresponding stakeholders and customers. **Last**, in these chapters an overview of the business case is provided elaborating upon the possible revenue that can be attained in the specific phase. What will not be discussed is the manner of attracting the necessary financial capital. Numerous routes exist, from VC's to subsidies to family loans, and a lot is written, told, and discussed on this topic. Even more so, attracting financial capital is quite a practical 'assignment', simply put: it's something that just needs to be done. Due to these reasons, I do not think I can add more value than what is already known within the company. Additionally, I do not think that figuring out how to attract financial capital suits the higher goal of this assignment.

[38] Personal definition, as no useful definitions were found in literature.

8. COMPANY ASSESSMENT

Around 2009, Pim first thought about the idea and in September 2017 he contacted two people to join in and further the development of the concept. At the moment of writing the company has not officially been founded yet: we are going to refer to it as if it were however. It is rather in the early beginnings with no formal structures in place. To be able to develop an implementation plan for the solution, the company must be analysed and discussed as well. The implementation design is, because of this analysis, able to factor in any shortcomings or limitations which improves the overall quality of the design. The Capital Model will be used to describe the characteristics of the company.

8.1 THE CAPITAL PERSPECTIVE

8.1.1 Social capital

From a social capital perspective the company is rather limited as no formal relationships have been established. Rather, the company is, partly due to this research project, starting to form relationships with relevant stakeholders in the industry. However, employing these relationships is still ineffective as no agreements or deals have been made. In all cases, the stakeholders can not expect anything in return for their guidance, and are therefore free to deny help (which will occur when other priorities demand attention).

8.1.2 Human capital

From a human capital perspective the company is rather limited as well. Three people are involved in the project, one former electrical engineer with business experience in founding and managing companies, one laboratory assistant with some healthcare and gastrointestinal disease knowledge, and one design engineer with no prior working experience. The competencies available in the company are quite broad, but knowledge and experience lacks in some vital aspects of this project. There is no knowledge or experience present regarding CRC, clinical validation, medical business development, biomarker identification and development, algorithm-based statistics and pattern recognition, or medical product development in general. Similarly, no competencies in these fields exist and must be either attracted through external talent or learned and acquired through extensive training and research.

8.1.3 Intellectual capital

From an intellectual capital perspective the competitive position of the company is also not strong enough for such a project. Even though it is highly unlikely that this idea gets stolen when in such an immature stage, the company must not overlook the importance of intellectual property protection. Currently, no patents belong to the company and no other measures of IP protection have been employed. In the implementation design suggestions are provided to start with protecting the company's valuable IP.

8.1.4 Organizational capital

From an organizational perspective the analysis has already been made: no formal structures are in place. During this research project it has occurred a handful of times where the formalisation of the company would have been desired to make more effective use of the conversations and negotiating power in these situations. However, during this research project it also became clear that no urgent need was present for formalizing the company. The development project was not hindered because of the absence of formal structures and as such, no action was taken.

8.1.5 Resource capital

From a resource capital perspective the company has made significant efforts. As the company quickly realized the potential and use of having a prototype, the first big project was the development of said prototype. Therefore, at the moment of writing, the prototype is nearly finished allowing for

additional negotiating and convincing power in conversations with relevant stakeholders. Additionally, the legitimacy of the company and their claim is significantly improved with a prototype. Especially in the Netherlands, and even more so in the region Twente, the Dutch mentality regarding new tech can best be described as ‘seeing is believing’ (= ‘eerst zien, dan geloven’). Which is why a prototype has significant added value.

8.1.6 Financial capital

From a financial perspective the company is rather limited too. Aside from private equity from Pim, no additional funds are present at the moment of writing. Some efforts have been made to attract funds through subsidies, but this process has proven to be time consuming and demanding. It has been learned that the company must formalize and protect their IP before consulting such companies capable of attracting subsidies.

8.2 CONCLUSION

In conclusion, it can be said that the company is rather limited in its capabilities and resources. No relationships or company structures have been established, necessary talent, knowledge, and competencies are missing, as well as funds and resources. Therefore, it is vital to incorporate these characteristics in the design of the implementation of the solution to come up with a way in which these limitations do not hinder the successful adoption of the technology. In the implementation design, a development trajectory will be developed that incorporates these limitations and finds a way to gather the necessary proof nevertheless. In separate phases, the company will become able to develop the solution further and implement it as has been designated from the early conception of the solution.

SUMMARY

This part starts with the value proposition of the solution. It quickly becomes clear that the solution offers a value that is new to its intended users, the stakeholders in the Dutch healthcare system, legislators, investors, and more. The solution offers insight into the health condition of the user be measuring and analysing stool and therefore offer value as the user becomes able to monitor their health and act when deviations occur. Even more so, the eventual establishment of a database of all user's stools might be used to gather new evidence and information on the development of CRC as a disease in relation to a change in health condition. The solution might have, based on research after the implementation and use of the solution, a predictive quality for CRC. However, this quality can not be confirmed as of now with available knowledge. Such a database does not exist yet and such research has not been performed. Therefore, the value proposition is something that can only be 'proven' after development and implementation. The assumption is there, however, that such a database containing longitudinal data on a large user group will have value for the academia.

Through research a collection of relevant stakeholders has been described, including their mutual relationships and cooperation. Through stakeholder theory, these stakeholders have been categorized into different groups explaining their position in regards to influence on the development or implementation of the solution. Three characteristics have been defined (power, legitimacy, urgency) that explain how each of these groups should be handled so that the development and implementation process do not get interrupted. What becomes clear is that the Notified Body and specialists have significant influence on the development and implementation of the solution. These organisations have a legitimate and urgent claim on demanding changes to either of the processes. The Notified Body will be the representative organization responsible for approving the solution and the specialists are the collective responsible for guiding the approval and acceptance process. Additionally, the insurer should be closely monitored as well, as in practice this stakeholder can have a serious influence on both processes, while the legitimacy of their claim is highly doubtful.

In addition, based on the Dutch healthcare system and stakeholder analysis, four routes have been defined allowing for a successful implementation of the product on to the market. The first route being the consumer approach which is more feasible from a start-up perspective, as less is demanded of the company in terms of legislative requirements and resources. The second approach is through care professionals, which can become ambassadors of the new solution in negotiations with insurers. The third route directly targets the insurers, which requires a solid business case and clear cost-effective or cost-saving capabilities of the solution. The last approach targets the government through the Ministry and the NZa, which is thought to be bureaucratic and demanding.

In addition, an assessment of the company has been made to determine (in **Part IV implementation**) how the solution must be implemented successfully. The Capital Model has been developed to assess the company, which will also be used to structure the implementation design. The Capital Model consists of 6 perspectives: the social, human, intellectual, organization, resource, and financial capital perspective. Social capital is "an asset available to individual or collective actors that draws on these actors' positions in a social network and/or the content of these actors' social relations" (Gabbay and Leenders, 1999). The social network of a founder is part of the social capital of a firm, consisting of actors and relationships with these actors. "Human capital can be defined as the accumulation of personal attributes (i.e. knowledge, abilities, personality, health etc.) that allow human beings to function" (Peña, I., 2002). This accumulation is throughout development of people and include education, business experiences, the level of motivation, attitude, skills and learning behaviours. Intellectual capital is "the sum of everything everybody in a company knows that gives it a competitive edge" and "create wealth" (Stewart, 1997). Intellectual capital can be divided into two categories: codified, which is knowledge structured in rules and relationships which makes it easier to document and communicate, and tacit knowledge, which is knowledge that is not codified and resides in people, routines, and institutions, and is therefore more difficult to transfer and communicate. Organizational capital is that what indicates how a firm is organized: structurally, hierarchically, strategically, legally, and culturally. Additionally, common business elements like a business model canvas, vision and mission statement, and strategy objectives are included in the organizational capital as well. Resource capital is the collection of assets, asset management, product life-cycle management practices and systems, and sustainability policies and processes. Whereas organizational capital focusses predominantly on intangible assets, like structure and culture, resource capital focusses on tangible assets (as well as the accompanying

intangible processes). Financial capital is used to describe the necessary investments needed for the execution of the suggested actions, the business model of the solution in context, and its adjacent business case (if possible). It has been evaluated that the company, being a start-up, is limited in the amount of risk that can be taken and possibilities to employ expensive resources and human capital. Therefore, during the implementation of the solution, a plan must be established to counteract these limitations and make it possible for the company to be able to develop and market the solution.

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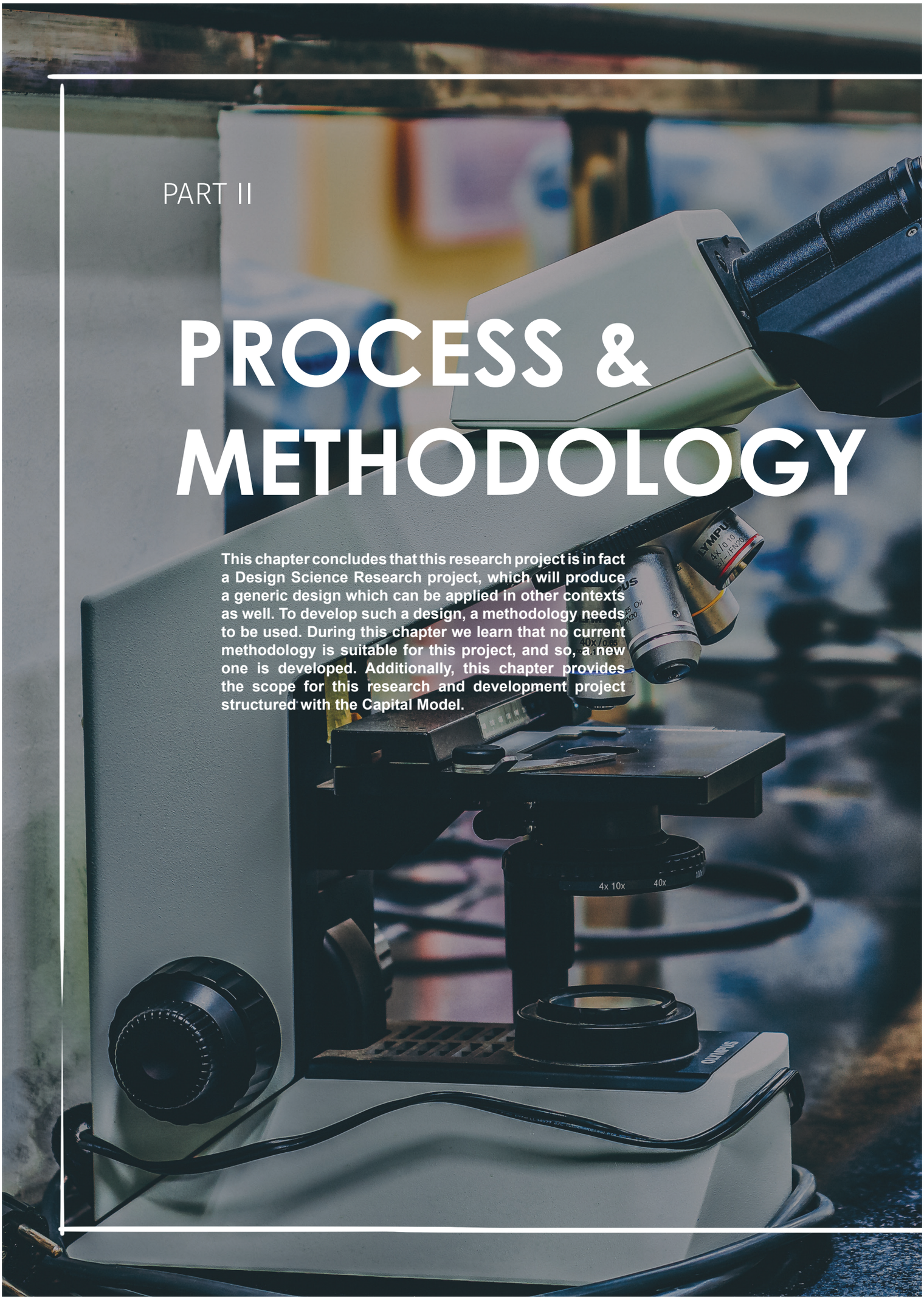

PART II

PROCESS & METHODOLOGY

This chapter concludes that this research project is in fact a Design Science Research project, which will produce a generic design which can be applied in other contexts as well. To develop such a design, a methodology needs to be used. During this chapter we learn that no current methodology is suitable for this project, and so, a new one is developed. Additionally, this chapter provides the scope for this research and development project structured with the Capital Model.


OLYMPUS

9. PROCESS & APPROACH

Early medical product development is often pushed into academic and research fields to reduce risk and bring down the costs (Rose, 2014). In this chapter, I will explain in how I will develop a solution for the problem stated in the beginning of the report. The scientific architecture behind this project is discussed and the methodology for the design and development of the solution will be explained. This chapter hopes to clarify how the solution came to be and what kind of scientific methods were necessary to achieve the result.

9.1 PROCESS GOALS

First, it is important to realize the goal of this research project. The goal of this research is to find a feasible, viable, and desirable[39] solution to the problem of CRC screening in the domestic context. Feasibility describes the practicality of the solution and considers available resources, skills and knowledge. Viability describes the profitability and the capability of maintaining this profitability over time. Desirability describes if this solution is wanted by the people it is developed for. In other words, if this solution is made (*feasible*) and it will sustain a business (*viable*), will people buy it (*desirable*)? Thus, the goal of this research is not to be extremely thorough, as it is not a literature review, but to find, explore and think about enough information to come to solution that meets the criteria. In other words, the knowledge that is looked for is "instrumental knowledge": knowledge used in a specific and direct way for action or design (Pelz, 1978). Or in other words: knowledge used to "design and implement actions, processes or systems to achieve desired outcomes in practice" (Simon, 1996).

9.2 WHY THINK IN SOLUTIONS?

As can be seen all over the world, traditional manufacturers of goods and products have started to traverse into service delivery to increase their competitive position and grow revenue. From Boldking[40] not selling razors but selling subscription packages to razors, to the Swapfiets[41] offering the usage of a bike in a subscription package so that the customer is free from issues like theft or damages. In both cases, the company is still responsible for the product they deliver, but not in the traditional manufacturer way. This change of focus is visible in almost all business markets (e.g., Antioco et al. 2008; Neu and Brown 2008; Sawhney, Balasubramanian, and Krishnan 2004; Vargo and Lusch 2004; Wise and Baumgartner 1999). The combination of goods and services (from now on called "solution"[42]), is a collection of "products and services combined into innovative offerings", "creating more customer benefits than if the good and service were available separately" (Shankar, Berry,and Dotzel 2009, p. 95). Even more so, this combination has the potential to "improve profitability through greater differentiation and thus satisfaction, loyalty, and willingness to pay" (Fornell, Rust, and Dekimpe 2010). And in many situations, it can be argued that through hybrid offerings the profitability of current offerings as well as new offerings can be increased with saving and reducing costs. These hybrid offerings often rely on smart technologies that allow the company to utilize usage data to improve and fine-tune the offerings. In light of this project, it is therefore logical to not think that the solution must be a product exclusively but to look at it like an offering, and find the ultimate configuration that will solve the problem.

[39] These three terms are often named in informal sources on design, innovation, and design thinking (e.g. as seen on https://designthinking.ideo.com/?page_id=1542 and https://medium.com/innovation-sweet-spot/desirability-feasibility-viability-the-sweet-spot-for-innovation-d7946de2183c). Due to the understandability of this concept, it was adopted to provide a framework of evaluation of the solution.
[40] https://www.boldking.com/
[41] https://swapfiets.nl/
[42] Theory and literature is taken from the Hybrid Offerings concept, but the name is changed to solution.

9.3 RESEARCH QUESTIONS

Table 7. Research questions.

	Developing a integrated system solution for early stage colorectal cancer diagnostics in a home setting
1.	How big a problem is colorectal cancer?
1.1	What is the societal and personal impact of colorectal cancer?
1.2	How many people are affected by this problem?
1.3	How is this problem currently tackled?
1.4	Who is tackling this problem and why?
1.5	How can the current solution be improved?
2.	How can you introduce a solution to the Dutch medical market?
2.1	What are the laws, regulations and ethics of the Dutch medical market?
2.2	How can the company introduce the solution to the Dutch medical market?
2.3	When should the product be introduced to the Dutch medical market?
2.4	How should the business model of the solution be?
3.	Which methodology should be used to develop the solution?
3.1	What is Design Thinking?
3.2	What is the Stage=Gate Approach?
3.3	What is User-Centred Design?
3.4	What is the effect of the medical market on the development of the solution?
4.	How can the company implement the solution?
4.1	How must the implementation be structured?
4.2	How must the solution adapt through the implementation?

The aim of this research is to develop a solution to the unnecessary late diagnosing of colorectal cancer. The new solution tries to improve the early detection of occult blood in faeces. The difficulty of this assignment is the field of application, namely medical diagnostics. The current medical world of the Netherlands can be characterized by heavy regulations, long time-to- market, ethical and privacy obstacles, and a sceptical view on the trustworthiness of new medical innovations. As this process can be quite experimental, the goal of the project is to develop a methodology that can help develop such a product for such a market by a start-up: a company that is often characterized by limitations and lack of resources. These research questions will be answered in Part V - discussion, conclusion, and recommendations. During the process of this research project, these questions will structure the knowledge gathering process.

9.4 DESIGN RESEARCH AS SCIENTIFIC BACKBONE

9.4.1 Introduction

Due to the nature of this research project and the intended goal, it is very much in line with Design Science Research (DSR). DSR is the academic conceptualization of the rather natural design process: “analyse the problem, design a solution and develop it further in cycles of testing and redesign” (Van Aken et al. 2017).

> Designing seldom is fully radical, producing a totally new product. Most designing produces a variant of a design model that fits the given assignment. For example, a civil engineer seldom designs a radically new bridge, but in most cases uses a carefully selected and well-documented type of bridge as a design model for a context-specific instantiation (Van Aken et al., 2017).

DSR focuses on improving the present through actor involvement and looks at what "can be", and therefore, the solution cannot be logically deduced from the context of the problem. Especially in the case of solutions that contain both "material and social mechanisms" (e.g. technical and human elements, which can be found in hybrid offerings, product-service systems, ...), the validity of what "can be" is harder to determine than a solely mechanical solution, due to the involvement of humans and human behaviour. In this case, the solution has to be adopted by regular people in order for it to work, and it must be trusted by healthcare providers in order for the results to be accepted. All involved actors (users, healthcare providers, insurers, the government, inspectorates, advisory boards, ...) "operate in different domains, are driven by different objectives and regulations, have different roles and responsibilities, yet execute interdependent tasks and share a commitment to patient welfare". It should not be far-fetched to claim that the human involvement in the implementation of this solution is most likely the biggest hurdle to overcome. Due to these characteristics, DSR is widely employed in engineering and medicine. Van Aken et al. (2017) also describe DSR as a "science of the average, as well as a science of the particular" with which they mean that DSR can focus on an average solution (e.g. by developing a type of bridge) for a particular context (e.g. for a river with unstable shores). Which is in line with the goal of this research project. In this case, the average can be found in the field of diagnostics where numerous solution already exist for discovering blood in faeces (most important marker for diagnosing CRC, will be discussed in detail in Chapter 2), and the particular can be found in the domestic application of the test and as of now, only 2 other examples provide a similar solution (more information, and especially why these solutions do not suffice, can be found in the **Appendix 5** competition analysis and **Appendix 6** patent research).

9.4.2 Results and content of a DSR project

The final product of DSR is a generic design (and a DSR article, will be discussed later) that can be justified with "pragmatic validity" or whether the implementation of the solution produces the desired outcomes. This generic design should be "well-tested, well-understood and well-documented" and must be field tested to establish the pragmatic validity (Van Aken et al. 2017). Following CIMO-logic (Denyer et al. 2008), this design proposition can be stated as "for this problem-in-Context it is useful to use this Intervention, which will produce through these Mechanisms this Outcome." This will also be used to define and evaluate the design proposition. This achieved through a DSR project consisting of two components, one focused on explaining the context of the problem and why it needs solving (describing) and one on developing a solution and showing that it works (designing and testing) (Van Aken et al. 2017). These two are not two separate phases of the project, rather intertwined activities that benefit from each other if practiced simultaneously and continuously. Additionally, these two components are "unequal in length and effort" which is depending on the field of the problem and the experience and skills available for the designing and testing of the solution. In this case, more limitations exist in the first component as I have no significant medical or medical engineering knowledge and expertise. I am more familiar with the design and development of solutions, but I also lack knowledge, experience and skill in testing solutions. Therefore, the most effort and time is spent on gathering the necessary knowledge to enable the design and development of the solution.

9.4.3 Contents of a DSR article

A DSR article (the summation and conclusion of a DSR project and also a mandatory deliverable of this master's assignment) must be equipped with the following elements (as proposed by Van Aken et al. 2017): the article should contain a "generic design for an action, process or system dealing with an

authentic [...] problem or opportunity. It is preferably well-tested, well-understood and well-documented and supported by a design proposition [...]: the problem in context, the design, expected outcomes and the material and social mechanisms producing these outcomes in the intended application domain. The design is to be described in sufficient detail that practitioners can use it as a model in their designing. Of additional interest will be information on the design process, its inputs (problem and context analyses, relevant literature), possible design principles used, decision-making on design adoption, and implementation and learning curve issues. Feasible design alternatives to the design also can be of interest for both academics and practitioners as they can highlight the unique or attractive properties of the design". Additionally Van Aken et al. (2017) defines criteria for the assessment of a DSR submission. However, as these were deduced from everything mentioned above and more, it is not necessary to mention them here. So, they can be found in the **Appendix 7**.
The practical and academic relevance of a DSR article depends on the quality of the generic design. The better the generic design is, the better practitioners can design and develop the implementation of the solution into a working system, which is quite logical. The academic relevance depends also on the quality, as the generic design can be used for teaching and research purposed. The generic design can become a challenge for others to come up with a better solution or use the design to develop a better version. Additionally, further implications of the generic design might not be understood fully, allowing for additional research and discovery which may be worthwhile (Van Aken et al. 2017).

> A good design is a pair of shoulders upon which the next generation of researchers can lean (Van Aken et al., 2017).

9.4.4 Validity of a DSR project and its outcome, and the validity of the process

Van Aken et al. (2017) explained beautifully that the justification or validation of the generic design (i.e., the solution to a problem) is not trough the justification of the process, but though justification of the outcome. In other words, the outcome of a DSR project is justified if can be proven that it solves the problem, that "it works". However, this is a grand contradistinction from the intended goal of this master's assignment. Namely, displaying my personal capability to develop a solution in an academic manner. Therefore, it is important to clarify that in this case, two validities exist. One pragmatic validity of the generic design as assessed through the practice of DSR, and one process validity as demanded through the university as an assessment of my developed capabilities as academic industrial design engineer. **First**, testing the validity of a solution can be done by either testing the solution "on paper" or by building the actual system, and the manner of testing is determined by the degree "to which the design determines system behaviour and performance" (Van Aken et al. 2017). In other words, how much of the total solution performance is dependent on the design of the solution and how much is dependent on the human interaction necessary to implementation the solution in the real context. A material system, a machine, can be built and tested quite easily. The social mechanics, like human interaction with the machine and a change in behaviour, are more difficult to validate. Therefore, it is necessary to determine which parts of the solution are "strong mechanisms" and which are "weak mechanisms" and thus determine how they must be tested. "Strong mechanisms" are mechanisms that can easily be understood, are "invariant, universal" and link cause with effect (Van Aken, 2014). "Weak mechanisms" are mechanisms that exist in the social domain of human behaviour and are somewhat regular and pattern-based, but often vary, fluctuate, and influence but not determine human behaviour (Pajunen, 2008; Hedström and Ylikoski, 2010). As Van Aken at al. (2017) do not mention specific examples of how to test validity of a DSR project and its outcome, as they state that this is heavily dependent on context, I am going to devise methods for each of the subsystems separately based on the mechanisms involved. This evaluation of validity will be performed in Part V of this research project. **Second**, the validity of the academic process, or in other words, the assessment of how I went through this process will be discussed on the day of my colloquium. To provide my interpretation and assessment of the process, Part V will discuss the validity of the process as seen by me.

9.5 SCOPE & ASSUMPTIONS

As the topic of this design research assignment is quite broad, a lot of emphasis will be drawn on the scope of the project. The intended goal of this project is not to cover all topics and collect all information, but to include enough information to develop a proper solution. Below is a collection of all elements that are outside the scope of the project. These collected items are topics/subjects/areas of possible interest that are excluded from the project with specific reasons. These topics and reasons why they are excluded are addressed at the proper chapters in this report, and are collected here as overview.

9.5.1 Scope - a combination of goals, limitations, and assumptions

The scope can roughly be summarized as a debate between thoroughness versus role and goals. My role during this project is to develop a solution and an implementation plan. Therefore, numerous subjects have to be explored and discussed in order to be able to do so. When significant additional efforts and resources are necessary that skew the focus of this research, then the edge of my scope has been reached. Additionally, if a certain competency is necessary to further explore a subject which I do not possess and does not fit my role during this project, then as well, has the edge been reached. Even more so, if the thorough exploration develops questions that are new fields of research or perhaps even a graduation thesis on its own, then the edge of my scope has been reached. To illustrate this, three examples[43] are given: **First**, one edge of the scope has been reached in the communication of the results to the user. The results must be able to show the gravity of the results in proportion to the health condition in such a way, that when something is wrong the user acts accordingly. A situation could occur that the results are interpreted too heavily and the user panics unnecessarily. Or, the results are not taken too seriously unnecessarily worsening the health condition of the user. In other words, a fine balance must be found between the gravity of the results and the gravity of the message communicating the results to the user. Even though this question is relevant and very interesting, it is outside of the scope of this research project. Such a question should be answered by someone with knowledge in communication sciences or psychology. **Second**, another edge of the scope can be found in the development of the medical/chemical technology necessary for establishing the measurements of the faeces of the user. I will provide insight in what kind of parameters could be measured that can provide an indication of the user's well-being, but the specific technologies to measure these are outside of my scope. This holds also true for other specific parts that can fulfil the functions of all the subsystems. I could select parts that are able to perform these functions, but knowing that someone with a thorough understanding of electrical components, chemical processes, system and control technology would deliver a significant better design, my efforts would be futile. **Third**, the solution must be clinically validated in a specific phase of the implementation phase to fulfil its potential. European legislation dictates us that the company must develop such a validation trial itself. The implementation design would offer significantly more specific and detailed insight if the resources and effort necessary for such a validation would be known. However, developing a clinical validation trial is a profession in itself with competencies I do not possess. My role dictates me to know enough to be able to advise the company successfully, but not to become a specialists in one of the adjacent fields of research. I am an industrial design engineer, not a chemist, doctor, or business specialist.

To provide some structure, I will employ the Capital Model (Part I Chapter 7) and look at the scope through six perspectives: social capital, human capital, intellectual capital, organizational capital, resource capital, and financial capital. From a **social capital perspective**, I will detail the target group and the relevant stakeholders of the solution in the different phases of implementation. Therefore, specific suggestions for possible partners are not included in the scope of this research project. This also includes the type of relationships that must be attained with these partners or the contracts that are necessary to establish such relationships. Additionally, I will not be looking beyond the Dutch medical device healthcare market even though, from a business perspective, this would be wise. Reason for this is that the legislation between healthcare markets, differs so significantly[44] that understanding these differences and developing implementation strategies for all these markets would take up too

[43] Examples from later phases of the solution and implementation design.

[44] Even though the backbone of healthcare device legislation is all based and dependent on European legislation.

much time. From a **human capital perspective**, I will discuss the competencies necessary to execute the implementation phases. I will not be looking at ways to attract, scout, or contract these competencies. As that is a better research project from someone with a human resource management background. From an **intellectual capital perspective**, I will discuss what kinds of intellectual property should be established and protected, and how these can be used in a strategic and competitive manner. Additionally, I will shed some light on what kind of processes can be used to establish such IP. What will be outside the scope of this assignment is the specifics of patents, trademarks, and rights. Additionally, I will not develop an IP strategy, detailing in which countries a patent should be applied for or how many designs should apply for design right. These specifics are something that the company should decide upon. From an **organizational capital perspective**, I will take a look at the company structure and the accompanying strategic goals during the different phases of implementation. The company structure will be defined conceptually: in functions and liabilities. Specific legal forms are not included in the scope of this research project. These are not relevant for the solution or implementation design. Other specifics, like by-laws or the distribution of shares, are not included in this project as they are irrelevant to the goal of this project and something that the company must decide upon itself. From a **resource capital perspective**, an indication will be provided detailing the resources necessary to execute the different implementation phases and achieve the set goals. How these resources are acquired (e.g. procurement), maintained (e.g. maintenance engineering), or used (e.g. allocation) is not discussed as it does not fit the research goal. Additionally, such perspectives can be answered more thoroughly by people specialized in these topics. Additionally, no look is taken at the sustainability of the development of the solution or the product life-cycle of the solution as these too do not fit the research goals. From a **financial capital perspective**, a look will be taken at the necessary investments (predominantly based on the human and resource capital) and the business model of the solution (based on the social capital). What will not be discussed is how these investments can be acquired or how they must be processed (e.g. accounting).

9.5.2 Limitations

The main limitation is centred on the length of this assignment, and thus the amount of effort that can be put into this project, versus the efforts of the company during the same time. What I mean can best be explained through the black-box technology example: during this research project I made suggestions to the company about the biomarkers in faeces that could be measured which provided useful results. The company is, at the moment of writing, still involved in the development of the technology capable of measuring these biomarkers. Therefore, I am unable to validate if these biomarkers can be measured and unable to determine the sensitivity and specificity of these measurements, and thus the efficiency of the system and thus, its value to the user. Even more so, I am unable to validate the solution and implementation design, the target group, the business model, and much more, due to the 'future' aspect of this research project. I circumvent this issue by discussing the solution and the implementation with experts.

9.5.3 Assumptions

In addition, I would like to reiterate the main assumption of this research project. Even though this has been mentioned before, I think it is important to stress that I will not spent efforts in developing the technology necessary for providing the measurements on which the entire solution is based. Simply put, I treat the inner workings of the solution as a black-box that performs as intended. The company is currently still enveloped in developing this technology, on which I cannot wait.

10. METHODOLOGY

As can be deducted from the titling of this chapter, DSR is not the methodology that on its own is going to produce a feasible, viable, and desirable outcome for this research project. As Van Aken et al. (2017) mention, "no straightforward approach exists for establishing the material and social mechanisms producing the outcomes and performance of a generic design. Neither is there one for gathering evidence on how these mechanisms affect outcomes and performance". The authors state that the entire process is a collection of methods, methodologies, experiences, skills, expertise, reasoning capabilities, understanding of the theory and much more that combined result in an outcome. Therefore, a look has been taken at the available and known design methodologies that can structure the development process of this solution. Structuring this process will improve the quality and thus the chances of successful implementation and is therefore highly advisable.

10.1 METHODLOGY-BASED DESIGN

When selecting methodologies, numerous other examples and depictions exist. From older examples (e.g. Hybs & Gero (1992) or Andreasen (1987)) to more recent methodologies (e.g. Reymen (2006) or Pahl & Beitz (2007)), a lot has been written. To be able, to select the most adequate methodology for the development of this solution, a careful analysis must be made of all available options. Some criteria have been established to compare methodologies to each other. These criteria have been established based on the intended goal and the context of this assignment. **First**, the methodology must have clear user/patient focus as this the main focus of the medical industry in which this solution must operate. **Second**, the methodology must be structured and deliver a result that is evidence-based. Structured so that it becomes able and attainable to transform this result into a project that can apply for CE-marking in the future. The output of the model must be evidence-based, to find common ground with the applicable stakeholders and convey a form of trust and legitimacy. **Third**, the methodology must practical and applicable. The process of developing this solution must be finished within the given time of this project and therefore, it must not take unnecessarily long or be to complex. **Fourth**, the methodology should deliver an output that can be transformed into a prototype. As mentioned before, the medical industry has a strong focus on making informed decisions and trusting on proper, scientific evidence and therefore, a pilot study where the solution is tested is inevitable. Therefore, the methodology should deliver a result that can be transformed into a prototype that can be used to perform such a study. **Last**, the process of the methodology should be repeatable, so that later versions of the solution do not require another methodology which only adds unnecessary complexity to the project.

10.2 METHODOLOGIES

Methodologies that were considered are methodologies that are, either already used in the medical device development industry, or, methodologies that I am familiar with which can be adapted to the context of this research project. However, that does not suggest that other methodologies[45] would not suffice or that other methodologies do not exist. The methodologies found seemed most appropriate. Methodologies that were taken into account, are the User-Centred Design (UCD) process (Norman, 1986), the Design Thinking methodology (Gordon, 1961; Osborn, 1963), and the Stage-Gate process (Cooper, 1986). **First**, studies have pointed out that many healthcare implementations failed due to requirements being assumed and not sourced by actual users (Rahimi & Ibarra, 2014). User-centred design is methodology that focusses significant effort on involving the user and understanding the user's perspective during the entire development cycle of a project. UCD is a collection of numerous methods and tools that can aid in understanding the user's needs and developing a solution that addresses these needs (Rahimi & Ibarra, 2014). In addition, UCD is also promoted by the regulatory standards as the methodology to develop medical devices (Privitera, 2017). Unfortunately, for UCD you need users which is a problem for a radical innovation that does not have users. So, also UCD cannot be used for the development and design of this solution. **Second**, Pietzsch et al. (2009) suggest that the stage-gate development process

[45] Integrated product development was mentioned often as well. However, due to practical reasons I was unable to include this methodology in this process: no literature was accessible.

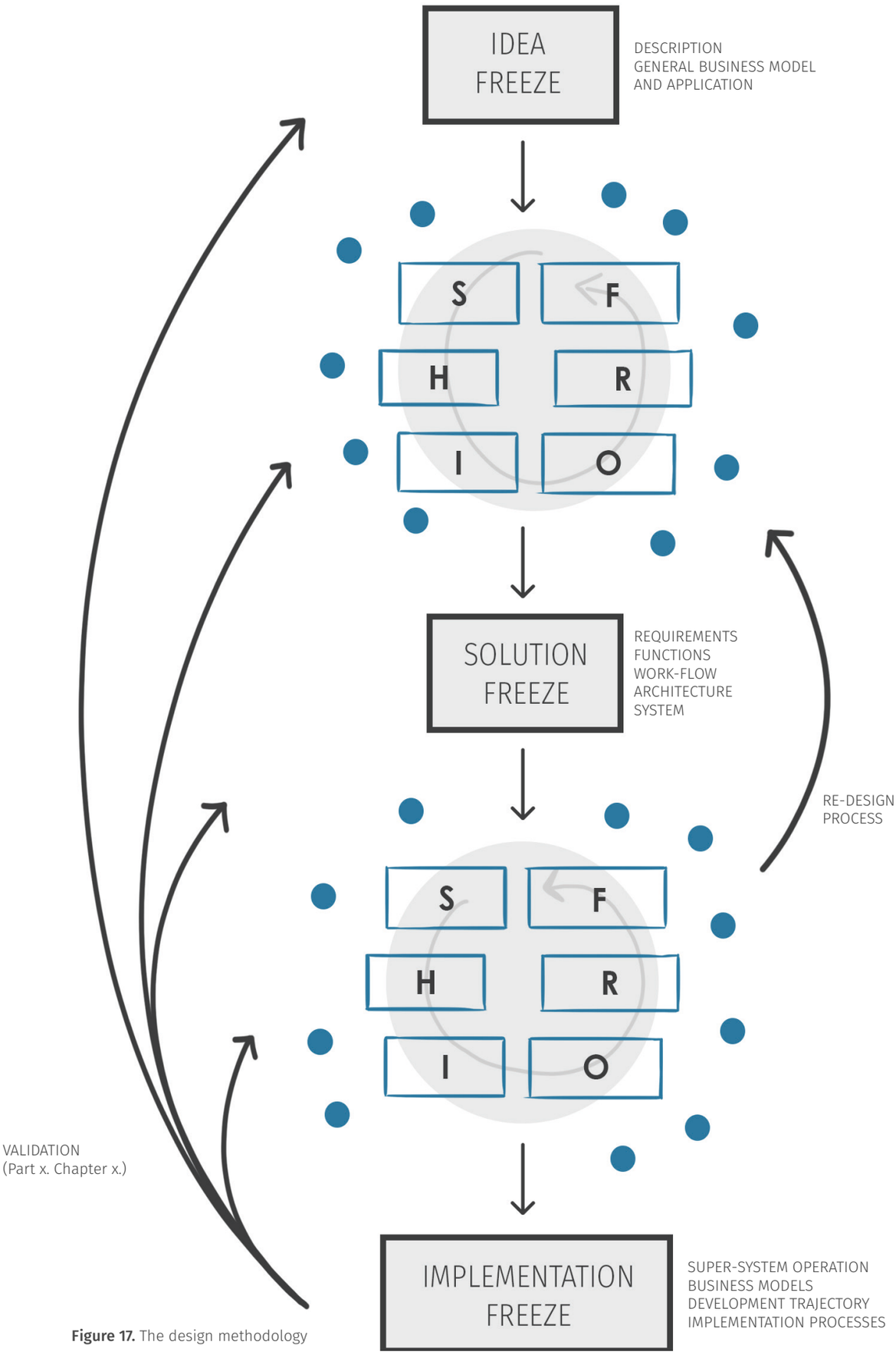

Figure 17. The design methodology

is the predominant model used in the American medical device industry, which is an indirect result of the influence of FDA regulations. Which is interesting, as user-centred design has also been called the most common methodology for medical device development. The stage-gate process is a model that divides the development process of a new device in multiple phases and incorporates gates that test, through a set of criteria, if the preceding phase has been completed sufficiently before advancing to the following phase: allowing for the development process to be managed. In the stage-gate approach a phase is completed and assessed before the next phase of the development project is started. This implies that time and financial resources should be available to complete phases before starting another. Unfortunately, this methodology does not seem as a viable option as logically, the start-up does not have access to these kinds of resources. A start-up is limited in resources and competencies.
Third, Design Thinking is a strategy that focusses on a thorough understanding of a given problem, using a human-centred approach to develop ideas quickly. Design thinking aims to turn problems and a deep understanding of these problems into viable business strategies and new, valuable products and services (Brown, 2008; Dorst, 2011). The design thinking process is characterized by three phases (Brown (2008) calls these "spaces"): "inspiration, ideation, and implementation". This process is milestone-based and circular. When repeated, the direction of the project is more refined, to improve the final result (Brown, 2008). However, Design Thinking does not offer the guided structure necessary for the development of such a complex product in such a highly regulated industry.
In conclusion, none of these methodologies were applicable for this project. Therefore, another methodology has been developed, incorporating elements from all other methodologies.

10.3 THE DEVELOPED METHODOLOGY

So, it can be concluded that neither of the proposed methodologies is suitable for or applicable to this specific design research project. So, another methodology must be developed that is applicable to the development of this solution. The developed methodology is a combination of the declined methodologies infused with the capital model[46]. The methodology combines stages from the stage-gate approach with the user-centric vision of UCD. The model follows a stage-gated approach whereby the idea is 'freezed' before the solution can be designed, and the solution is 'freezed' before the implementation can be developed. This is due to practical reasons. As figuring out how something can be implemented in the real world can only be done when the thing that must be implemented is clear and fully established. However, as in most design trajectories, the development is a cycle rather than a clear cut route. Even though this model suggests that the development of the solution and implementation followed a linear path, in reality these divisions are much more vague and undetermined. To illustrate this, feedback loops have been added to the methodology that show that even during the design of the implementation, the solution is susceptible for change. The design freeze occurred in the early stages of this design research project. Around that time, the company settled on the idea and I established a proper description necessary for starting this research. The feedback loop between the implementation design and the solution design was part of the process and can be seen as a re-design cycle. The feedback loops after the implementation design freeze are not part of the design process, but rather from the research process. As these feedback-loops are addressed in the validation of this project (**Appendix 2** and Part V). Between the 'freezes', the capitals were researched and solutions were developed and designed. Before the solution freeze, requirements were defined which guided the development of functions and the function work-flow: the order of functions in the (super)system context. This also occurred in a cyclical/reiterative manner and is definitely not a linear path. This design process is structured through the Capital Model. The CM provides a framework with which the solution and implementation can be designed. Additionally, the model can be used as a scope when looking for and discussing with experts and or other external sources. When a part of the design is under development that originates from the financial capital perspective, then an expert must be found in the medical device industry with knowledge on the financial aspects of the super-system. Even more so, experts and specialists can evaluate and assess if the literature review has been sufficiently thorough.

[46] Will be discussed in Part I Chapter 7

SUMMARY

This part focusses primarily on the academic approach to the development of the solution. Research questions have been established that guided the analysis phase in which information was gathered to understand the context and to become able of developing a solution that is feasible. These research questions focussed on the Dutch healthcare system, colorectal cancer from both the individual and the societal perspective, the methodology necessary for the development of the solution, and how the solution can be implemented. After establishing research questions, it became clear that the goal of this research was in line with Design Science Research and that the solution must become a 'generic design', a design that is translatable to other contexts to become valuable for the academia. DSR has also been used to evaluate the solution and validate the results of this project. Additionally, this part also discussed the scope of this research, structured by the previously develop Capital Model. Generally speaking, the scope signifies the role of the author during this research project as a generalist: someone responsible for the system design of the solution and relation to the super-system context, not the person responsible for the actual measuring and communication technology. In other words, functions have been defined and placed in context, but how these functions will be executed is the responsibility of others. In addition, the author had to assume that the company was able of developing a system capable of measuring and analysing stool to such a degree that the designed business model (Part IV) is feasible. Even more so, the author was limited due to time and available opportunities to test the conceptual design 'on paper' in the real world through prototyping. Therefore, in Part V, the validation can only be done theoretically.

Three methodologies have been considered to be used for the development of the system. However, neither of these fulfilled the established criteria or were feasible, and so, another methodology had to be developed. The developed methodology is a combination of the declined methodologies infused with the capital model. The methodology combines stages from the stage-gate approach with the user-centric vision of UCD. The model follows a stage-gated approach whereby the idea is 'freezed' before the solution can be designed, and the solution is 'freezed' before the implementation can be developed. This is due to practical reasons. As figuring out how something can be implemented in the real world can only be done when the thing that must be implemented is clear and fully established. However, as in most design trajectories, the development is a cycle rather than a clear cut route. Even though this model suggests that the development of the solution and implementation followed a linear path, in reality these divisions are much more vague and undetermined. To illustrate this, feedback loops have been added to the methodology that show that even during the design of the implementation, the solution is susceptible for change. Through the development of the methodology, it became possible to design and validate.

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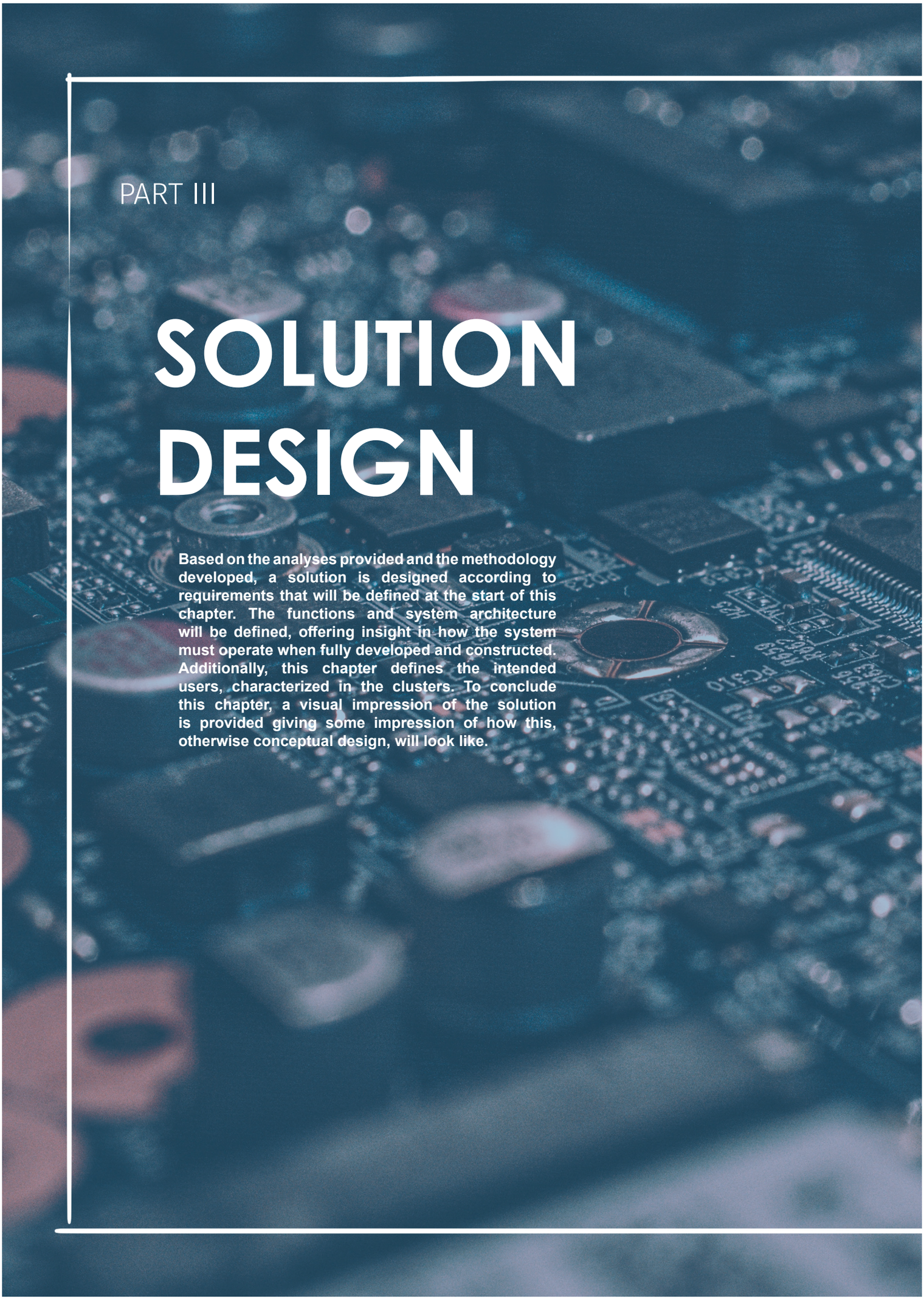
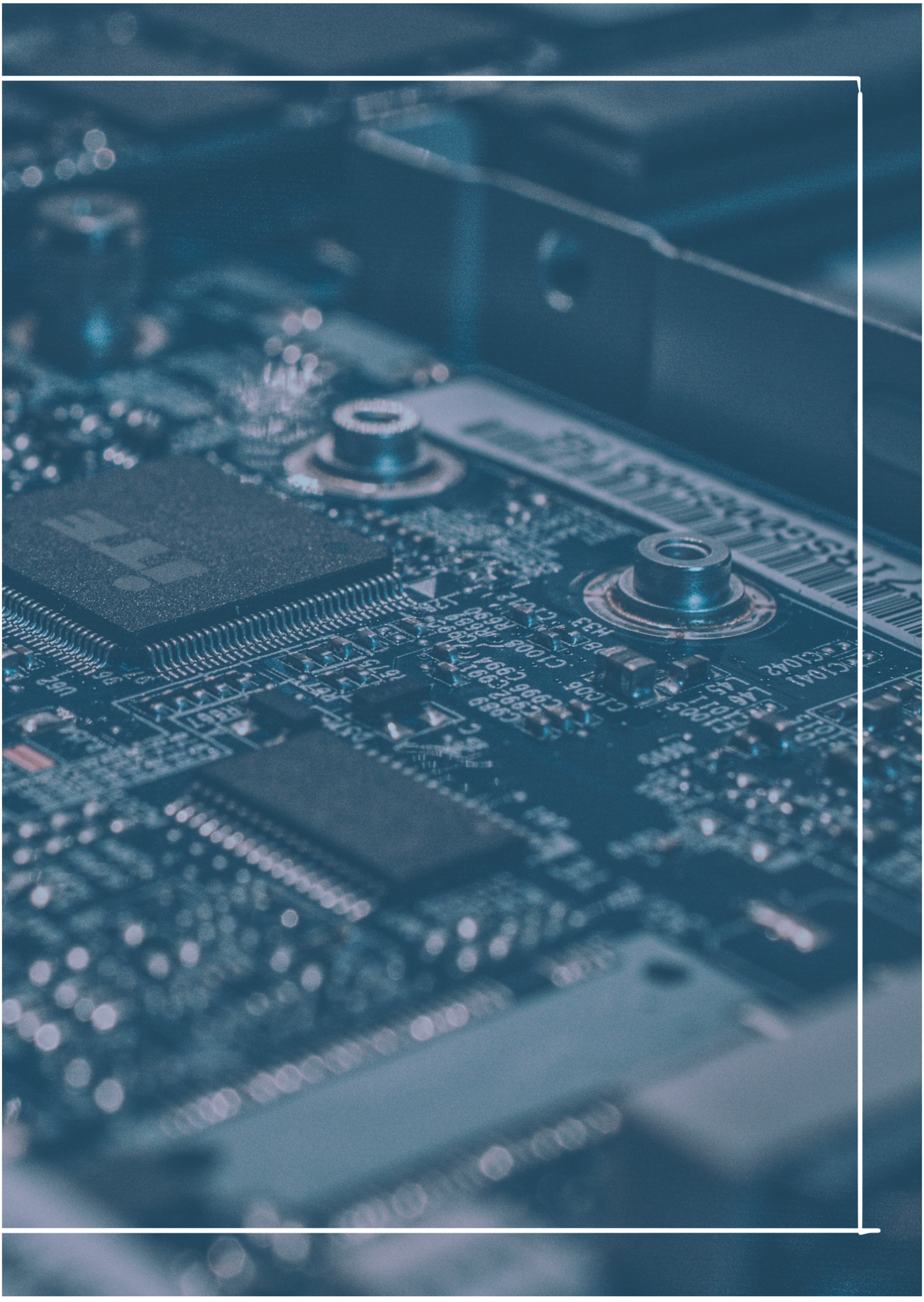


PART III

SOLUTION DESIGN

Based on the analyses provided and the methodology developed, a solution is designed according to requirements that will be defined at the start of this chapter. The functions and system architecture will be defined, offering insight in how the system must operate when fully developed and constructed. Additionally, this chapter defines the intended users, characterized in the clusters. To conclude this chapter, a visual impression of the solution is provided giving some impression of how this, otherwise conceptual design, will look like.



11. TARGET GROUP DESIGN

When developing a solution knowing the user is vital for the successful adoption of the product into the desired context. This holds especially true for the development of consumer products: products that lean heavily on usability and user friendliness in order to attract users, and thus customers. Establishing a target group for a product that does not exist yet in any way, shape, or form is a tough feat. In this case, a system, as that what is designed here, cannot be found in the current medical consumer market. Therefore, an established target group cannot be found and must be designed.
However, designing a proper target group for this assignment is not without difficulties. **First**, it is desired by the company that the designed target group must be based on data and logic. However, although many metrics are available and many databases are accessible, not much interrelatedness can be found. In other words, when establishing variables which characterize members in the target group, it is often impossible to match variables with each other to establish a multivariate target group. **Second**, another issue regarding designing based on the data resides in the trustworthiness of some datasets. As sometimes not much data is available from trusted sources, the search for data must deviate to less reliable sources to at least gather some sort of understanding of the size of such a group. **Last**, the target group design can be characterized as a 'guestimate': an estimated guess. The available data used for designing the target group is socio-economic, and does not show behaviour or intention[47]. Estimating if the selected individuals residing in the designed target group are actually willing to purchase such a solution, remains a question data cannot answer. Nevertheless, descriptions and data of the target group and the different angles from which it can be accessed should provide an overview with which the company is able to attract customers for the purchasing and users for the testing of the system.

11.1 ESTABLISHING CHARACTERISTICS

To establish some understanding of possible customers and users, this section will address characteristics describing an archetype of user. An user that can be found in multiple clusters of people, which will be described later on. The archetypical user can be described[48] as follows: **First**, the user must have an understanding of the chance of developing CRC as well as a more established understanding of the consequences of having such a disease. Typically, this will be established through a relative contracting the disease and seeing the consequences in real-life, or hearing from the consequences of having CRC through conversations with acquaintances. Even more so, a user could also be a former CRC patient wanting to monitor the potential of metastases. A lack of knowledge about the disease, effects, and its care path will result in a lower sense of need for the solution[49]. **Second**, the user must have the financial capacity to purchase such a solution. As can be imagined, a toilet capable of monitoring your health, ridden with sensors and big data analytic capacities can be seen as a luxury product. Therefore, the spendable income of the user should be sufficient to cover the purchase of this solution. As mentioned before, during this research project no components and parts are going to be selected and thus, it becomes impossible to define a price for this solution. However, in conversation with multiple experts[50] it was estimated that a reasonable price for such a solution should reside somewhere between €400 and €1.000. **Third**, the user must be of an age that is susceptible to CRC. Otherwise, the need for such a system will be severely lacking which, in turn, will most likely not result in purchasing the system. Therefore, two large segments of people are considered: (1) people eligible to the national screening, age 55 to 75, and (2) people becoming eligible for the national screening, age 35 to 55. The first segment was considered for the same reasons as stated by the Health Council (Gezondheidsraad, 2009). The second segment is considered as this group of people is also susceptible for developing CRC, whilst not being included in the national screening due to cost-effectiveness reasons. However, this group might also be interested in (or scared about) developing CRC and monitoring their health and should therefore be included. **Fourth**, the archetypical user must have a certain interest or desire in monitoring

[47] Intention can be deduced from surveys and questionnaires. However, in my opinion they offer unsatisfactory insight in the target group due to various reasons I am not going to discuss.
[48] To do so, no marketing, psychological, or other theoretical frameworks were used. Rather, the description provided is based on many discussions with experts and uses everyday language to provide the necessary insight. Which is deemed sufficient.
[49] Explaining why monitoring your health condition could be beneficial, is something the company could attempt to through marketing efforts. However, it is assumed that in the early phases of the company not much financial resources are available to do so.
[50] Two business developers, see **Appendix 2**.

and, above-all, seeing physiological data about him/herself. There must be an interest to know so much more about your body. When looking at similar health insight providing consumer products, a clear divide can be seen between people willing and desiring to see such information, and people who have an aversion for such products and services. **Last**, the user must be willing to modify their toilet for the installation of the product. This can be an issue for people living in rental property, as it can be imagined that these people are unwilling to 'invest' in property that is not their own.
Overall, it is unlikely that a combination between these four characteristics can be found in a group of people large enough to sustain the company. However, a combination of two or three of these characteristics might suffice in convincing such individuals in purchasing the solution. Therefore, examples of groups that have a combination of these characteristics are discussed.

11.2 CLUSTERS

11.2.1 Demographic data, cluster 1

Socio-economic characteristics of the Dutch population can be found in the online database from CBS (*Centraal Bureau voor de Statistiek*, Statistics Netherlands). In that database information can be found on at least four characteristics: age, spendable income, and living situation, in combination with mortality due to CRC.

Table 8. Population, age, living situation, and CRC mortality in 2017 (CBS, 2018a, 2018b).

	Population	**Rental**		**Homeowner**		**Deceased**
	Total number of people	Total households	Spendable income of the household	Total households	Spendable income of the household	CRC
	x 1.000.000	*x 1.000*	*1.000 Euro*	*x 1.000*	*1.000 Euro*	*Total*
Age						
..-24	4,8	342,7	12,7	26,4	37,0	1
25-29	1,1	363,5	25,2	181,9	43,8	3
30-34	1,1	274,8	28,7	308,2	49,4	11
35-39	1,0	218,3	29,2	367,3	54,3	20
40-44	1,1	211,9	29,4	418,3	58,1	40
45-49	1,3	246,4	30,1	522,2	60,9	108
50-54	1,3	254,1	30,1	523,6	63,0	171
55-59	1,2	245,5	28,7	479,5	61,1	259
60-64	1,1	228,5	26,7	420,7	53,6	434
65-69	1,0	233,0	25,4	386,1	46,7	611
70-74	0,8	210,2	23,7	303,7	42,2	799
75-79	0,6	186,2	22,6	199,1	37,7	735
80-84	0,4	160,1	21,6	128,7	35,1	817
85-..	0,4	162,4	20,2	88,4	33,1	1.094
Total	17,1	3.337,7	25,2	4.354,1	53,0	5.103

Considering the defined characteristics and the information from **table 8**., the first cluster of people would consists of over (an estimated) 5 million people, living in 3,4 million households, with an average spendable income of €55.000 Euros a year, of which 2.442 people (1 out of 20) passed away from CRC and its complications.

11.2.2 Those who are worried, cluster 2

The second group that will be discussed is the group of people that undergo a full body scan at PreScan (PreScan B.V, n.d.), the infamous[51] Dutch company. PreScan is a Dutch company that offers 'total body scans', medical examinations of 'all' parts of the human body. The ambition of PreScan is similar to the start-up of this research: prevent unnecessary deaths due to belate diagnoses. Additionally, PreScan claims to be fighting unjust diagnoses. Such a preventive screening is currently available when the consumer pays for it itself. An examination costs between €950 and €1.999 (PreScan B.V., n.d.-b). Estimating the size of this second cluster is rather difficult. Even though PreScan boasts the size of its clientele (60.000 clients, PreScan B.V., n.d.-c), no statistical information is disclosed. Based on a review site, the numbers suggest a smaller group of people (1.872 people, Feedback Company, 2019).

11.2.3 Those who are interested, cluster 3

The third group that will be discussed, is the group of people heavily interested in tracking anything about their body, mind, and health: the Quantified Self (Wolf, 2010). The Quantified Self (QS) is a movement focused on gathering, understanding, and learning from data generated from the human body. The term was coined in 2007, when Gary Wolf and Kevin Kelly, both writers for Wired, noticed that more and more people were busy with gathering data of themselves, quantifying physiological processes, and sharing this on social media. They saw this trend and decided to hold meetings for people interested in this topic. Some years later, this movement came to the Netherlands as well: the Dutch Quantified Self Institute was established in 2012 (Quantified Self Nederland, n.d.). The QS movement is characterized by a heavy use of technology[52]. In doing so, the movement believes that a paradigm shift is happening where data resides more and more on the side of the technology users (and future patients) instead of healthcare professionals. They believe QS could aid in the development and implementation of individualised medicine and treatments (De Groot, 2015). Similarly, to the previous target group, from the QS movement no clear numbers are known. It has been said that QS Netherlands has 1.000 active members, but the social platform 'Meetup' shows at least 2.800 members active all over the Netherlands (Meetup, n.d.).

Figure 18. Data from table x. plotted for visual analysis (CBS, 2018a, 2018b).

[51] Research institute TNO has found that 1 in 8 people performing a total body scan were referred to specialists (secondary) care (n=3600) and that in 80% of the cases, it was confirmed that the patient "had something" (Gezondheid&Co, 2018). Strangely enough, however, this research has neverbeen publicized.

[52] Examples include: the Jawbone UP, the Fitbit, the Misfit Shine, the Spire respiration monitor, Melon, the Ladybug Kit, and Validic.

11.3 CONCLUSION AND ETHICS

Based on the previous data, no real conclusion on the target group can be drawn. Numerous groups of people exist containing, based on logical characteristics, at least several cluster in which potential customers and users can be found. However, it remains unclear what the potential of these groups is. Additionally, further research into this topic lies outside the scope of this assignment. Therefore, I hope that the company is able to make use of these defined clusters in any further marketing and research efforts.

One last topic remains: the ethics of selecting a target group. Selecting a group of people cannot be done without excluding others. Therefore, the argument can be raised if making this solution available to only a smaller part of the Dutch population is ethical or not, given the financial aspect of financing the development of the solution. Socio-economic factors (e.g. the inability to purchase such a solution) or issues regarding preventive screening in general (e.g. health illiteracy (Elders, 2009; Baker et al., 2007) or lower participation rates among minority groups (Deutekom et al., 2009; Kewenter et al., 1994) and others (Hol et al., 2009; Zorzi et al., 2009; Weller et al., 2007; Malila et al., 2008; Wardle et al., 2005)). Even though this is interesting question to raise, it lies outside the scope of this assignment due to its philosophical nature and ethical context.

12. SOLUTION DESIGN

This part will describe the development and design of the proposed solution. **First**, a look is taken at the specified design principles. These principles are not requirements nor are they demands for how the result of this project must be, but rather thoughts to consider and guide the process. They guide the development of the requirements. **Second**, a look is taken at the defined requirements which were used to design as well as evaluate. **Third**, these requirements were then translated into a set of functions that could deliver the desired output. **Fourth**, these functions are specified to understand the effects of the functions on the successful execution of other functions and the time period necessary to successfully execute said function. **Fifth**, a diagram is presented showing the work-flow of the system in relation to the user as well as the healthcare industry. Here the system is treated as a black box (as has been mentioned in the scope, Chapter 9.5). This work-flow also addresses specific topics related to functioning of the system, like communication and data sharing. **Sixth**, this diagram as well as all the functions are placed into another, more detailed, work-flow diagram showing how the functionalities relate to each other. Especially important here is the order in which each of the functions operate. **Seventh**, a depiction of the system, super-system and subsystems is provided that display how these functions are delivered through machinery, electronics, hardware, software, and other units. **Last**, a discussion is provided that explains why the development of the solution is at it is and why no further progression was made in combination with the goal of this solution design and how it is used in the following part about implementation.

> Data shouldn't replace human judgment. Data should inform human judgment. Knowing what works on average still requires you to assess whether the average applies to your situation (Grant, 2019).

12.1 PRINCIPLES FOR DESIGN

To aid the functionality of the methodology, some principles for design can be defined before establishing the requirements. These principles transform the contextual knowledge provided in the analysis chapter as well as the understanding gained from the target group design, into concise guidelines which can aid the development of the solution and justify certain design decisions. Bear in mind, these principles are logical and perhaps even obvious.
First, the principle of 'safety by design. This first principle indicates the importance of the safety of this solution. Common in medical device development, risk management methods are employed to define and avoid safety hazards. As can be imagined, a toilet capable of measuring excrements is unlikely to cause any real harm to a user, other then perhaps interpretation mistakes of the report. Nevertheless, it is important to guarantee the safety of the people, not only physically, but also mentally, financially, and safety through cybersecurity. Therefore, if a decision has to be made regarding the design of the solution, this principle may be used to enforce an option. **Second**, the principle of 'maximizing value'. This principle embellishes the important of the maximization of value. If with little to no effort the value can be maximized than it should be so. As has been mentioned in Chapter 1, the value proposition of the solution should be clear to the user in order for the user to adopt the technology. If a decision has to be made regarding the design of the solution, then this principle might be the decisive factor. **Last**, the principle of 'Usability, simplicity, and affordability above functionality'. The usability of the system is vital for the adoption of the technology by the users. Additionally, the simplicity of the solution design should be prioritized above functionality. In other words, if a functionality could be added that will make the solution significantly complex, then it should be opted to leave that functionality out of the solution design. This is due to the aim to develop a working prototype of the solution. Complexity will only add to the costs and time it takes to develop the prototype. The company has addressed that speed is essential as not much money is present to sustain the business for longer periods of time. Getting proof as soon as possible is therefore essential for the survival of the company, and thus the survival and implementation of the solution. Even more so, if the choice is between added functionalities and cost price, the possible cost price of the solution should be prioritized above the functionalities. This may seem contradictory with principle 2, however, this principle wishes to emphasize the importance of usability, simplicity, and affordability of the solution.

12.2 REQUIREMENTS

Before any solution can be designed, it must be clear which requirements this solution must fulfil. Requirements for the development of this solution are based on the analysis of this research project (Part I) and common sense and they were validated by experts and the company. However, it is immensely important to stress that these requirements can only be truly validated when a user group is available to test them. For now, it is only possible to deduct requirements from information gathered during the analysis phase and it is only possible to validate them with conversations with knowledgeable experts and the use of common sense. Important to notice, is that good requirements are often defined in a similar pattern to this: Object + Imperative + Action + Condition + Declaration Of Purpose. Doing so, it becomes clear how this requirement can be tested and which subsystem will become responsible for performing the process that will deliver the desired output. In this case, however, it is near impossible to define concrete requirements that are testable. No target group is present that can guide the establishment of the conditions and specifications and the development of the system has not progressed enough to be able to deduct specifications from the process. Additionally, establishing requirements often requires the development team to think about contextual conditions and situation in which the system must operate. One can imagine that a machine performs differently when it is operating in a humid and warm cabin compared to a cold and dry production hall. The established requirements for this project do not factor in such a difference in operating environment. First, because it is deemed unnecessary as most toilet will operate in similar conditions: relatively small rooms, quite humid, room temperatures. Second, because it is impossible to define other operating environments as that data cannot be gathered when no target group is available. Therefore, instead of requirements, characteristics of the system are defined. Characteristics in this sense mean untestable requirements of the system that indicate how the system *must be*, which can become testable requirements in later stages of the development process (which is outside the scope of this project). The goal of establishing requirements in this phase of the development process is to deduct and define functions of the system. Using characteristics instead of requirements will not hinder this process. Even more so, it could even be argued that using characteristics (i.e. unspecified requirements) might even accelerate the process as less time has to be spent on specifying requirements and more can be spent on deducting functions. Additionally, an attempt has been done to define validation methods and goals for each of these requirements. They serve as a guideline for the company in later stages of this development project. As has been mentioned before, validating the requirements is outside the scope of this assignment. The company will become responsible for specifying and validating the requirements and evaluating the performance of the system.

12.3 FUNCTIONAL DEVELOPMENT

Functions are derived from requirements (i.e. in this case characteristics). Defining the functions allows for a detailed generic design and the possibility to assess super-system behaviour in relation to stakeholders. Deriving the requirements deliver the following functions: (1) From requirement 1 to 5, no clear functions can be deducted. These characteristics focus on effects of the system on the context in which it operates; (2) Requirement 6 to 12 are requirements that result in functions. These functions are *to measure*, *to analyse*, *to report*, *to store*, *to clean*, and *to recognize*; (3) Requirement 13 and 15 state conditions to which the output of the system, the analysis report, must meet. The functional development focusses exclusively on the system, in order to define system architecture and subsystems, and therefore, requirement 13 and 15 are excluded from the function work-flow and allocation development; (4) Requirement 14 focusses, similarly to requirement 1 to 5, on effects of the system on the operating context.

12.4 FUNCTIONAL SPECIFICATION

The functions to take into account are *to measure*, *to analyse*, *to report*, *to store*, *to clean*, and *to recognize*. To establish a work-flow, and more specifically, the order in which functions follow each other up, it is important to establish the necessary time period the function needs to be fully executed as well as the

effect of the function on the successful execution of other functions. In other words, it is essential to dissect the functions and how they are going to be executed to understand what the appropriate order of execution must be.

12.4.1 To measure

The most important function of the entire system is the ability to measure the faecal matter of the user. To understand the complexity of this function and its place in the system and work-flow order, it is vital to elaborate on the biomarkers that must be measured. Otherwise, correctly processing this function in the design of the solution is impossible. As can be read in Part I Chapter 2, the variable that can be measured to predict CRC is FOB, and the variables that can be measured to indicate the health condition of the user are viscosity, frequency, pH, weight, bristol stool chart index, colour, and volume. To develop the functioning order of these measurement methods, it is necessary to define how these biomarkers could be measured. Important to realise, is that is not the scope of this research project to develop the best possible ways to measure each of these markers. Rather, it is necessary to at least assume some measuring methods to be able to develop an order of execution.

Table 9. Measurement methods for each of the biomarkers.

Biomarker	Measuring method	Necessary preparation	Consequences of measuring
FOB	Chemical reaction triggered by a reagent	The reagent should be able to reach the faeces	Reagent remains in the faeces and can distort other measurements
Density	Calculation based on weight and volume	Weight and volume have to be measured first	No effect
Frequency	Calculation based on time and number of visits per user	No preparation needed	No effect
pH	Measured with a sensor	Sensor should be able to reach faeces	No effect
Weight	Measured with a scale	The faeces should fit the measuring container of the weight scale	No effect
Type on Bristol Stool Chart	Image-recognition through camera	No preparation needed	No effect
Colour	Image-recognition through camera and colour sensor	No preparation needed	No effect
Volume	Measured through input flow	No preparation needed	No effect

As can be seen in **table 9**, the measurement of FOB effects the stool as a reagent is added. Therefore, this measurement must be last in line so that it will not distort other measurements.
However, doing so will not resolve all issues regarding the measurement of the faecal matter. Another issue is present in the measuring ‘spot’ of the different measuring technologies. As one can imagine, only that what passes the sensor will be measured. Generally speaking, a stool is not a uniform sample. Rather, it is skewed sample consisting of both dry and wet, as well as, dense and sparse segments. To be able to accurately measure parameters like density and pH, it is necessary to blend the stool into one, uniform sample. Blending the faecal matter is therefore also a function the system must perform. Blending must occur before the measurement of density and pH and after the measurement of colour and the type of faecal on the Bristol Stool Chart. Blending before the type assessment will distort the results and deliver an invalid measurement.
All things considered, the correct order of measuring methods is: colour, type on the Bristol Stool Chart, (blend,) volume, weight, pH, and FOB. Frequency does not have to be considered in establishing the order of functions, as frequency is automatically measured through using the system over time. No alterations to the stool have to be made to measure frequency and no consequences for other measuring methods are existent.

Table 10. Characteristics and requirements

	System characteristics	Validation
1	The system must be **easy to use**, so that using the system will not discourage the user from using the system in the future.	Usability testing with the desired target groups.
2	The system must be **affordable**, so that the user will not be discouraged from purchasing the system.	Market research in cooperation with samples from the target group.
3	The system must be **reliable**, so that the results of the system can be trusted and used for evaluating the health condition of the user.	Performance testing with a prototype/consumer configuration.
4	The system must **achieve compliance**, so that it may be sold on the European market.	Expert consultation, in cooperation with a NB.
5	The system must be **able to sustain a business**, so that the company is able to progress the future development of the system	Market research, expert consultation.
6	The system must be **able to measure specified biomarkers** with a sensitivity and specificity competitive with the current alternative.	Performance testing with a prototype/consumer configuration.
7	The system must be **able to analyse the results from the measurements**, so that the user can be informed about his/her health condition.	Performance testing with a prototype/consumer configuration.
8	The system must be **able to report the analysis of the measurements**, so that the analysis can be shared with the user.	Performance testing with a prototype/consumer configuration.
9	The system must be **able to store the analyses and reports in a safe and secure location**, so that the privacy of the user can be guaranteed.	Performance testing with a prototype/consumer configuration.
10	The system must be **able to clean the sensors**, so that measuring the biomarkers is not obstructed and the measurement can be trusted.	Performance testing with a prototype/consumer configuration.
11	The system must be **able to recognize the user using the system**, so that the measurements can be linked to the right user.	Performance testing with a prototype/consumer configuration.
12	The system must be **able to recognize the measurements of the biomarkers**, so that the measurements can be linked to the right biomarker.	Performance testing with a prototype/consumer configuration.

	Output characteristics	Validation
13	The results must be **understandable** by the user, so that the user is enabled to undertake the appropriate action.	Usability testing with the desired target groups.
14	The communications between the system and the user must be **secure**, so that the privacy of the user is guaranteed.	Performance testing with a prototype/consumer configuration.
15	The results must be **translatable/transferable** to other systems, so that the user is able to use the results outside of the operating context of the system.	Usability and performance testing with the desired target groups.

12.4.2 To analyse

The function *to analyse* describes the process of processing the measurements in a statistical way. As has been mentioned, the biomarker blood and the characteristics of relief pattern are to be measured. These must be analysed for their statistical patterns to be able to provide insight in the health condition of the user.

The method to analyse the measurements is taken from the Lean Six Sigma method: the control chart (Theisens, 2016). A control chart displays samples of a process to demonstrate the process' performance over time. In the case of a production process, such a control chart can show the variance in output of a piece of machinery allowing the production engineers to monitor the machinery and act when the process is making mistakes. Such a chart is able to show the outliers in the measurements which can be used for monitoring health. For this system, the measurements of an individual user will establish a 'baseline' (i.e. the average) for each of the different biomarkers that is measured. This baseline will be established over time; the user must use the system over a period of time before an average can be calculated. When the system measures a different value of one or multiple of the biomarkers (i.e. an

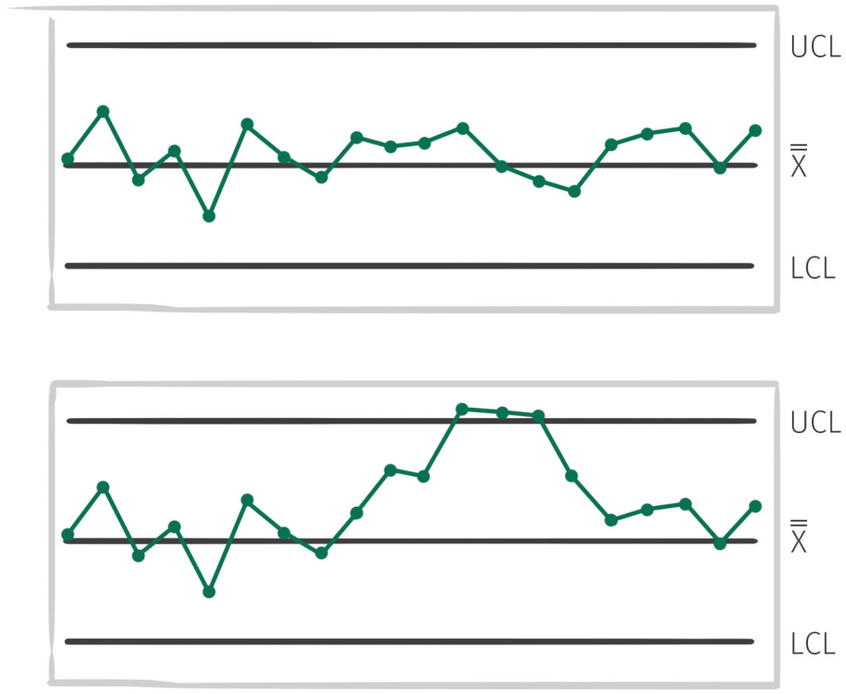


Figure 19. A control chart (illustrated).
Upper: a process that is in control. All measurements are within the natural (statistically calculated) bounds.
Lower: a process that is not in control as outliers are measured.
UCL: upper control limit
LCL: lower control limit
X: average

outlier), the user is alerted. When these outliers keep occurring, and thus the measurements deviates from the user's average, the system can suggest the user to visit a healthcare professional. In other words, when the contents of the faeces of the user are different from what is 'normal' for him/her, it could be that the user is or is becoming sick. When an individual is healthy, it is expected that the measurements remain within the control limits (i.e. natural deviation) devised from the baseline of the user.

Using pattern recognition to define someone's healthiness[53] is a relatively new method in the healthcare industry (methods have been developed for Alzheimer's disease (Farooq, A., et al., 2017), heart disease prediction (AbuKhousa and Campbell, 2012), and diabetes (Anand and Shakti, 2016). Yet methods are rarely implemented in actual clinical practice (Deo, 2015). Usually, a diagnosis is made based on the presence or absence or the level of a certain biomarker. Whereas now, however, a deviation from an established pattern is used for diagnosis. It is thought that using pattern recognition provides significantly more and more detailed insight in the health condition of the user. One of the main concerns with the current alternative, screening, is the problems that arise from measuring only once. When measuring over time, longitudinal, measurement errors can be detected and excluded, normal variation can be detected and recognized, and above all, the user will receive a personalized report based on the performance of his/her body. Instead of an averaged, population-based measure to which someone should conform. To illustrate, conventional diagnostic methods are, still, predominantly 'snapshots': one-time measurements. This system, however, provides a 'film': measurements over time. E.g., an individual could have had an evening in which a lot of salty food had been consumed. Let's assume in this scenario, that a screening exists for high levels of salt in faeces (which is deemed unhealthy) and that this individual is being tested the next day. The screening would suggest that this individual is unhealthy as the test points out the high level of salt. Therefore, this individual will be subdued to many more diagnostic tests to find the reason for these high levels. The individual will believe that he/she is sick and will start worrying as more and more tests will not deliver a diagnosis.

[53] In conversation with two C-level executives of a medical device company, I learned that pattern recognition between healthy and sick individuals (so not longitudinal), is starting to become accepted in the diagnosis decision-making process. However, this acceptance is slow and often obstructed by conservatives and sceptics.

In this case, it is safe to assume that perhaps the salty food from the night before triggered the screening and resulted in a false positive. A system that would measure over a longer period of time would rightfully recognize this measurement as an outlier. Saving much trouble for both healthcare professionals and the healthcare system as well as for the individual.

12.4.3 To report

The analysis must be processed into a report that must be sent to the user. Therefore, the system must have some sort of connection method so that the user is able to interact with the system and the sending and receiving of information is possible. Therefore, a connection must be established between the system and the user. This connection must be secure and safe, so that the privacy of the user can be guaranteed. Such a connection can be performed through multiple means. E.g., the company could decide to install a USB port into the system that is accessible for its users. A laptop can be connected to the USB port, which receives all constructed reports from the system from all users connected to the system. Or, the system could be able to transmit the documents through BlueTooth or WiFi channels when in contact with a user's phone or personal computer. The type of technology used depends on the target group's desires concering the configuration of the solution. Reporting can only be done when the measurements have been analysed and a report is constructed. This function does not have a specific time period in which it must operate. In the end, it is the desire of the users to dictate the frequency in which such reports become available. It can be imagined, that user's are not interested to check their relief pattern on a daily basis but are rather interested in a monthly overview. As the reporting function does not have any effect on the successful execution of other functions, it is disconnected from the work-flow order. To be able to report, the system must also have the capabilities to construct a report based on the analysis. Therefore, either an automated script must be devised capable of plotting the measurements in a control chart and provide explanatory information, or, the system must be able to transmit the results to the company which can construct such a report.

12.4.4 To store

The system must also be able to store the information of the user(s) and be able to access this storage when the user demands a report or if the system is directed to provide a report as a predefined amount of time has passed. Storing healthcare data is a crucial part of the system as the privacy of the user must be guaranteed. This is especially topical since the introduction of the GDPR. However, data protection and encryption protocols are not part of my competencies and not within the scope of this assignment. Therefore, I will only consider the function in light of subsystem development and interaction with other subsystems and functions.

12.4.5 To clean

The system must also be able to clean the sensors of any remnants of excrements before performing a new measurement, as otherwise, the results cannot be trusted and validated. Therefore, it is decided that, in order to guarantee a certain level of performance, the system must clean all sensors before and after measuring the samples. Additionally, the system must test the measurement technology to assess whether or not the sensor technology is capable of producing a valid measurement. This can best be explained through an example: Let's consider the pH sensor. The pH sensor should be cleaned before the measurement, to guarantee a valid measurement, and afterwards, to improve the longevity of the system. Additionally, to test if the pH sensor is capable of producing a valid measurement, the sensor can measure a test-liquid with a predefined pH level. If the sensor is capable of matching the pH measurement with the predefined level, it shows its competency to produce a valid measurement and therefore, it can be used to measure the sample. Cleaning the sensor beforehand reduces the possibility of a measurement error due to the dilution of the test-liquid from excrement remnants. It is assumed that the cleaning process is not a process that takes considerably amounts of time. As has been mentioned, measuring the faeces must occur when the faeces is depleted in the toilet. As has been said, before measuring the sensors must be cleaned. The system is aware of the usage of the toilet when the user is recognized (see 12.4.6 To recognize). Therefore, it is decided that the cleaning process starts as soon as the system recognizes the user. Additionally, from a maintenance perspective,

it could be beneficial for the company to monitor the performance of its sensors to guarantee a working product for its customers, as well as improve any future configurations. Therefore, the system must also be able *to report* these performance tests to the company.

12.4.6 To recognize

The system must be able to recognize different users. Otherwise, measurements can be linked to other users, nullifying the validity of the statistical analyses and thus, ruin the trustworthiness of the solution. Recognizing the user is a process that can be executed by numerous technologies. E.g., the system could connect with the smartphone of the user through a BlueTooth connection or the user could 'check-in' into the toilet through a hardware interface connected to the system. Even more so, these technologies could also be used to establish the communication between the system and the user so that the reports can be transferred. However, as stated in the scope of this assignment, I have to assume that the company is able to develop a technology capable of recognizing the user.
Either way, the recognition process is essential for linking the measurement to the individual user. Additionally, based on the premise that other activities are 'triggered' by the recognition process, it is decided that the recognition process must be executed as one of the first processes. Even though the recognition, as a separate process, could take as much time as the usage of the toilet would. To be able to recognize different users, the system must be able to hold multiple user accounts so that it can differentiate. Therefore, users must be able to establish such an account, which can be done through the communication methods as talked about before.

12.5 FUNCTIONAL ALLOCATION

The allocation of functions is separated in two sections. **First**, the order in which functions are executed is defined based on the execution time and effects of functions on other functions. **Second**, the functions are allocated to subsystems of the solution. This is also separated into two different configurations: the Maximal Configuration and the Minimal Configuration. The difference between these configurations can be found in the comprehensiveness of the system. As the names might suggest, the Maximal Configuration aims to be the most ideal configuration of the system, if costs were of no issue. The Minimal Configuration aims to reduce the amount of parts and subsystems as much as possible, and can be seen as a lean configuration of the solution. These two configurations aim to aid the company in deciding the actual configuration of the solution in later stages of the development process. Additionally, these configurations might cater to different target groups, which can and should be explored. These configurations might aid that process.

12.5.1 System work-flow order allocation

First, what is important to include in the measuring process is the method of measuring the biomarkers FOB and pH. Measuring FOB is done by adding a reagent to the excrement and detecting the reaction, whilst pH is measured with a sensor that is placed in the excrement. Therefore, the 'spot' of the stool that is measured should be an accurate representation of the total stool as otherwise, the measurement can be deemed invalid. **Figure 20** explains this idea further, showing the effects of measuring a heterogeneous stool. To be assured that the system is capable of providing a valid measurement, it is therefore decided that the stool will be mixed before measuring. As it is assumed that a homogeneous sample will provide a more representative measurement that is valid. Important to emphasize that mixing and dividing the stool over channels are new functions added to the system that were not originally included. **Second**, measuring FOB can distort any subsequent measurements as a reagent must be added. Therefore, FOB must be measured as last in the process. **Last**, mixing the sample will distort measurements of the type on the Bristol Stool Chart as well. Therefore, this measurement must precede the mixing process.
Therefore, the work-flow order has been decided, which is depicted in **figure 21**. As the stool is mixed and it is assumed that each of these 'splits' (= samples) are representative for the entire stool, it has been decided to make use of this newly added benefit. The system will have multiple channels that each receive a splitted sample of the stool to perform a measurement on. Based on the system

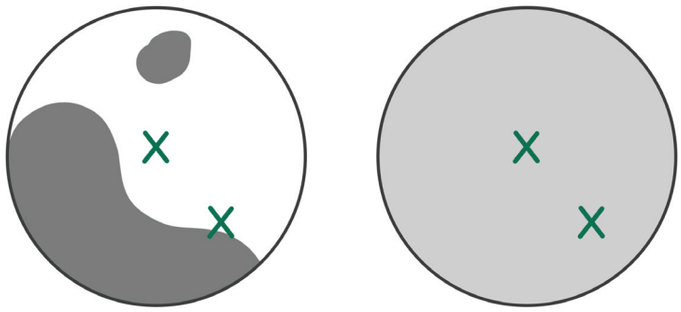


Figure 20. Measuring spot, illustrated. Left showing the dangers of measuring a heteregnous stool. Right showing the effects of mixing. The x's mark the measuring 'spots'. The grey color and its saturation indicate the presence and the level of presence of a biomarker.

design, two channels would suffice: one for the pH measurement and one for the FOB measurement. However, in light of possible future developments, it is advised to increase the amount of channels to prepare for a future where more biomarkers are found and identified that should be included in new configurations of the solution. To illustrate, let's assume that the sodium level in an individuals stool provides information about the health condition of that user, then it would be highly beneficial if the system already as a 'free' channel available that receives a part of the sample that can be fitted with a sodium measurement system. Doing so, it would not be necessary to transform the entire system design but rather some smaller subsystems. Additionally, when newly added measurement methods also distort the sample (e.g., similarly to measuring FOB which requires a reagent to be added to the sample), then these can be added rather easily without the need to redesign the work-flow order of the system.

12.5.2 Subsystem allocation

Based on the defined functions, a system hierarchy can be developed. Such an hierarchy defines subsystems of the system that are responsible for the established functions. This allows the company (as this is outside my scope, see Part 2 Chapter 9.5) to define detailed specifications for these functions and subsystems, and select components capable of performing these functions within the specified bounds. Additionally, this hierarchy makes the connection with the stakeholders and users, located in the super-system context of the solution. The next paragraph details the work-flow of the system in the super-system context, combining the work-flow order (figure 21) and the subsystem allocation (figure 22). To be able to develop such a hierarchy, the necessary additions need to be made. **First**, another function and subsystem are introduced to the system (not visible in figure 22), which are responsible for directing and driving all other functions and subsystems: the brain of the system, the computer. This subsystem is the connecting unit capable of both bringing all other subsystems in action, as well as connecting relevant subsystems which need to cooperate with each other. **Second**, two other subsystems are introduced as well: the inner and outer shell of the solution. The first being there to support and connect all physical components of all subsystems together and providing the necessary physical support and structure to the system. The second being there to connect the system to the super-system interfaces[54] as well as protecting the interior of the system (from water, dirt, damages, etc. In conclusion, the following subsystems can be defined. **First**, the computer subsystem which is responsible for matching the user with the stool deposited in the toilet, analysing the measurements provided by the sensors, constructing a report from the analyses in combination with the communication subsystem, controlling all subsystems, connecting subsystems with each other. When thinking about this subsystem, a circuit board with multiple connection points should come to mind (E.g., an Arduino or something similar). **Second**, the identification subsystem which is responsible for recognizing the user in order to aid the computer subsystem in matching stool measurements with users. When

[54] See **Appendix 8**.

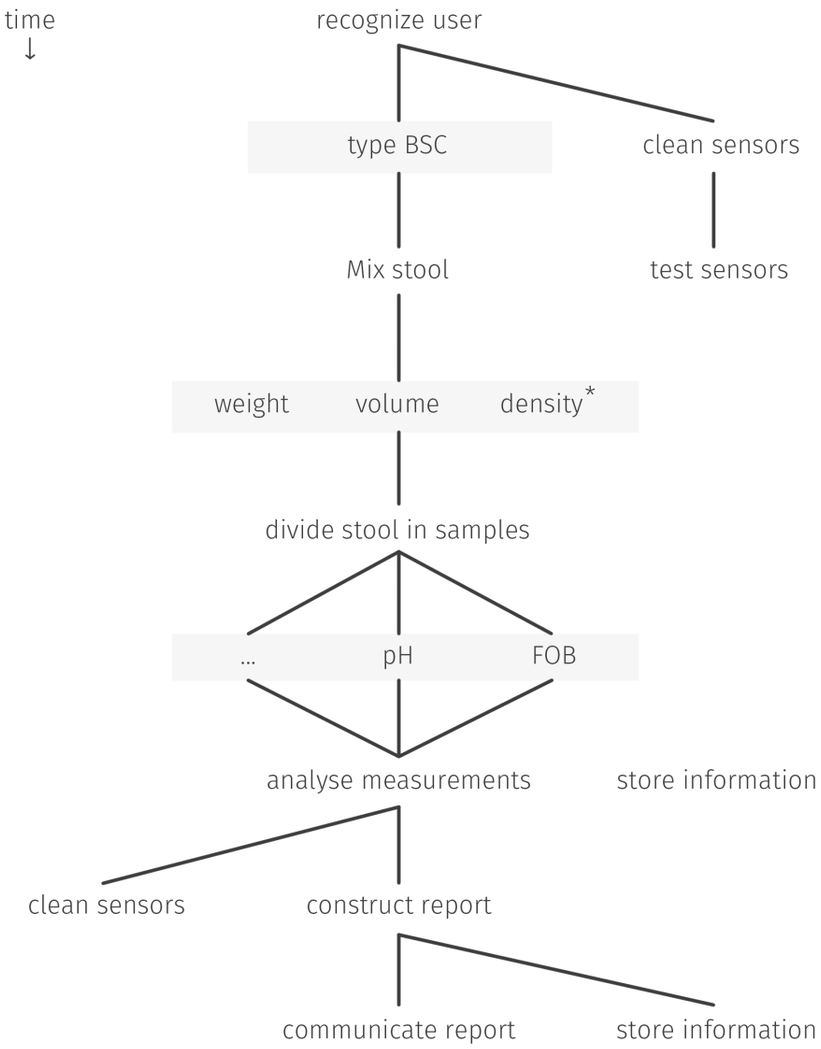


Figure 21. System work-flow order.
* density is calculated based on weight and volume, as been mentioned in Part I Chapter 2.

thinking about this subsystem, a BlueTooth or WiFi module should come to mind capable of connecting the computer subsystem with the user's phone. When downsizing the product price of the solution, the company could opt for other recognition methods (one could think of hardware buttons that the user needs to press to identify his/herself or an USB connection point to which the phone must be connected[55]). However, as the system must be able to communicate the results to the user it is assumed that such a connection system must be present any way. **Third**, the communication subsystem, which is responsible for connecting with the user, communicating the results of the user's measurements and the analysis reports, and storing all this information. Similarly to the identification subsystem, when thinking about this subsystem some module should come to mind capable of connecting with the user's phone through BlueTooth or WiFi. Additionally, this subsystem should also have some sort of memory module as it is the storage place for all collected, processed, and generated content. **Fourth**, the mixing subsystem which is responsible for mixing the stool to a uniform blend and guiding it to the different sample channels. When thinking of this subsystem, a mixing component like that of a Sanibroyeur[56], a faecal matter mixer. Guiding the mixed blend to different sample channels will

[55] Options which are not in line with design principles 2 and 3. See Chapter 12.1
[56] As can be found on http://www.sanibroyeur.info/products/index/show-product/lang/nl/type/all/id/58

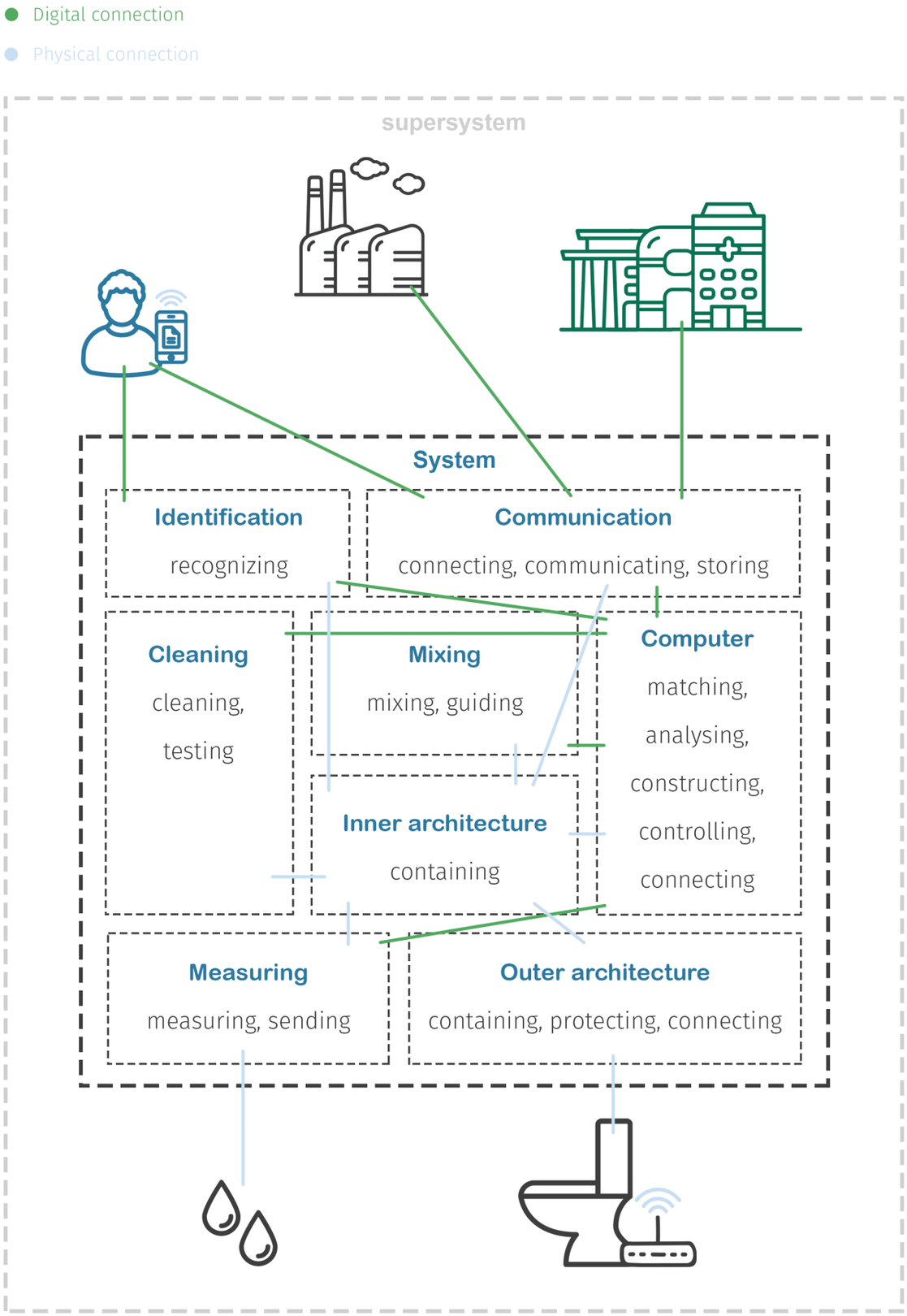


Figure 22. System hierarchy.

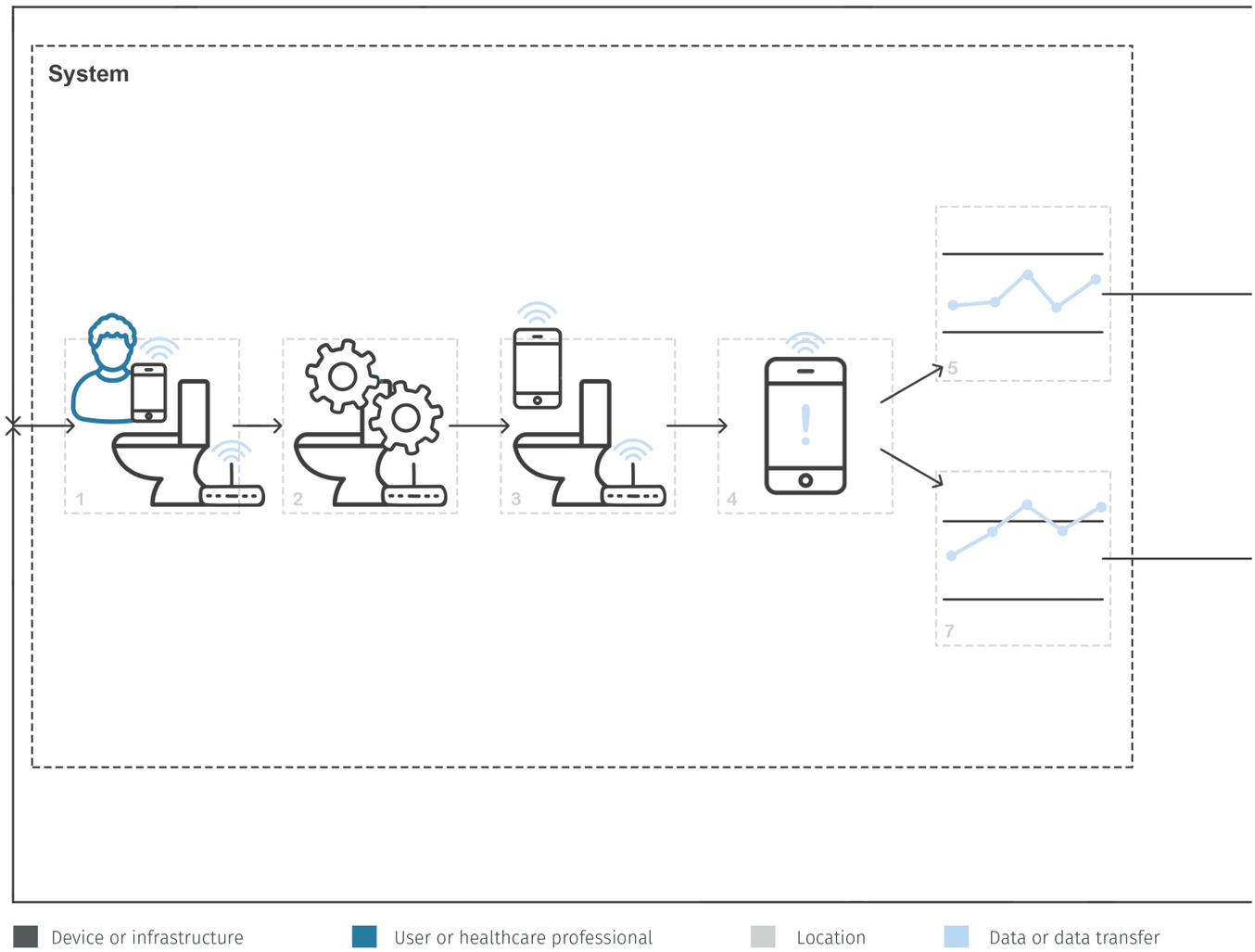


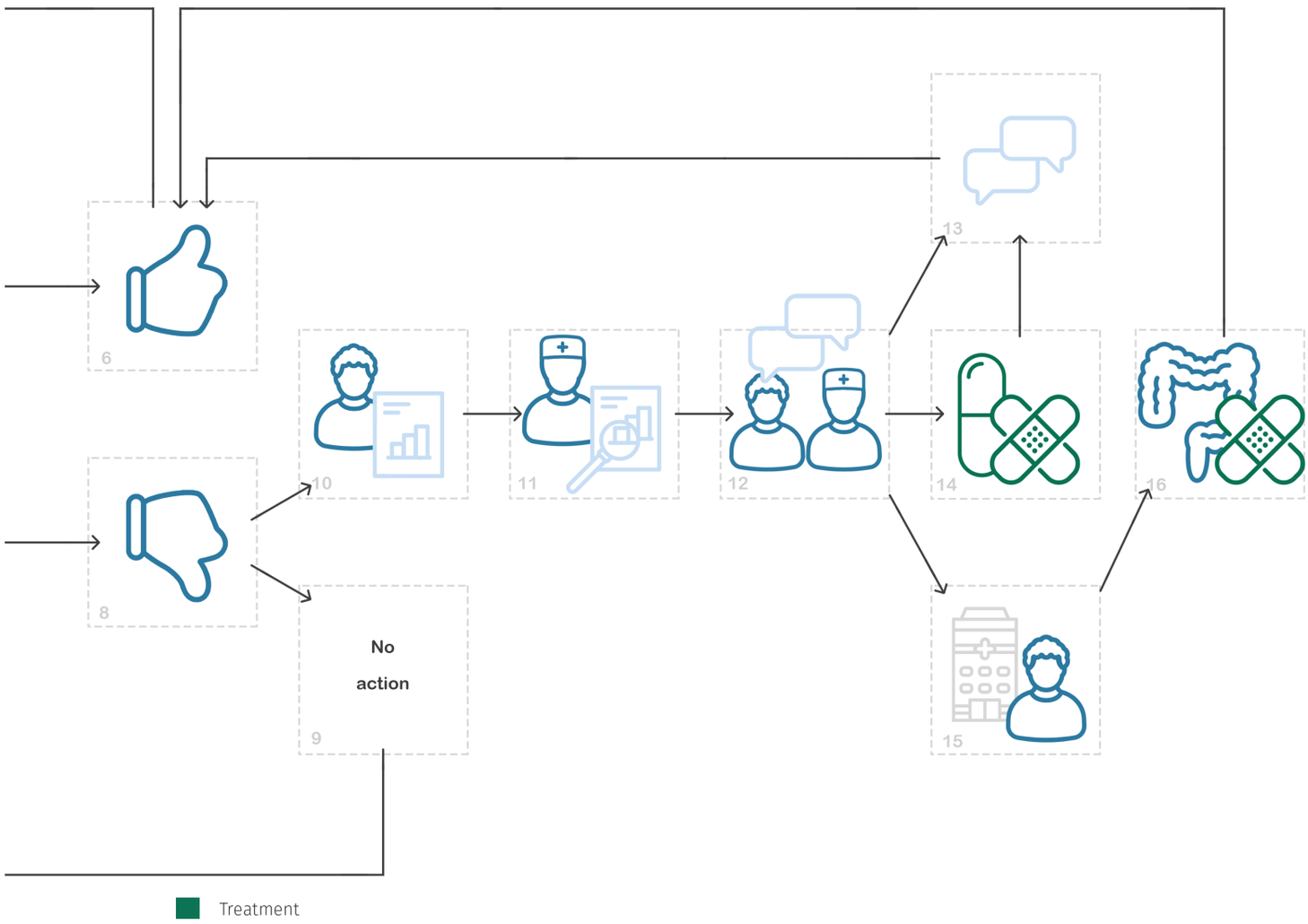
Figure 23. System work-flow in the super-system perspective.

most likely be done through the physical design of the system. **Fifth**, the cleaning subsystem which is responsible for cleaning the sensors before and after testing as well as testing the sensors for their capability of providing a valid measurement. When thinking about this subsystem, a system should come to mind with physical cleaning tools as well as basins containing unpolluted water to serve as baseline measurement. **Sixth**, the measuring subsystem which is responsible for measuring the biomarkers. When thinking about this system the measurement methods, as described in Part I Chapter 2, should come to mind. **Last**, the inner and outer architecture subsystems which are responsible for containing all inner parts and protecting the system against pollution and damages while connecting to the super-system context, respectively. When thinking about either of these two subsystems, plastic parts should come to mind which are watertight and, depending on the target group, neatly designed representing the company.

12.5.3 Super-system work-flow allocation

Finally, it is necessary to depict the workflow[57] of the system in combination with the relevant stakeholders to demonstrate how the user could and should use the system to monitor their health condition. Additionally, this depiction can demonstrate the role of the medical industry and the relevant care professionals. Step 1 to 7 describe the work-flow of the system, which is a simplified version of the work-flow depicted in figure 23. Important to notice is that the system, and most importantly its

[57] The work-flow is divided into steps.



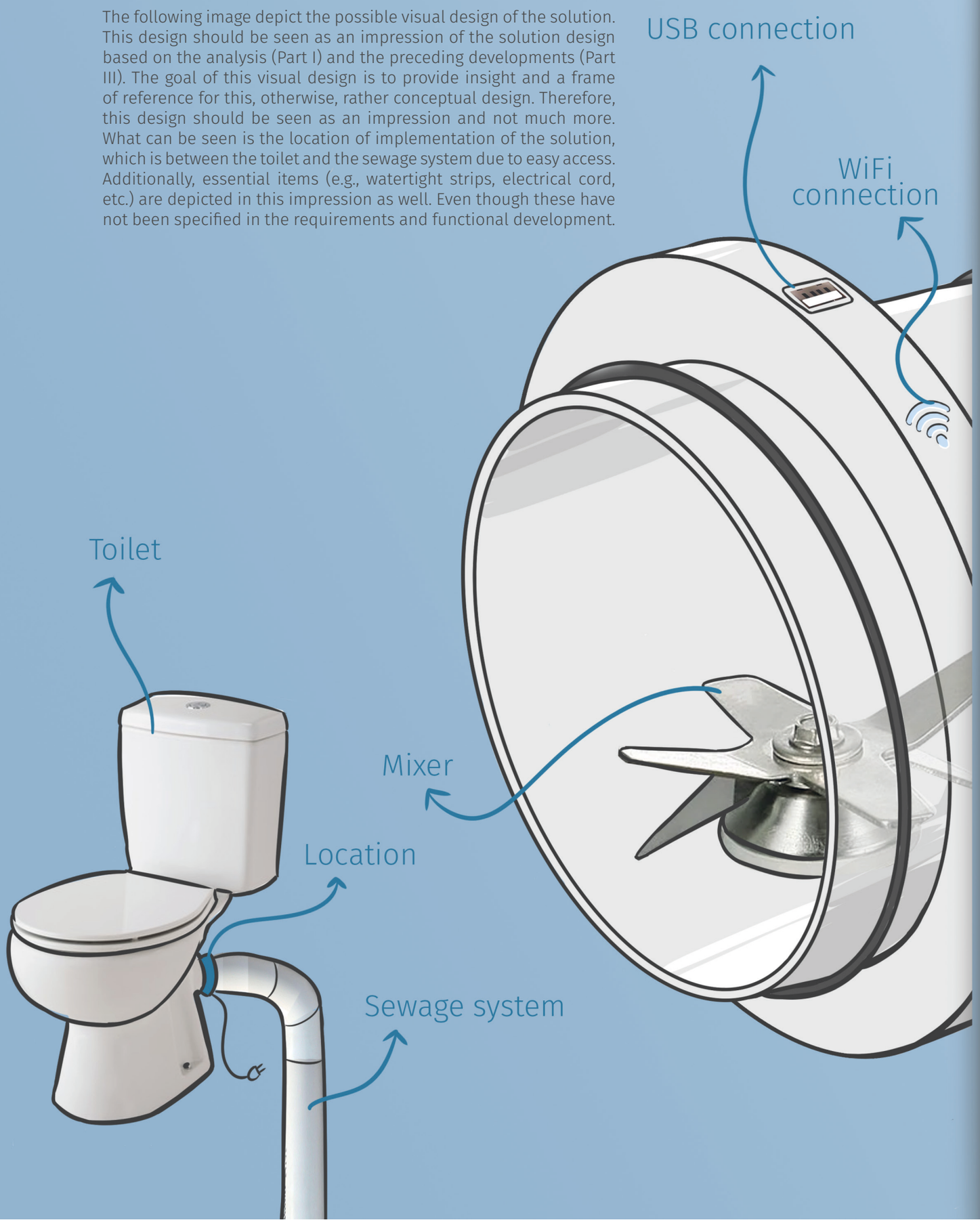
responsibilities, do not exceed these bounds. As has been mentioned in Part I Chapter 4.3, the intended use of the system does not include the interpretation of the analyses and measurements made by the device. Otherwise, the solution would be considered as a diagnostic device with all consequences considered. This changes in the future development and extension of the solution, which can be read in Part V. Step 6 and 8 depict the interpretation of the results. Step 10 is depicts the user transforming the data to something that the GP can read and understand. In the first versions of the solution, it is advised to develop the system in such a way that the user is capable of printing the reports and taking these physical copies to the GP (as digital means or impractical and undesired, Part I). In line with design principles 2 and 3, such a connection should be avoided. At step 11, the user makes contact with the GP and is able to show the reports containing the analyses of the health condition of the user. Ideally, the GP is convinced of the value, trustworthiness, and validity of the system and regards the results as trustworthy and usable. From step 12 to 16 the treatment options are defined based on the expertise of the GP. After that, the cyclical nature of this super-system work-flow makes its appearance and the process repeats itself from the start.

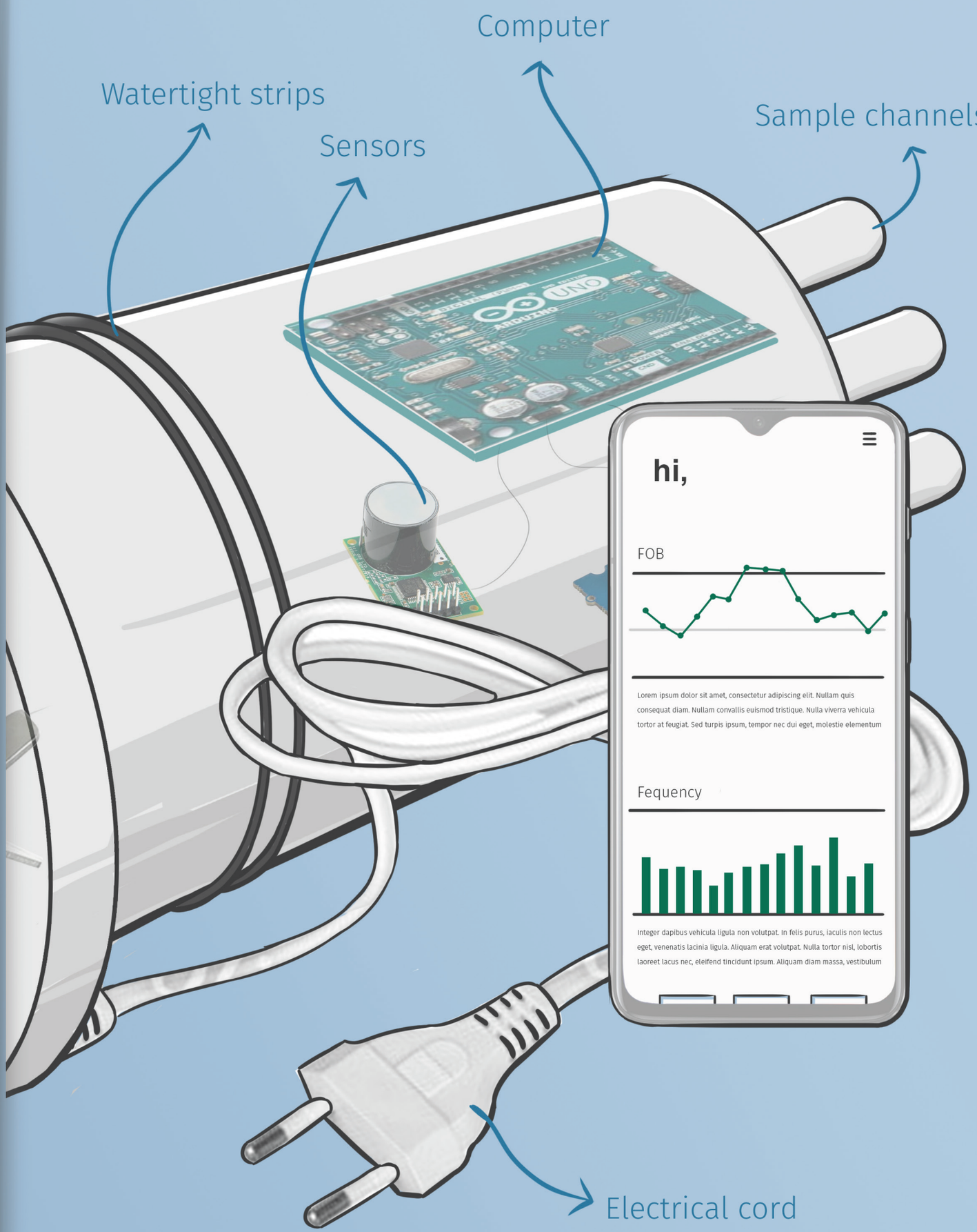
This super-system process work-flow should show the functioning of the system in context with its user and the relevant care professional, the GP. Additionally, this process serves as the generic design that can be applied to other contexts as well: when doing so, the relevant stakeholders or the type of users might change, but the main process flow remains the same. Additionally, such an overview allows for making alterations, and improving or expanding the process to include other functions as well.

The next page shows a visual depiction of the solution.

12.6 DESIGN IMPRESSION

The following image depict the possible visual design of the solution. This design should be seen as an impression of the solution design based on the analysis (Part I) and the preceding developments (Part III). The goal of this visual design is to provide insight and a frame of reference for this, otherwise, rather conceptual design. Therefore, this design should be seen as an impression and not much more. What can be seen is the location of implementation of the solution, which is between the toilet and the sewage system due to easy access. Additionally, essential items (e.g., watertight strips, electrical cord, etc.) are depicted in this impression as well. Even though these have not been specified in the requirements and functional development.

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SUMMARY

When developing a solution knowing the user is vital for the successful adoption of the product into the desired context. This holds especially true for the development of consumer products: products that lean heavily on usability and user friendliness in order to attract users, and thus customers. Establishing a target group for a product that does not exist yet in any way, shape, or form is a tough feat. In this case, a system, as that what is designed here, cannot be found in the current medical consumer market. Therefore, an established target group cannot be found and must be designed.
Four characteristics have been established that can describe potential individuals belonging to the designed target group. First, the user must have an understanding of the chance of developing CRC as well as a more established understanding of the consequences of having such a disease. Second, the user must have the financial capacity to purchase such a solution. Third, the user must be of an age that is susceptible to CRC. Otherwise, the need for such a system will be severely lacking which, in turn, will most likely not result in purchasing the system. Fourth, the archetypical user must have a certain interest or desire in monitoring and, above-all, seeing physiological data about him/herself. Last, the user must be willing to modify their toilet for the installation of the product.
Examples of groups that have a combination of these characteristics have been discussed resulting in three clusters: the first cluster of people would consists of over (an estimated) 5 million people, living in 3,4 million households, with an average spendable income of €55.000 euros a year, of which 2.442 people (1 out of 20) passed away from CRC and its complications. The second group that will be discussed is the group of people that undergo a full body scan at PreScan, the infamous Dutch company. The third group that has been discussed, is the group of people heavily interested in tracking anything about their body, mind, and health: the Quantified Self (Wolf, 2010). The Quantified Self (QS) is a movement focused on gathering, understanding, and learning from data generated from the human body.
For the development of the solution, three design principles have been established derived from the analysis in Part I. First, the principle of 'safety by design. This first principle indicates the importance of the safety of this solution. Common in medical device development, risk management methods are employed to define and avoid safety hazards. Second, the principle of 'maximizing value'. This principle embellishes the important of the maximization of value. Last, the principle of 'Usability, simplicity, and affordability above functionality'. The usability of the system is vital for the adoption of the technology by the users. Additionally, the simplicity of the solution design should be prioritized above functionality. In other words, if a functionality could be added that will make the solution significantly complex, then it should be opted to leave that functionality out of the solution design.
From these principles, requirements have been established for the solution which resulted in functions and workflows. Defining the functions allows for a detailed generic design and the possibility to assess super-system behaviour in relation to stakeholders. The functions to take into account are to measure, to analyse, to report, to store, to clean, and to recognize. First, what is important to include in the measuring process is the method of measuring the biomarkers FOB and pH. Measuring FOB is done by adding a reagent to the excrement and detecting the reaction, whilst pH is measured with a sensor that is placed in the excrement. Therefore, the 'spot' of the stool that is measured should be an accurate representation of the total stool as otherwise, the measurement can be deemed invalid. To be assured that the system is capable of providing a valid measurement, it is therefore decided that the stool will be mixed before measuring. As it is assumed that a homogeneous sample will provide a more representative measurement that is valid. Important to emphasize that mixing and dividing the stool over channels are new functions added to the system that were not originally included. Second, measuring FOB can distort any subsequent measurements as a reagent must be added. Therefore, FOB must be measured as last in the process. Last, mixing the sample will distort measurements of the type on the Bristol Stool Chart as well. Therefore, this measurement must precede the mixing process.
In conclusion, three diagrams have been developed showing the functioning of the system. The first diagram discusses the work-flow of each of the functions to provide a valid measurement. The second diagram shows the architecture of the system and its subsystems in context to relevant stakeholders. The last diagram shows how the system operates in relation to the super-system and stakeholders. In addition, a visual representation of the solution (not the final design but an impression) has been provided to add some sense to the, otherwise rather conceptual, approach in this report.

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PART IV

IMPLEMENTATION DESIGN

This part focusses on the implementation of the solution in its intended context. Based on the thorough analysis, four routes have been defined through which the solution can enter the market and in combination with the assessment of the company's capabilities, an implementation design is presented. This design consists of four phases describing how the company can transform the solution into its intended medical application, over time. The Capital Model is used to structure these phases, providing insight through the six perspectives.


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13. DEVELOPING THE IMPLEMENTATION

This chapter describes the goals, limitations, structure and manner of validation of the solution implementation. Each of these subjects is elaborated upon to make it clear why this chapter is so important. First, limitations of the company are discussed that affect the ability to realise the solution. Most of these limitations are resource-based and will the capabilities of the company. Second, the necessity of providing proof is discussed. Third, the concept of minimal viable product (MVP) is discussed as it tries to circumvent the limitations as discussed before. Fourth, a roadmap is provided showing how the solution can be implemented in the appropriate context and how financial means, stakeholder influence and other interesting characteristics weigh in. Last, general pitfalls of this approach are discussed to emphasize how the roadmap should be implemented and what the value of this roadmap is. In the following chapter the 'capital model' is discussed that will provide the structure of the phases of implementation.

13.1 GOAL OF PHASED IMPLEMENTATION

The goal of the implementation is to describe the conditions of the development that will allow for a successful integration of the solution in the appropriate context. These conditions alter between the different phases and are in need of a detailed exposition so that the company can use this implementation chapter as a roadmap of development. In other words, this implementation chapter could, and in my opinion should, be used as a roadmap for the development of the solution. As mentioned before, this roadmap is separated into four phases. Each of these phases describe a different application of the solution and the associated conditions. Important to realise is that these phases are not the typical phases that follow each other in a linear fashion. The first two phases do so, yet the following two phases are more of a pick-and-choose based on the current state of the solution, the development process, the availability of resources, the company's status and its intended pursuit. It might occur that the goal of the company with application of the solution alters during the development and execution of a particular phase. In that case, the company could opt to no execute one of the remaining phases. It's a decision that only the company can make.

13.2 OBSTACLES

A starting company has limited resources available for developing radical innovations and new solutions. However, these resources are necessary for the development and must be acquired. A small software start-up might make do with a few laptops and some cash, but in this case, that will not suffice. In this case, we are looking at a product-service system containing both software as hardware components in a heavily regulated industry with lots of sceptical stakeholders that all have to interact to implement the solution successfully.
The implementation overview provided is not the absolute truth. It is an analysis-based sequence of events that is ought to be suitable for achieving a successful implementation of the solution.
Therefore, it is vital to understand the possible obstacles (i.e.., limitations and pitfalls) of the implementation roadmap. By doing so, it should become clear what the error margin of the roadmap is and thus, what value it brings to the company.
These obstacles are discussed in three different categories. **First**, a look is taken at resource-based obstacles: restrictions and limitations due to the resource availability of the company. **Second**, value-based obstacles are discussed that show the difficulty in implementing a radical innovation. **Last**, project-based limitations and pitfalls are discussed, including the discussion on theory versus practice.

> Succeeding in business is often dependent on "overcoming a series of potential barriers, e.g. limited human capital, management capabilities, high uncertainty in terms of product and market, volatile development process, weak partnership ties" (Fielden, Davidson, & Makin, 2000).

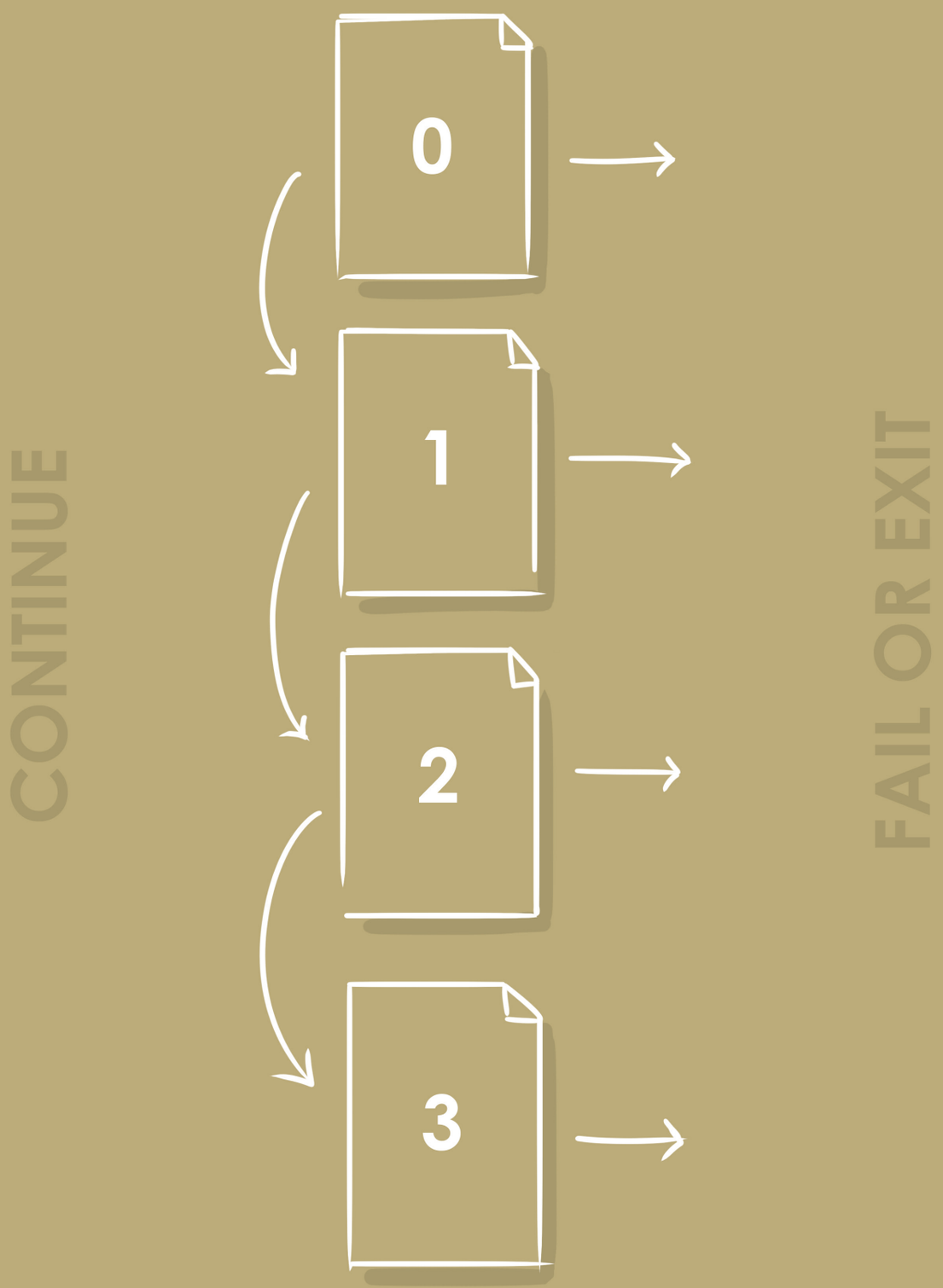


Figure 24. Implementation phases and their interrelation

13.2.1 Resource-based obstacles

The **first** generic issue is the lack in resources, especially time and money. As would not be surprising, a company of three has limited access to financial investments when just started. With three employees, the time available that can be spent on the development of this solution is also severely limited. The **second** limitation is in the available experiences and knowledge of this solution and of the industry and context in which the solution will operate. The company has three employees of which one works in the medical industry. At the start of the development of the solution, no knowledge was available on CRC or gastroentology which are vital research topics. Additionally, no experience was present on starting a medical device company and thus, no knowledge was available on the regulations and liability issues present in medical device development. Knowledge that is essential, as the solution must be developed according to the regulations for it to be accepted onto the market. Developing a solution but disregarding the regulations will result in rejected proposal and obsolete investments. **Third**, even more so, due to the lack of medical knowledge and the lack of proof of being capable of developing medical devices, credibility limitations also play part. A company that has not shown being able to develop a medical device and that company also not being supported by trusted care professionals, is not being seen as credible. Due to this lack in credibility, convincing necessary key partners of providing necessary resources and knowledge is quite difficult and will hamper development. In addition, acquiring necessary financial investments is also difficult and will, therefore, negatively impact the development and business viability of the entire operation. Especially in the case of acquiring investments, (angel) investors and venture capitalists (VC's) look at the team, credibility, and market opportunities to base their investment decision on.

13.2.2 Value-based obstacles

Understanding what the value is of something that does not yet exist is difficult. Seeing the potential in a new innovation or understanding what something could become in the future, are difficult skills to master, burdened by experiences and perceptions.
Convincing customers, key partners, relevant stakeholders, regulatory bodies and other involved actors of the value of the solution when it does not exist yet, is also difficult. When a key actor sees no value in the proposed solution, interaction will be most likely be ruled out.
This has been made abundantly clear during the development of this solution : not everybody is capable or willing to see value in something that has not been fully developed yet. This is partly due to the common Dutch mentality, "eerst zien dan geloven" ("seeing before believing"), as well as due to the evidence-based nature of the industry (which coincides with each other).
This concept can be best explained with some pragmatic examples.
In the case of the **customers**, buying something that you do not know if it works or not, is highly unlikely. Especially in the current consumer market place that is driven by online reviews, the solution must have proven its functionalities and value. An example could be the introduction of the first iPhone. A new telephone with a touch screen that provided more functionalities than ever seen before. However, Apple needed to develop and built the device to show the consumer the value it offered. Would Apple offered a vague concept and asked consumers if they would be interested in buying such a solution, than the story might have gone a different way.
Even more so, before a medical device can be sold, it needs to demonstrate its functionalities in a clinical study before it can be approved and sold on the market (as mentioned in chapter x.). Therefore, in the case of **regulatory stakeholders**, a working device must be built as otherwise the clinical studies cannot be performed. Changing variables or functionalities in this device will result in the clinical studies having to be performed yet another time. So, the device must be almost identical to the actual consumer version of the solution.
In the case of the **healthcare professionals**, promoting a product that has not been tested and accepted is a dangerous move. Especially as all healthcare professionals can be traced in the BIG register (online accreditation register) and can be held responsible for misconduct. So, the solution must be tested and approved upon by the regulatory stakeholders before a care professional is willing to attach his/her name to it.
In the case of **governmental** and **insurance stakeholders**, without proof no financing structures can be employed to implement the solution . The efficiency and (cost-)effectiveness of the solution must be studied and proven before these stakeholders will even go into discussion on adaptation and implementation.

In the case of **production** and **operation stakeholders**, without definite proof of customer and market value, no business can be done. In other words, if there is no proof of commercial viability and the possible pay-off, attracting the necessary partners to deliver parts of the operation of the total solution will be an impossible feat. Therefore, due to resource dependency one must be able to contract partners which can provide.

13.3 LEGEND

Across the entire implementation design part, similar symbols are used to display the super-system and system design, as well as the business model of the solution. These symbols include the company (as legal manufacturer), the user/patient/consumer, a healthcare research institute (which is necessary during the validation studies, the insurer, and the NB. Figure 25. shows which of the relevant stakeholders is depicted with which symbols, providing guidance to understand the illustrations.

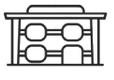
	Common representation	Specific organization(s)
	**Legal Manufacturer (LM)**	The company
	**In Vitro diagnostic device**	The solution system
	**Database**	Gathering point of health and usage information, as well as construction place for the individual reports.
	**User**	The user, patient, and/or consumer.
	**Sample**	The feacal matter that is measured and analysed.
	**Population**	Individual(s), employees, research population, user base.
	**Research institute**	Gastroentology research department in a hospital, a specialized research centre, TNO, etc.
	**Sponsor**	The organization paying for the clinical validation study. Can be either the company, or another organization. E.g., KWF, RIVM, etc.
	**Insurer**	Insurance company. E.g., Achmea, VGZ, CZ, Menzis, etc.
	**Notified Body**	BSI Group

Figure 25. Legend.

14. PHASE 0 - PROTOTYPING

This phase describes the start of the further development of the solution. Whereas other phases are targeted at specific applications in specific contexts, this phase purely serves to deliver a proof of concept. That is the goal of this phase and it is important, as without proof it becomes nearly impossible to convince stakeholders of participating in this project. **First**, this phase is elaborated upon in the six perspectives as mentioned before: financial, human, intellectual, social, organizational, and resource capital. In these chapters, suggestions on actions that the company should perform based on the analysis of the context are provided in combination with a summary of possible pitfalls that detail avoidable risks. Additionally, mitigation strategies are provided that can aid the prevention of such risks. **Second**, a description is provided that details how the company can judge if this phase is successfully executed and completed. **Last**, decision criteria are provided that should be used to decide if another phase should be entered. To emphasize, the final decision is that of the company. It is not I who decided whether or not a phase is successfully completed or if it's time to move to the next phase.

14.1 SOLUTION DESIGN

In this phase, the solution should be developed as a prototype. It will become the first real-life implementation of the solution. As mentioned in the introduction, the goal of this phase is not to develop the most ideal version of the solution, but to develop and construct a version that is testable and able to be used for testing and the gathering of feedback.

> Prototypes should command only as much time, effort, and investment as are needed to generate useful feedback and evolve an idea. The more "finished" a prototype seems, the less likely its creators will be to pay attention to and profit from feedback. The goal of prototyping isn't to finish. It is to learn about the strengths and weaknesses of the idea and to identify new directions that further prototypes might take (Brown, 2008).

Therefore, not all functions from the ideal version of the solution are included in the prototype. The functions that are essential to showcase the possible applications of the solution focus only on measuring the faecal components, processing these so that the results can be analysed and an evaluation of the health status of the sample can be provided. Other functionalities, like performing big data analyses or communicating the results to the user, are either impossible due the lack of gathered information, or unnecessary as the product is not yet in the consumer product development phase.

14.2 KEY ACTIVITIES

A short description is provided detailing the key activities that the company must undertake to secure the survivability of the project as well as the company. These activities provide an overview of the main focus of this phase and what the company must do or a successful execution. In the following paragraphs, more detail is spent on the implications of these activities in light of each of the capital perspectives.
First, The main activity of this phase is the construction of the prototype. Most effort should be spent on this activity, as it will define the successfully completion of this phase. **Second**, as equity loans, investments, subsidies, and other financial capital measures take considerable amounts of time to finalize, it is important to make contact in this phase. Not only will it allow for a quicker resolution when the money is most needed, it is also beneficial for the chance on attracting the necessary capital funds. Making contact as early as possible allows for the company to question the amount and type of evidence the investor would like to see before investing. Doing so, the company is able to prevent the situation wherein 'wrong' proof of the concept is gathered. **Last**, for talking with (potential) investors, it is important to secure the idea and the future of the company against possible threats. Additionally, investors in high-tech companies are especially interested in the intellectual property position of the company[58]. I believe this is due to the fact that the intellectual property of a high-tech firm is the asset which can be commercialized and not easy copied.

[58] Fund the Future, 9-4-2019, Gallery, Enschede.

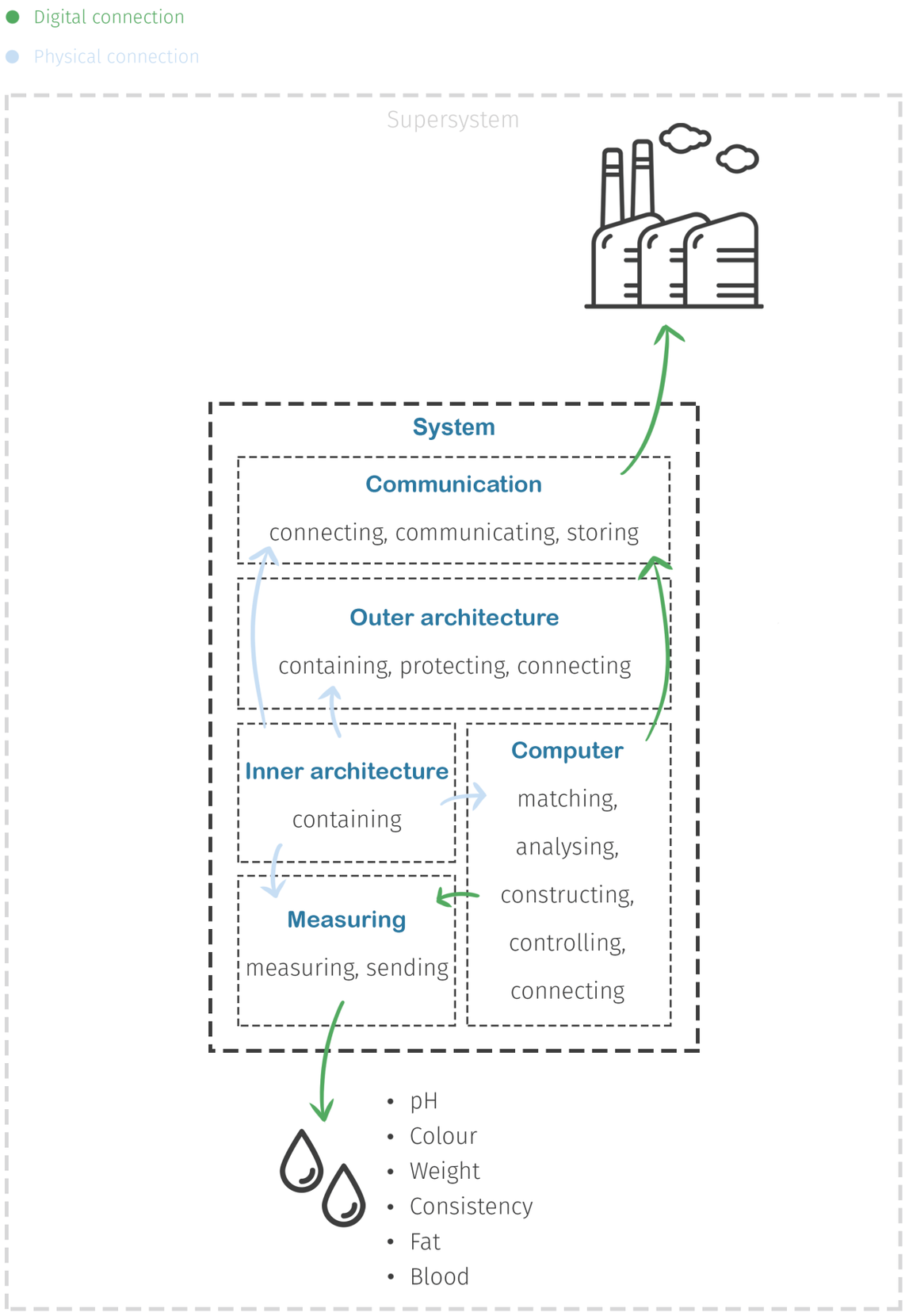


Figure 26. System overview of the prototype during the prototype phase.

14.3 SOCIAL CAPITAL

The social capital perspective looks at the relevant stakeholders that should become involved in the development of the solution and what the relationship must be like. During the prototyping phase, no target group has to be accounted for. As mentioned in the previous part (Part III, Chapter 11.2), people that identify as Quantified Self could become involved in the development of the prototype. The Quantified Selfers could be included in the development of the solution as they are the designated early adopters. Quantified Selfers can, through co-design principles, guide the set of requirements and specifications. Doing so, the first prototype will be better aligned with the first consumer version (phase 1), saving costs and resources upfront. However, the calculation between costs and benefits should carefully be evaluated. If the costs of including Quantified Selfers outweigh the benefits are even reach break-even, than it would be wise to disregard this group for now. Especially due to the limited resources. During this phase, only one stakeholder is truly vital to the progression of the company: the angel investor. To clarify first, this can be any person or organization that is willing to invest into the company to make up for the lack in necessary resources. The investor stakeholder should be contacted as soon as possible as 'the runway'[59] of the company in this phase in the development is relatively short. The relation must be intense and based on trust, as the company should convince the investor to invest into the product as soon as the prototype has shown 'proof of concept'. Starting a relationship before financial involvement (and thus the accompanying interference of diverging interests), is assumed to improve the ease of attaining the investment as well as the trust of the investor into the company and the team. A stakeholder that adds value to this phase is the healthcare professional specialized in CRC and, possibly, other digestive diseases (i.e. gastroentologist). The healthcare professional stakeholder can guide the requirements and specifications in such a way that they align more with the application of the solution as a healthcare device (phase 2). Both of these stakeholders are not necessary for the successful execution of phase 0, yet save costs and trouble in later phases. Therefore, it is advised that when possible these stakeholders should be included. When the investment necessary to include these stakeholders is beyond the limits of the resources, then it must be passed aside.
One of the possible pitfalls in this phase, is the possibility to gather the wrong proof. In other words, it is important to have intensive discussions and clear agreements with the relevant stakeholders on what proof needs to be delivered. Especially in this phase, where the company is still fragile and immature, it is important to have a clear target. Nothing can be as sour, as spending considerable effort and (financial) investments and then, realize that the relevant stakeholders are not convinced as the data does not meet their standards. Therefore, it is advised that the company makes clear agreements with the stakeholders on what proof must be gathered. As can be deducted from discussions, most stakeholders in this context are open for discussion on this topic[60]. What should be remembered in the preparation for and during these conversations, is safeguarding the intellectual property. As mentioned in the Intellectual Capital paragraph, the intellectual property of the company about the solution is the predominant piece of value for the company and the safety of this information is therefore without-doubt linked to the survivability of the firm. During these conversations it is therefore vital to do two things: (1) don't tell too much, and (2) use an non-disclosure agreement (NDA). Often it is thought that using the NDA is a sign of mistrust, as it is a contract prohibiting from passing on information. However, rather the opposite is true: using an NDA shows seriousness and professionalism.

14.4 HUMAN CAPITAL

The human capital perspective looks at the needed team competencies and skills to execute the given tasks. To start of, it is important to realize that this paragraph will describe the necessary competencies and not specific people or roles. Especially in the ex-ante period, multiple competencies can be present in one person (and would be ideal, as then one would need to hire less). To be able to understand what competencies are necessary, a look is taken at the functions that the solution is intended to perform. These functions must be developed by the development team members and through logic it can be assessed what set of skills are necessary. Derived from the solution design paragraph (24.2),

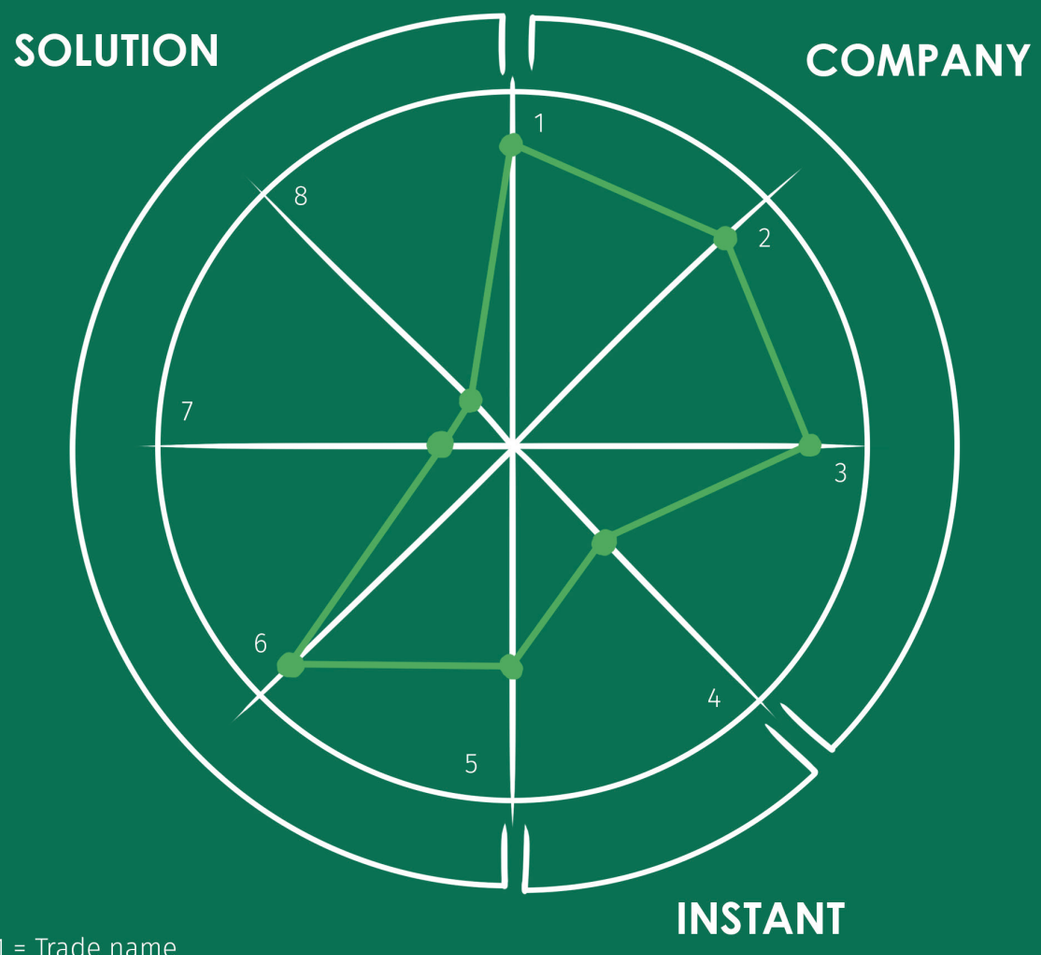
[59] The time a start-up has left before running out of resources. Concept from 'The lean startup' by Ries (2011).
[60] In conversation with a healthcare insurer at a conference ('Wie gaat dat betalen?', 26-11-2018, Hotel theater Figi, Zeist), as well as a business developer for Oost NL (11-12-2018, Gallery, Enschede).

the only functionalities that the solution must perform is the ability to measure the faecal contents of the sample and communicate these results with a computing unit that can deliver visual and written feedback. For the measuring function, sensors and electronics need to be developed that can measure the different parameters. **First**, someone with the competency to work with such electronics must be present in the team. **Second**, Without proper coding, those electronics will not function and therefore, someone with the competency of programming should be present in the team. This person should also be able to develop a program that can read out the sensors and transpose their measurements in some sort of visual report. All the components must be installed in some sort of housing device that is capable of receiving the faecal sample, has room for the measuring units, and is capable of disposing the sample. **Third**, someone that is capable of developing such a hardware unit must be present in the team. **Last**, someone with business experience must also be present in the team that is able to make contact with possible investors and is able to communicate the idea and convince the investors of funding.
Summarizing, the team must have the following competencies: electronic skills, coding and programming capabilities, engineering capabilities, and being able to make contact, communicate, and convince.

14.5 INTELLECTUAL CAPITAL

During this phase, the only competitive edge that the company is able to attain is the knowledge that has been gained by developing this solution. In other words, intellectual capital is the one asset that can secure the future of the company and can be used to defend their place in the marketplace. Even more so, the intellectual property position of a company (e.g. the number of patents the company has) is a strong reason for investors to invest into a company or not[61]. In this chapter, a look is taken at the types of intellectual capital that can be secured and maintained as well as the types of knowledge that should be gained and cumulated. To have an understanding of what actions need to be performed to safeguard and capitalize on intellectual property, it is necessary to understand the relevant types of intellectual property first. Therefore, a summation is provided in this paragraph that should clarify the topic[62]. In short, the relevant pieces of intellectual property protection methods are trade name, trademark, domain name, copyright, trade secrets, patent, chip right, and design right. A trade name (*handelsnaam*) is the name the company uses to do business with other companies. It is registered at the Chamber of Commerce (KvK), yet does not offer much protection. However, it can breach the domain name (*domeinnaam*). The domain name is the name of the company's website. The trademark (*merkenrecht*) is a strong measure for the protection of intellectual property. It is publicly registered name and offers a monopoly on doing business with a specific type of product in a specific type of market. In this phase, these should be applied as soon as possible. With all these measures, the procedure is first come, first serve. Additionally, the costs for these types of measures are limited, as they do not exceed €1,500. Copyright is well-known example of an intellectual property right. Copyright originates as soon as some piece of work is created. Copyright is free, however it is advised to document the creation of copyrighted material which could cause some costs. In this phase, it is important to mark all created documents with the copyright symbol and keep records of created pieces of work. Ideally, if some sort of documentation hub exists, an archive could be created collecting all versions of created pieces of work. This could aid to the claim of a created piece of work. Similarly to copyright, trade secrets are essentially free but can have additional costs as trade secrets should be included in HR policies, by-laws, and other company related policies. In this phase, essentially everything that is created and is not patented or publicized, is a trade secret. Therefore, the company must be watchful during conversations with third party organisations and people. One option that could be effective, is to document the trade secrets and place them under the protection of an depot (www.i-depot.nl, a subsidiary of the BBIE, the Benelux patent office) or a notary. This will only be effective, if these allocations are included in the NDA's that third party stakeholders sign. Last, patents, chip right, and design right all are results of the product development. In addition, It is advised to start with the implementation of a small PLM system to document al finding and start building the intellectual capital of the firm. Therefore, documenting all reports, thoughts, and findings into some sort of system that aids to the internal visibility of this information can prove its merits.

[61] In conversations with healthcare and business professionals, **Appendix 2**.
[62] Basis intellectueel eigendom workshop, 6-11-2018, RVO, Utrecht.



1 = Trade name
2 = Trademark
3 = Domain name
4 = Copyright
5 = Trade secrets
6 = Patent
7 = Chip right
8 = Design right

Figure 27. Intellectual capital mix.
This figure shows the amount of focus should be laid upon each of the intellectual property protection methods. The dot on the axis shows the relative amount of focus that should be invested. A dot closer to the centre of the model, indicates a low level of focus. A dot near the edge of the model, indicates a high level of focus.

14.6 ORGANIZATIONAL CAPITAL

During this phase, it is not yet necessary to officially start a company. During this phase the main priority should be on developing the prototype and establish the necessary relationships that aid the further development of the solution. As the company structure is not vital for the development of the solution, it can be neglected during this phase. The only structure that should be present, is the division of task between the founders regarding the development aspect, as well as the business and network aspect. Similarly, the only strategic objective during this phase is the rapid development of the prototype. Some tactical goals include the development and establishment of intellectual property, and the building of relationships that can ease the attraction of the necessary workforce.

14.7 RESOURCE CAPITAL

During this phase, not much assets are needed to complete the development. Due to the high experimental character, the likelihood that the necessary assets are not anything else than common tools (that could be in the possession of the founders of the company) is rather high. Examples include, a laptop for the development of the software for the operation of the machine, tools like a claw-hammer, a socket wrench, screwdrivers, and pliers. Even more so, tools could be borrowed from family and friends, further reducing the necessary capital to construct the prototype.

14.8 FINANCIAL CAPITAL

The financial capital perspective looks at the necessary investments that need to be done, the business model and business case describing how the company can capitalize on the solution. **First**, during this phase not much investments are necessary to execute the goal of this phase: developing a prototype as a 'proof of concept' that is able to convince the necessary stakeholders. Therefore, the investment that must be made during this phase is the investment in personnel (human capital), equipment and materials (resource capital) needed for the construction of the prototype. To save costs, it is possible to either rent or loan the equipment necessary for the construction. In personnel costs, it could be possible that the founders of the company are willing to hand in their salaries for the benefit of the company. On materials no costs can be saved, other then the cheapest options. Therefore, it is reasonable to assume that the cost of the development of the prototype (assuming no human capital and equipment expenditures) to be <€5.000 (Additional information can be found in **Appendix 9**). **Second**, during this phase no customers exist and therefore no business model exists. The goal of this phase is to develop proof of the functioning of the system. The following phases will spend more time and effort in gathering proof that customers are interested in such a solution and are willing to pay. In the next phase, this topic is more elaborated upon. **Last**, during this phase no actual business case exists. Literature suggests the Headroom method to calculate the difference between the maximum reimbursable price and the production and commercialization costs (Vallejo-Torres et al., 2008). Yet not enough information exists to do so. Even more so, a business case is only relevant to a (potential) investor, and the business case that should be looked into is the business case of phase one and two.

14.9 SUCCESSFUL COMPLETION

This phase is successfully completed, if the prototype has been developed and built, and the company, through the prototype, is capable of convincing an investor in investing into the company. The decision criteria that should be used to decide if enough progress has been made to proceed to the next phase are the following: this phase must be successfully completed. That is, the prototype must be working and funding must have been secured.

***** Literature, as well as mentioned numerous times during Fund the Future, 9-4-2019, Gallery. Enschede.

15. PHASE 1 - CONSUMER PRODUCT

This phase describes the development trajectory going from the prototype to a fully-fledged consumer product. This is the first phase that the solution is applied in a real-life context. Additionally, it is the first phase where the company must formalize and structure to prepare for future growth. **First**, this phase is elaborated upon in the six perspectives as mentioned before: financial, human, intellectual, social, organizational, and resource capital. In these chapters, suggestions on actions that the company should perform based on the analysis of the context are provided in combination with a summary of possible pitfalls that detail avoidable risks. Additionally, mitigation strategies are provided that can aid the prevention of such risks. **Second**, a description is provided that details how the company can judge if this phase is successfully executed and completed. **Last**, decision criteria are provided that should be used to decide if another phase should be entered. To emphasize, the final decision is that of the company. It is not I who decided whether or not a phase is successfully completed or if it's time to move to the next phase.

15.1 SOLUTION DESIGN

15.1.1 A marketable solution

During this phase, the goal is to develop a version of the solution that can and is allowed to be sold onto the market. This allows for multiple benefits. **First**, selling the product can be used as a gauge for consumer interest. Every sale indicates an increase in consumer interest into the product. Additionally, customers that purchase the product can be interviewed about their motives of purchasing. Doing so, it also becomes possible to contact them for future development. **Second**, by selling the product the company has a form of income, that can prolong the runway and increase the chances of survival. **Third**, by selling the product and showing consumer interest, it becomes easier to attract more capital funding and start phase three of the total implementation roadmap. **Last**, by selling the product it also becomes possible to start the development of the database that will be the defining piece of intellectual property in phase three. This will be discussed in the following chapter. This all will be possible as the solution is *intended* as a consumer product and not a medical product. As has been learned from Part I Chapter 4.3, a consumer product is easier to achieve compliance and acquire the necessary CE-marking. This process is less resource intensive than the clinical validation needed for a medical device. A consumer product is easier to test and validate, and therefore, it is easier to get such a product on the market.

15.1.2 MVP

The consumer product should be regarded as a Minimal Viable Product (MVP). An MVP is a product consisting of minimal functionalities that still satisfies customer needs, whilst needed significantly smaller investments and fewer resources to be produced[63]. Additionally, such a MVP can be used to gather feedback from actual users and therefore, can be used to optimize any future iterations and releases of the product. The specific configuration of the MVP is something that cannot be defined as of now. Mostly due to the fact that currently, no established user group exists. However, some guidelines can be provided that can conduct the development of the MVP into the proper direction. **First**, a good look should be taken into the functionalities of the system. Functionalities that are vital for providing value for the users and feedback for the company must be included in the system. Functionalities that are only there to optimize the system's processes or to maximize user comfort could be regarded as less vital and therefore excluded from the MVP. E.g., excluding the subsystem that is responsible for communicating the usage of the system to the company is vital for a better understanding of the users. Therefore, this subsystem cannot be excluded from the MVP. **Second**, a good look should be taken into the actual realisation of the functionalities and how alternatives are able to reduce costs. An example: instead of a beautifully designed mobile app that displays the results, the user could also receive the results through a mail provided by the company or by plugging in their personal computer via USB. It should be carefully considered how much leniency the users are willing to provide. **Last**,

[63] In some sense, a MVP can be regarded as a pilot study for the successful implementation of the solution and the accompanying infrastructure. A pilot study can be used as a burden of proof when negotiating with insurers and the NZa in later phases of the implementation.

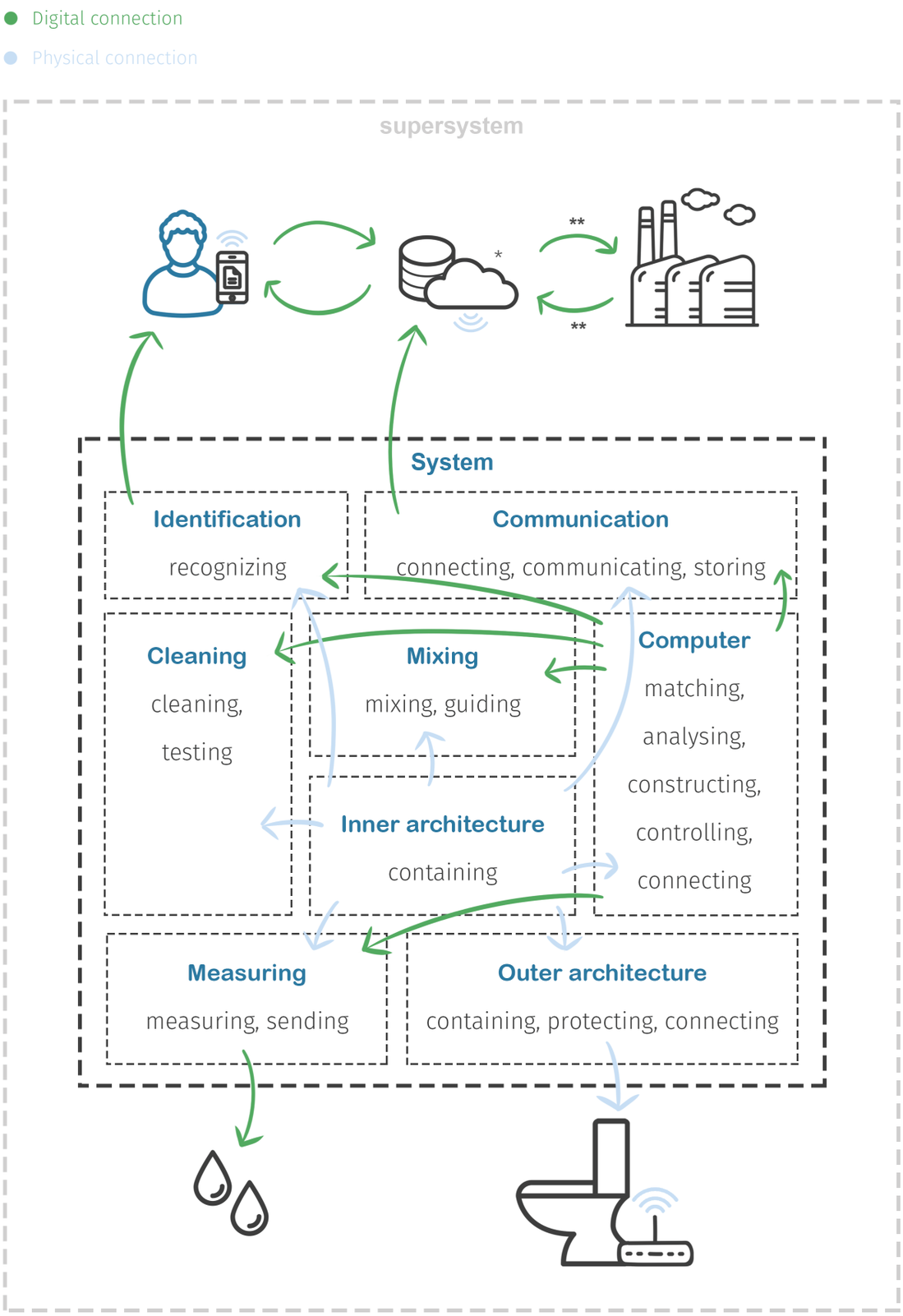


Figure 28. System overview of the prototype during the consumer product phase.
* A part of the communication subsystem has been taken over by the online database.
** If allowed by the consumer, personal health information could also be visible for the company. Otherwise, the company will have access to usage data and anonymized information.

the company could shift focus: from CRC diagnosis to lifestyle monitoring. In doing so, it becomes possible for the company to disregard measuring methods and systems (necessary for CRC diagnosis) that are too expensive to develop and implement in the MVP. However, it is important to notice that separate configurations of the solution need separate validation trials to achieve compliance. In other words, if the company desires to clinically validate the MVP configuration of the solution, so that no intermediate configuration has to be developed and released and thus saving costs, that version must have the CRC measurement subsystem included. Otherwise, a clinical trial does not make any sense if the CRC measurement system is excluded from the product.

15.2 KEY ACTIVITIES

A short description is provided detailing the key activities that the company must undertake to secure the survivability of the project as well as the company. These activities provide an overview of the main focus of this phase and what the company must do or a successful execution. In the following paragraphs, more detail is spent on the implications of these activities in light of each of the capital perspectives.

First, during this phase it is essential to formalize the company and establish proper structures and policies. Otherwise it is impossible to attract investors and to process the investments. Additionally, formalizing the company adds additional legitimacy and a sense of professionalism and proper intent. Which is beneficial in any stakeholder discussion. In addition, formalizing the company allows for the hiring of new talent, receiving subsidies, hiring office space, access to business networks, and much more. **Second**, as the intellectual property of the firm is the still the most defining asset, also in this phase much focus must laid upon securing intellectual property. Additionally, by protecting and safeguarding intellectual property, the company allows itself to generate business from the IP as well. If the company decides not to produce the solution itself, it can also sustain the business by licensing the ideas, knowledge, and solution generated through the early development. **Third**, new competencies are needed to execute the development process of the solution. As can be read in the company assessment (Part I Chapter 8), the company has no relevant experience in full-scale product development and engineering processes. Therefore, product developers, mechanical and electrical engineers must be attracted. In addition, a new marketing department must be established for people with the necessary capabilities of promoting, marketing, and selling such a solution. Otherwise, the product might be fully developed but no one will buy it. Additionally, preparations for the following phase must be started. So, the current limitations of the company, in the medical research field, must be overcome by hiring new competencies. Therefore, people with the necessary understanding in biomarker detection and medical device performance must be attracted. These people should be able to identify and define how this system must be validated and how such a test design will look like. Even more so, such a medical expert will also add to the sense of legitimacy of the company[64]. **Fourth**, the main activity during this phase is the development of the consumer product version of the solution. If done properly, enough financial capital has been attracted to complete the development, construction, and shipment of the consumer product. Otherwise, a tough financial situation has been created where the company is dependent on the next investor to succeed in this phase. As has been mentioned in conversations with experts[65], this often occurs at medical device companies but has to be avoided if possible. In such a situation, when the following investor is aware of the necessity of new capital investments, the negotiating power of the investor is significantly dominant. Possibly resulting in a unfavourable deal for the company. **Fifth**, in this phase, a consumer product will be developed and therefore, these consumers must be targeted and alerted that this solution exists and is available for purchase. Therefore, effort should be put into marketing. Selling products as a start-up used to be a difficult task as start-ups usually don't have access to the entire logistics and distribution parts of the supply chain. Therefore, co-operations with companies must be found to deliver products to the users in within a reasonable time. Working with such partners pose benefits as the distribution of products will be outsourced reducing the need for investing in establishing such a complex system self. Additionally, with reliable partners the service level of correct and on time distribution of products can be guaranteed to the customers. Handling errors might pose some delays as customer complaints have to reach the company most likely through

[64] Important for attracting funding and convincing more conservative stakeholders.
[65] Medical business owners, start-up investors, and company supervisor, **Appendix 2**.

the distribution partner. Nowadays, organizations like Amazon offer such services which demand steep service costs, but still offer a cheaper alternative to developing a supply chain self (Weldon & Clarkston Consulting, 2019). Unfortunately, developing such a system self could allow for additional customer data sourcing, but the question remains if that is the goal of the company. Therefore, it can be advised that establishing a deal with a distribution partner is most likely the most cost-effective solution to delivering the products to the customers. **Last**, it is important to start developing and future-proofing the database. As soon as one product is sold to a customer, the database should be up and running and able to process this data successfully. In the next phase it is important to possess and be able to access as much data as possible. Starting earlier will only allow for this to happen.

15.3 SOCIAL CAPITAL

The social capital perspective looks at the relevant stakeholders that should become involved in the development of the solution and what the relationship must be like.

15.3.1 Target group

During this phase, the main focus should be on the interested target group: the Quantified Self and similarly interested people. Due to the relative small size of the group and the relative high level of feeling the desire to group together and build a community, it should be relatively doable to make contact with this group. When investing in marketing methods, it is often highly desirable to directly target the predetermined target group. As the Quantified Self are heavily involved in building a community, marketing investments should be within limits. Additionally, the QS are believed to be capable in customising the product and the experience of the product to their liking, due to being heavily invested in novel technologies and pioneering prototypes. Regular healthcare customers are not (Van Wermeskerken, 2015).

15.3.2 Relevant stakeholders and their relations

During this phase, several relevant stakeholders ‘emerge’ (See Chapter 5). **First**, the QS should be used to finalize one part of the design: what is to be measured. The target group can be employed to co-design the solution and determine which elements should be measured as well, to create as much of a valuable product as possible (see figure 28). Therefore, though intensive target group analysis the company should be able to redefine and upgrade the set of biomarkers that the solution is able to measure. The deciding factor for including these measurement methods must be based on the technical feasibility and the business viability. In the most ideal situation, a measurement method is included that brings significant value for the target group, yet is relatively cheap and easy to implement for the company. **Second**, the relationship with the party that invested into the company based on the proof-of-concept should be maintained massively. As mentioned before, such an investor is often only looking for a return on investment. Therefore, it is highly advisable to develop the consumer version of the solution on only the funding provided by the first investor. As has been mentioned before, negotiating when being completely dependent on a new investment will only result in a deal with high demands and negative terms. Such a dependency on a second investment could result in bankruptcy, which must be avoided at all costs. **Third**, to prepare for the upcoming phase (Phase 2 - medical application), introductory talks could be scheduled with the relevant stakeholders of phase 2. Relationships (especially cooperative relationships) might take some time to develop in the Dutch medical industry. Any preparatory work regarding these relationships can pose significant time benefits in the following phases. **Last**, it is advised that the company focusses on the development of the solution and not on the production of the solution. Looking for and attracting a business partner capable of taking over the production is most likely significant cheaper than to procure the assets and personnel and construct a complete production line. As the company has limited resources, and numerous production partners for consumer products exist, it is considered a more suitable option to find a business partner that will deliver the production of the solution.

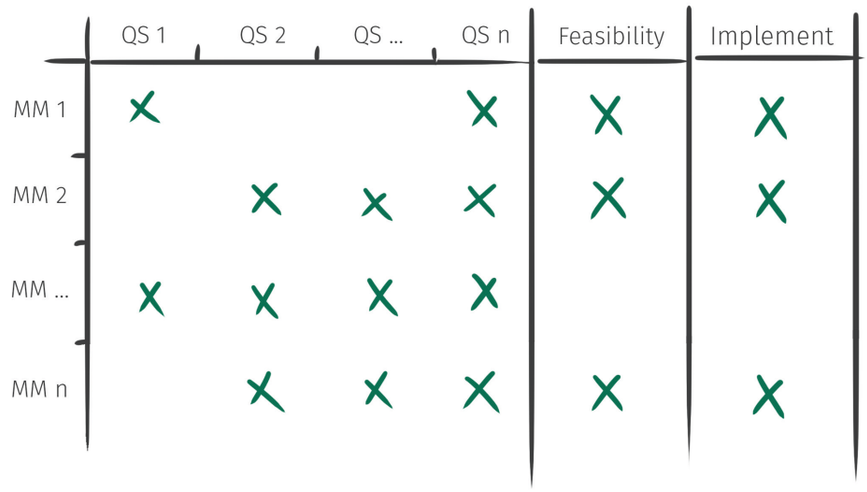


Figure 29. Example of the co-design matrix. Combining target group desires (QS) with the technical feasibility of the measuring method (MM) and thus, the decision to implement or not.

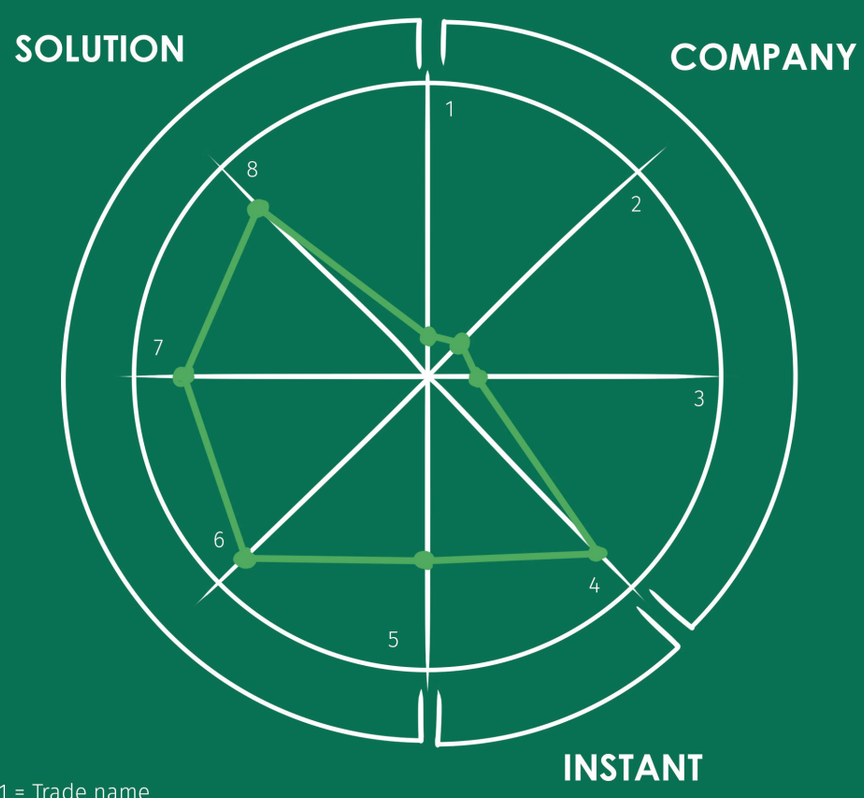
15.4 HUMAN CAPITAL

The human capital perspective looks at the needed team competencies and skills to execute the given tasks. **First**, as a preparation for the upcoming phase, it would be highly advisable to attract some sort of medical expert specialized in performing clinical studies. Preferably, someone that is a key opinion leader in the colorectal cancer research and is willing to commits to the project, and most importantly, attach his/her name to the project and the company. This is necessary for multiple reasons: **Second**, this medical expert is needed to lay the foundation for the randomised controlled trials set in phase two. This expertise is, since phase zero, lacking and should now be attracted. **Third**, this expertise would allow for receiving additional investments. Such a high-profile name and additional skill-set is vital to an investor. As research shows, that VC's invest most predominantly in teams they believe in[66] (Baum & Silverman, 2004; Byrne, 2000; Macmillan et al., 1987; Robinson, 1987; Hall and Hofer, 1993). Especially with start-ups, as other information that is used to make an investment decision (i.e. statistical analyses, cash-flows, ...) are not present in a start-up (Stinchcombe, 1965; Aldrich and Fiol, 1994; DiMaggio and Powell, 1983; Baum & Silverman, 2004; Podolny, 1993; Miloud, Aspelund & Cabrol, 2012; Narayanasamy, Hashemoghli & Rashid, 2012; Mousavi & Gigerenzer, 2014). **Last**, someone with marketing and advertisement competencies should become available to the company. Even though the target group is quite defined and relatively easy to contact, someone with the proper competencies should do so.

15.5 INTELLECTUAL CAPITAL

In this chapter, a look is taken at the types of intellectual capital that can be secured and maintained as well as the types of knowledge that should be gained and cumulated. During this phase, intellectual property is still the single competitive edge the company has against the competition. In this phase, it is vital that the company has secured a patent. Otherwise, a competitor might purchase the product, file a patent, and consequently sue the company. As in the previous phase it was emphasized that the company specific types of protection should have been applied for, the focus shift to the patent and to other methods. In addition, it is important to already start the intensive documentation procedures necessary for the clinical validation during phase two. Therefore, it is highly advised to document the complete development, construction, and testing of the solution. Additionally, it is also important to start with detailing and understanding the supply chain of the development of the solution as this is one of the demands that the IVDR states[67]. Even though this extensive type of documentation is not necessary for the development of consumer product, it is still highly advisable as this would save massive amounts of resources in the future when the solution is being tested and validated. Therefore, it should be taken into account that if the company decides not to start phase two, this will be wasted effort to some degree.

[66] This was also mentioned during 'Fund the Future' See **Appendix 2**.
[67] **Article 82**.



1 = Trade name
2 = Trademark
3 = Domain name
4 = Copyright
5 = Trade secrets
6 = Patent
7 = Chip right
8 = Design right

Figure 30. Intellectual capital mix.
This figure shows the amount of focus should be laid upon each of the intellectual property protection methods. The dot on the axis shows the relative amount of focus that should be invested. A dot closer to the centre of the model, indicates a low level of focus. A dot near the edge of the model, indicates a high level of focus.

15.6 ORGANIZATIONAL CAPITAL

During this phase, it is necessary to formalize the company and register it in at the Chamber of Commerce (KvK). Otherwise, it will not be possible to receive the investments needed for the development of the solution. Additionally, a company structure is necessary for the division of tasks and, more importantly, to establish clear responsibilities and accountability.
During this phase, a holding and a company should be set up. The holding will be the company that possess the intellectual capital, parts of the financial capital, and this company will be used as a coat rack for the operating company A. A holding offers several benefits[68]. **First**, risks can be minimized as the financial capital is allocated in the holding, yet the operating company bears the responsibility. **Second**, if the holding holds more than 95% of the shares of the operating company (which is the case in the early start-up phase), a fiscal unity between the two entities can be achieved offering various tax benefits. **Last**, a holding construction offers more flexibility in starting new and selling existing companies. Which should be taken into account from the start.
The strategic goal of this phase is cleverly adapting the database, the product, and the company for phase two. Decisions should be made by the company between extra effort in this phase, where the company is still relatively new and fragile, while preventing unnecessary costs and actions in the next phase. And choosing not to do so, and choose a more 'here and now' policy.

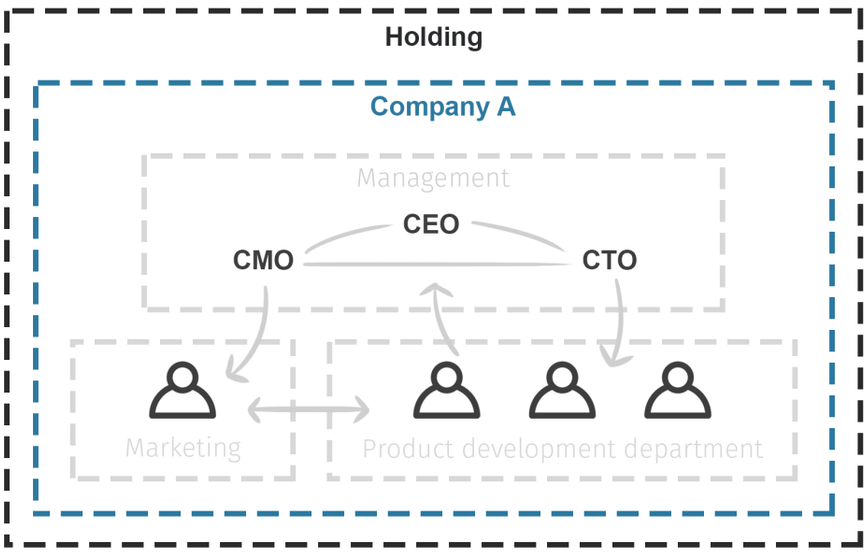


Figure 31. Illustration of a possible company structure during phase 1.
In the management team, a medical expert should be present as mentioned in the paragraph human capital. Additionally, in the product development department, a data analytics specialist should be present as well.

15.7 RESOURCE CAPITAL

The resource capital of the firm in this phase depends entirely on the decision of the company to outsource the production of the system, or not. Outsourcing can be a useful production strategy when a company does not have or is unwilling to invest in the necessary production resources, housing, and personnel. When outsourcing, the only assets that should be accounted for are the machinery and tools necessary for the development of the product (i.e., not the production), an office with office supplies, and most importantly intellectual property assets like (e.g., patents) that are needed to safeguard the knowledge and know-how of the company regarding the system. When insourcing, all the previously mentioned assets should be included, as well as production related assets (i.e., heavy machinery and tools, a production hall, an additional office located at the production site, etc.). Insourcing provides

[68] Grey literature, as well as business developers (**Appendix 2**)

the benefit that all knowledge and know-how will remain within the company, but for the cost of investing in the development and execution of a production line. Additionally, other implications have to be considered as well: quality control must be developed in included in the production process, more investments will be made in labour costs, and the liability for wrongfully produced systems will pose a significant threat. A multifold of literature has been written depicting the decision criteria for either one[69] of these strategies (Meixell and Gargeya, 2005; Kremic et al., 2006; Antràs and Helpman, 2004). In this case, the decision to in- or outsource should be made by the company. Additionally, the development of a supply chain incorporating in- or outsourcing processes (in which even parts of the production can be in- or outsourced) is not relevant to the research questions, and therefore not included in the scope of this assignment.

15.8 FINANCIAL CAPITAL

The financial capital perspective looks at the necessary investments that need to be done, the business model and business case describing how the company can capitalize on the solution. Investments necessary in this phase of the development, depends solely on the decision of the company to outsource or self produce. The cheaper option would be to outsource the production[70], mainly due to the fact that production assets are incredibly expensive. In this phase, the business model is one-sided. The company delivers the product to the consumer, and the consumer pays for the product or for the analyses provided by the product. Ideally, the consumer allows the company to gain access to the individual analyses of the consumer which are anonymously added to the database. If this access is allowed, the company will become able in phase two to start with the clinical validation of the system as data from several customers over a long period of time is available. As this is quite essential, the company could opt for a reimbursement for the collection and usage of data. The thought process here should be that in the future this database becomes more valuable than the reimbursement could ever be.

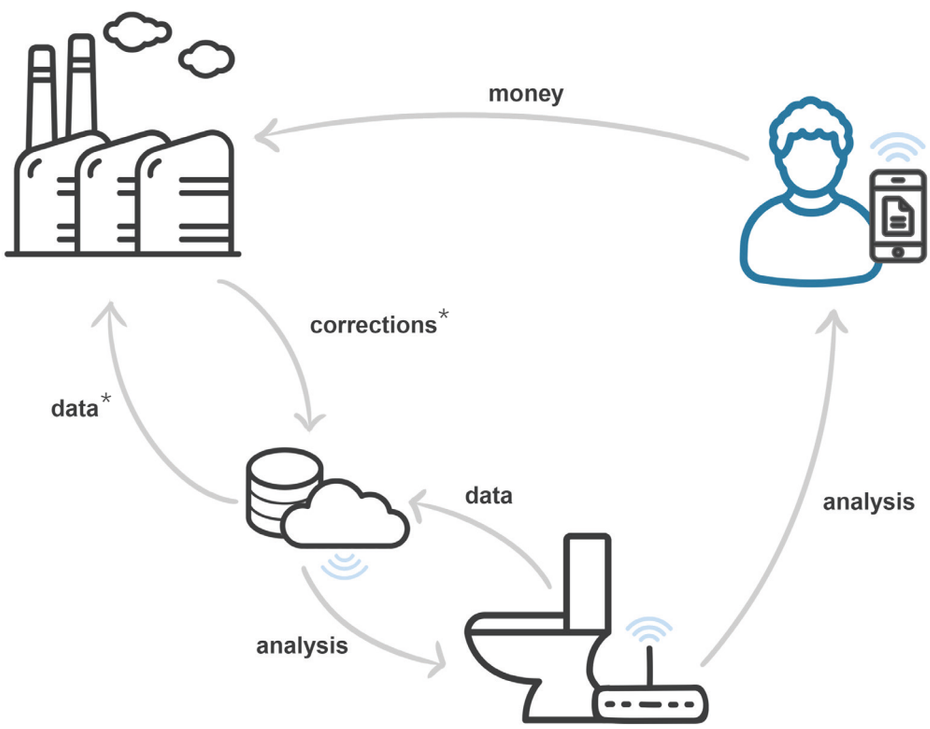


Figure 32. Business model illustration during phase one.
* If allowed for by the consumer. For more information, see Chapter 16.8.2 in Phase II.

[69] Actually, three strategies exist: inshore, nearshore, or offshore production.
[70] €2 million has been estimated by experts, **Appendix 2**.

Calculating the cost-effectiveness of the system is in this phase very difficult. In this early stage, the availability of the necessary economic data is limited which makes most preliminary calculations difficult. Two options exist: (1) What can be done, is that a business case in this phase should be developed based on the estimated expenditures for each of the six capitals. The company must differentiate three different outcomes (positive, neutral, negative, as per usual) in which a prognosis is made on the possible return on investment. As has been mentioned before, the MVP tactic allows the company to reduce costs of the development, production, and shipment of the product, as well as the necessary infrastructure to operate the communication of results. Such decisions before the actual development of the solution, have more impact on the final costs of the project, than more detailed decisions on specifics later on in the process. (2) The headroom method (Cosh et al., 2007) can be employed to calculate the difference in production and implementation costs, and the maximum reimbursable price. This maximum reimbursable price is deduced from the Quality Adjusted Life Year (QALY): the threshold to determine the cost-effectiveness of a treatment. If a treatment costs more than that threshold, then we, as a society, have decided that the treatment is not cost-effective and should therefore be carefully considered. The lower threshold for preventive care in the Netherlands is determined to be €20.000. The upper threshold for intervention and care is €80.000 (Zorginstituut Nederland, 2015). Based on these thresholds, a manufacturer should be able to calculate if the production and cost price of the system fall within these bounds, and more importantly, if using the system will improve the quality of life for patients. When it does, then the system can become reimbursable. In this case, however, the system has a preventive function, of which the QALY is determined at €20.000. If the company wishes to establish a business case and calculate the cost-effectiveness, then the company must be able to calculate the QALY of using the system versus not using the system.

15.9 SUCCESSFUL COMPLETION

This phase is successfully completed, if the consumer product is developed and sold, creating revenue for the company and proof of the value of the solution. The amount of revenue could be related to the amount of success that this phase has achieved, as more revenue indicates more success, but that is beyond the goal for this phase. The gathering of proof of concept of the solution and its value is what will make the difference in the ability of the company to attract more funds and enter phase 2.
An important distinction should be made regarding the MVP and the upcoming phase 2, where the system will be clinically validated. The company could opt for the development of a second version of the system, with more functionalities and value for its users, to increase the possible (clinically validated) medical applications of the solution in phase 2. The important distinction here is, that the device that will be clinically validated and approved, will be the only device that is allowed to be sold on the European market for its medical application. In other words, the NB might demand a new clinical validation process as consequence for changing the system configuration. The system that the company desires to be eligible for sale, must be the same system that will be clinically validated[71]. Careful thought should therefore be put in the decision which product configuration will become the system that will be clinically validated. If the MVP provides insufficient medical applications and benefits, then the company is forced to developed a second version which does have these applications and benefits. When that has been decided upon, the following criteria must be met as well to determine the readiness of the company to proceed to phase 2. **First**, the company must be able to afford the extra investments necessary for starting the following phase. These investments include (but are not limited to) extra personnel: a clinical validation department including experts in clinical validation studies and study design, and people capable of performing big data analytics. As well as additional office space for the increase in personnel, additional computing power for the additional statistical processes, and additional testing equipment. **Second**, sufficient amounts of data must have been gathered to perform the clinical validation. To assess whether or not enough volume has been achieved, it is essential to first attract competent people that are able to make such a judgement. **Third**, preferably, the company should have access to faecal matter from people diagnosed with CRC. This matter can be essential in the validation study as the device must be able to distinguish between healthy and sick individuals.

[71] Only one exception exists, as Annex IX states that in the case that the device is similar (i.e., "equivalent", **Annex IX Article 4 Paragraph 5**) the NB might assess that the clinical evidence of that equivalent system is sufficient for the safety assessment demonstrating conformity.

This is essential for the clinical validation and the assessment of the device's performance, sensitivity, and specificity, as well as the data analytics regarding pattern recognition. However, gaining access to such a resource is quite difficult (e.g., due to clearance to use such samples, gaining access to organizations that have such samples, dealings with ethical commissions, etc.). To remove as much barriers as possible, the company should try to gain access to left-over specimens from other research projects and studies. Left-over samples have the benefit of not needing to be authorised by the NB ((**73)**), saving some bureaucratic steps in the validation process. **Last**, the company should evaluate the possibilities to attract research funding that could be used to cover the expenses of a clinical validation. More explanation can found in Chapter 16 Phase 2.

16. PHASE 2 - MEDICAL APPLICATION

This phase describes the process of validating the consumer product version of the solution, so that the solution can finally achieves its original goal of the intended medical use. **First**, this phase is elaborated upon in the six perspectives as mentioned before: financial, human, intellectual, social, organizational, and resource capital. In these chapters, suggestions on actions that the company should perform based on the analysis of the context are provided in combination with a summary of possible pitfalls that detail avoidable risks. Additionally, mitigation strategies are provided that can aid the prevention of such risks. **Second**, a description is provided that details how the company can judge if this phase is successfully executed and completed. **Last**, decision criteria are provided that should be used to decide if another phase should be entered. To emphasize, the final decision is that of the company. It is not I who decided whether or not a phase is successfully completed or if it's time to move to the next phase.

16.1 SOLUTION & TEST DESIGN

The system configuration of the system itself will not change in relation to phase 1. As said at the end of phase 1, the device must be equivalent to the device that is going to be validated in the performance study. Thus, the most interesting change in configuration can be found in the super-system context, as can be seen in figure 33.

16.1.1 Intended use and its implications

Important to notice, the 'intended use' of the device will be the defining characteristic in the classification process. The intended use will not only define whether or not the device is a medical device, but also the classification of said device based on the risk it poses to the user. Based on **Annex VIII** (Classification rules), it can be argued that the device belongs to class C in the IVDR. The annex rules that any device intended for the screening, diagnosis, or staging of cancer (**Rule 3 under h**) as well as any device intended for self-testing should be considered class C (**Rule 4 under a**). Important to notice, is that any accessories, calibrators, control materials, or software[72] intended to be used with the device shall all be considered as the same class as the device. Therefore, the software of the system will be subject to the same regulatory challenges as the system. As has been mentioned before in The severity of measures which the company is obliged to correlates with the classification class of the device. Simply put, the higher the class of the device, the more stringent the measures as defined by the EU council become. Implications for class C include[73]: (1) The manufacturer of a class C device must publicize a document summarising the main safety and performance aspects of the device as well as the results from the performance study (**(45)**). (2) The manufacturer is subject to a conformity assessment regarding the quality management system (QMS) and the administration of the company (**Article 48 Paragraph 7**). More specifically, the QMS should be assessed on its conformity with the Regulation and the documentation regarding the conformity of the product must be kept at least 10 years after the last introduction of the device on the market (**Annex IX**). (3) The performance evaluation report for class C devices must be updated at least annually with newly gathered data regarding the performance of the device (**Article 56 Paragraph 6**). Additionally, the company shall prepare a periodic safety update report (PSUR) which updates (a) the benefit-risk determination, (b) the main findings of performance evaluations, and (c) the volume of sales of the device, usage data of the device, and an estimate of the population using the devices and characteristics from this population (**Article 81 Paragraph 1**). (4) The QMS system, the post-market surveillance system (PMSS), and the risk management system (RSM) of the manufacturer in place must be proportionate to the risk class of the device. In other words, the higher the classification of the device, the more functionalities these systems must have (in terms of administrative purposes) and the more guarantees it must be able to make regarding the correctness of data gathered (**(31)**). (5) The manufacturer shall have financial measures in place to cover for potential liability (in case the device malfunctions) proportionate to the risk class of the device (**Article 10 Paragraph 15**). In addition, the manufacturer must be able to report any incidents regarding the usage of the device within at least 15 days (**Article 82 Paragraph 3**) after becoming aware of the incident. In the event of a death, the manufacturer must be able to report on the incident within 10 days after becoming aware (**Article 82 Paragraph 5**) and within 2 days for any public health threats (**Article 82 Paragraph 4**).

[72] Software can in itself be a medical device as well (**(17)**).
[73] This is a summary of the most important rules and articles of the Regulation. This summary consists of rules applicable to class C, but could also be applicable to other classes of the Regulation.

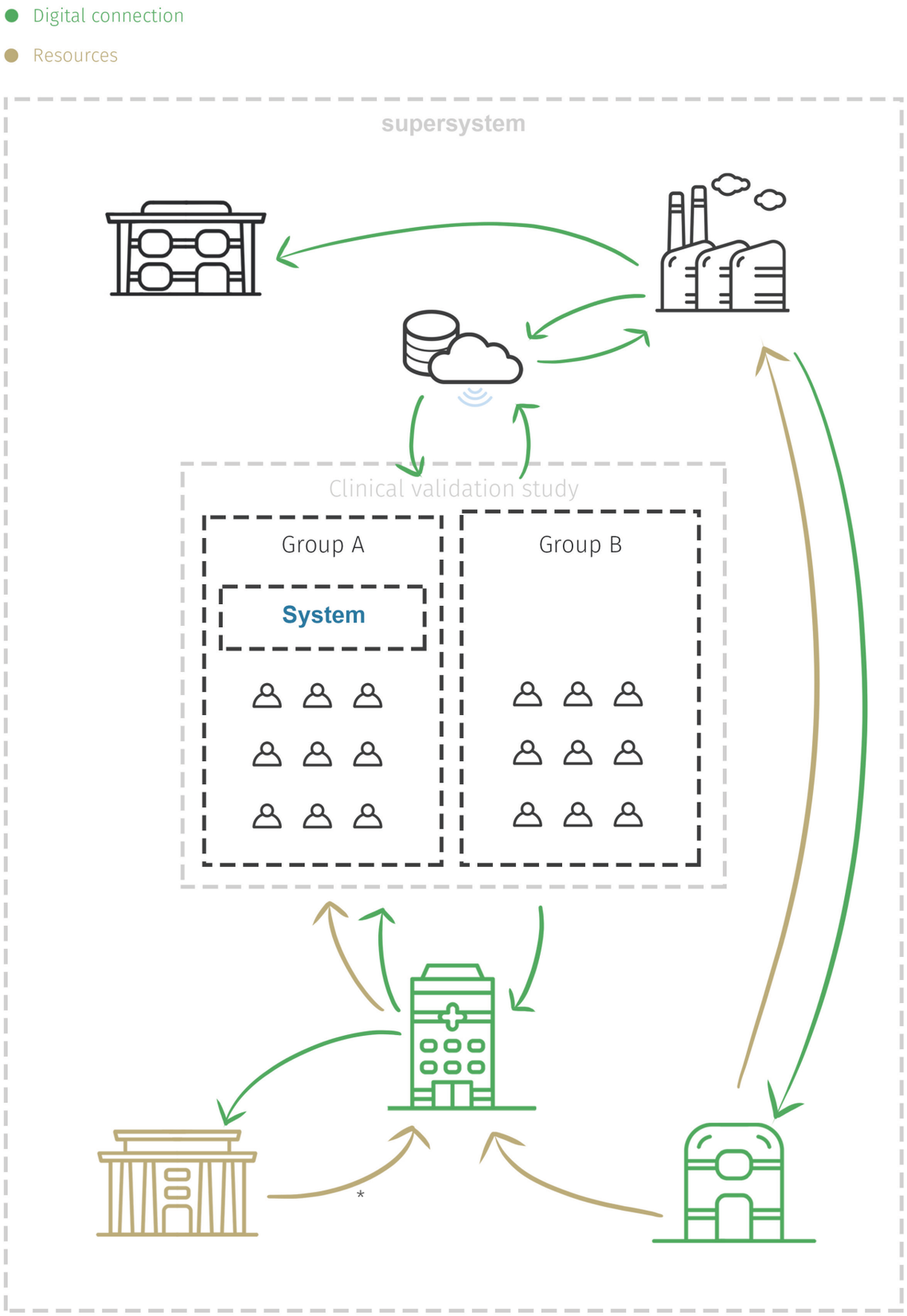


Figure 33. System overview of the solution during the clinical validation in phase two.
* An insurer might be willing to provide financial support for a clinical validation study. However, this is not guaranteed.

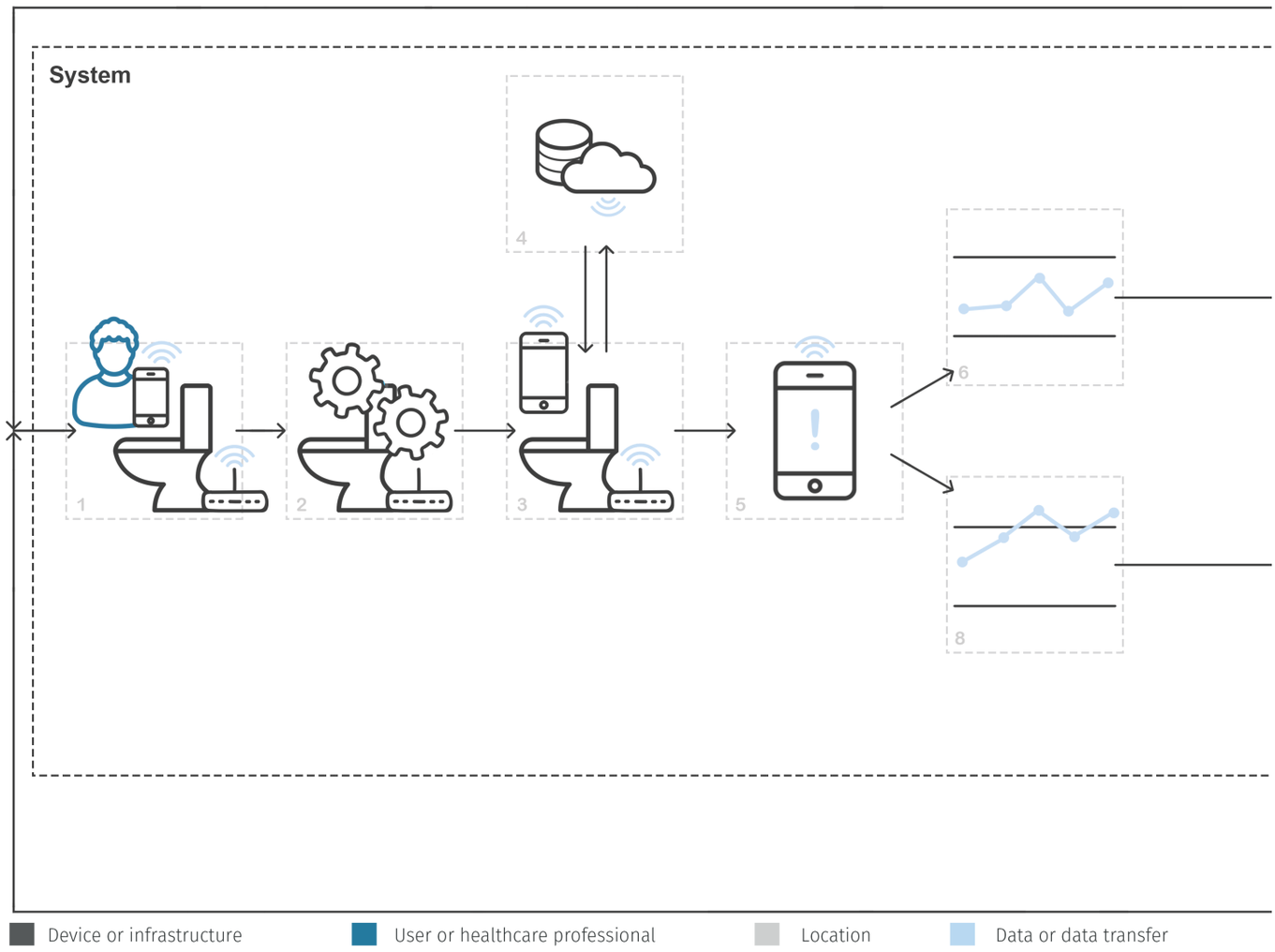
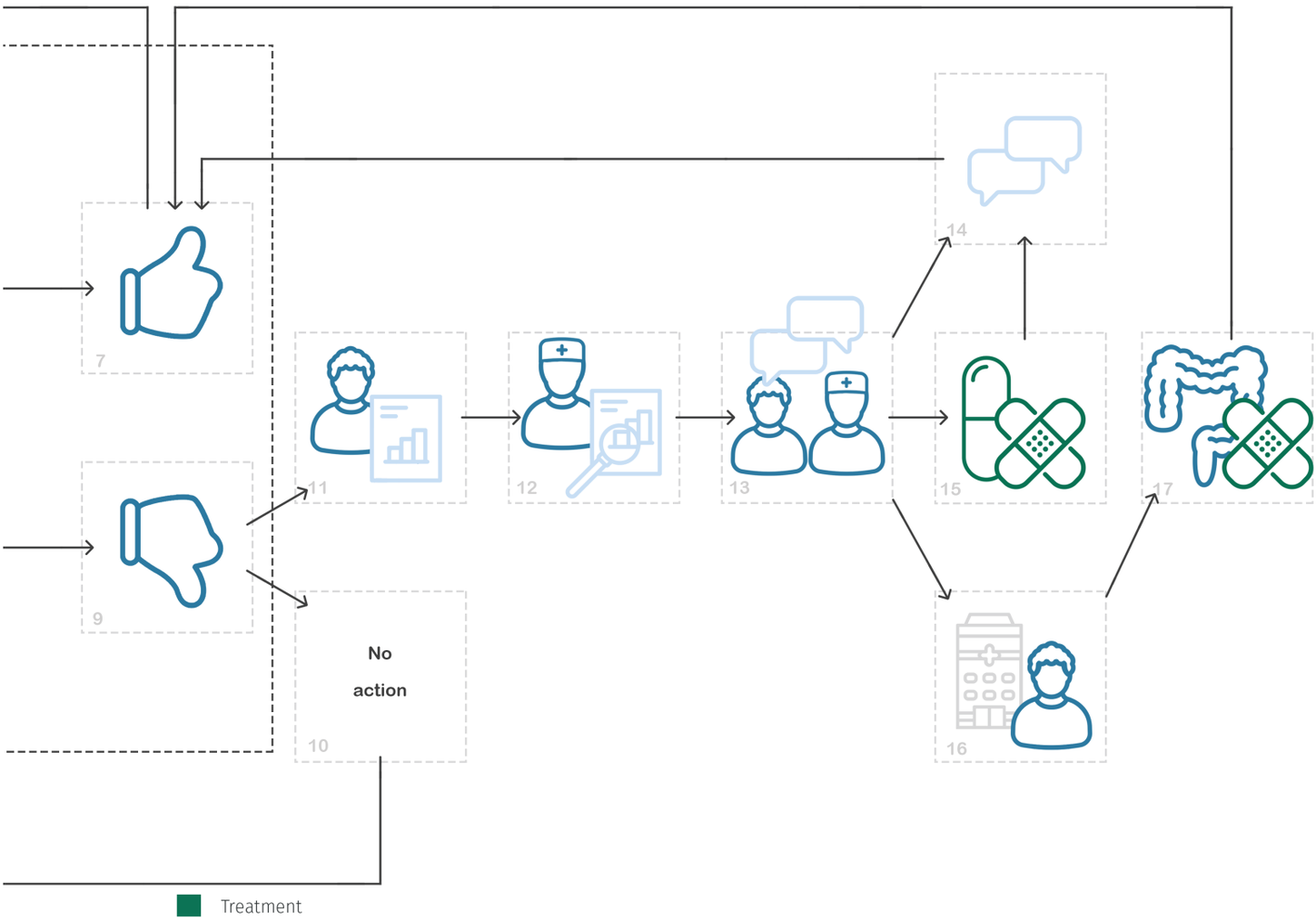


Figure 34. System work-flow in the super-system perspective during phase 2.

16.1.2 Clinical validations and test design

Clinical evidence of the effectiveness of the device can only be sourced through performance studies. These performance studies must be under the responsibility of a sponsor, which can be both the manufacturer as any other natural or legal entity (**(62)**). For class C devices, this validation process will be monitored by a NB on “an appropriate level of involvement” (**(56)**). As has been mentioned in Part I Chapter 4.3, the IVDR states that the clinical performance study should be in line with international guidance, like the standard ISO 14155:2011 (**Appendix 11**). Which allows the company to be (somewhat) free to determine the test design and the process of the validation. Therefore, for this case it is highly advised to toil specialist(s) and employ them in the development and trial studies of this solution. Such an expert panel will increase the chance of success of the validation study itself, as well as increase the convincing power of the company in regard to the Notified Body. As has been mentioned, the results from these performance studies must be published (**Article 29 Paragraph 1**), so that the intended user is capable in deciding whether or not to use the device, and the outcome must be updated frequently (**Article 56 Paragraph 6**).

Developing a clinical trial is the responsibility of the company and beyond my personal competencies and my role during this project. Therefore, I have to assume that the company is capable of either developing the test itself or finding someone capable and willing to do so. For illustrative purposes, I depicted the test design as a common A-B test design where one group is subjected to the device and the other is not. Which can be seen in figure 33. For the rest of this chapter, I will describe the capitals in familiar order and depict the necessary investments in each of the capitals.



16.2 KEY ACTIVITIES

A short description is provided detailing the key activities that the company must undertake to secure the survivability of the project as well as the company. These activities provide an overview of the main focus of this phase and what the company must do or a successful execution. In the following paragraphs, more detail is spent on the implications of these activities in light of each of the capital perspectives.

First, a subsidiary of the holding company must be established. Doing so, any risks concerning the clinical validation as well as the necessary financial transactions due to funding, can become the responsibility of the subsidiary. Therefore, making a clear division between the company involved in the clinical validation of the consumer product and the company that develops, constructs, and sells the consumer product. From legal and risk perspectives, this offers serious benefits. **Second**, to perform the clinical validation, new talent must be present possessing the necessary competencies. What has been mentioned before (e.g. 'wrong proof'), it is very important to decide on the test methods, proposed outcome, conditions, and more before starting the actual validation trial. Especially, if the company's desire is to capitalize on the medical application as then both the care professionals as well as the insurers should be on board. Additionally, the company will undergo structural changes, due to up-scaling of the development processes, and needs new employees to adjust for this growth. **Third**, in the case of clinical validation, most likely some sort of cooperation must be established with third parties:

(1) the care professionals performing the validation and monitoring the patients will have to know about the technology they are working with, and (2) the control party (NB) that will evaluate the process and the outcome will need information about the technology. As also in this phase, the intellectual property of the company is vital for its succession and existence, therefore correct protection measures should not be disregarded. It should not necessarily be assumed that the organizations cooperating on the validation studies will make use of the newly learned information, yet it must not be underestimated that these organizations are for-profit too. **Fourth**, a clinical validation performance study is extremely expensive[74]. From the test design, defining the method for testing, to analysing the results, and reporting on the outcome of the study, all components add significant costs to the entire project. Additionally, to perform such a clinical validation, additional people have to be employed: from medical staff to the data analysts that perform the statistical analyses. Luckily, the shear amount[75] of subsidies and funds that can be addressed for performing a clinical trial is plentiful (**Appendix 10**). As long as the academic benefits as well as the value for the population are clear, it is possible to get access to multiple financial funds and support structures.

16.3 SOCIAL CAPITAL

The social capital perspective looks at the relevant stakeholders that should become involved in the development of the solution and what the relationship must be like.

16.3.1 Target group

Assuming the device is approved and has shown its conformity to the IVDR Regulation, then the intended target group can be divided into two segments. The first group is similar to the target groups of phase 1, as the interested or worried people are most likely interested in purchasing such a solution. As the device is capable of screening for CRC (with a certain sensitivity and specificity), these people might opt for such a device instead of the bi-annual national screening. Another group can be 'created' if a deal with insurance companies can be made. Such a deal would entail a discount on the insurance fee when the device is bought, or reimbursement of the system. The insurance company would have to be convinced of the fact that owning and using such a device will, in the long run, save healthcare expenditure of its users. More on this will be explained at the business model paragraph (Chapter 16).

16.3.2 Relevant stakeholders and their relations

In this phase, the number of stakeholders involved expand significantly. Two groups of stakeholders are discussed: (1) the stakeholders related to the validation and implementation process, and (2) the sponsor of the validation process. Later, the key partners necessary for the resources during this phase are discussed. **First**, the stakeholders involved in the validation process will be discussed. These stakeholders include the dominant stakeholders (Chapter 5), the EU, the MVWS, and the RIVM, as well as the definitive stakeholders, the specialists, the NZa, the IGJ, the ZiNL, and the NB. As their roles and influences on the validation and implementation have already been discussed, a look will only be taken at the dependency on the specialists when designing and executing the validation study, as well as attract resources, human capital, and funding. Specialist play the most predominant role in convincing other stakeholders. (1) When consulting GP's, it is often mentioned that there are two organizations that can shape the opinion of a general practicioner[76]: the NHG, the scientific GP organization that develops the guidelines and advises on the newest technologies, and the specialist. The NHG itself also consults experts before approving any new technology and communicating this to all connected member GP's. Therefore, from the GP perspective, the specialist is the stakeholder with the most influence in the acceptance of the technology. An example can be found in the situation regarding the initial start of CRC screening: in 2004, a questionnaire among GP's from Amsterdam (response rate 32%) showed that only half of them were of the opinion that a national screening was necessary, while 92% of gastroentologist were in favour of the screening (Terhaar sive Droste et al., 2005; 2006). (2) From a

[74] Factual numbers cannot be found. Emergo, (n.d.) depicts figures related to the costs regarding the regulatory approval (ranging from less than $5.000 to more than $50.000) of medical devices for the European market. The clinical validation study or the QMS implementation is not included.
[75] As has been said by numerous experts in business development. See **Appendix 2**.
[76] In conversation with two GP's, see also **Appendix 2**.

governmental perspective, the NZa always employs and consults experts before developing guidelines or mandates regarding innovative development. (3) When looking through the perspective of the insurer, it became clear that an insurer will only cooperate with a company in the development (and possible funding) of a new solution, when that solution has already proven its functional validity and when a care professional "ambassador" is connected to the project[77]. Even more so, an insurer will only listen to the plea for the value of a new solution when this plea is coming for a care professional, a company won't be listened to. In addition, to acquire the necessary scientific proof of the practical validity of the solution, specialists must be involved already to establish and guide the (clinical) validation study. In other words, without a specialist, an insurer will not be willing to accept and aid the solution and the development of the solution. Then the question still remains if the solution is accepted, how[78] the insurer can aid the roll out and scale-up of the implementation of the solution. In conclusion, it is highly advised to toil specialist(s) and employ them in the development and trial studies of this solution. Without such an expert panel, the chance that reserved stakeholders will be convinced are slim.

> "Most start-ups start by working with an industry partner with an existing supply chain, but eventually many of these start-ups will vertically integrate at scale, which will improve margins. The existing margin profile of many healthcare products allows start-ups to compete by offering lower prices to consumers, while still maintaining attractive unit economics" (Citrin, 2018).

Second, another stakeholder can or cannot influence the validation and implementation process significantly: the sponsor. As has been mentioned before (**(62)**), the sponsor can be any legal or natural entity and could therefore be the company. If the company sponsors its own clinical validation process, then the role of sponsor as stakeholder will become obsolete and the practice of stakeholder management will be eased. The company must not see itself as a stakeholder in the Power Grid analysis as this does not bring any further understanding of the context and the complexity of the development and implementation processes. However, being the sponsor of its own clinical validation process has two downsides: (1) The company must be able to be the actual sponsor of this process as sponsoring, of course, indicates that the company must be able to pay for the validation study. Not being able to sponsor this process, requires the company to look for an external sponsor. (2) Being sponsored for the validation by an external organization well-known and respected, will add to the legitimacy of the company and the outcome of the studies. From a marketing and brand image perspective, it could therefore be wise to look for an external sponsor with such a position in the Dutch healthcare system. **Third**, relationships with key partners during this phase must be closely monitored and maintained. Most importantly, it becomes increasingly more important to define responsibilities during this process: who becomes responsible for the execution of the validation studies? Who becomes responsible for the analysis of the outcome of the validation studies? Who will become responsible for the communication with the NB, or the NZa, of the ACM? These questions must be answered, but more importantly, they must be documented and agreed upon. Even though most questions can quite easily be answered (it's either the company's responsibility or that of the organization approving the specific process), they must be agreed upon and they must be documented in such a way that all parties understand who is responsible for what. This understanding of responsibility can be traced back to the IVDR, as the regulation requires the manufacturer to produce a report of any accident and determine who is responsible for the mishap, and thus, who is responsible for the damages.

16.4 HUMAN CAPITAL

During this phase, the predominant influence on the needed competencies is the clinical validation process. **First**, the clinical validation asks for people capable of developing the test (in accordance with ISO 14155:2011) and executing this entire process. Therefore, competencies regarding clinical validation

[77] Wie gaat dat betalen?, 26-11-2018, Hotel theater Figi, Zeist. **Appendix 2**.
[78] For solutions that must function in a hospital, the insurer will only alert the manager of innovation and purchasing of the hospital that the solution exists and that it could be an option to cut down costs. In other words, the insurer is only a network able to provide the necessary connections to get the solution to the appropriate care providers more quickly.

studies and randomised-controlled trial experience and competencies are necessary. **Second**, in accordance with the Regulation (IVDR), three systems must be procured or developed, and implemented. The QMS asks for the administration and management of the development process. The PMSS asks for the surveillance of the installed base and the additional liability accounts. The RM (ISO 14791:2007) asks for engineering skills to assess the possible risks regarding the system and its components. Therefore, competencies in software development, strategic management (for the establishment of goals of these systems), and engineering competencies (capable of estimating risks). **Third**, liabilities regarding the implementation and testing of the system will have consequences for the necessary competencies. The legal competency is necessary for establishing guidelines and practices regarding risks and malfunctioning of the system and the rights of the users. The accounting competency is necessary for the establishment of funds which can be employed to pay for damages and injuries. **Last**, the company will be scaling up and will therefore need new competencies to account for the new human capital, new intellectual capital, the newly implemented systems, and more. Business related experiences and competencies would ease this process. People experienced with change management could prove beneficial.

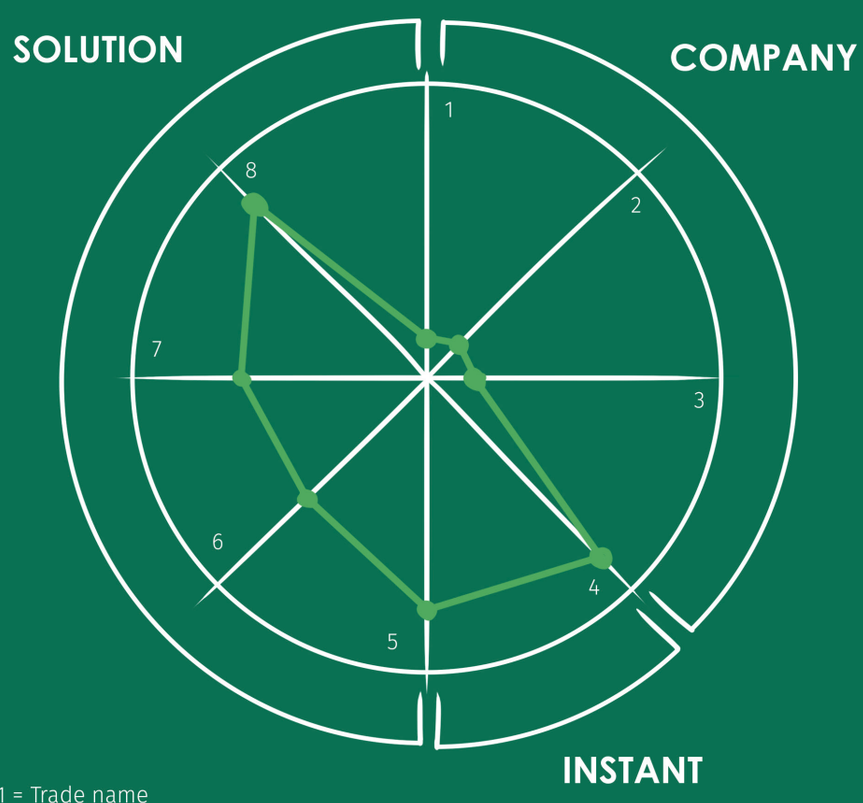
16.5 INTELLECTUAL CAPITAL

Similarly to the previous phase, during this process the intellectual capital is still the asset with the strongest competitive advantage. Therefore, effort should be put in the protection of information through appropriate measures. To further establish and improve the competitive position of the company, additional patents could be applied for. Assuming that the product is being sold, the revenue allows for the application of patents, and the company still has some parts of the design that can be patented, than these patents could signify to competitors that the competitive position of the company is improving. In other words, patents can be used to communicate to others which solutions and innovations are claimed by the company. In the case of chip- and design right, most likely the company will have submitted their designs and the focus now shifts to monitoring instead of applying. However, if the financial capital position of the company allows it, more design could be submitted for these rights.

Codified knowledge during this phase regards the validation process. The performance of the system, the sensitivity and specificity, will be determined and documented as clinical evidence. The documentation of knowledge during this phase will be less of a demanding process than in the previous phase, as process of clinical validation intrinsically entails the need for documentation and codification. The company will be forced to document all relevant information under the standard for clinical validation (ISO 14155:2011, other interesting and relevant standards can be found in **Appendix 11**) and, in addition, this standard will specify how this information must be documented. From an intellectual capital perspective, however, it is important to realize that the outcome of these validation studies must be published (**Article 29 Paragraph 1**) because of the risk class of the device (Class C). Therefore, this information can only be protected through copyright. Other information (e.g., participant specific information, other performance related metrics of the system or the process, etc.), can be left out of the published report if the NB allows it. Therefore, some evidence gathered in the validation process can be protected as a corporate secret or through other means. Important to emphasize, is that clear agreements must be made on the ownership of newly developed intellectual property (as other organizations are involved in the validation process) and the protection of this information (through NDA's, contracts, and such).

16.6 ORGANIZATIONAL CAPITAL

The holding structure mainly offers benefits during this phase. The holding allows for the company to differentiate the departments responsible for the 'regular' product development and the newly introduced clinical validation process, into separate companies. As has been mentioned before (under the notion that no academic literature was used to reach this conclusion), a holding decreases the total amount of risk for all subsidiaries as when one subsidiary goes bankrupt, others are not liable for



1 = Trade name
2 = Trademark
3 = Domain name
4 = Copyright
5 = Trade secrets
6 = Patent
7 = Chip right
8 = Design right

Figure 35. Intellectual capital mix.
This figure shows the amount of focus should be laid upon each of the intellectual property protection methods. The dot on the axis shows the relative amount of focus that should be invested. A dot closer to the centre of the model, indicates a low level of focus. A dot near the edge of the model, indicates a high level of focus.

damages. Additionally, assets can be placed under the ownership of the holding company preventing other organizations to cease those assets[79] in the case of debt or bankruptcy. The holding company also offers tax benefits, the possibility to diverge into more subsidiaries in the future[80] allowing for more flexibility than if the company was consolidated into one legal entity, and the ability to control the subsidiaries with fewer investments as the majority shareholder of the holding company controls the subsidiaries[81]. Therefore, allowing the original founders to maintain more control over the companies when new investors get involved and dilute the initial shares. Establishing a holding company after initially starting a 'regular' firm, is more difficult than starting a holding company first. Additionally, the costs of starting a holding company are relatively low, so from a (financial) investment perspective it is advised to start the holding first. As has been mentioned in Phase 1 (Chapter 12)

16.7 RESOURCE CAPITAL

A look must be taken at the key activities during this phase to define the efforts and resource capital investments necessary. Doing so, immediately eliminates the need for investments for four of the five key activities. For starting a subsidiary, attracting talent, establish new IP protection measures, and attracting funding, no additional resource capital investments are necessary. For these four activities, the only investment needed is financial funding and/or effort and time, not assets. The last key activity describes the clinical validation study for which significant assets are necessary. **First**, additional devices must be built for the defined population, so that all participants have access to using the device. **Second**, the digital infrastructure must be implemented capable of recording, transmitting, and storing the data resulting from the clinical validation process. Therefore, digital connections must be established between the devices and the computer hubs which operate the data monitoring process. These computers must therefore become available to the company. **Third**, additional monitoring equipment might need to be acquired (and/or purchased) capable of measuring additional metrics if deemed necessary by the designers of the validation studies. **Last**, part of the validation study might be the testing the capability of the device to distinguish between healthy and disease-ridden faecal matter. Therefore, samples must be present from both healthy and sick individuals to perform such a test. To allow for collecting such samples, the IVDR states that left-over samples (from other tests or studies) do not have to be authorized by the NB to be used (**(73)**), saving some bureaucratic steps in the validation process.

16.8 FINANCIAL CAPITAL

The financial capital in this phase will describe the necessary investments, the business model capable of making profit for the company with the approved device, and how the company can become able to calculate the cost-effectiveness of the entire project.

16.8.1 Investments

Estimating the costs of the entire clinical validation process is a near impossible feat. No academic literature is present on cost analysis of RCT's and the only available information varies significantly: a clinical validation process for a new technology costs either up to $100 million (Innovative Molecular Analysis Technologies, n.d.) or $266 million (Relman and Angel, 2002). These differences can be explained by the item that is being tested. Normally, clinical trials for medical devices pale compared to the costs of these studies for pharmaceuticals: which cost $802 million (Hansen and Grabowski, 2003) or more (Adams and Brantner, 2003). Through Horizon 2020, an EU initiative to boost the European economy and the development of new (medical) products and services, has released €130 million in grants for the development (and validation) of new medical devices developed by SME's in the diagnostic

[79] BlueShore Financial. (2014, October 20). The advantages of holding companies. Retrieved June 5, 2019, from https://biv.com/article/2014/10/advantages-holding-companies

[80] LegalVision. (2019, January 22). What are the Advantages of a Holding Company? | LegalVision. Retrieved June 5, 2019, from https://legalvision.com.au/what-are-the-advantages-of-a-holding-company/

[81] Accounting Notes. (2016, June 28). Holding Companies: Definition, Advantages and Disadvantages. Retrieved June 5, 2019, from http://www.accountingnotes.net/companies/holding-companies-definition-advantages-and-disadvantages/8965

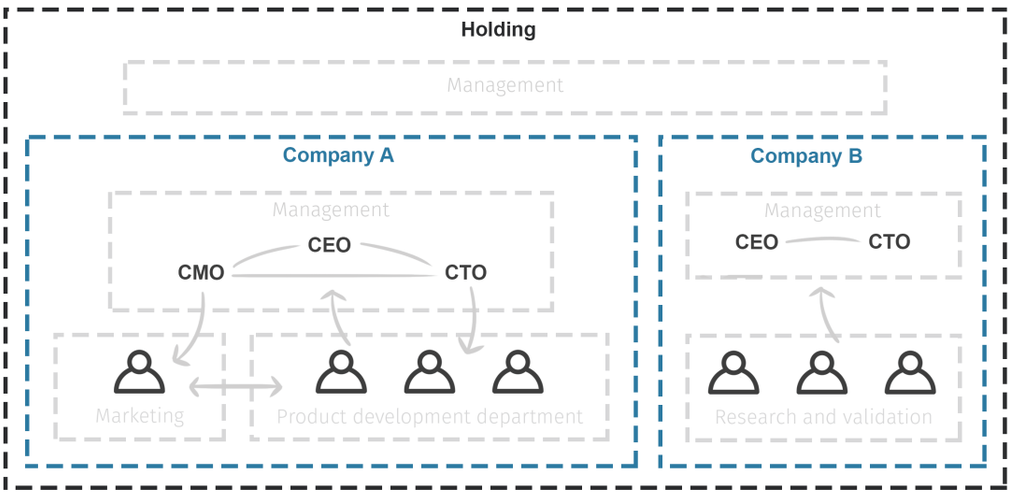


Figure 36. Company structure during phase 2.

field (Sanne, 2018; for a collection of available grants and subsidies, see **Appendix 10**). However, the average grants used for the validation of new biomarkers or diagnostic devices did not exceed the €3.3 million. Similarly, crowd-funding campaigns have been started to fund RCT's, however the maximum funds raised did not exceed $3.1 million. As can be concluded, the information to properly assess the amount of investments necessary for a clinical validation of the system is severely lacking. Available information only paints a skewed image of the costs connected to such a process and the ability to attract and the size of funding.

16.8.2 Business model

The system will become capable in measuring the health condition of its users and alerting them when the condition deviates from that what is 'normal'. In doing so, the system will become able to prevent complicated and expensive treatments, just by being earlier than alternatives. Preferably, the business model must incorporate this cost-saving capability to create a situation in which this capability is used to enforce insurers to provide a discount on the healthcare premium of the system's user. In other words, using the system must become reimbursable, as it saves costs for the insurer (through prevention and early detection), decreasing the initial practical price of the solution making it even more attractive for new customers. In essence, the insurer will be paying a part of the purchasing price of the solution hoping that the system is able to save more money through prevention. The actual specifics of such a deal are hard to define due to a lack of access to knowledge. For instance, how much premium can the insurer offer? Is the customer actually willing to purchase such a solution when a premium discount is offered?[82] Or, can an insurer be convinced that such a system will save more costs than the discount will add? During this process, however, insurers were unwilling to talk and discuss such a deal. Therefore, most information used to base this business model design on has been deduced from sources regarding other technologies and conversations with experts that have had communication with insurance companies. Additionally, the infrastructure must be in place for such a system to work. Such a deal would result in that the insurer must be able to monitor the health condition of its users (either fully or only in the case of emergency) and the usage data from the device, so that the insurer knows that the device is being properly used and that the good health condition of the user is maintained. Thus, guaranteeing the cost-saving capabilities of the system. However, sharing health information with an insurer is a complicated matter (Zorgverzekeraars Nederland, 2011; Verbond van verzekeraars, n.d.). The General Data Protection Regulation (GDPR), prohibits the insurer from accessing personal health data. The insurer can access and process personal health data only when the execution of the insurance agreement asks for the handling of personal data or if the individual has given explicit permission (AVG, **Article 9 Paragraph 2**). To judge whether or not the permission is

[82] Literature has found that a discount of as much as €15 per month can have a significant influence in the decision making process on insurance plans (Determan et al., 2016).

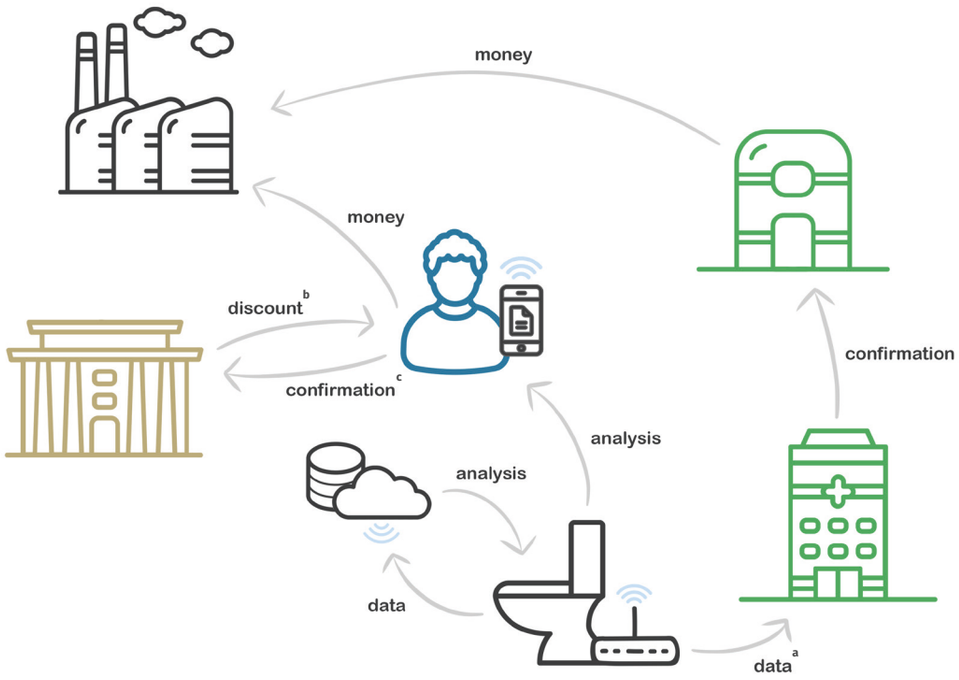


Figure 37. Business model during Phase II.
[a] Raw and anonymized
[b] On healthcare insurance premium
[c] Of purchase

valid, criteria have been defined in the GDPR. These criteria include: (1) the handling of data must be in accordance with the law, (2) the handling of data must be justified with a clear and comprehensible goal, (3) it must be made clear how the data will be handled and processed, (4) the identity of the person or organization handling the data must be known to the owner of the data, and (5) the data must be protected properly to guarantee the safety of its users (Autoriteit Persoonsgegevens, n.d.)[83]. Therefore, when considering such a business model the proper regulation must be considered. Even more so, it is highly advisable to make clear agreements with insurers on the level of discount that is provided, the type and shape of the information that the user must provide to the insurer to confirm the purchase of the solution, and the infrastructure necessary to process this transaction.

16.8.3 Business case calculations

To calculate the 'potential commercial viability' of a new medical device, a Health Technology Assessment (HTA) is often performed (Vallejo-Torres et al., 2008; Berg, van der Grinten & Klazinga, 2004). A HTA is a 'support tool for evidence-based introduction and use of technologies in the healthcare system' (Fuchs et al., 2017) and, despite being more often used for pharmaceuticals, is increasingly more adopted to evaluate new tech. A thorough HTA requires examinations on the safety and cost-effectiveness of new solutions, and goes far beyond the legal requirements from the IVDR (Tarricone et al., 2017). During this phase, enough clinical evidence should have been gathered that allows for a thorough HTA, headroom analysis, and a calculation of the QALY threshold. Additionally, during this phase it should become possible to perform sensitivity analyses, showing which components of the system add most the production and validation costs (Vallejo-Torres et al., 2008). Generally speaking, a HTA follows the same basic steps (EUPATI, 2015): (1) Identification of the subjects that need to be assessed, (2) gathering of

[83] I will not go into more detail as that is outside the scope of this assignment. I have to assume that the company is capable of developing a system that meets the demands set in this Regulation.

available evidence, (3) creation or gathering of new evidence, (4) assessing the quality of the evidence, (5) integrating the evidence into one plea, (6) formulate and spread claims and recommendations, and (7) monitor the impact of implementation. As can be deducted, such a HTA follows a similar approach to the RCT's and validation process. Therefore, combining these two processes is assumed to be doable. As certain companies are specialized in performing HTA's (EUPATI, 2015), it is most likely that if the company decides to employ an HTA to develop and evaluate the business case, a company will be hired to do so.

16.9 SUCCESSFUL COMPLETION

This phase has been successfully completed, if (1) the product achieves compliance and is approved for sale on the Dutch and European market, (2) a deal is made between the company and an insurer for the reimbursement of the product as a benefit and added sales argument for the user, and (3) the installed base has been approved as well allowing the user to receive diagnostic results instead of only numbers and figures. Successful execution of this phase means that the initial goal of the company has been achieved. A new product has been developed that is capable of assessing the health condition of its users and alert them of any deviations from that what has proven to be normal. Such a product will be reimbursed by insurers as they realise that prevention is incredibly cheaper than treatment, and in doing so, the consumers are more drawn to the purchase of such a solution. The healthcare industry will have accepted the solution as it has proven its performance and diagnosing capabilities, and care professionals are accepting these results and using them in the diagnosis and development of a treatment plan for their patients. In doing so, the entire healthcare industry will reduce its healthcare expenditure as numerous cases of CRC patients are now treated either before or early in the CRC diagnosis. The company is able to improve the product and monitor the product in the Dutch healthcare consumer market through its established QMS, RM, and PMSS systems. Additionally, as users are willing to share their personal health information (although tactfully anonymized), the company is now able to perform research with the clinical researchers and gastroentologists from research institutions and hospitals, and gather more evidence and insight in CRC development as a cancer. A new understanding will be developed of the disease and how a deviation in health condition can predict the establishment of such a disease. Therefore, solving all problems as stated in the introduction: both societal as individual.
If that situation can be created, then this phase has been successfully executed and the company has achieved its mission and goals.

17. PHASE 3 - THE NATIONAL SCREENING

Just be to clear, the chance that this solution is able to first become a successful consumer product, then a validated medical device, and then a system that is able to be an alternative to the current test method is rather slim (68% of started companies continue after 5 years (Kamer van Koophandel, 2018). Therefore, one cannot assume that this is an inevitable path that must be executed, but rather a possibility that might occur. Similarly to the previous phase, the solution design cannot change. Otherwise another clinical validation study must be performed to assess the efficiency and effectiveness of the system. Additionally (as with the current testing method (Gezondheidsraad, 2009)), selecting a new alternative to the current method entails a selection of multiple methods. In other words, just being included into the selection process does not mean that this solution will be chosen to replace the current method. That being said, a description of this phase is provided in a more summarized version which can be read in the following paragraphs. This summation is necessary as not much information can be found about this transition from a medical device to a national screening method, therefore limiting the amount of detail that can be gone into. Even more so, when the company will come into the position to decide whether or not to transfer into this phase, numerous years will have passed. As this phase will the supposed last phase of the entire implementation trajectory, there is no need for a discussion on the criteria which guide the decision to move to the following phase. Instead, the question is posed whether the company should be able to want this. This question will be discussed from multiple standpoints.

17.1 THE CAPITAL PERSPECTIVES

From the **social capital** perspective, the amount of stakeholders and the corresponding amount of relationships, as well as the intensity and complexity of those relationships will increase significantly. As the national screening is a governmental responsibility, numerous organizations will become involved. From the Health Council that selects the solution as the new alternative, to the Dutch Healthcare Authority watching over and evaluating the process, and from the Ministry of Health, well-being and sports that is responsible for the entire operation, to the actual organizations that are involved in the up-scaling and supply chain of the screening. From the **human capital** perspective, the company must grow significantly to execute such a task in a similar frequency as the current screening. Causing the need for massive investments in resources. From the **intellectual capital** perspective, the need for additional protection measures increases with each stakeholder participating in the screening. Especially, as the governmental institutions involved in this project must have access to the technology in such a way that it can be evaluated and compared to other screening methods. From the **organizational capital** perspective, due to the massive increase in stakeholders and the intensity and complexity of stakeholder involvement, additional bureaucracy and limitations in operation will become present. Especially when dealing with governmental institutions no accidental wrongdoing is allowed and so, every decision must be checked and checked again. From the **resource capital** perspective, significant investments are necessary to develop and implement the supply chain necessary for such an operation. It can be expected that additional resources from the government will become available to cover for additional expenses and add wherever necessary. From the **financial capital** perspective, this project will be costly and not just from an investment point of view. As has been mentioned before, additional resources must be attracted to be able to execute such a screening however, from a liability standpoint the screening can become tremendously expensive as well. Even in the Netherlands doctors and other care professionals are being sued because of the screening, the procedure, and its outcome[84].

17.2 DESIRE AND THE PERCEIVED BARRIER OF ENTRY

All things considered, the answer, to whether or not the company should try to become the next national screening method, is not easily given. What first must be discussed to answer this question, is the barrier of entry and most importantly the perception on this barrier. As figure 38 depicts, the barrier of entry can be put between being a consumer product or being a medical device. When the company

[84] Bakker, K., & Veen, M. (2017, April 26). *Medische missers kosten ziekenhuizen steeds meer geld* [Press release]. Retrieved June 5, 2019, from https://nos.nl/nieuwsuur/artikel/2179846-medische-missers-kosten-ziekenhuizen-steeds-meer-geld.html

wants the latter to be true, significant more effort must be put in the development process of the system and significant more resources need to be available to allow for such a development process. Even though this is entirely true, it does not paint a complete picture. Rather, I think that the concept of 'barrier to entry' must be analysed according to the same four phases defined in this report. Therefore, an improved barrier to entry and amount of effort necessary is depicted in figure 39.

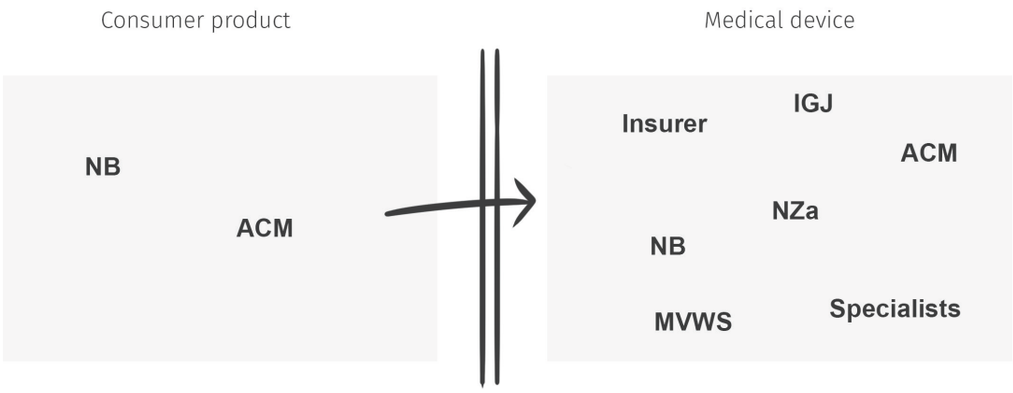


Figure 38. Simplified barrier of entry.

This is due the dilemma that is present between the target group and the necessary investments. From one perspective, gaining and maintaining an (additional) installed base of over 2 million people that are using the solution will provide significant benefits. For instance, the analyses possible with the database increase tremendously, improving its value. Additionally, the survivability of the company will increase as the Dutch government is, up to a certain degree, dependent on the solution and thus on the company providing that solution[85]. However, that does mean an incredible amount of additional effort, including additional responsibilities and thus additional liabilities, will be demanded of the company. Even more so, due to the political nature of such screenings and the long implementation periods (The Health council published the report in 2009, yet in 2013 the screening was implemented) the question arises if the benefits outweigh the costs.

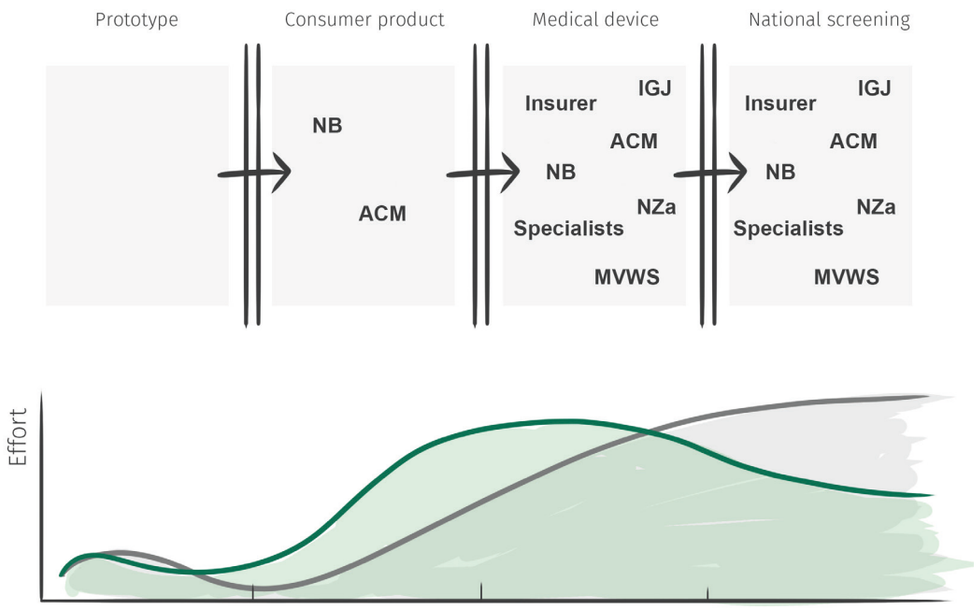


Figure 39. Barriers to entry for all four phases of the implementation design.

[85] In the Gezondheidsraad rapport 2009 it was mentioned that specific suppliers was also factored into the decision. This was necessary to calculate the cost-effectiveness of all methods included.

The perception of these efforts differ between the company and me (figure 38 and 39). It is the company's assumption that once the clinical validation process has been executed and the device has been approved, the amount of effort to scale-up and transfer into a new phase will decrease. The company believes that the most amount of effort and resources must be put into the clinical validation process, and that after that, proceeding with the implementation will become easier due to gathered evidence.
My perception, however, is that the amount of effort and necessary resources will only increase proceeding from phase to phase. **First**, scaling up the production and implementation process will drive costs and the need for resources (although this is by far not the most pressing argument). **Second**, the involvement of the Health Council and the MVWS will increase significantly. Even though these organizations are involved in the medical application phase (See the Implementation power grid, Part I Chapter 5), their involvement changes from being in the background and monitoring to active involvement and becoming a definitive stakeholder. When becoming the method for the national screening of the Netherlands for CRC, much more emphasis will be placed on the clinical evidence that been provided, much more demands will be made regarding transparency of corporate information, data, test results, and designs, and much more dependency will be placed on the legal ramifications of false positives and negatives. Even though most criticism regarding the current nation screening method and its process is placed on the Health Council and the MVWS, and the argumentations of the decision are under scrutiny, the test method is also being criticized. Even though criticism is not an immediate threat to the sustainability of the product or the company, it must not be underestimated. **Last**, because of the increased involvement of the Health Council and the MVWS, additional political games will become part of the implementation process and the execution of the screening. Suddenly, the ministry has become dependent on the company to perform properly as mishaps in the screening could result in parliamentary questions or even resignations.
In conclusion, answering this question is difficult. Even though the analysis provided formed the basis of these perceptions for both the company as for me, our perceptions differ significantly. Therefore, it has to be concluded that answering this question now is futile as this decision should be made in the years to come.

SUMMARY

The application of the solution changes over time. These changes are described and divided into multiple phases. In doing so, it should become clear what the company needs to do the implement the solution successfully.
The first phase is Phase 0 focussed on prototyping. In this phase, the solution should be developed as a prototype. It will become the first real-life implementation of the solution. As mentioned in the introduction, the goal of this phase is not to develop the most ideal version of the solution, but to develop and construct a version that is testable and able to be used for testing and the gathering of feedback. This phase is successfully completed, if the prototype has been developed and built, and the company, through the prototype, is capable of convincing an investor in investing into the company. The decision criteria that should be used to decide if enough progress has been made to proceed to the next phase are the following: this phase must be successfully completed. That is, the prototype must be working and funding must have been secured.
The second phase is Phase 1 focussed on the configuration of the solution as a consumer product. During this phase, the goal is to develop a version of the solution that can and is allowed to be sold onto the market. This allows for multiple benefits. First, selling the product can be used as a gauge for consumer interest. Second, by selling the product the company has a form of income, that can prolong the runway and increase the chances of survival. Third, by selling the product and showing consumer interest, it becomes easier to attract more capital funding and start phase three of the total implementation roadmap. Last, by selling the product it also becomes possible to start the development of the database that will be the defining piece of intellectual property in phase three. The consumer product should be regarded as a Minimal Viable Product (MVP). An MVP is a product consisting of minimal functionalities that still satisfies customer needs, whilst needed significantly smaller investments and fewer resources to be produced. Additionally, such a MVP can be used to gather feedback from actual users and therefore, can be used to optimize any future iterations and releases of the product. This phase is successfully completed, if the consumer product is developed and sold, creating revenue for the company and proof of the value of the solution. The amount of revenue could be related to the amount of success that this phase has achieved, as more revenue indicates more success, but that is beyond the goal for this phase. The gathering of proof of concept of the solution and its value is what will make the difference in the ability of the company to attract more funds and enter phase 2.
The third phase is the phase in which the solution will be approved as a medical device, so that the solution can finally achieves its original goal of the intended medical use. Important to notice, the ‘intended use’ of the device will be the defining characteristic in the classification process. The intended use will not only define whether or not the device is a medical device, but also the classification of said device based on the risk it poses to the user. Based on the classification rules, it can be argued that the device belongs to class C in the IVDR. The annex rules that any device intended for the screening, diagnosis, or staging of cancer as well as any device intended for self-testing should be considered class C. Clinical evidence of the effectiveness of the device can only be sourced through performance studies. These performance studies must be under the responsibility of a sponsor, which can be both the manufacturer as any other natural or legal entity. For class C devices, this validation process will be monitored by a NB on “an appropriate level of involvement”. As has been mentioned, the IVDR states that the clinical performance study should be in line with international guidance, like the standard ISO 14155:2011. This phase has been successfully completed, if (1) the product achieves compliance and is approved for sale on the Dutch and European market, (2) a deal is made between the company and an insurer for the reimbursement of the product as a benefit and added sales argument for the user, and (3) the installed base has been approved as well allowing the user to receive diagnostic results instead of only numbers and figures. Successful execution of this phase means that the initial goal of the company has been achieved. A new product has been developed that is capable of assessing the health condition of its users and alert them of any deviations from that what has proven to be normal. Such a product will be reimbursed by insurers as they realise that prevention is incredibly cheaper than treatment, and in doing so, the consumers are more drawn to the purchase of such a solution. The

healthcare industry will have accepted the solution as it has proven its performance and diagnosing capabilities, and care professionals are accepting these results and using them in the diagnosis and development of a treatment plan for their patients. In doing so, the entire healthcare industry will reduce its healthcare expenditure as numerous cases of CRC patients are now treated either before or early in the CRC diagnosis. The company is able to improve the product and monitor the product in the Dutch healthcare consumer market through its established QMS, RM, and PMSS systems. Additionally, as users are willing to share their personal health information (although tactfully anonymized), the company is now able to perform research with the clinical researchers and gastroentologists from research institutions and hospitals, and gather more evidence and insight in CRC development as a cancer. A new understanding will be developed of the disease and how a deviation in health condition can predict the establishment of such a disease. Therefore, solving all problems as stated in the introduction: both societal as individual.

The last phase describes the application of the solution as a national screening method. Selecting a new alternative to the current method entails a selection of multiple methods. Even though assuming the possibility that the solution will be selected in the iteration of the national screening, the questions remains if the solution will be selected however that answer is not easily given. This is due the dilemma that is present between the target group and the necessary investments. From one perspective, gaining and maintaining an (additional) installed base of over 2 million people that are using the solution will provide significant benefits. For instance, the analyses possible with the database increase tremendously, improving its value. Additionally, the survivability of the company will increase as the Dutch government is, up to a certain degree, dependent on the solution and thus on the company providing that solution. However, that does mean an incredible amount of additional effort, including additional responsibilities and thus additional liabilities, will be demanded of the company. Even more so, due to the political nature of such screenings and the long implementation periods (The Health council published the report in 2009, yet in 2013 the screening was implemented) the question arises if the benefits outweigh the costs.

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PART IV

CONCLUSION & REFLECTION

This part will discuss the results of this research project through different perspectives. The validity of the design is discussed as well as the quality of the results. The research questions will guide this discussion. In addition, recommendations are proposed of how to continue this project and what additional analyses, methods, and tools could be used to gather more information and improve the provided designs. A reflection on my personal perception of this research project will be given, concluding the report.

18. DISCUSSION AND CONCLUSION

This chapter will evaluate the contents and the process of this assignment through the assessment of the research questions (which can be found in Part II Chapter 9.3). These questions will address the initial problem that needed solving, the context surrounding that problem, the possible methods to solve the problem, and the implementation of that solution in the context. From a design research perspective, the solution is discussed and evaluated. Doing so, the entire project and its process will be discussed to understand it better and learn for future projects (of which some will be discussed in the next chapter, Chapter 20) In addition, this process also allows for the possibility to assess the research questions itself and determine, in hindsight, if they have been formulated properly and cover relevant theory. After the evaluation of the research questions a conclusion will be formulated on the result of this project, under guidance of DSR theory.
So, all aspects of this research project (i.e., content and process) will be discussed providing a thorough assessment of the validity of this thesis.

18.1 THE PROBLEM

1.	How big a problem is colorectal cancer?
1.1	What is the societal and personal impact of colorectal cancer?
1.2	How many people are affected by this problem?
1.3	How is this problem currently tackled?
1.4	Who is tackling this problem and why?
1.5	How can the current solution be improved?

The first subset of research questions focus on the problem of colorectal cancer (CRC), and discussed it from both the individual as the societal perspective. From an individual perspective, CRC is a terrible disease: it's slow growing (up to 15 years before health complaints), hard to detect (health complaints occur late stage II and begin stage III), yet deadly. As the survival chances of CRC improve radically when it is found earlier (from 11% in stage IV to 95 in stage I), the focus should be on early detection and prevention, rather on treatment. This has been recognised by the Ministry of Health, Welfare and Sport, which ordered the Health Council to device a screening solution. The national CRC screening was introduced in 2013, but had problems of it own: from a relatively low sensitivity (67%), to the issue of 'interval carcinoma's' (occurrence in which malignant neoplasms grow between screenings and not detected in the first screening. Giving a false sense of good health), and the lead-time bias. In Part 0 Chapter 1, I provided an overview of these problems and how they lead to the execution of this research assignment. Originally, the national screening was discussed in a separate part with more detail about the development of the screening, the considered alternatives, the cost-effectiveness of this solution, and more. However, that changed significantly during the rewriting of this thesis, as the conclusion can be made that the only information about the screening is truly relevant is that it does not perform as well as other, new alternatives might. The screening lacks in effectiveness, due to its many problems, costs a lot and demands additional effort and resource of a healthcare system that is already under pressure and I think that the introduction made that sufficiently clear.
However, one question regarding the analysis of the problem needs additional discussion: was it is the right problem? When reading the introduction (Part 0) it becomes clear that CRC is one of the most common causes of death, yet, while reading the analysis (Part I), the target group of people possibly interested in CRC is smaller than the possible target group for a device that is more generic. It could be argued that the solution has been pushed into a direction because CRC, that is not the direction in which the solution provides the most value and positive impact on the individual and society. Due to its strong focus, the development process might have been influenced and perhaps misdirected. However, the goal of design research is to develop a 'generic design', a design that can be translated to other contexts and solve problems there as well. In other words, even though the initial focus on CRC might have steered the development of the project and its solution, the generic design should still offer value. If the solution offers more problem-solving capabilities in another context, then the quality of

the design must allow an easy re-adoptation of the solution in said context. Even more so, the concept of 'biomarkers' (a measurable characteristic used as an indicator of the health condition) is a generic design in itself. This concept can be applied to many other contexts and problems, from measuring the acidity of groundwater to determine the safety, to measuring CO2 in the exhaust gasses of cars to determine the composition of fuel and the performance of the engine. The solution is a combination of biomarkers, generic designs, that together form a new generic design which can be applied in other contexts then the Dutch healthcare system. Therefore, it can be argued that any doubt regarding the focus of this research project will be negated through this method.

18.2 THE CONTEXT AND ANALYSIS

2.	How can you introduce a solution to the Dutch medical market?
2.1	What are the laws, regulations and ethics of the Dutch medical market?
2.2	How can the company introduce the solution to the Dutch medical market?
2.3	When should the product be introduced to the Dutch medical market?
2.4	How should the business model of the solution be?

The second set of research questions focus on the context from which the problem originated and in which the solution must operate. A look has been taken at the 'barrier of entry' and entry points for new medical devices and services, the relevant stakeholders, their relationships, and influence on the development and implementation process, and the company responsible for the execution of the development and implementation process. In answering these questions, it became clear that developing a new medical product, a radical innovation for such a conservative, risk-adverse, and sceptical market can be rather difficult. Part II describes all these aspects from a general overview perspective, while in Part III and IV the specific solutions are discussed.
Based on the work of Kroneman et al. (2016) and additional literary sources, and expert interviews and validation, a comprehensive overview has been constructed that answer these research questions and provide the necessary groundwork for the development of the solution. However, some aspects still need to be discussed. **First**, the analysis would have benefited from conversations with three of the most important stakeholders: the NZa, the insurer, and the Notified Body (NB). However, it has not been succeeded to contact these stakeholders and have a fruitful discussion. Even though the NZa is a governmental organisation and therefore transparent, the possibility to contact one of its employees regarding medtech development was unsuccessful. The NB is a commercial organization unwilling to cooperate without payment or incapable of providing advice to maintain their impartiality. Insurers are also nearly unreachable. Similarly to the NZa, only a general help-desk mail could be found leading to nothing. Additionally, what has been learned from an event focussed on payment structures[86], insurers are unwilling to talk to medtech developers, unable to imagine new business models, products, and services, and incapable of taking risk. It would have benefited the research significantly if conversations with the appropriate representatives of these organisations would have been possible. Nevertheless, the necessary information has been obtained, but from surrounding stakeholders, and is essentially hearsay. **Second**, the discussion on health data, ownership, privacy, and reimbursability is still ongoing and no conclusion has been reached. During an event in the final phase of this thesis project[87], the Director-General of Curative Care department of the MVWS posed the question if products that sell customer (health) data should be reimbursed. In other words, the congregation of smart technology and healthcare is a topic of which the implications and implementations are still debatable. Especially from the MVWS, who standpoint on healthcare is strongly focussed on preventive and remote care, and autonomy. Therefore, it remains unclear if a business model as proposed in this report will actually be feasible in the future if legislators are unsure of the societal ramifications of such technologies. **Third**, the IVDR and the GDPR are the most prominent pieces of legislation applicable to this solution and were therefore included in this research. However, it must be understood that my personal capabilities

[86] 'Wie gaat dat betalen?', 26-11-2018, Hotel theater Figi, Zeist.
[87] The TechMed Event, 6-6-2019, Vliegveld Twenthe, Enschede.

are perhaps lacking to fully understand these regulatory works and their implications. Both pieces of legislation cover important aspects of many business and research processes in the European Union and are therefore lengthy and dense. Even more so, due to the many articles and paragraphs discussing all relevant facets, rules, and exceptions, these pieces of legislation are in contradiction with themselves. So, it could occur that my personal interpretation of these legislative works is wrong or wrongful. Even though experts have validated the specific implications from the solution and implementation design, it might occur that a hidden exception changes all. Most critical for the IVDR, is the classification of the device. The assumption exists that without a medical intended use of the device, the system can be presented as a consumer product capable of measuring but not diagnosing. However, it could also be that a NB or another legislative organization claims the opposite and states that the device should fall under the IVDR even though the intended use is non-medical. Nevertheless, in such a scenario the product has entered or is about to enter the European market, before such a discovery is made, allowing the company to further research this topic and confirm my findings. **Last**, due to the introduction of the IVDR, the previous piece of legislation is replaced: the rules change. Therefore, NB's need to reapply to be accredited again with the responsibility of assessing and approving new tech. Which has left many organizations severely concerned[88], as this accreditation process will take a significant amount time. Therefore, the situation appears to be taking place where no organizations has received the accreditation to operate as NB and so, no new medical devices can be assessed and approved. Even more so, the NB is also responsible for yearly assessment and audits, which will be delayed as well, rendering the post-market surveillance of the installed base useless. What kind of impact this will have on the feasibility of the implementation design is left to be discussed. With the current system, it appears feasible and viable, and experts have confirmed and validated the design. In such a new future scenario, it remains to be seen.

18.3 METHODS

3.	Which methodology should be used to develop the solution?
3.1	What is Design Thinking?
3.2	What is the Stage=Gate Approach?
3.3	What is User-Centred Design?
3.4	What is the effect of the medical market on the development of the solution?

From a methodological standpoint this research project has been interesting. In total, four methodologies have been considered to guide the development process of the solution and direct (parts) of the implementation design, however none was suitable (based on literature found). Design Thinking offered not enough handles and specific tools to guide the process. The Stage Gate Approach assumes access to vital resources (which are inaccessible) and plans stages and gates which are not in line with nature and state of this project. Integrated Product Development was considered too, however, I was unable to access the appropriate literature to understand and apply this methodology. The last methodology was the User Centred Design methodology which offered the best fit to this project and its (research) goals. However, this methodology focusses specifically on incorporating users in the design and development process and that's exactly were the problem occurs: for such a radical innovation no users exist. The new developed methodology combined the best elements of the researched methods and seemed sufficient for the goal of this research project. The level of sufficiency cannot be tested as no criteria for the evaluation of the use of the methodology were established. However, that is not the goal of the methodology. The goal of the used methodology is to produce a solution that can be validated and implemented and in that, it has achieved its goal. Additionally, the cyclical nature of the methodology suggests that the current solution design can be improved upon even further. Yet, it is my understanding of the process and its results, and my experience as a product developer that the most logical next iteration of the concept will be a prototype: the first step of the implementation design. Additionally, another method has been used to analyse the company and structure the implementation design and development: the Capital Model (CM). As has been mentioned before, the CM started out as

[88] Workshop Risk management & ISO 14971, 25-10-2018, Techmed Centre, Enschede. Production in Low Quantities, 04-12-2018, Techmed Centre, Enschede

a way to analyse and compare[89] companies based evaluated characteristics, but has now been adapted to structure a new design process. In regards to assessment of design methodologies, it can be argued that the CM as a method should also be evaluated. During this process, the CM has proven to be an effective tool in representing the differences and changes from one phase to the other. All relevant topics regarding this project has found their place in either of the six capitals. However, when finalizing this project it did came to mind that perhaps a Legal Capital would have been a good addition to the current model. In the current model, legal aspects are either not included and referred to at other paragraphs of the phases (e.g., the classification is included in the key activities of Phase 2 Chapter 16), or divided under other capitals (e.g., the GDPR is included in the business model under the Financial Capital of Phase 2). Additionally, legalities like by-laws are placed under Organizational Capital. Even though the model works as intended, the addition of a legal capital could have a positive effect on the usability of this system.

18.4 RESULTS

This paragraph will not be guided by research questions as no questions have been posed directly related to the output of this research project. Rather, the design research theory suggests how the results of this project as well as its scientific contribution must be assessed and validated. In general, two questions will be answered: "(1) How strong is the evidence that the design will produce the desired results (i.e. pragmatic validity)?; and (2) In what way does the design make a valuable contribution to addressing a significant field problem or exploiting a promising opportunity (i.e. practical relevance)?" (Van Aken et al. 2017). Van Aken et al. (2017) stresses that it is vital to understand whether the solution is more mechanical or more social. Mechanical solution can be tested with analytical processes and assessments, whereas social solutions must be tested with case studies and usability tests and such. In this case, as the end result will be an "on paper" solution (that will be used to develop a prototype), only "on paper" testing can be done. When the solution is more mechanical, this is much easier through things like mathematical modelling and running simulations. However, in this case, that can prove quite difficult as one of the most important aspects of the solution is not the technical part but the social part.

First, criteria have been established to validate the result of the project: a generic design. The output of a design research project should be "well-tested, well-understood and well-documented and supported by a design proposition" which describes "the problem in context, the design, expected outcomes and the material and social mechanisms producing these outcomes in the intended application domain" (Van Aken et al., 2017). The design of this project fulfils at least three of these four criteria. It can be argued that the design is well-understood and well-documented of which the evidence lies before you. Even more so, the design proposition is encapsulated in this thesis report, which will be published fulfilling the purpose of DSR: add to the body of knowledge and offer new insights interesting for both academics and practitioners (Van Aken et al., 2017). However, the solution is not well-tested. The theoretical representation of the design has been validated with experts, but the practical workings of the solution have not been developed and tested. It has not been possible to establish the sensitivity and specificity of the system for all defined biomarkers, which would be beneficial for convincing stakeholders and the attraction of resources, as the technology was treated as a black-box. Resulting in the inability to define the theoretical validity of the business model as the reimbursable capability of the system cannot be calculated. Therefore, the performance and effectiveness of the total solution cannot be validated. The solution will, in its current conceptual state, not prove that it is capable of solving the problem and solving it effectively. As has been mentioned in the scope of this assignment, practical (or pragmatic) testing has been excluded as it is neither my specialty nor my responsibility in light of this project. Thus, the company will become responsible for showing the pragmatic validity of the solution and its effectiveness in solving the problem. All things considered, the solution hopefully meets the criteria to such a degree that the published results are useful for others therefore proving its scientific validity. **Second**, criteria have been established that assess the validity of a publication as a DSR article (Van Aken et al., 2017). These criteria cover the same ground as the criteria for the

[89] Comparing companies would ask for a quantifiable result and so, the output of an assessment with the Capital Model would some sort of representation of the collected metrics. For this research project, the comparison was unnecessary and therefore excluded.

solution, adding (1) the use of relevant literature to form a solid base of analysis, (2) the production of a body of evidence proving pragmatic validity, (3) insights in the use of material and social mechanisms necessary for the production of the desired outcome, and (4) insight in the use of methodologies, approaches, inputs, implementation processes, and feasible alternatives. Van Aken et al. (2017) stress that the quality of a DSR article can be found in the quality of field testing the solution, not in the design of the solution. In other words, the level of testing the solution and the processes used to test the solution are valuable to other academic design engineers as they can be reproduced and applied to other problems and contexts. By including the methodology used and describing the process from initial idea, to clear requirements, functions, system architectures, work-flows, and more I hope to have contributed to the DSR field in a just way.
In conclusion, the relevant literature used to form an analysis of the context and implementation approach of the solution can be found in Part III and IV. Pragmatic validity has partially been proven through conversations with experts to confirm the findings of the analysis as well as the design of the solution and implementation. The use of materials and social mechanisms necessary for the successful operating of the generic design can all be found in the four phases of implementation (Part IV), describing the necessary resources, development processes, the business models, relevant stakeholders, and more. Last, Part II describes the used methodology and how the generic design has been developed as it has, meeting the fourth criteria. The result can be used as input for the redesign and improvement of the next iteration of the solution, therefore adhering to the principles of DSR (Van Aken et al., 2017).

18.5 IMPLEMENTATION

4.	How can the company implement the solution?
4.1	How must the implementation be structured?
4.2	How must the solution adapt through the implementation?

The last subset of research questions focus on implementation of the solution in its appropriate context: the Dutch consumer medical device market and the Dutch healthcare system. The phases of implementation (Part IV) provide a detailed overview of the steps that must be taken to implement the solution in its appropriate context and subsequently shows how the solution changes over time to adapt each of the phases. The newly developed Capital Model provides the necessary structure to this implementation roadmap by subdividing the entire process into 6 perspectives: social, human, intellectual, organizational, resource, and financial capital. In addition, the analysis of the legislation (Part I Chapter 4.3) and its influence on the implementation (Chapter 16) have been discussed as well. Therefore, it can be argued that all three research questions have been answered. However, due to practical limitations (as in not being able to guarantee future assessments) as well as theoretical and scientific limitations (e.g., inability to speak with some of the relevant stakeholders), the amount of detail of the implementation design can be seen as lacking. The current implementation design should be used as a roadmap to project the necessary actions and precautions to make and prepare for, but some specifics (e.g., the hiring of actual people instead of a description of competencies necessary) will be left for the company to define.

18.6 CONCLUSION

In conclusion, the answers for each of the research questions provides a solid overview of the achieved result. The problem has been well-defined from both the individual, societal, business, and healthcare perspective which combined with the analysis of the system, its stakeholders, and barriers provide a thorough and more then sufficient understanding of the problem and the design space. The method

used to develop the solution has been a process of creatively incorporating the best elements of other methodologies and by adding at least one redesign and improvement cycle. Therefore, it can be argued that the solution has proven its validity “on paper”. The lack of pragmatic validity has always been outside of the scope of the assignment, but this exclusion has had influence on the detail of the implementation phase. What was known and what could have been known has been included, and showing pragmatic validity during the first phase of the implementation design will result in the incremental improvement of detail of the following phases.
Therefore, it can be argued that the goal of this research project has been achieved and that the company has been enabled to further the development of this solution.

19. EVALUATION & REFLECTION

A personal view on this project is given in the reflection. First, a look will be taken at the contents of this research assignment. The use of theory will be discussed, as well as the scientific significance. Second, the approach of this assignment will be described in light of planning, initiative, and control. Last, a reflection of this report and the publication will be provided. Combined, these perspectives will provide insight in my personal reflection of this project.

19.1 EVALUATION

First, what has been developed during this assignment is a solution and an implementation plan. To develop a successful solution and a usable implementation plan, multiple theories and scientific papers were used. Kroneman et al. (2016) described the Dutch healthcare system, which was added upon with knowledge and detailed information from the IVDR and sources from the NZa and the MVWS. In addition, the CBS depicted how large the Dutch market is and Janssen et al. (2014) described how this market can be approached which has been validated with insiders and experts. The stakeholder theory from Mitchell et al. (1997) (with additional knowledge from Hillebrand et al. (2015)) was used to define stakeholders and their relationships based on research and analysis from Kroneman et al. (2016). It was identified that this assignment should be considered as Design Research (Simon, 1996; as told by Van Aken et al., 2017) aiming for a generic design and a new body of knowledge applicable in multiple contexts. For the development of such a generic design, a methodology was needed. Three methodologies were considered, from the User-Centred Design methodology (Norman, 1986; as told by Rahimi & Ibarra, 2014), the Design Thinking methodology (Gordon, 1961; Osborn 1963; as told by Brown, 2008), and the Stage-Gate Approach (Cooper, 1986). However, due to their limitations, neither was used. Therefore, a new methodology was developed combining the best elements of the three methodologies. How this solution can provide value was described through the Hybrid Offerings theory (Ulaga and Reinartz, 2011) providing insight into how such a solution can deliver value to multiple stakeholders in a complex network. Identifying the stakeholders (Mitchell et al., 1997) was crucial for the development of such a network. When the solution had been developed, the implementation of that solution into the Dutch market had to be developed as well. From a broad collection of over 20 literature papers, the Capital Model was developed able to structure the multiple phases of implementation. The Capital Model consists of 6 perspectives: the social, human, intellectual, organization, resource, and financial capital perspective. This model was also used to scope the assignment and in doing so, provided cohesion between research and practice. The result of this entire project has been validated throughout the project as at the end of the development process. Representatives of a large collection of relevant stakeholders were requested to provide advice and guidance in the development of both solution and implementation. From a professor gastroentology, to business developers in the medical industry, a former member of the Health Council as well as general practitioner, to researchers involved in the establishment of clinical trials and the cost-effectiveness calculations of screening methods. Looking back, I think I can claim that sufficient effort has been made to use relevant and applicable (pieces of) theories and integrate them in the development process. Even though the results are only testable and verifiable in the future, when the solution will be developed and the implementation design will be applied, I think the validation with industry experts from multiple backgrounds and with a combined body of knowledge has been sufficient for such an assessment In doing so, the capability to use and reproduce theory of the level relevant to my academic education has been demonstrated. Hopefully, a part of this research project can be communicated and reworked in such a way that it becomes applicable for a scientific contribution, may it be a publication or another admission. When looking at the produced work, I think the most suitable piece of work is the Capital Model and its use in structuring the development plan of a new medical innovation. The actual implementation design of this project could then be used as a case, depicting the practicalities. **Second** the start of this assignment was quite smooth. A supervisor was quickly found and, even though his background was not necessarily the most logical for such an assignment, it fitted the goals of the project. However, a month into the project, this supervisor had to leave the assignment due to medical reasons. Then came a doubtful phase in which it was completely unclear how this problem should be solved. During that phase, I think I showed ownership and agency of the problem and, even though it had been promised that another supervisor

would be found, I had officially contracted Jörg three weeks later. Despite this slight hiccup, the nominal project time has been exceeded slightly. Starting on the 10th of September, the master thesis will be concluded on the 11th of July. The process progressed sufficiently over time, due to clear agreements with the company supervisor Pim, in which it was decided to meet every week and discuss the progress that has been made. Additionally, with Jörg a similar agreement had been found, although the frequency of meeting was lower (but sufficient enough!). Across the board, ownership has been shown of the assignment and its deadlines. Clear agreements have been made that pushed the project forward, even though external factors would sometimes obstruct any progress. Additionally, I think I have shown a critical attitude towards the project, its goals, and its process. Resulting in the delivery of a solution and its implementation that is both new and applicable, based on literature and expert opinions. **Third**, the report and publication have been discussed in the previous chapter. However, I would like to address other aspects not mentioned previously. A lot of effort has been put in the scientific quality of the report. A lot of literature has been addressed to form a solid academic basis for this report that has been validated and improved upon by experts in the appropriate fields. In doing so, more effort has been put into the gathering, processing, and placing of information in the report than in the linguistics and grammar. Unfortunately, it has been mentioned that the English in this report is not always on par with what should be expected of an academic design engineer. However, due to time limitations it has proven to be undo-able to correct and rewrite all lacking chapters and paragraphs. Therefore, I made the decision to focus my last efforts on the information in this report, rather then the use of language. Additionally, more effort has been put in the structure of the report and the presentation of information. Hopefully it comes across that the information is structured logically and allows for a pleasant read in which the overview perspective maintains its clarity and understandability. From a personal perspective the last stages of this assignment regarding the report have been pleasant. Especially in the last weeks and days of finishing the report, it seemed that all information finally found its rightful place in the report adding to the understandability and quality of this publication. **Last**, the biggest influence on the process of this project has been the change in tutors and therefore, the chance in project scope. I started out with the intention to develop a common guide (framework, roadmap, etc.) for start-ups that want to develop a medial product for the Dutch medical market. In hindsight, this would have been almost impossible as so many factors influence how such a product should be developed are so broad that one of these factors could have been an entire research topic on its own. Since the tutorship of Prof. dr. ir. Henseler, the assignment has become more specific and therefore more manageable. Henseler advised me to focus on the case of the company, giving a clear goal for my research. Additionally, the company is more satisfied with this research, as it clearly serves a better-lined purpose. Nevertheless, the change in scope still surfaced in some situations were it was difficult to discern the new from the old. In hindsight, the biggest personal struggle during this assignment has been of motivational nature. Despite finishing many deadlines and getting positive feedback from both tutors, as well as finishing the massive amount of work that had to be done and the effects of changing the scope that brought along additional work, the motivational issues did not pass. Eventually, pushing through and simply starting to write proved helpful. When the actual deadline came insight (as the ‘groenlichtgesprek’ was approaching and the colloquium date was set), the pressure to progress was increased allowing for the successful completion of this master thesis.

19.2 CONCLUSION

In conclusion, the overall process has been pleasant and effective. In some occasions, the progress and process of this research project have suffered. From motivational problems, to having lost the capability to view the problem from a larger perspective due to the sheer overload of information, and to the lack of necessary input from stakeholders unwilling to talk. In other ways, however, the process has been a complete joy. From working with my supervisors who allowed me to lead this process and show ownership and responsibility, to experts who were incredibly eager to enlighten me with all the information and knowledge they had, and to the many events, workshops, lectures, and more I was allowed to attend allowing me insight into an industry which I was never part of before. Even though the change in scope has left its mark on the efficiency and quality of the process, the resulting publication is something that I can honestly say I am proud of.

FUTURE RESEARCH

An impression is provided of future events and changes in the industry which might influence the successful implementation of the solution. Additionally, recommendations are provided for future research that might strengthen the understanding of the subject matter as well as insight in relevant topics which were excluded for this research project.

20. RECOMMENDATIONS & FUTURE RESEARCH

This chapter presents several notions and recommendations that might improve the quality of the continuation of this project. Additionally, suggestions for future research are provided that can aid in a better understanding of the total system and might prove beneficial for the company. As the solution and implementation design are both recommendations to the company, this chapter might be a bit confusing. However, this chapter addresses recommendations based on topics outside the scope of this research project.

20.1 RECOMMENDATIONS

First, the perception of value of this solution will determine the adaptation of the device by consumers. The more value it brings and the clearer it is that this device will deliver that value (it is perceived properly), the more willing a consumer will be to purchase the solution. Therefore, it should be taken into account how the value can be increased significantly without driving up the costs unnecessarily. Especially in the case of chronic diseases, this solution might offer some benefits in monitoring the disease and evaluating the effectiveness of treatment options. As mentioned, CRC is a slow-growing disease and therefore, the consumer is asked to invest in something that might become relevant in twenty years. Chronic diseases are diseases that stick for a lifetime and so, the sales pitch might be a lot clearer. One of those chronic disease could be diabetes (type 1 and 2). Diabetes is a chronic disease that must be monitored. Due to the large population of Diabetics in the Netherlands (1.2 million) and the high costs for the healthcare system (1,6 billion), this could be an interesting target group. Some solutions have already been developed , yet actual results must be waited for . Another type of disease could be inflammatory bowel diseases (IBD, Crohn and colitis ulcerosa fall under that typology), is also a large group of people (85.000). This solution could offer benefits in the case of treatment monitoring and help people with IBD to better control their disease. Additionally, when changing the focus of the solution, and thus its intended use, the efforts to comply to the regulations might decrease. With an intended use that is less-evasive and poses significant fewer risks to the users, the regulatory influence on the development and post-market surveillance decrease significantly as well. Therefore, changing the focus of the solution might prove useful in reaching market and CE conformity. **Second**, pivots are drastic rearrangements/changes to the current solution, implementation or business model that change the course of the company into another direction. Pivots should be employed when it is clear that the current route will not achieve the desired results or even could cause the company to fail in their quest and go bankrupt. I read about this in 'The Lean Startup' (Ries, 2011) and thought that it would be an interesting topic to mention and address. The company could pivot the application of the solution. Instead of human faeces, the focus could go to livestock monitoring (some even plea for the 'connected cow'). Or, the company could pivot the business model and instead of at-home use go for use in the clinical context (at a GP for instance). Another way the company could pivot is not by developing the solution self, but by licensing the solution to another company and profiting from every sold product. Or instead of focussing on health and health conditions, the solution could now prevent unnecessary wear to the drainage and piping system. Thinking about possible pivots will increase the survivability of the firm in one or two ways. First, pivoting can turn an undesirable and infeasible solution into something that can be implemented. Especially in the case of firms that rely solely on one solution, this may be vital. Second, mapping possible pivots and establishing the preventive relationships for such pivots might offer new chances of applying the solution in other fields generating additional revenue streams. To be able to pivot depends on the firm's ability to develop a generic design. The goal of a design research project is to develop a generic design: a design that "can be transferred (within a certain application domain) to contexts other than the one in which it has been made and test without losing its basic effectiveness" (Van Aken et al. 2017). For instance, when pivoting to livestock the essential functionalities of the solution remain the same: it analyses the contents of faeces and communicates them to the appropriate user. When the generalization of the design is taken into account and a generic design is strived for, the possibility to pivot becomes much more achievable and feasible. Therefore, it is wise to always consider the generic parts of the solution and how some design decisions might affect the generalizability of the solution and thus limit its survival chances.

Third, during this research project it became clear that information sharing is vital for the development of this solution. As can be read in Part I Chapter 8, the company lacks certain expertise and knowledge due to human capital related restrictions. Gaining this knowledge is only possible through discussions with experts. Therefore, sharing knowledge is insurmountable for attracting new knowledge. However, be conscious of whom the knowledge is shared with and what knowledge is shared. A basic background check can prevent many issues. As well as using an NDA with every meeting. A professional that is not in it to scam, steal, or lie will most of the times be willing to sign an NDA. Additionally, don't be disappointed if one of those experts says 'no'. As has been mentioned before, the medical industry is suspicious of and reluctant in adopting new tech. **Last**, during this research project, effort has been put in the formalizing of the company and most predominantly, in finding a suitable name. Even though I provided suggestions, the final decision was never made. Which was slightly awkward at times when applying to workshops, courses, and events: I was the graduating student for a company with no name. Additionally, from a legitimacy standpoint, it would have strengthen my exploratory claim if the company had a name and a website which could be researched by my conversation partners.

20.2 FUTURE RESEARCH

As medical devices take considerate amounts of time to be implemented completely into their appropriate context. Future events[90] could have a severe impact on the development and successful of the implementation, but the able to continue the development of the solution additional research is required.

First, the functionality and thus the desirability of this solution depends heavily on the technology and capability of the technology to analyse faeces and provide results. In the scope I mentioned, that for this assignment I am going to assume that the technology works and that the solution is able to provide the necessary results. However, in the current state of the solution this is not the complete truth. At the moment of writing, the company is able to determine some variables (as depicted in Part I chapter 1). However, the specificity and sensitivity of these measurements are still unclear. In the medical industry these must be defined. Therefore, future research could be employed to look for the appropriate technology and biomarkers that can deliver the necessary results. Organizations like MESA+ on the university are focussed on the development of methods to diversify between materials and could, therefore, from a micro-chemist perspective add to the understanding and competitive knowledge of the firm. **Second**, when the hardware is able to deliver the measurements, the software must be able to analyse these measurements and transform them into results that can be understood by the user. Such a software system must be able to establish a baseline measurement of all variables for a specific user and be able to distinguish results that do not fit this baseline based on statistics. Such algorithm-based software is becoming more and more embedded into the medical industry. However, the medical industry is still most predominantly reluctant to trust such systems. As these systems diagnose diseases not on a given amount of a biomarker present in the user, but rather on the similarity of physiological processes of the user compared to users with a specific disease. This is quite a big change in thinking that also this solution is subjected to. **Third**, what has come in many discussions with the company is the idea that the toilet in itself could also benefit from a total redesign. Developing a toilet that less dependent on massive amounts of water and perhaps cleans even more efficient could attract an additional target group. Even more so, such a redesign could remove the need to make significant changes to bathrooms, as only the toilet needs replacing, and additional grants might be applied for due to its environmental impact. **Last**, the last piece of future research is focused on communicating the results. The solution should be able to inform the user of its health condition in such a way that the appropriate actions can be taken. However, there is significant challenge in doing so. The results must be clear so that the user understands the importance of the results and when something is wrong, the user should take the appropriate measures. However, the solution should not scare the user or amplify unnecessary doubt in the user. So, the results must be so clear that they are understandable and that the proper action is taken, but not too direct so that the user gets scared. Decreasing the importance of the communicated results could lead to a disregard from the user about serious health issues, potentially causing disastrous results.

[90] For an overview, see **Appendix 12**.