



CHALMERS

Success factors for innovations entering the medtech market

A case study on a start-up launching a diagnostic tool for analysis of genetic diseases

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SUMMARY

A start-up success could be learned and taught. By performing a case study on a start-up this thesis explores factors that can increase the odds of successful market adoption when developing medical technology. Theoretical frameworks about customer development and innovations within medical technology have been compiled to build a theoretical base, and chose methodology. Stakeholders are verified and knowledge and insights are gathered through interviews, observations and validation in customer settings. Financial- stakeholder- and market analysis are performed on insights and information is gathered to strengthen the understanding about how to succeed with innovations and deliver, capture and validate value as well as avoiding risks.

Economy and quality is found to be the most important factors for market adoption within medtech. Economy implies the importance of a good cost benefit analysis and cost should be equal or superior to competing methods if positioned on an existing market. Quality is built through providing accurate products with benefits compared to competing methods on the market. Market and disease must be thoroughly investigated to understand competitive factors and opportunities. When investigating the market personal relationships with customers are important to collect insights, build competitive advantages as well as to build knowledge through cooperation with customers. Further education is important to teach customers how to handle the innovated product and their personal tasks. Customers prefer automatic systems where manual steps are simple to perform and critical steps are reduced. Safety marginal should be built through solutions as overcapacity and short throughput times.

To reach the market co-operation with experts and market-professionals is essential to create a brand identity on economy and quality. Local knowledge could be used to manage target market, risks and regulations. Patents and investments are crucial to success and should be investigated globally, the best investors has knowledge about the market. Most of the assumptions made could be further developed and improved through the implementation of the first minimum viable product, MVP, in a customer setting where the product-market fit could be completed.

Keywords: Medical technology, medtech, start-up, customer insights, business model canvas, cycle of care, market analysis, cost benefit analysis, clinical trials, MVP

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1 INTRODUCTION

The success of a start-up is not luck, it is a process that could be learned and taught (Ries, 2011). When aiming to launch a product on a complex market; know-how and knowledge is of highest importance. This thesis is a case study of a start-up creating a diagnostic tool for analysis of genetic diseases, aiming for adaption on the global medtech market. The product/offer at the core of this case study aims to provide a new simplified analytic tool with low throughput times and fast answers, superior to implemented method due to higher accuracy, reduced risks and a good cost benefit balance when conducting genetic analysis. However, a superior product is not always equal to market success.

Robert B. Woodruff predicted 1997 that the next stage of competitive advantage will be built on customer learning. Customer needs is often presented as key to success, and customer needs are investigated extensively in this thesis, by the use of modern theory and classic methods to give recommendations about how to use market insights to increase the probability of a successful market launch. The conclusions could be use as guidance for innovators striving to get medical technology adapted on the global medtech market.

1.1 Background

The European Office has a high amount of patent applications within the field of medical technology, higher than in any other field, and numerous start-ups with medical inventions are aiming to get complex innovations with high research level on the market, to bring value to stakeholders; owner, investor, buyer, customer, user and so on. The stakeholder situation on the market is complex and stakeholder requirements, user problems, regulations and specific situations must be clearly understood to ensure that value is created to end users, organizations and other stakeholders.

The start-up for which this study emerges from is developing a diagnostic tool for genetic analysis. The company is run by entrepreneurs that earlier have succeeded with an innovation and know the importance of customer insights. R&D (Research and Development) and patent work is ongoing. With a high amount of venture capitalists, interest in development and time plans are strictly held and the goal is to launch the product during next coming year. Regulations need to be understood and recommendations and conclusions about the product are created to ensure a good market-fit before this stage is entered. The theoretical framework is built to grow knowledge about how to create a good product-market fit, the customer development phase combined with the process of innovating verifies how to understand customers as well as specific challenges within medical technology. Due to the size, complexity and cost of the diagnostic tool a MVP, minimum viable product, is not yet ready to be placed in a customer setting.

Experiences drawn from earlier projects have led them to request a third-party investigation in regards to the business design for the new product. The start-up has experts within the medtech area represented on the board, their insights is an exclusive source of knowledge when creating hypotheses and validating insights. This thesis is a sub-set of what has been presented to the board of the start-up.

1.2 Purpose

The purpose of this case study is to explore factors that can increase the probability of market adoption when launching a new product (diagnostic tool) within medical technology on an existing market.

1.3 Limitations

This thesis will not disclose the name of the company from which the study emerges. Neither will detailed technological considerations be included. The study is done in real time and all factors considered are yet not validated or verified. Steps applied from the two frameworks used will be limited by time and all steps from the customer development process will not be included. Neither will steps as invention and implementation be used from the process of innovating, as the nature of these procedures is not applicable to the specific case as Zenios teaches how to find technological innovations from customer findings and implement by testing the MVP, that will not yet be finished during the time of the thesis.

In the field of medical technology and diagnostic the market is often global. This study has however been set to investigate mainly the Swedish market. Some insights from the Finish market are also included in the study.

Since neither company name nor product details can be disclosed in this report. This report will focus on the non-product specific findings as well as the non-company specific findings.

2 THEORETICAL FRAMEWORK

The theoretical framework is built to grow knowledge about how to create a good product-market fit, to facilitate market adoption. The customer development phase combined with the process of innovating provides basic theory about how to understand customers as well as specific challenges within medical technology.

Success is reached by understanding the nature of the market as well as by understanding customer requirements (Kahn, Castellion, & Griffin, 2005). Many start-ups fail to reach economic success because of lack of understanding about their customers (Ries, 2011). Thus, there seem to be of highest importance to understand the customer's requirements to reach success. The theoretical framework used for this case study is selected to receive a better understanding of the customer, general factors of success and specific challenges within medical technology through two established frameworks:

1. Customer development process (Blank & Dorf, 2012)
2. The process of innovating medical technologies (Zenios et al, 2010)

The theoretical frameworks recommend some proven models that could be used to create a successful innovation and strengthen the odds of market adoption:

- The business model canvas (Osterwalder, Pigneur, & Clark, 2010)
- Cost and benefit analysis (Williams, 2008)
- The cycle of care (Zenios et al, 2010)
- Affinity diagram (Courage & Baxter, 2005)
- The five forces (Porter, 1990)
- The SWOT analysis (Grant, 2012)
- Risk analysis (Kunimatsu, 2011)

2.1 The customer development process

Through the process of customer development customer insights are collected, to ensure that customer requirements are met and a market exists. The customer development guide is implementable for entrepreneurs with start-ups as well as entrepreneurs that launch new products. It is a broad method that focuses on a thorough customer understanding. Insights are gathered through an out of building approach where customer meetings take place. The meetings are conducted to identify core features, market, customers, test values and identify the economic buyer, the person in charge of the purchase decision (Blank & Dorf, 2012).

The process is divided into two phases:

- 1) **Customer discovery phase**, implemented to ensure that customer needs are found and understood and product development is successful through building on insights from customer interactions.
- 2) **Customer validation phase**, ensure that customer needs are found and understood. The customer validation phase starts when it is verified that the market is scalable and big

enough and it is understood what needs and problems the product solve to customers, unlike competitors. The phase focuses on gaining orders on given features, price and channels (Blank & Dorf, 2012).

2.1.1 Customer Discovery phase

The customer discovery phase is described as a 4-step framework to discover and verify that a market has been identified and that the product is developed to answer to customer needs, by as few features as possible (Vlaskovits, Cooper, & Blank, 2010). The product-market fit is created by matching product to market- and stakeholder requirements (Blank & Dorf, 2012).

The business model canvas, invented by Osterwalder et al, (2010) serves as a foundation, holding results from the discovery phase. It is implemented with the purpose to create, validate, deliver and capture customer value. The canvas is an ongoing project, where findings are entered and pivoted until perfection. When validation is completed and markets and customers understood the result should be a scalable, profitable and repeatable business (Blank & Dorf, 2012).

The four steps consists of:

- 1) State hypotheses
- 2) Test problems with customers
- 3) Test solution with customers
- 4) Verify, pivot or proceed

2.2.1.1 State hypotheses

The process starts with a market definition, to investigate the size of the market and payoffs. Naturally, before spending time and resources it is important to ensure that there is a market (Blank & Dorf, 2012). Often when business fails the problem is not an underdeveloped product but an undeveloped market (Vlaskovits et al, 2010). Trough reading market research reports, analyses, competitor's press releases, and talking to customers, market can be understood (Blank & Dorf, 2012). The company must understand which type of market they enter, an existing market, a new market, a re-segmented market or a niche market. This kind of characteristics will bring information about market needs and market competition (Blank & Dorf, 2012). To ensure that requirements on the particular market are met, eventual competition must be understood (Hill, 2000). On insights, hypotheses are built and entered into the first version of the business model canvas (Blank & Dorf, 2012) this information will be used to test problems and create solutions.

2.2.1.2 Conduct experiments and interviews to test problem with customers

Experiments and interviews are conducted with customers to test hypotheses and parts of the business model to ensure that the business plan answers to customer requirements. Market and competitive knowledge is captured and hypotheses tested during this stage and made to fact, pivoted or discarded (Blank & Dorf, 2012).

Through customer meetings understanding should grow about their daily life: workflow, organization and buy-in processes (Blank & Dorf, 2012).

2.2.1.3 Present and test solution with customers

Hypothesis and assumptions are tested and it is important to listen to customers as presenting product, solution, benefits and price. The first version of the product is the MVP, the minimum viable product. The MVP should be the easiest product possible built to answers to customer requirements without unnecessary features. By presenting the MVP the problems and solutions might be tested and customers and their problem are understood. It is important that the MVP is built on the least amount of features needed for success, it should not be a list of all mentioned features (Blank & Dorf, 2012).

2.2.1.4 Assess the results, verify or pivot.

Make sure to assess result and ensure that customers are known, problems and needs are understood and product and market fit have been found. It is important to know that company growth is possible with a large enough segment of customers, when customer discovery is finished, customer validation and sales might start (Blank & Dorf, 2012).

2.1.2 The business model canvas

The business model canvas created by Osterwalder et al, (2010) is presented in figure 2.1 and consists of nine (9) building blocks: The value proposition, customer segment, channels, customer relationship, key partners, key activities, key resources, revenue streams, and cost structure. Steps that are further explored and tested in the customer discovery step (Blank & Dorf, 2012). The business model canvas used throughout the customer discovery process is the model used to create, pivot and validate hypotheses about the product to gain a summarized business model explaining how value is created, captured and delivered (Blank & Dorf, 2012).

Value proposition: When building the value proposition the market should be evaluated through the mapping of market type and understanding of switching costs, network effects etc. Customer insights collected through interviews is the main sources of information when identifying needs, benefits, and problems and build an understanding about how to outperform and differentiate from competitors.(Blank & Dorf, 2012). Factors making the solution superior than competitors should be integrated (Skok, 2013), it is important to know how to outperform competition by features, convenience, service, brand etc. (Blank & Dorf, 2012). The value proposition should hold the short time vision as well as a long- term vision for 3-5 years (Blank & Dorf, 2012).

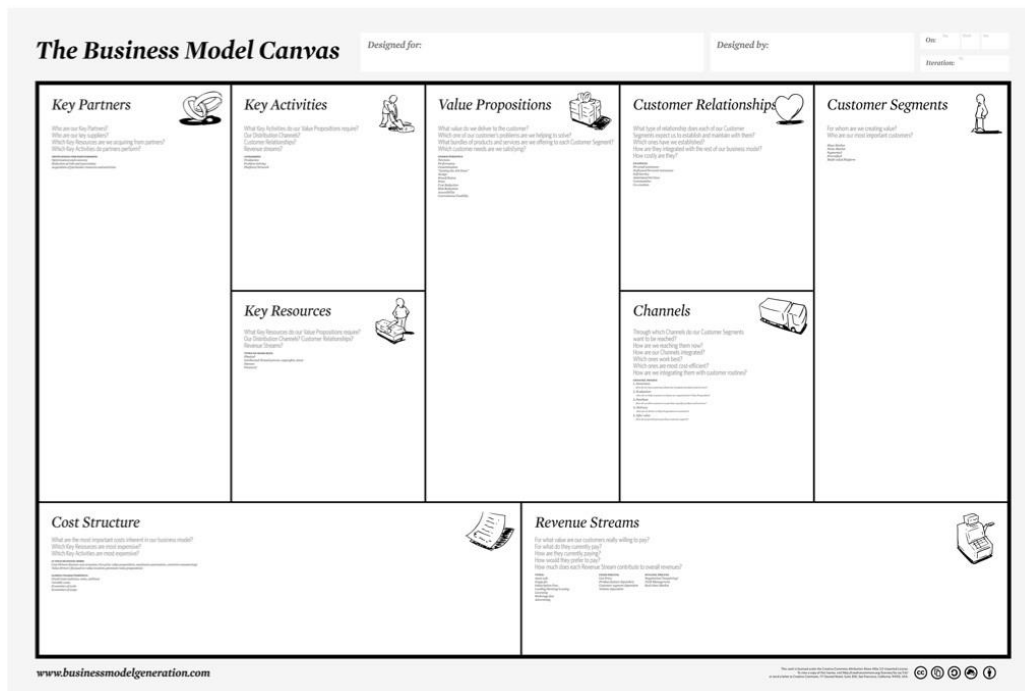


Figure 2.1: Osterwalder's business model canvas (Blank & Dorf, 2012) page 36

Key resources: are the resources needed to offer and deliver the business. Resources critical for success should be known and secured, as well as everything the company is dependent upon, including key partners (Osterwalder et al, 2010).

Key Partners: provides resources that are acquired outside the company (Osterwalder et al, 2010).

Key activities: explains the activities needed to make the business model operate successfully, and ensure that the value proposition is delivered (Osterwalder et al, 2010).

Customer segment: It is important to select a customer segment. A map of influence could show organizational influence and help to verify economic buyers, decision makers, end users, influencers etc. Within the segment all stakeholders and their problems and needs should be understood. It is recommended to understand a "day of the customer" (Blank & Dorf, 2012). All actors that could "kill" a sales process should be investigated and understood.

Revenue Model: An early revenue model could help to set price, understand quantities and forecast the future (Blank & Dorf, 2012). The main issue is to understand what customers are willing to pay and how they want to pay for the product, factors that might be investigated through analyzing current solutions (Osterwalder et al, 2010).

Channels: describes how to reach customers with the value proposition, how to manage communication and build awareness that trigger sales (Osterwalder et al, 2010). Earned media (i.e. free media, like blogs, social media search engine, events and public relations) might be used to get, keep and grow customers. Investigating how to distribute and reach customers is also needed. Mapping established buy-in habits could ease the building of customer channels (Blank & Dorf, 2012).

Customer relationships: When customers are identified it is important to have a plan for customer relationships for each segment. What service to provide and how to manage relations (Blank & Dorf, 2012).

Cost structure: describes most important costs that will be occurring when maintaining the value created by the building blocks. Value driven cost structures focuses on premium value, and often includes a high amount of personalized services. Fixed costs, variable costs and economies of scope are cost factors that might occur through key activities, resources, partners, channels etc. (Osterwalder et al, 2010).

2.2 The process of innovating medical technologies

The process of innovating medical technologies presents methods applicable to create successful innovations. The method starts with an introduction that is written to entrepreneurs in the search for an innovation, many steps are applicable in start-ups with innovations and product development. The process is divided into three steps: Identification, invention and implementation (Zenios et al, 2010). Mainly the identification phase consists of methods applicable to the start-up.

Identification focuses on exploring and screening needs, information that is used to create a need statement describing the product solution. Mainly the identification phase presents applicable methods that could be implemented to strengthen the understanding of requirements and marketplace. It consists of:

- Disease fundamentals
- Existing solutions economic impact
- Stakeholder analysis and needs screening
- Market analysis, regulations, risks and patents
- Need selection

The invention phase is performed to investigating IP (Intellectual Property), regulations and reimbursements. Concept exploration is performed to explore factors important when developing a prototype with minimal features. A business model must be chosen on important characteristics, which are researched until best choices can be made built on customer feedback. Factors included in the chosen business model should be price, revenue, sales, education, differentiation, IP barriers, regulation, reimbursement and finances needed (Zenios, 2015)

The implementation phase is performed to create a strategy that navigates the company through the steps that build values. Strategies are implemented as regulatory strategy, patents, R&D strategy, risk protection, and strategies for iterating and creating quality as well market and stakeholder strategy (Zenios, Biodesign, 2015).

2.2.1 Disease fundamentals

When developing tools within the med-tech industry, it is crucial to understand eventual disease, technology and benefits compared to eventual competitors (Zenios et al, 2010). The

positive predicted value is considered to be the most important measures when investigating diseases with diagnostic tests, it measures the amount of tests that are truly positive among the positive results (LaPierre 2010). To gain understanding of the disease and financial needs, patient population, growth rate, treatment impact, effectiveness, competition, and treatment options needs to be explored. Interviews and observations create insight about needs, problems and latent needs, which are compared to competing methods to gain the deep understanding needed to succeed (Zenios et al, 2010).

2.2.2 Existing solution

Create a comprehensive description about solutions within the field. Assess why the solutions are used, their efficiency, safety, indications etc. Efficiency should be compared by: treatment costs, total negative outcomes, and treatment success rates, economic impact of disease, costs avoided and reduced long term costs (Zenios et al, 2010). A strategy canvas could be created to visualize how the company differentiates from competitor according to the most important factors communicated (Osterwalder A. , Pigneur, Barnarda, & Smith, 2014). For a deeper analysis the cost benefit analysis could be used to compare existing solution to the innovation.

2.2.2.1 Cost and benefit analysis

R&D in medical technology is a costly journey to companies and customers and the cost benefit analysis is used to create an overview visualizing benefits and differences in monetary terms, an important tool to create clarity to stakeholders (Zenios et al, 2010). Often seen as the strongest and most comprehensive tool due to its possibility to explain benefits in monetary terms (Williams, 2008). A thorough understanding of competition and disease, economic impact, consequences of untreated disease, as well as future growth rate is essential when creating the cost benefit analysis (Zenios et al, 2010).

Benefits might be measured in different ways translated to cost savings. If less false true positive outcomes occurs this will be shown in a lowered cost for unnecessary procedures, when less false positives occur costly invasive procedures will be reduced. Incremental costs and secondary benefits without monetary value could be visualized separately, as days away from work, time spent in healthcare, reduced length of stay, opportunity costs, accelerated patient recovery etc. (Zenios et al, 2010). To bring understanding about future and total impact costs and benefits in a sufficient time horizon should be included (Williams, 2008).

Probabilities might be assigned to measure probabilities of different outcomes (Williams, 2008). Probabilities might be tested through a sensitivity analysis (Zenios et al, 2010). A CBA is only as good as the sensitivity analysis. The sensitivity analysis might take into account changes in probabilities, costs, growth rate etc. to better understand the future and estimate limits for success (Williams, 2008)

2.2.2.2 Venture capital

Investor involvement often creates a need to show, create and reach milestones, technological and economical estimations of improvements and deadlines. Trends should be investigated, a business plan built and risks evaluated to answer to their need of information (Zenios et al, 2010). A good venture capitalist has knowledge valuable to the board as well as experience and proven skills that might grow the company (Zider, 1998).

2.2.3 Stakeholder analysis

A stakeholder analysis is done to identify stakeholders, gather and weight their requirements, understand their routines and how the product might affect them as well as understand their specific interest in a possible product adoption.

2.2.3.1 The cycle of care

The stakeholder analysis is done through a cycle of care analysis. The cycle of care analysis maps the patient's way through the system identifying all steps and persons involved. The stakeholder situation is rather complex when presenting medical technology B2B, Business to Business, and stakeholder analysis should be carried out early to define stakeholders, their roles and interconnection that might influence their behaviors. Facilities, limitations and opportunities in the setting, are also important to consider as stakeholder (Zenios et al, 2010).

When stakeholders are identified, interviews should be built to ask what they think, what could be better, what is a practical etc. to get knowledge about on what requirements and factors to act on (Zenios et al, 2010). Haughey (2011) states that customer needs might be different than they communicate, as customers not always are clear about what they want. Hence, customer input should be used as a source of information, not strictly implemented (Ries, 2011). Often different opinions are communicated about: attribute, performance, appearance, service, training, prices, delivery, payment, economic trust and other factors influencing the adoption decision. As some features might promote adoption, or resistance, all needs should be identified and problems, benefits, needs, expectations and dissatisfactions with competitors should be investigated with stakeholders. Findings should then be screened according to influence of the given stakeholder (Zenios et al, 2010).

Blogs, trend and other Internet sources might influence the decision made by the patient to a large extent. Patients that have been searching the web often enter the healthcare setting with a decision already made, looking for guidance and answers instead of decisions (Rowe, 2015).

2.2.4 Stakeholder requirements

The affinity diagram presents a method to screen need. Comments are summarized on sticky notes, and similar comments grouped together. The groups allow for common features and trends emerge from natural relationships (Courage & Baxter, 2005).

When ranking customer needs, they may be divided into different kinds of attributes with different importance. Must be attributes brings high dissatisfaction if not integrated. One-dimensional attributes, brings greater satisfaction the greater they are. Attractive attributes bring satisfaction if integrated but not dissatisfaction if not integrated within the solution (Chaudha, o.a. 2011).

2.2.5 Market analysis

Risks and uncertainties could be minimized by knowledge about the market (Brem & Voigt, 2009). The strongest forces should be identified and understood, as market forces and trends will decide the rate of success (Osterwalder et al, 2014).

2.2.5.1 Porters five forces

Porter's five forces are used to investigate external market forces, to ensure that a market space is possible. The market forces presented in the Porters five forces analysis, visualized in Figure 2.2, are: threat of substitutes, threat of new entrants, rivalry among competitors, bargain power of suppliers and bargain power of buyers (Grant, 2012)

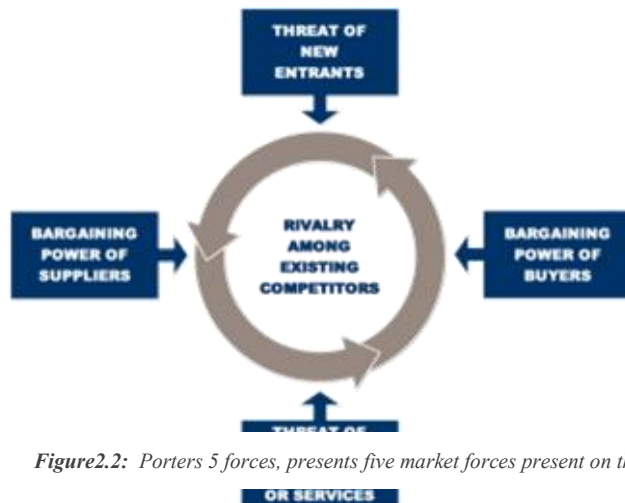


Figure2.2: Porters 5 forces, presents five market forces present on the market (Grant, 2012)

All products that might affect the demand of the specific product create threats of substitutes. When the amount of substitutes are low or when the product is crucial, customer are insensitive to price. Threat of new entrants might be managed through barriers. The intense competition is lowered when barriers to entry are high, making the prices more stable increasing chances for success. Grant (2012) presents barriers to entry as: economies of scale, capital requirements, regulatory limitations, distribution channels, product differentiation, government and legal barriers as IP. Rivalry between competitors will depend on concentration, similarities and differentiation of competitors. Bargain power of supplier will depend on the number of buyers, size of their buys, their cost to lose the company, or companies' possibility to vertically integrate (Grant, 2012).

2.2.5.2 SWOT analysis

The SWOT analysis is used to map Strengths, Weaknesses, Opportunities and Threats to a company, or product. The situation is mapped as showed in figure 2.3, and information gathered is used to increase the odds of success when developing the business strategy as a link between firm and environment. It could also be used to provide an overview useful for understanding a future market position (Grant, 2012). Strengths and weaknesses are investigated to overview the internal environment of the company and opportunities and threats overview the external environment. Strengths should be used to leverage opportunities. Weaknesses and threats evaluated to weight risks.



Figure 2.3 SWOT analyse to map Strengths, Weaknesses, Opportunities and Threats

2.2.5.3 Regulations, risks and patents

Regulatory issues and reimbursement basics must be investigated. Relevant information about regulations needs to be gathered early, and expert should be involved in the process before business strategy is set, and production starts. Regulatory pathways and requirements should be outlined (Zenios et al, 2010).

By talking to customer, observing competitors and gather insights within facilities further knowledge might be built (Zenios et al, 2010). EU-regulations for medical technology are created to minimize and clearly verify risks, if not specific risks are included with the technology investigation might be performed by producer that verifies that demands are met, if essential risks are involved third part investigation is needed. CE marking must be attained before the product is allowed to enter the market. After market entry a reporting system that documents the product is needed (Medical products agency, 2014). Risk management is important to evaluate and analyze treats. ISO 31000 could be implemented as a system to overview organizational risks.

Risks could be explained as = negative impact x likelihood to occur. Essential risks and their impact need to be understood to decide which risks to eliminate, avoid, shift or accept. Risks might be: legal, regulatory, financial, based on relationships and dependence, policies etc. (Kunimatsu, 2011).

Market entry and development is relying on patents to be approved. Approved patents are valid for 20 years. From the day an application is sent the time will start, and the innovation is secured. As soon as the first application is sent, the company has one year to apply for patents abroad. In the end of the 3rd year, gathered patent costs are paid (Nilsson, 2015).

2.2.5.4 Market adoption

Factors and needs important to understand to reach the market with new medical technology are explained in the Mini Health Technology Assessment, the mini HTA. The mini HTA implemented at many of the Swedish hospital supports and describes necessary actions and considerations for implementation of new technology. It is structured according to SBU, Swedish Agency for Health Technology Assessment and Assessment of Social Services, and is a systematic method that investigates diagnostics, treatments and consequences with focus on patient benefits (Skåne, 2014). The full document is found in Appendix II. Through reading it insights are gathered about important factors that might influence market adoption. Factors and features as:

The product should be easy to learn, and guidance should be available. The solution should be political and socially correct and incitements should be built for macro level. The solution should be secured through expert opinions, effective marketing and a need analysis where patient expectations are met with technological solutions. The nature of the technology, push or pull as well as the purpose of the technology should be further investigated to estimate market adoption. Factors as size, environment, time, maintenance etc. will also influence the adoption (SBU, 2009).

Early adopters are visionaries that see potential in new products, the early majority is the mainstream market that needs finished product with good price. Between these groups a crack is illustrated crack, the chasm is created by the different needs of the early adopters and the majority market. The chasm often needs some extra consideration to ensure that the majority of market is reached (Moore, 2014).

Steps are presented to ensure that the majority market is reached:

- 1) **Target the point of attack:** Ensure to strategically focus all resources on one market where dominant leadership might be built.
- 2) **Assemble the invasion force:** Create a complete product, through understanding the customer problem and create a compelling product and service. Ensure to deliver the value proposition.
- 3) **Define the battle:** Understand competition and know what competing alternatives to defeat.
- 4) **Launch the invasion:** Set a price, distribute and create channels. A direct sales channels is superior (Moore, 2014)

When market is entered some common factors are seen to connect to the rate of adoption as: relative advantages, compatibility, integration of values, experiences and needs, complexity, trialability and observability (Sahin, 2006).

3 METHODOLOGY

This chapter presents an overview of the methodology chosen, as recommended by the theoretical framework. Presented are the research approaches, data collection methods as well as the analytic approach, validity and reliability

The customer development process is implemented as an experience based method to gather insights and the process of innovating to extend the customer development method with extensive analyses that might be used to recognize opportunities and develop deep insights, a method found to be suiting for complex and costly products bound by regulations and competition.

Chalmers library have been used to extend the theoretical framework with information about: cost-benefit analysis, customer development, Porters five force, SWOT analysis and Lean start-up. About 45 scientific reports, clinical studies, competitor publications and systematic overviews about the subject are included in the gathering of knowledge, all considered to have a medium high quality due to the involvement from professionals with financial interests in competing methods and solutions.

Swedish Agency for Health Technology Assessment and Assessment of Social Services, as well as hospital homepages and competitors' homepages has been used as a source with knowledge within medical technologies, high credibility and good knowledge about Swedish regulations.

3.1 The case study

Recommendations are deduced from combining the frameworks and conducting a case study on a real time startup. The case study is developed to create high ecological validity and explore factors that improve odds of success for the specific innovated product. Internal validity is created by securing minimal bias (Bryman & Bell, 2011). The study is based on real life facts built on gathered material as explained below.

3.2 Data collection

Data is collected through interviews, observations and secondary data. Six major public health care hospitals were identified to use a competing tool/method. These were approached and most of them granted an interview. Clinical managers, section manager and lab technicians were interviewed. Some insights were also collected through phone where mainly lab technicians were heard.

Interviews made with the biggest actor at the initial stage of the start-up was saved and used as information about the actor's opinions as secondary data. The largest actor in Finland participated in the study, with clinical managers, lab managers and lab technicians.

Interviews and observations were also conducted with other stakeholder such as employees at healthcare settings, private health care, clinical genetics department and end users.

3.2.1 Interviews

The interview was designed to serve as input in to the methods presented in the empirical framework. Interviews were conducted to gather knowledge about competitors, problems and requirements and verify, or pivot, assumptions in the business model canvas. Open discussions where held, the business model canvas was used to collect insights and work as an roadmap for verification that all subjects was included. If questions was found to be needed, to ensure that insights about all factors where gathered, they were open-ended questions stated in a manner created to avoid presenting solutions and putting words in mouth of the interviewee.

The interviews were slightly adapted to the stakeholder. Interviewees which had knowledge about previous methods and could benefit from understanding the details, such as clinical managers and lab managers, signed an NDA before the interview and got to overview PowerPoint and other models and diagrams created to visualize a possible MVP, they were also able to describe their workflow and experiment with a possible workflow schedule and communicate thoughts and consideration about the subjects.

The interviews were recorded, transcribed and translated into English – when conducted in Swedish.

3.2.2 Observations

Observations were performed at two Swedish hospitals, giving the chance to evaluate and compare the presently used technology/system as well as observe problems, needs and present workflow. As it is essential to be familiar with the setting in which the interviewee works (Bryman & Bell, 2011).

3.2.3 Secondary sources

Secondary sources such as professional statements, scientific researches, clinical trials and information from SBU (Swedish health centre for knowledge and care) has also been used to gain technological- and market understanding. Radio recordings and interviews with experts have been considered, as well as online patient blogs that has been used to provide awareness of issues and concerns from end users (i.e. patients). A great understanding of the disease, treatment options, market sizes, global trends, prevalence and positive predicted values are important not only to explain benefits but also for the interviews, this was gathered through reports, internet and competitor publications.

3.3 Data analysis

The collected data was analysed through the framework (chapter 2) created by “the customer development process” and “the process of innovation”. The models implemented to explore factors that might increase the probability of market success were:

- * Business model analysis - The business model canvas
- * Financial and competitive analysis - Cost and benefit analysis
- * Stake holder analysis - The cycle of care
- * Stakeholder requirements - Affinity diagram
- * Market analysis – Porter’s five forces analysis, SWOT & risk analysis

3.3.1 Business model analysis - Business model canvas

The business model canvas, BMC, is used to gather customer insights and experiences when performing the customer development process. The canvas was used and updated throughout the process to ensure that hypotheses and technological requirements were explored and validated. The BMC kept visible all factors and building blocks of the innovation, as well as values and services offered by the designed business model.

The business model canvas is used to perform the customer development process, which is divided into 4 steps. Where the first two stages are performed and the third is started. Hypotheses are stated and market chosen, problem are tested in customer settings through interviews. Market and payoffs are investigated as well as market type. All hypotheses validated, tested, pivoted or confirmed was visible in the business model canvas. Stage three, present solution, is started as models of the technology and a possible workflow fit is presented to customers, but to finish the third stage MVP should be used in a customer setting to gain customer interaction and final insights before final steps are completed and sales initiated.

The business model canvas was also used to communicate changes and make them visible to all internal stakeholders. Easing the process of discussing and validating changes with technicians, partners, researchers, boards and other internal stakeholders with interest in particular changes. As the process moves along with financial, stakeholder and deeper market analyses, changes will be made and tested through the use of the customer development process and the BMC.

3.3.2 Financial analysis – The cost benefit analysis

The cost benefit analysis was created to translate benefits and costs into monetary terms as requested by customers and mini HTA. From interviews, scientific reports and clinical trials costs and prevalence were collected. Disease fundamentals and existing solutions were investigated and as much as possible translated into numbers.

Reports and studies used were ranked according to: strong scientific evidence (x3), moderately strong scientific evidence (x2), limited scientific evidence (x1) or insufficient evidence (x0). When differing, average costs and prevalence were compiled with regards to

the scientific evidence of the study. Strong scientific evidence was ranked when studies were posted in well renowned journals. Low evidence would be scientific reports written by competitors, or other writers that might be considered as a stakeholder within the field.

The financial analysis worked as a base of knowledge when communicating with stakeholders and board. As the cost benefit analysis was created on a sensitivity analysis this mathematic model was used to easy to change prevalence, probabilities and number of end users on request and when trying to anticipate future changes. Hence, questions, stated by the mini HTA, or stakeholders, could easily be answered as well as hypotheses in the business model canvas verified or pivoted as new information emerged. A top down model was used to estimate incomes and set a price.

3.3.3 Stakeholder analysis – The cycle of care

The cycle of care starts as the patients decide to visit the healthcare setting, and ends when the patient leaves the setting with a finished result. Within medical technology the patient is represented by the sample moving through the process.

By mapping the cycle of care stakeholders as patients, healthcare employees and hospital employees were identified and interviewed for opinions, further mapping, information about working routines and interests. By meeting all stakeholders all requirements, routines and influences are understood and no deal breakers overlooked. As an existing patient flow existed with a competing method, it was also possible to observe implemented cycles to further strengthen the understanding.

3.3.4 Stakeholder requirements – The affinity diagram

Requirements gathered from the stakeholder interviews were evaluated through the use of the affinity diagram presented by Courage & Baxter (2005). Sentences from the interviews were transcribed onto sticky notes, when repeated by same interviewee several times sentence was only considered and used once.

These notes were grouped together to allow for groups without pre-defined features to emerge. Groups were categorized and common themes emerged that could be translated into common factors, features and technological solutions. As not all input should be used to create or influence features, as this would result in too many features. Features were then ranked into must-be, one-dimensional and attractive attributes based on information gathered through the interview, this too ensure that must-be attributes were prioritized followed by one-dimensional attributes.

Some stakeholders clearly communicated the importance of some specific factors, same factors did in all cases emerge in the biggest groups. Hence, the biggest groups were seen as the most important themes when assessing important features for the MVP. By weighting groups to the importance of stakeholders same groups still emerged to be the biggest groups. Weighting was done by multiplying sentences according to stakeholder importance: Clinical managers x 4, lab managers x 3, lab technicians x 2, checking doctors x 2 and end users x 4. This weighting was based on perceived importance and knowledge gathered through the cycle of care, interviews and observations. End users will always be the end factor for rate of adoption and their opinion will be considered as important as the opinion of the informed clinical

managers, doctors does not have a lot of influence in the process but all workers in contact with the diagnostic tool are considered crucial for the adoption and their insights about diagnostic tools is considered to be more comprehensive.

3.3.5 Market analysis – Porters five forces and SWOT

Porter's five forces and the SWOT analysis are used to gather knowledge about external and internal factors. All knowledge collected from interviews, observations, cycle of care, clinical trials and the cost benefit analysis was used to evaluate company, competition and risks based on the factors described as important in the literature work as: laws, regulations, finances, relationships, politics etc.

3.3.6 Validity and reliability

Validity and reliability is about establishing truth and ensuring trustworthiness and quality of the research. Making sure that bias is eliminated and social phenomena are real, by eliminating researches perspective on the subject. This could be done by working with triangulations and searching for convergence (Golafshani, 2003).

Interviews were based on open ended question, to ensure that the interviewees spoke freely about subjects that interested them. The results were compiled by the affinity diagram and only converging insights were inserted to the business model canvas that was used to draw conclusions. It is possible that all stakeholders have not been identified by the use of the cycle of care, due to the complex stakeholder situation within medtech. Influencers and other actors might have influence in the decisions done by the stakeholders identified, but all actors involved with the diagnostic tools, the result and the main decisions are verified.

Secondary sources, scientific reports and other information found is triangulated to ensure validity. Extra care have been taken to reports written by stakeholders within the medtech area as their perspective is supposedly slightly biased to their favour.

The writer held an open mind and the goal was to gain thorough insights about medtech adoption, and did not have a personal interest in the innovation investigated in the case study.

4 EMPIRICAL FINDINGS

The empirical findings is written to communicate findings about the start-up, existing market characteristics, stakeholder insights and other important knowledge gathered when exploring what factors could foster a market adoption.

4.1 The new diagnostic tool: Short insight about the innovation

The innovation is a diagnostic tool for analysis of specific genetic diseases, a simplified method with benefits compared to implemented competing solutions. A treatment gap is found compared to implemented technology and by implementing the new diagnostic tool hospitals will be provided the possibility to conduct high quality DNA testing in house with a highly automated system, with superior accuracy and good throughput times. The solution is cost effective with better detection rate and better positive predictive value. The amount of false results will be reduced, which is important as a false negative result will result not only in unnecessary stress but will also increase the risks, and might in rare cases result in death due to unnecessary invasive procedures.

A lab technician in the hospital setting handles the tool. It is mainly automatic and will need no further integration of data as the tool has processed the test. The technology is still being developed, and technological hypotheses about needs are made, some characteristics might still be altered according to requirements and requests. Samples would most probably need at least 48 hours to be processed within the diagnostic tool, a process planned to run day and night in order to finish as soon as possible.

The start-up will focus on development of the system, included technology and the features needed to make the analysis run smoothly, fast and accurate. Partners will be used to build the casing and implemented systems around the innovation, the technology will be developed in-house. Efforts will be spent on R&D development of the diagnostic tool as well as patenting. The complexity of the products make it hard to develop an early MVP and efforts are set on validating hypotheses considering market, technology and system layout before a first layout is completed to be tested and validated in a customer setting.

4.1.1 Existing market: The competing solutions

The total grown up population could be served if needed, but only a small amount of these are considered in need of analysis. This group is estimated to around 100 000-150 000 end users per year in Sweden (SBU, 2000), a number that is further investigated and verified by analysis and insights. Growing populations, changing lifestyles and other trends also shows that a growing target market is to be expected. Due to local regulations some municipalities have different regulations, some divide end users in risk groups where only the individuals with highest risks get access to the test. In the targeted group of end users, among 40% of the total amount is presented to the diagnostic tool used to verify the diagnostic disease.

Two competing solutions are actively presenting substituting devices for the genetic analysis on the global market.

Competing solution 1 consists of two provided tools implemented in Sweden at six hospitals, placed at the clinical chemistry department. Competing solution one has a substituting method that does not involve genetic analysis. Hence, accuracy is low with many false negative and false positive results.

The tool only runs for 4-8 hours but as further patient information is collected from different settings, the integration of result is often communicated to be a problem resulting in time delays, unnecessary waiting times and problems. Samples that run in to problems are double checked with doctors.

About 70% presented to the method choose to go through with analysis, if tests are positive about 70% continues with the invasive procedure to verify disease. As the use of competitor 1 results in many false positives a high number of unnecessary invasive procedures occur. Invasive procedure brings end users stress as it includes risk, injury or death. Death is expected to occur in about 1 % of invasive procedures. Days away from work are always to be expected.

Invasive samples are run through clinical genetics, a costly process. False negatives result in undetected diseases.

Competing solution 2 consists of a few different companies, providing a process of genetic analysis. Results are more accurate, resulting in lower risks and less invasive procedures than the method provided by competitor 1. As earlier methods, positive samples need to be confirmed through invasive procedures. Competing solution 2 is currently spreading abroad. The method provides benefits that are identical to the benefits provided by the innovated tool, compared to the innovation and Competing solution 1, Competing solution 2 is more expensive and time consuming.

Competing solution 2 is not implemented at the Swedish market, and samples are sent for diagnostics abroad. Patents on the US market are infringing on each other and a large amount of litigation has occurred. The cost for this method is about 700-1200 USD on all markets, in Sweden end users privately carries cost if the method is chosen. The method might be chosen through contacting private clinical actors as TATA and Unilabs, which are supplied with tests collected in the healthcare setting and send them to foreign actors.

Quality is investigated by experts and seen to be constant despite that tests are sent, but results often takes about two-three weeks to be processed. This due to time of sending as well as a more time needed to extract these test of genetic standard with the particular method. Despite these waiting times and cost end user, not supported by the healthcare pool or unsatisfied with accuracy of competing solution 1, show an interest in sending samples.

In England where the method presented by competing solution 2 is increasingly adapted, 90% of the total market is reached, indicating that safer methods will create a growing interest for the diagnostic method. Many customers and secondary sources communicate that it appears likely that the improvement of the methods might grow awareness and strengthen these numbers. The growing trends has resulted in a systematic overview, which is being developed with SBU at the time to investigate competing solution 2, evaluate risks and develop suggestions about the method (SBU, 2015)

4.1.1.1 Clinical chemistry & clinical genetic as choice

Hospitals are divided into different departments where medical technology might be placed, clinical chemistry and clinical genetics. Clinical genetics run low quantity, special tests, demanding processes with long throughput time whereas clinical chemistry normally runs higher amount standardized tests with faster throughput times.

Currently Swedish samples are collected at any healthcare facility and sent to be processed by competing solution 1 at clinical chemistry, which is analyzed to withhold information about existing sample flow, workflow and existing routines and problems.

Even though the tests are of genetic standard, the innovated diagnostic tool is built to generate high quantities through a highly automated tool. This better fits the clinical chemistry department than clinical genetics and it seems that the best way to integrate the tool is to place it within the currently existing sample flow, where the diagnostic tool could be placed at clinical chemistry at hospitals and samples are received from healthcare facilities. The knowledge available at clinical chemistry is considered sufficient to use the diagnostics.

4.1.1.2 Private sector as a backup market for the innovated tool

As the innovation is aiming to replace a tool on the existing market regards have been put into understanding the current solution. As the current solution is implemented in the healthcare setting and governmentally founded it seems reasonable to chase this position and implement the innovation as governmentally founded and free to end users, ensuring them the benefits that the innovation might bring.

Also, the private sector is an interesting alternative as the private health market is growing and end users at the moment turns to them to privately perform the tests when better tests are requested. As the general growth in healthcare has fallen, the private healthcare has remained stable and partly increasing, it can be argued that greater competition on the market brings better quality. Private healthcare ratio in Sweden is increasing with 7%, Stockholm increased 20% between years 2007-2012, a trend that seems to be emerging also abroad (Capio, 2014). Unilabs and TAATA, private laboratory actors in Sweden are sending their samples to be processed by competing solution 2. They are aiming at delivering a value proposition with high quality, modern equipment and short waiting time (Unilabs, 2012), a vision which seems to answer to the value proposition created by the innovators.

4.2 Stakeholder

The workflow in the healthcare setting was analyzed: The end users, patients, meet with healthcare employees in a health care setting that is often positioned outside the hospital setting, and are influenced by employees as well as influencers in the external world, friends, family and internet. The economic buyer gets recommended by a clinical manager to make a procurement decision. The decision might be supported by the mini-HTA, which predicts the implications and economical results etc. The clinical managers make decision on benefits overall goals, to fit lab manager, lab technicians, doctors and fit to the facility.

4.2.1 Existing work- and sample flow for competing solution 1

The end users decide to contact the healthcare settings, due to illness or influenced by Internet or friends. At the healthcare setting the end user is further influenced by employees, if decided samples are collected by healthcare employees and patient info entered into a patient system, samples are sent to hospital with existing carriers that provide perfect conditions for samples.

At the receptions samples are gathered and sent to the implemented tool. Lab technicians are educated to handle and overlook specific machines, generally most processes starts and finish in one workday and are handled by one person. Continuous flow is implemented to competing

solution 1's diagnostic tool, but despite hectic workdays when the process was lagging behind the employees were never seen using the function. Other features as possibility to fill reagents while running, real time status display, reagent indication, fill levels etc. seem to be standard. Automatic data integration is preferred when tests are done. Some implemented high quality tests are checked by lab technicians and directly sent to end user or healthcare facilities, if no problems occurred. If problems occur doctors' double check the results.

If the sample is positive, (i.e. indicating disease) end users might choose to undergo invasive, possibly risky, procedures to verify disease. These samples are run through clinical genetics.

4.3 Stakeholder insights

Insights were mainly gathered to understand what was requested from technology and features to ease the product market fit, adoption and purchase by understanding different stakeholders requirements, stakeholder workflow, and facilities.

4.3.1 End user insights

End-users (i.e. patients) provide a split picture about their view on the new diagnostic solution. Some consider this to be the next step that is needed, a solution they have longed for and others seem to have no interests in the solution provided. End users interested in the solution might be supported by healthcare settings, as other actors chasing a leading position.

Generally all end users positive to competing solution 1 seem to be positive to go through with the diagnostics if supported by government as they consider the diagnostic to bring benefits with the higher accuracy. Some end users are prepared to pay a lot for the test when not provided by government, to ensure their safety as they are unsatisfied with the method provided by competing solution 1. Some end users consider the test to be too expensive, some are satisfied with supported solutions.

End users' rejecting the test does it for different reasons, some do not want to go through the invasive procedure if the test is positive others do not want to know. Time is very rarely communicated to be an urgent factor from an end user perspective and one-two weeks is often considered to be satisfying. Different local regulations and trends are seen, and end user living in bigger cities shows and communicates a bigger interest in advanced health care and the specific diagnostics, argued to be a trend emerging there basically because of the ease to reach advanced methods in bigger cities.

4.3.2 Healthcare insights

The healthcare setting and facilities communicate a need for knowledge. Some are concerned about maintaining a leading position, and are actively searching for and relying on updated technology. Health care employees need to be informed about specific tasks and new routines, as ordering specific glass tubes from central warehouses. They also want to be informed about benefits, risks and substituting methods to ensure that end users get best care available and that they are educated to provide end users with educated answers.

4.3.3 Hospital and Facility insights

Within the hospital setting clinical manager, lab manager and lab technicians give insights about facility, process, routines and expectation. Clinical chemistry or clinical genetics is

communicated to both be suiting to this kind of tests, but clinical chemistry could by all be considered to be the best possible setting. The departments co-operate and do not compete.

At clinical chemistry samples are gathered around the clock and always available. Samples are handled with the specific care needed, and perfect conditions are always applied. Samples are not allowed to go through unnecessary risks and labelling and barcode should follow the sample throughout the process. A diagnostic tool that reads the barcode is preferred.

Manual steps are sources of errors that should be minimized. Many processes are changing and becoming more automatic, having usual simple manual steps as centrifugation done by employees is by none of the customers seen as a problem. But result management is preferred to be more automatic and integration of different results is communicated as disliked. Service is by all hospital stakeholder assumed to be integrated in the reagent rental agreement preferred. Two days downtime when problems occur, and two days of service per year seem to be praxis.

It is important to have accurate samples to ensure patient safety and perhaps save lives. The test accuracy is by all stakeholders seen as almost as perfect as it gets. For the diagnostic answers within a week is considered enough by all external stakeholder, which would allow for about two-three days of throughput times. To ensure that samples are processed within this time overcapacity is needed to ensure that holiday, stochastic changes and unexpected problems are handled. Most actors are accustomed to overcapacity and at least 30% is needed. One larger actor is accustomed to 100% overcapacity even thou they admit it is a lot. Having two instruments is a cost issue that could be accepted if needed, two instruments are often implemented when time is critical.

Operator handles one test from start to stop, often in one day, and this is considered to bring quality. Often procedures are planned at different times. Employees operating the tests normally work about 8 hours a day at a flex schedule. 250 days per year. Diagnostic tools are often run by collecting samples in plates, when full the machine starts. The plate consists of 48 or 96 samples. Operators, lab technicians, tasks should be easy, and some customers communicate the benefits of flexibility and possibility to adapt the procedures and prepare processes at is suits the employees (other communicate it to be a luxury not really needed). Stable reagents make processes and steps more flexible, shelf life of reagents would preferably be at least 6 months.

Night runs should only be done by qualitative instruments that do not usually break down. These hours often are guarded by personnel checking facilities, but not handling diagnostics. Some hospitals could imagine running diagnostic tools weekends, one actor does not. One actor states to have the least amount of samples on Fridays. Hence, weekend runs would probably not be needed. If test are emergent and it is considered to be needed employees working outside normal working hours might be arranged by a few actors. When tests are done, doctors normally check tests that have been through problems or need checking. Doctor delays often occur and diagnostic test might be approved without doctor involvement to bring speed and cost benefits.

Costs are relying on benefits and some external stakeholders explain that they can't pay more for benefits, other are ready to pay more if there are advantages with tests. All mention a need of understanding numbers and benefits clearly, further communicated through the mini HTA implemented for procurement decisions. All clinical managers and section managers communicate that they dislike leasing, all prefer a reagent rental agreement with a set cost per users.

Clinical manager informed about the procedure sees a problem as some of tests will not bring answers at all due to the nature of the test. It would be time consuming to call customers back for new tests, it would also worry them. The possibility to bring two tests through the process is by all except one actor refused as a solution, as this would also include extra work.

External stakeholders does not seem to have knowledge about CE marking and regulations, but they are aware of some strict rules, as for that the water leaving the hospital is strictly controlled and unfriendly substances mixed within liquid solutions is regulated to really small quantities. They communicate that there might be regulations about genetic procedures and facilities.

4.3.4 Procurement process in the healthcare setting

Clinical managers makes purchase proposal to the economic buyer, actor representing the governmental healthcare pool in charge of purchase decision. Clinical managers need an overall picture before presenting a procurement suggestion. Their understanding of other stakeholders and workflow is high and further investigated through the use of the mini HTA, used to present the purchase proposal and gives guidance about important factors to explore before they make a proposal.

Economy, benefits and risk are of high importance and to provide a successful innovation overall cost for healthcare should be decreased, or at least have a neutral effect on the budget.

The procurement process is built on interviews conducted with the clinical managers and on information from the mini HTA:

- A procurement requires a requirement specification. It is time demanding to write a requirement specification as an overall picture of how facility-, stakeholders- and resources get affected (Requirement specification is usually formed along a good business model, so that they get the answers they want when running the public procurement)
- The mini HTA was presented by customers, and is mainly used by the biggest hospitals to advocate the new instrument/process. But, factors considered are important to all managers working with purchase decision. The mini HTA that is presented in Appendix II provides arguments for purchase.
- The mini HTA is built on an idea description where the technology is explained, gathering of systematic reviews or recommendations from professionals is done, substituting competitors are understood as technological benefits, patient benefits, risk, effects, impact, ethics, workflow fit, education needed, average number of patients, action needed, investment needed, costs and incomes if implemented.
- When it comes to economical solutions there are alternatives as reagent rentals, a purchase of diagnostics, or a mix of these alternatives. Leasing is disliked within the healthcare setting. Reagent rentals contracts often runs two-three years and is by all customers preferred. Today the Swedish labs are reimbursed from a central pool of money that pays per test.
- When a technology is found interesting a request is sent to the economic buyer. Decisions about requests are normally done once a year, if it is not an emergency purchase. The specific diagnostics is not considered to be emergency urgent, but still favorable.
- Depending on the size of the deal the purchase may be required to be handled as a public procedure, according to Swedish law. The decision is open to appeal. Then when all is done, purchase is made

4.3.5 Competitive benefits in numbers

Disease fundamentals are investigated before interviews to create knowledge, many factors are found needed to answer the mini HTA. Knowledge about factors is created from experts, interviews and from secondary sources.

Benefits and costs are requested in clear figures. Through translating benefits into financial numbers they are clearly explained. Many disease and benefits factors as detection rate, negative positives and false positives will eventually result in costs.

Competing solution 2 is very similar to the innovated technology and all numbers, as for detection rate, prevalence, false positives etc. is identical. Throughput time for this solution is two – three weeks and costs 700-1200 USD. Making the process more time consuming and more expensive than innovation, where a final price is yet not set.

Competing solution 1 has many differences as it is of another standard, it has a high degree of false negative and positive tests. False positive test are strenuous to all patients that choose, or choose not to, go through invasive procedure and the risks involved. When not detected in time the disease and emergency procedures will result in great costs to the healthcare pool. This is further showed in probabilities and costs in Table 4.2 where prevalence, detection rate and benefits that could be translated to numbers are compared between competitor 1 and the innovated technology. The end users are in some municipalities divided into two risk groups, segment 1 and segment 2. As less false positives occur with innovated technology a higher amount of end users are expected to go through with invasive procedures if diagnosed positive.

Probability variables	Percent
Prevalence all	0,184%
Prevalence segment 1	0,131%
Prevalence segment 2	0,510%
Not detected disease	75%
Competitor detection rate	85%
Competitor false positive	5%
Competitor false negative rate	15%
Diagnostic tool detection rate	99%
Diagnostic tool false positive	0,1%
Diagnostic tool false negative rate	1%
Proportion Segment 2	14%
Electing test	70%
Electing test diagnostic tool	70%
Electing invasive procedure after competitor	75%
Electing invasive procedure after diagnostic tool	99%
Life's lost due to invasive procedures	0,7%
Cost variables USD	
Cost per visit	140
Cost competitor	43
Cost diagnostic tool	-
Cost additional healthcare	150
Cost invasive procedure	1500
Cost emergency procedures if not detected.	79000

Table 4.2: Variables and probabilities interesting for benefits and costs. Visualized is diagnostic tool and competing solution 1.

5. ANALYSIS

Analysis analyses the empirical findings by presented methods to deduce factors of success. Sub chapters present findings extracted from chosen methods: business model canvas, stakeholder analysis, affinity diagram, market analysis as well as financial analysis.

5.1 Business model canvas

Building the business model canvas based on the findings.

To prepare for a product-market fit built on reliable insights that are up to date and collected thoroughly, insights are gathered from the interviews to build the business model canvas, BMC. Requirements, problems and technological solution are explored through the interviews.

Stated by Moore (2014), as well as the customer development manifesto: First the market is understood and then the value proposition should be developed and delivered to create value. All factors as price, distribution, channels, and sales are explored with stakeholders to build the BMC. The canvas will eventually be used to present the strategy to be implemented, and value to be created and the canvas was altered many times throughout the process and still need more validation before requirements are completely understood and a set business model is possible. The final canvas visualized in figure 5.1 is explained in following chapters.

Next step in the customer development process should be initiated by putting the MVP in a customer setting, the MVP could be further be used to adapt the solution to customer requirement and ensure that the company is ready to scale.

5.1.1 Value proposition

The vision is to replace today's method with the product, step by step and eventually completely. The product provides accurate and fast DNA testing available in hospital setting with a highly automated system without need for unnecessary steps of data integration. The accurate DNA testing will also provide value as it reduces unnecessary risks.

Value proposition: "The product will offer a cost effective, simplified and accurate diagnostic tool for analysis of genetic diseases in hospital settings. End users will be provided with reduced risks compared to implemented methods".

The product must still be integrated into a customer setting in form of an MVP, where requirements are understood and value created by a product- market fit.

Key Partners Provider of general parts Service provider delivering high-class service	Key Activities Complete a product that might be integrated in a customer setting and respond to requirement	Value Propositions <i>The product will offer a cost effective, simplified and accurate diagnostic tool for analysis of genetic diseases in hospital settings. End users will be provided with reduced risks compared to implemented methods</i>	Customer Relationships Personal relationship Easy system to order reagents Mini HTA to understand customer needs and requirements	Customer Segments Managers of clinical chemistry is buyers and main customer as they promote the idea to the economic buyer End users are grown-ups that get influenced by the healthcare setting, family, friends and internet. 20% of clinical chemistry departments should get 80% of end users
	Key Resources Technology Venture Capital Global patents Reagents Software		Channels Personal contact with buyers Earned media, systematic overviews, internet, blogs and brochures	
Cost Structure R&D is costly and Venture capital needed. Suppliers need to be payed and human capital is costly. CE marking and patents needed. Sales, installation and service costs. Reagents			Revenue Streams Reagent rental contract is preferred and the cost benefit balance is used to ensure that the price is equal to or better than previous method, needs to be presented in clear figures. Economic buyer preferably government (or private actors)	

Figure 5.1: The created business model canvas, describing the product solutions

5.1.2 Key resources

As the product is still under construction the key resource is the technology within the diagnostic tool, the innovation that is still being refined. Hence, the human capital in the R&D team is a key resource to success. As well as investment and venture capital to support R&D. Intellectual property, as patents will be a key resource to protect the innovation and the FTO, freedom to operate, on a global market.

When the business model canvas is finished and ready to be scaled, software to run the process and integrate with hospital system will probably be found a crucial resource as well as reagents that need to be provided the diagnostic tool.

Venture capital needed to support R&D, patents crucial, human capital.

To deliver the value proposition, software that might be integrated with patient info and result management is crucial. Reagents are needed.

5.1.3 Key Partners

A partner to build the general parts is chosen due to price and performance. Partners providing service maintenance will be needed as the product is delivered, to provide high-class service that is up to speed.

Service providers are needed as well as provider of general parts.

5.1.4 Key Activities

The key activity will be to provide the innovated technology to a hospital setting, as well as provide the reagents needed through an easy order system.

To get there R&D development will be of main focus to get the system working as soon as possible. Healthcare and hospital facilities and employees need to adopt the solutions, the company must respond to integration demands and requirements found through customer insights. Further validation of requirements should be done with customers and technicians and importance should be reflected upon continuously to minimize waste, and waste features. Hence, until the product is on the market these activities need focus. It is also important to verify that work and facility integration is possible at the found customer setting, with normal workflows, focus should be set on further developing and integrating the product as well as receiving the general parts of the diagnostic tool through the chosen partners.

Drive R&D, adopt solutions to insights and requirements with focus on finding needed features and a market fit to ensure that innovated technology is placed in customer setting. Then, ensure that customers have access to reagents and innovated technology is working.

5.1.5 Customer segment

Clinical chemistry department is found at all bigger hospitals. Focus will be set on hospitals with big implemented customer flows. Decision makers, the managers of the clinical chemistry department, will be considered to be the start-ups customers, as they promote the idea to the economic buyer.

End-users interest in the medical technology will set the outcome and actions and focus is needed to awake their interest in the solution. Patients are the end users, sometimes payers, and these will be guided within the healthcare by influencers, employees and external knowledge and information found on internet, a trend that seem to need more focus these days than ever. Internet will also be considered an influencer.

Managers of clinical chemistry are the main customers and end users are influenced about their decision from friends, family, Internet and employees within healthcare.

5.1.6 Revenue streams

To understand how the revenue stream should be completed, a great understanding of competition and customer procurement process is collected. Today the diagnostics has reagent rental agreement and a set price per test and this seem to be preferred in the healthcare settings. All customers agree that the reagent rental provides a safe method often applied as it provides a set cost for each sample. This will also reduce the switching cost to the new diagnostics. As economy is seen as the most important factor this is an important choice. Customers want clear

figures, communicated through interviews and showed in the mini HTA. This might be promoted through the cost benefit analysis, which might be used to show cost savings to the economical buyer.

Reagent rental agreements are preferred by customers and figures needs to be clearly visualized.

5.1.7 Customer channels

Decision makers might be interested in keeping the solutions earlier implemented and the positive effects, differentiation and value should be explained thoroughly, every meeting with customers should be seen as an opportunity to create a future market and present the value proposition. To do this, needs should be understood. Long-term relationships should be built on personal interaction. Reputation, trust and references are factors that might be important to build relationships. Systematic overviews and clinical trials might be created to strengthen the position. The clinical manager will be the key person within the procurement process and it is important to understand them and their needs to create a great sales channel.

End-users could provide strong forces to strengthen the market position. To gain their interest sources that might influences them should be considered, advertising and promotions might grow end user awareness, earned media, systematic overviews, clinical trials, internet, blogs and brochures might be used.

Personal relationships should be built through personal contacts and clear information, as systematic overviews and clinical trials.

End users are reached through earned and paid media, overviews, internet and brochures.

5.1.8 Customer relationships

After placement of a reagent rental agreement customer should gain advantages from using their in-house method. Up sale of reagent will be the main income. Hence, to order and keep reagents in house should be easy and a longer life span of reagents is communicated to be preferred. If volume savings occur, buyers could possibly be more interested in promoting the product to end users.

End user relationships are mainly built through advertising channels, hospitals and healthcare.

Personal relationships create sales, easy order system for up sale needed. End users are mainly in contact with customers, hospitals and healthcare.

5.1.9 Cost structure

Costs will mainly be relying on service providers and reagents. The company costs to get started will mainly be carried by investors.

Costs will be mainly R&D to develop a working technique with needed features, buying it from

a supplier that customize the system to fit the innovation as well as putting the diagnostic product at customer facilities, getting patents approved and approving the CE-marking.

Sales, installation, providing service as well as providing reagents will become future costs in the business canvas.

CE marking, patents, sales and reagents are crucial to the cost structure.

5.2 Stakeholder analysis

Stakeholder analysis on the existing competing solution.

To understand all needs it is important to ensure that all stakeholders are understood and integrated in the requirement and need analysis. The stakeholder analysis is done through the cycle of care analysis to ensure that no important stakeholder's need have been left out.

5.2.1. Cycle of care

Because of the complex situation of B2B with multiple stakeholders, the full cycle of care analysis is done to map the process and identify economical buyer, recommenders, end users and influencers.

The finished cycle of care identify how stakeholders interact in the daily implemented processes.

- Patients get in contact with healthcare setting. External forces as personal characteristics, Internet, trends, friends and family could influence this decision.
- At the first meeting the end user, patient, arrives at the healthcare setting. Healthcare employees will be able to give information about, and further influence the end user to decide on diagnostics or not.
- If decided a sample is drawn by the nurse, to be tested by the diagnostic tool in the hospital setting.
- Patient info is inserted into patient system at same time as sample labeling is done. Additional meeting might be booked. Other results from the meeting are also entered to the patient system.
- Carrier collects samples and ensures that samples are handled under perfect conditions, when transported to the hospital setting.
- At the hospital the sample arrives to the reception and are collected and sent to correct department for diagnostics. Most samples are automatically sorted and centrifuged by machines at reception. Samples as this, made of glass are handled manually.
- Samples are carried in racks to associated departments, and placed by the diagnostic tool.
- The lab technician overviews the diagnostic tool and perform steps as planned.
- The lab technician reviews the results. Today there is a need for other tests and variables to be integrated when the answer from the diagnostic tool, this is handled by the lab technician when the tool is finished.
- If needed, tests are double checked by doctors at the department. A good system lets the system operator verify the sample without doctor's consensus, if nothing particular has happened. Hence, doctors do not always make a final check of tests, as this might result in delays and unnecessary costs.

- The patient receives results through mail if negative or is called back for a meeting if positive. If tests are positive guidance and physiological attention is offered, often multiple times. For end users with negative tests the process stops here.
- Positive samples need personal follow up and a decision is made about invasive testing that is needed to confirm disease.
- If invasive procedures are decided risks are communicated with end users.
- Invasive samples go through clinical genetics.
- Results from clinical genetics are communicated through personal meetings.

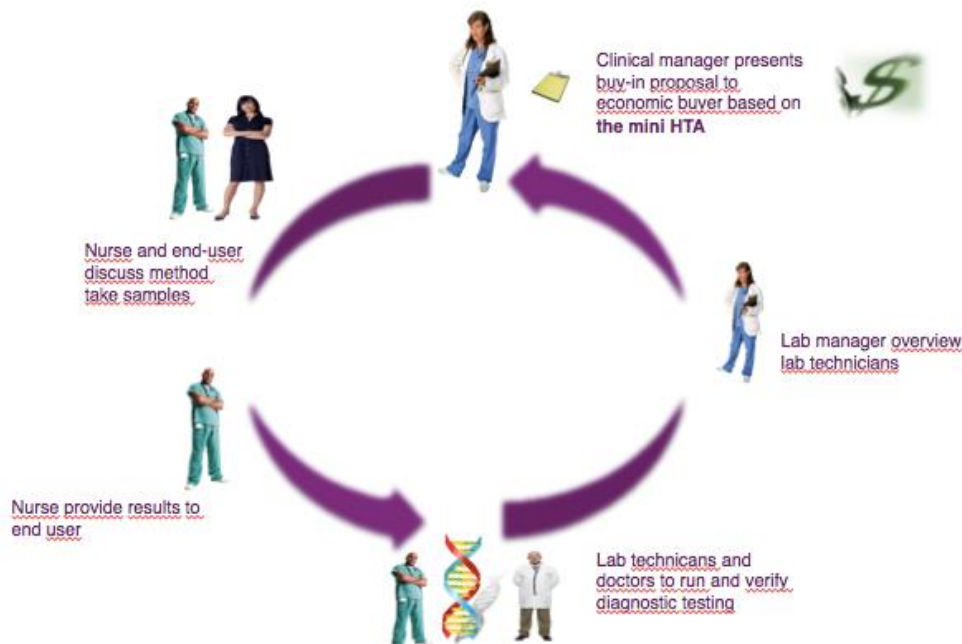


Figure 5.2: The cycle of care

Stakeholders found are: End users, the patient, and their influencers as family, friends and healthcare setting. Healthcare setting consists of employees as nurses, receptionists, economic buyer, clinical manager, economic manager, lab technician and doctors.

It is important to ensure that employees in the healthcare setting are informed and educated around the diagnostics tool. They must know how to influence end users and how to give answers that fit their needs. The sample flow should be easy to handle and tasks should be known, as ordering of glass tubes to contain samples within, ordering reagents, gathering knowledge, managing results.

5.2.2 Stakeholder Requirements

The stakeholder requirements found from the open ended interviews, general and technological results have been analysed.

As mentioned when developing the business model canvas it is important to know on which features to compete, as well as what is considered to be value in the eyes of the customers. All efforts should bear in mind that customer meetings are a first introduction of the solution and customers and interviews should be handled with care. Communicated sentences found through interviews used in the affinity diagram are visualized in Appendix I. Here subjective thoughts are translated into stable repeatable and tangible factors as technological solutions.

Values are described in declining order, starting with what is found to be the most important needs and requirements for the product to be accepted and implemented. Main value is created from: Economy, Service and Quality.

Economy is the most important factors, mentioned by 100% of the interviewees and in many secondary sources. Economy is a one-dimensional attribute, the better the economic gains are the better customer feel about the solution. Cost effectiveness and benefits created is investigated when investigated. Reagent rental agreement is preferred by all and seen as an attractive attribute, the diagnostic tool is placed in the setting for free and a cost occurs per test as each test will need reagents a method that reduce risks as number of end users is not as crucial and costs are kept controlled and easily understood.

Service is mentioned by all hospital stakeholders, a must be attribute that is expected. Error is not permitted more than once a year and service is needed within one-two days. Preventive service seems to normally run twice a year and this is accepted.

Quality is about sensitivity, specificity and positive and negative predicted values when integrating diagnostic tool within health care. These factors are given and accepted for the innovated tool. Many of these are one-dimensional attributes, which should be as high as possible to get highest customer satisfaction. The diagnostic tool will not need further integration with other information when finished as competing solution 1, but some tests will be conducted without results, which concerns stakeholders within hospitals as it is time consuming to call up end users. End users might be concerned and worried when waiting for new tests if this occurs. Stakeholders often wants information to strengthen the quality by expanding knowledge and understanding about the product, also showed buy the mini HTA.

5.2.2.1 Technological solutions from requirements

To ensure quality and stakeholder value technological solutions and factors to ensure work integration and a system fit is also gathered in an order of importance to create a system fit.

Economy: Costs and benefits need to be understood, preferably with a system built on a reagent rental model. The cost benefit analysis could strengthen further understanding.

Manual automatic: More automatic is not necessarily better but human factors including risks should be prevented by ensuring that critical steps of handling and labelling are automatic, for example the diagnostic tool should have a barcode reader and pipette tests. Centrifugation and

inserting samples could be manually performed, as the human factors are not perceived to contribute to risks in these easy steps.

Overcapacity: Samples run in batches, with a set number at the time. If delays occur the automatic systems might have a harder time to catch up and overcapacity will be needed to avoid bottlenecks, ensure throughput times and handle stochastic variations. A safety marginal is necessary and between 30-100% overcapacity is requested, the bigger hospitals seem to have a need of higher safety marginal as conducting a higher amount of batches, smaller hospitals seem to consider 30% overcapacity as enough. Critical tests needs higher overcapacity than general tests, this problem is sometimes solved by implementing two set of diagnostics, depending on costs.

Workflow: Quality is sometimes considered to be the possibility to have the same operator throughout the process, free schedules allowing technicians to plan their workdays as well as reliable reagents brings advantages. Education of employees should preferably be short, and tasks should be kept simple without risks.

Reliable reagents: Reagents should easily be provided and have long shelf life.

Turnaround time: Fast answers and processing times brings quality. As the specific diagnostics is not emergent results are provided within 7 days, to ensure this a throughput time of 2 days is reasonable.

System flow: The diagnostics will need to run nights to get finished as soon as possible. Most customers does not at all look at it as a problem, one single actor mentions weekends as off limit, another customer states that few samples arrive Fridays. Glass samples are not seen as a problem.

Sample management: Some tests with high quality are sent to customers by technicians without doctors checking them. And tests of higher quality should provide result after technicians have approved them. Only tests running into problems should need doctor consensus.

Facility factors: Environment important and controlled by regulations.

Requirements could be translated to three main factors: Economy, Service and Quality. The need for a cost benefit analysis to overview economy and benefits is seen in the business model canvas as well as through stakeholder requirements and the mini HTA. Service is a must be attribute that is needed for adoption but does not bring further value. Hence, further investigation is not needed. Reagent rental agreement is concluded to bring advantages and is generally done for three years. Patens and regulations must be clearly understood.

Quality is important and could often be translated to technological requirements as: barcode reader integrated pipetting in diagnostic tool, no manual barcode steps, and overcapacity at least 30%. Other factors required for the tool are: verified workflow fit with reliable reagents, education kept short, turnaround time within two days, results should preferably be provided automatically and regulations for medical technology should be followed.

Feature	Specified requirement	Technological solution	Type of requirement
Economy	Cost effectiveness with benefits understood Reagent rental agreement	Cost benefit analysis	One dimensional attribute Attractive attribute
Service	1-2 times preventive service each year. 1-2 days to fix occurring errors	Good service provider	Must be attribute
Quality	Barcode follow sample Balance automatic vs. manual Overcapacity needed Free hands-on might be nice About seven days from sampling to results is accepted. It is low quality when phone calls have to be made as well as when doctors always check the answer. The flow of the diagnostic could already be implemented	Barcode reader Integrated pipetting No manual data steps with risks. Ensure overcapacity depending on expected sample flow. 30-100% Ensure that the process stops in a stage where delays do not bother the process or cooling is needed. Reliable reagents. Education. Throughput time 2 days. Night runs Try to solve test without answer. Provide a method with clear answers ready to be sent to customer if process is successful. Validate regulations and hospital rules about environment etc.	Must be attribute Must be attribute Must be/ Attractive attribute Attractive attribute Attractive attribute One dimensional attribute Attractive attribute Must be attribute

Table 5.2: The most important requirements through the interviews conducted translated to technological solutions and types of requirements.

5.3 Financial analysis

The cost and benefit analysis further investigate quality in terms of economy and benefits compared to existing competitive solution 1.

As showed by the business model canvas and stated by Moore (2014) it is important to understand how to outperform competitors and understand required value, costs and revenue streams. Requirements collected, the BMC and the mini HTA show a need for clear figures built on reliable sources and the cost benefit analysis built on a sensitivity analysis was communicated to be the best method to visualize economy and benefits.

The cost benefit analysis is created with perspective built to answer to the economic buyer. Product benefits are compared to competition and by implementing the cost benefit analysis, benefits, risks, impact and costs are translated into clear figures to develop and explore revenue streams as well as estimate incomes, economic buyers costs savings, and eventually set the price that customers are willing to pay, through a price estimation done in the end of the chapter.

5.3.1 Cost benefit analysis – Quality and benefits

Competitive solution 2 is not presently active as a competitor in the chosen customer segment, healthcare, and is not seen as a competitor for governmental founding. One could look at competitive solution 2 as an almost equal competitor, where the big difference is their way to reach end users, their price and throughput time.

The cost benefit analysis was conducted with comparison to competing solution 1, and the complete cost benefit analysis is found in Appendix IV. Table 5.3 is based on approximately 100 000 end users and probabilities presented in the cost benefit analysis in chapter 4.3.3 is implemented. Competing solution 1 was chosen due to its implementation in the setting and stakeholders and buyer is familiar with the method. As positive tests and the positive predicted value increases, the number of invasive test will be reduced by ninety three percent. When reducing the number of invasive procedures costs and risks will be reduced, more diseases will be detected and life will be saved. The earlier high amount of false positive test is the main reason for unnecessary invasive tests and life lost. This high number result in the great difference in the positive predicted value and the innovation is shown to be far superior competing solution 1 according to the important positive predicted value. As seen a great reduction in invasive tests and lost lives is to be expected if the innovated method is implemented.

RESULTS	Positive tests	Invasive tests	Diseases detected	Life Lost/year	Disease detected per lost life	Percent detected	Positive predicted value
Competitor1	4 079	3 059	93	21	4	45%	2%
Innovation	223	221	143	1	261	69%	64%

Table 5.3: Results from the cost benefit analysis on competing solution 1 if customers are estimated to 100 000 and probabilities are used as presented in chapter 4.3.3

5.3.1.1 Cost benefit analysis – Factors of value creates benefits

Competing solution 2 was not included in the full cost benefit analysis as it only differs with the few aspects mentioned. The strategy canvas further looks at the full market of competitive solutions. The strategy canvas is seen as a complement when understanding the value created and works as a contribution to the cost benefit analysis as it investigates all competitors and substitutes, beneficial factors are visualized in Diagram 5.4 where factors of competition is compared to the two competing solutions.

The shaded zone in the diagram shows an area in which the price is to be set for innovation and still generate benefits and incomes, the lowest zone of the span would probably not bring an income and the highest income would just about match the implemented method, as customer communicates that costs must be equal to or less than the currently used solution.. Cost per test is higher for the innovation compared to competing solution 1 (showed in red) per test. Competing solution 2 (showed in blue) as the most expensive solution is considered to produce cost saving 0. Cost reduction to economic buyer is showed to appear when looking at the long-term costs for the innovation. The saved cost per year includes all costs, as invasive testing and revisiting the setting

Competing solution 1 shows lower results on all competitive factors, and has its only strength in the throughput time, where the demanding process of manually integrating results still brings problems to lab technicians and reoccurring delays not visualized in diagram. Comparing accuracy, detections, positive predicted values and cases diagnosed per life lost, competing solution 2 is superior to competing solution 1.

Compared to the method implemented abroad, Competing solution 2, the biggest superiority is seen in cost savings as well as reduced throughput times. As the solutions show a lot of similarities these features will be important to create a unique market space, especially economy as seen important to stakeholders. Placing the diagnostic tool in the customer setting might bring advantages and “lock in” effects that competing solution 2 can’t create. Personal relationships and local knowledge are factors not visualized in the diagram that might bring advantages to the innovated technology.

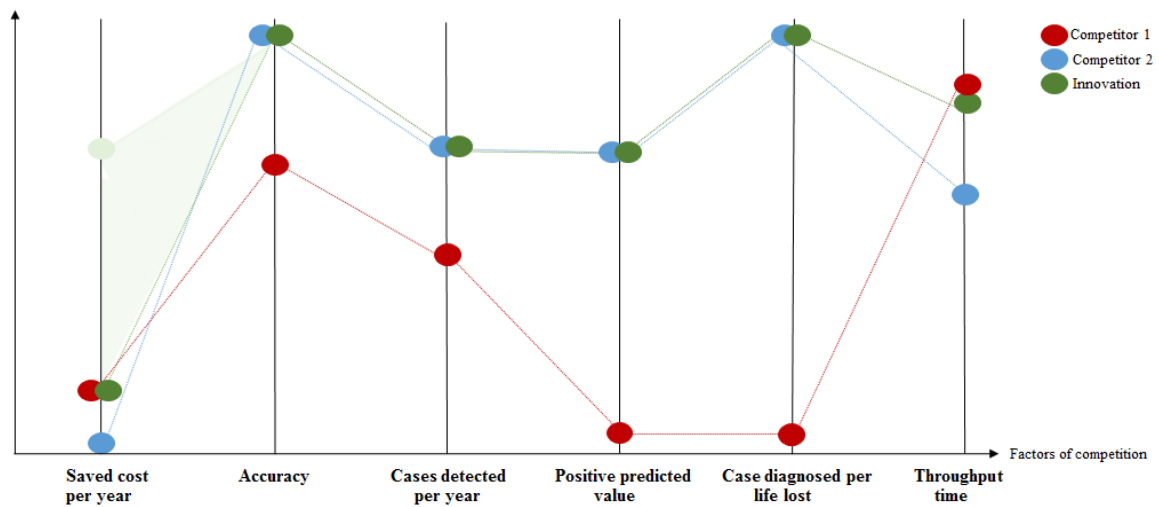


Diagram 5.4: Strategy canvas, competitors compared on factors of competition and percentage of most effective solution

Many benefits and advantages are showed, but to ensure that the diagnostic tool is found to bring value and economical and qualitative superiority it needs to be superior to both competing solutions when looking at factors creating value and main effort in the specific case should be spent on throughput time and cost to exceed competing solution 2. Prevalence, assumptions and future consideration might further be investigated with the sensitivity analysis when needed.

5.3.1.2 Cost benefit analysis – economy and price estimation

By applying prevalence, proportions and communicated rates of accuracy (validated by clinical trials) the cost benefit analysis shows total costs in numbers, costs for unnecessary procedures, invasive procedures based on false positive as well as false negative and emergent costs are included to calculate a price motivation. Days away from work, end-user stress and deaths were not translated into numbers. Factors that might create stress or deaths occurring are further verified in the decision tree.

By using the numbers presented in the sensitivity analysis with all total costs included and competing solution 1's price estimated to be 40 dollars, the new product would result in a neutral cost situation if 113 dollar were charged per person. In this price, smaller cost savings because of reduced work ability is not included. Hence, economical and beneficial benefits will be occurring if price is set to 113 dollars or less.

The financial analysis answers to request from earlier analyses by showing clear numbers. The figures might be used to predict the situation as well as the future. Within present situation price might at maximum be set at 113 dollar, which is equal to competing solution 1 and less than competing solution 2.

5.3.1.3 Decision tree – immeasurable factors

To complete the analysis the tree diagram ensures that some immeasurable benefits and reduced risks are visualized compared to competing solution 1. Not included in the economic analysis nor the tree diagram is factors like loss of working ability, total stay at hospital and other outcomes that might be the result from invasive procedures. When building the tree diagram variables and probabilities are kept constant to probabilities in chapter 4.3.3, even though it is expected that innovation could possibly reach more end users and the trend of getting tested could probably grow, the sensitivity analysis created could be implemented to maintain more results and experiment with future results. The sample outcome is visualized in the three diagram showed in figure 5.5, where end users are estimated to 100 000. Samples processed will result in true positive, true negative, false positive or false negative. When resulting in false negative undetected disease will come with a high cost. False positive verdicts results in unnecessary invasive procedures which my results in critical complications and lives lost. For every lost life with the innovated product, 21 lives will be lost if the old method is kept as indicated in the red fields. Non-detected cases are followed by unnecessary risks and greater costs as shown in black, diseases found is showed in green.

The tree diagram is used to ensure that factors that could not be translated into numbers are visualized.

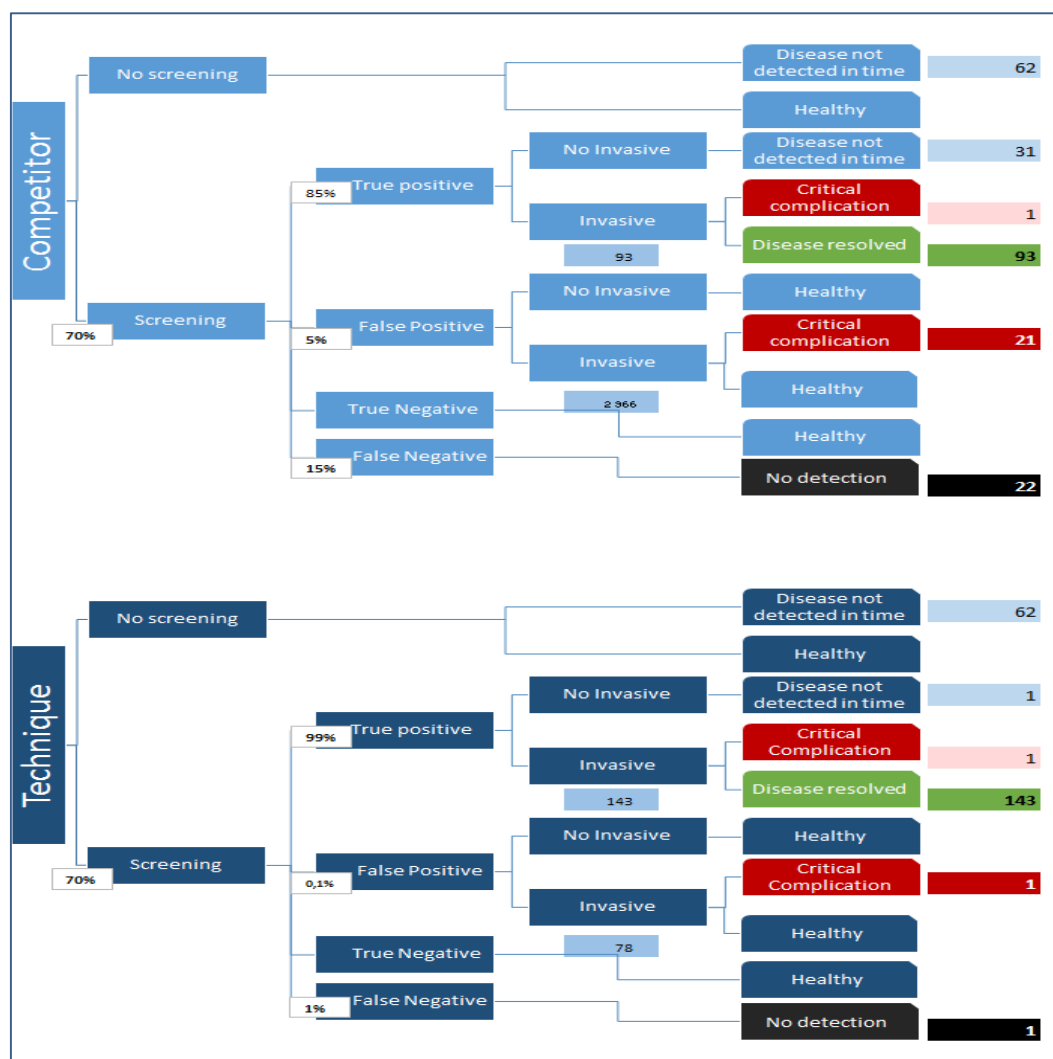


Figure 5.5: Decision tree showing sample outcomes for 100 000 end users.

5.4 Market analysis

Market is analysed with both competitive solutions in mind, to understand the market space as well as the competitive factors.

Market forces were investigated to understand the market space, external forces affecting the company are investigated through the methods recommended and found: Porter five forces are done on the company. The SWOT analysis is done on the company as well as the two competitors found on the market. The risk analysis further investigates regulations, patents etc.

As shown in figure 5.6 the start-up has a good efficiency at a good price per users, at a differentiated market space. Competing solution 1 offers an economic solution when looking at immediate price per patient, as earlier investigated in the cost benefit analysis other conclusions have been made about long term cost, due to unnecessary procedures.

Competing solution 2 offers a similar solution with a higher cost. The efficiency is slightly lower than the innovated diagnostic tool because longer throughput time and the lack of personal relationship and local knowledge that might create benefits.

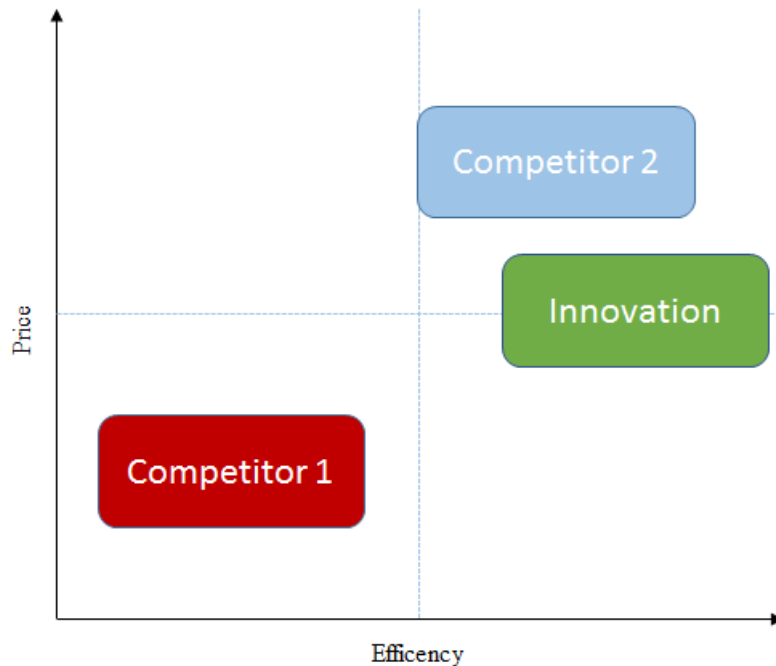


Figure 5.6: Competitive market space price/efficiency

5.4.1 Porters five forces

Porter's five forces are used to investigate the external forces in the field and are summarized in Figure 5.7. With few competitors, high entry barriers, low bargain level of buyers and non-exclusive suppliers, the market looks good for the diagnostic tool.

Entry barriers

Barriers are created by high capital requirements. R&D investments. Strong relationships and a product placed in customer setting to create switching costs by a strong product-market fit. Patents must be secured and freedom to operate must be investigated.

Competition & New entrants

Industry growth big but competition in the specific area low, due to high entry barriers. Further competition could be prevented by high entry barriers as well as brand identity. Important to be superior competitors within the field

Bargain of suppliers

Important that all critical processes are vertically integrated, and dependence is avoided

Bargain leverage & Substitutes

Few competitors and substitutes, the bargain power of buyers low.

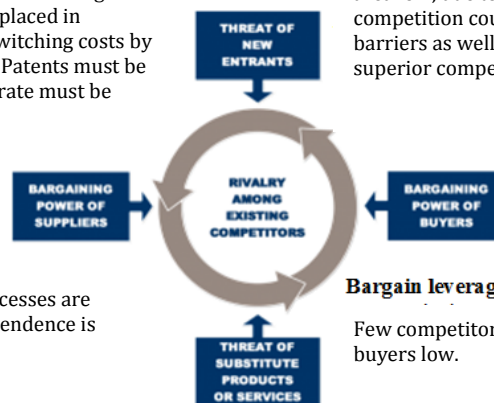


Figure 5.7: Porters five forces created on the market space of the innovated product

Barriers could further be strengthened through developing high a differentiated innovation with high switching costs, as customers are interested in a reagent rental agreement the best way to create high switching cost is by building an easy system that runs smoothly and is integrated with other processes. Patents must be secured and freedom to operate investigated. Software fits and automatic results might improve the system fit and quality. Reagents should be easy to order and the flow adapted and integrated. Good follow up and customer relationships might strengthen this position.

A brand identity is important to build by creating an early market space. The innovation should be superior within economical and qualitative benefits to create high barriers. It is crucial to handle the dependence situation when choosing suppliers; critical steps and resources as reagents should always be vertically integrated, included into the main business and developed and provided by the company.

Software must be simple and an automatic process to order and produce results could create strengths. Relationship should be built to ensure that strengths are created, and dependence must be avoided. Brand identity might be built on economy and qualitative benefits.

5.4.2 SWOT analysis

Swot analyses are as recommended done on company as well as competition.

5.4.2.1 SWOT analysis on company

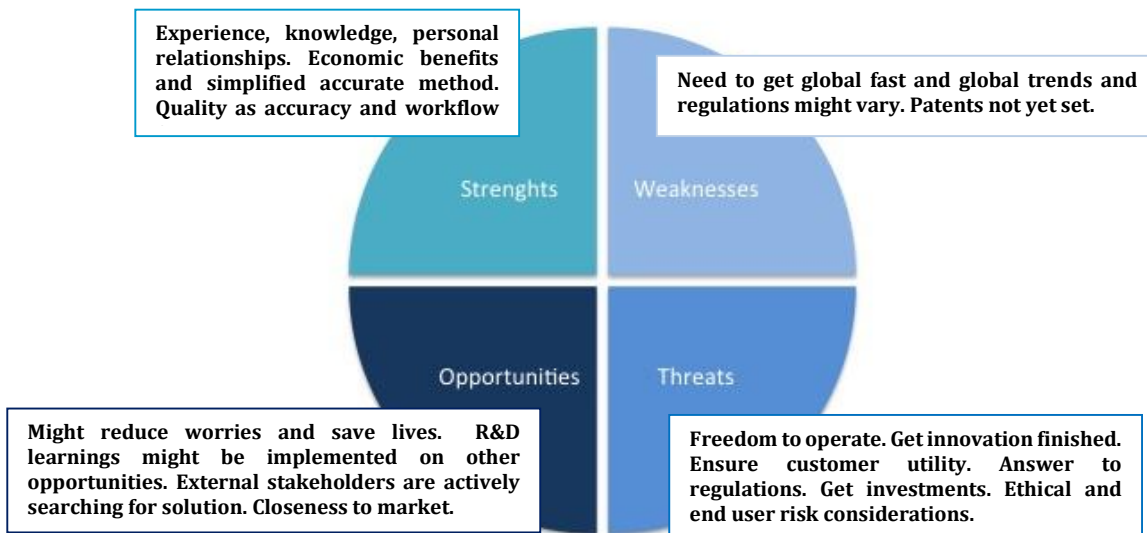


Figure 5. 8: Swot analysis on company built on gathered insights

The product shows strengths in economy and qualitative benefits, has high accuracy easy to integrate to workflow. The creators have previously succeeded with similar innovations, indicating a strong base and good technical knowledge as well as experience about how to succeed. Good personal relationships with experts, Finnish hospitals and co-operation with Karolinska university hospital. Market might be growing slightly.

The Swedish market is small, bringing a weakness, there is a need to move fast into the European market to reach a greater amount of customers. Global trends might vary and further customer validation and analysis is needed. The medical setting needs heavy validation due to rules and regulations. Patents and protection will be needed for Swedish and global market, after filing patents only one year is available to further investigate next market.

The product present higher accuracy, bringing great opportunities, with a long R&D that has come to the end of its cycle. The product improves the diagnostic process and brings benefits, reduce worries and save lives. The innovated technology might further be used to create a simplified, accurate and a faster method that could be used to investigate other diseases. End users are actively searching for the solution. Closeness to the Swedish market and understanding of regulations, as well as personal relationships might further be used.

Possible competitors could threat as they enter the market with superior competing innovations, or patents which could hinder the FTO. Still innovations are under development to reach

specificity and sensitivity of test, as well as easy interpretation of results and a high positive predictive value at low cost. Some customer requirements still need to be met to ensure that customer utility is perceived and the diagnostic tool gains acceptance.

All regulations, standards and legislations must be followed. Government need to approve to support the solution from the healthcare pool for maximum revenues to occur. Investments are needed and more funding will be searched as the innovation is costly and R&D investments strong. Venture money keeps on being collected and the Swedish market has a limited amount of investors and investors must be searched abroad as well.

The company has strengths that could be used to collect opportunities, experience and knowledge about local market and requirements. Personal relationships, expertise and contacts should be explored. Professional involvement and clinical trials might be used as PR to reach external stakeholders and customers which communicates to actively be searching for solutions. The innovated diagnostic tool is easy to integrate to present workflow and the MVP should collect insights that build a perfect product market fit. Reduction of end user risks is a strong benefit, as the fact that they are actively searching for the solutions. As completed the innovated technology should be visible on market and easy to find for end users searching for a solution.

Investors could be found globally. Investors with regulative- or market knowledge with personal relationships with important actors could bring grand benefits. It is of importance to understand and answer to regulations and patents globally.

5.4.2.2 SWOT analysis on competing solution 1

In short-term costs competing solution 1 might seem cheaper, but as presented by the cost benefit analysis the method will result in higher long-term costs and is not as efficient as the others. A SWOT analysis gives us more information.

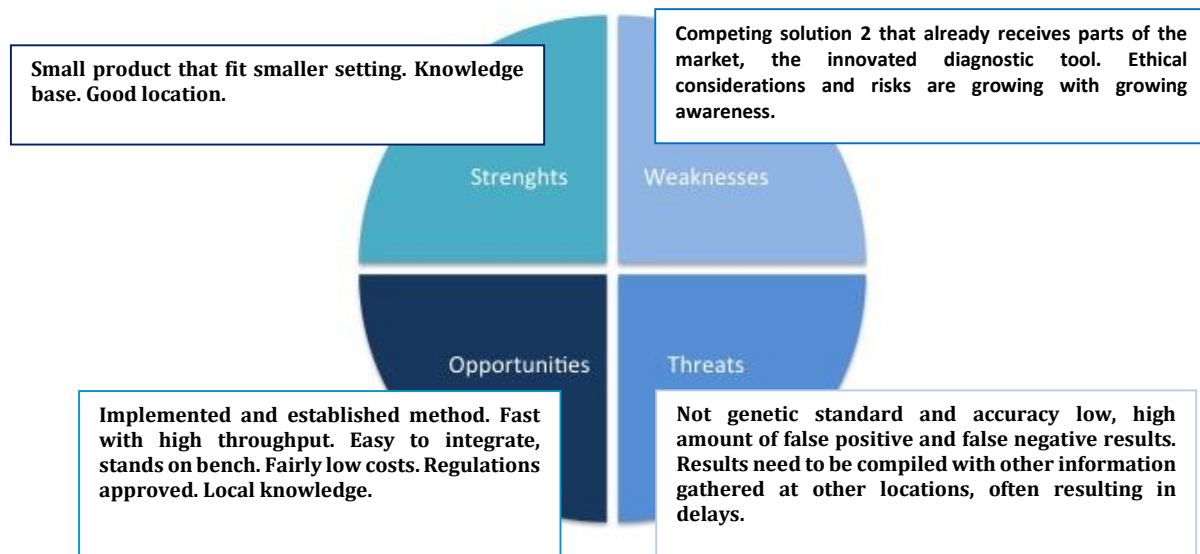


Figure 5. 9: Swot analysis on competing solution 1 built on gathered insights

The solutions biggest strengths is that it is implemented with established customers globally, with set customer flow. Systems are well known. Their diagnostic system runs fast and handles a high throughput. It is easy to integrate, stands on a bench, employees know how to use the device. Cost per user is fairly low, short-term. In Sweden governmental healthcare pool supports the test. Regulations and legislations approved and local knowledge built

The solution does not hold as good quality as competitors and accuracy is low, false positive and false negatives, results in unnecessary critical outcomes and end user risks. When process is done results need to be compiled with facts gathered at other locations resulting in an unnecessary step and possible and problematic time delays.

Their small product could be integrated in smaller settings where space is an issue, due to cost and ease, this is an opportunity. Their knowledge base could provide something innovative if used correctly. Good location, well-educated employees and a medium amount of investment capital if ideas emerge.

One threat is that the competing solution 2 and the innovation are providing better accuracy. Due to the risks that follow the testing poor results may be unaccepted. Competing solution 2 already receives part of the market, and does as the innovated technology provide better results.

Looking at competing solution 1, the main opportunity created is that the tool might still be superior for a small setting with insufficient space. The diagnostic tool is implemented and approved for use but as technology is improving the false results seem to be a crucial threat and losing market shares seem to be showing that the market position is weak.

5.4.2.3 SWOT analysis on competing solution 2

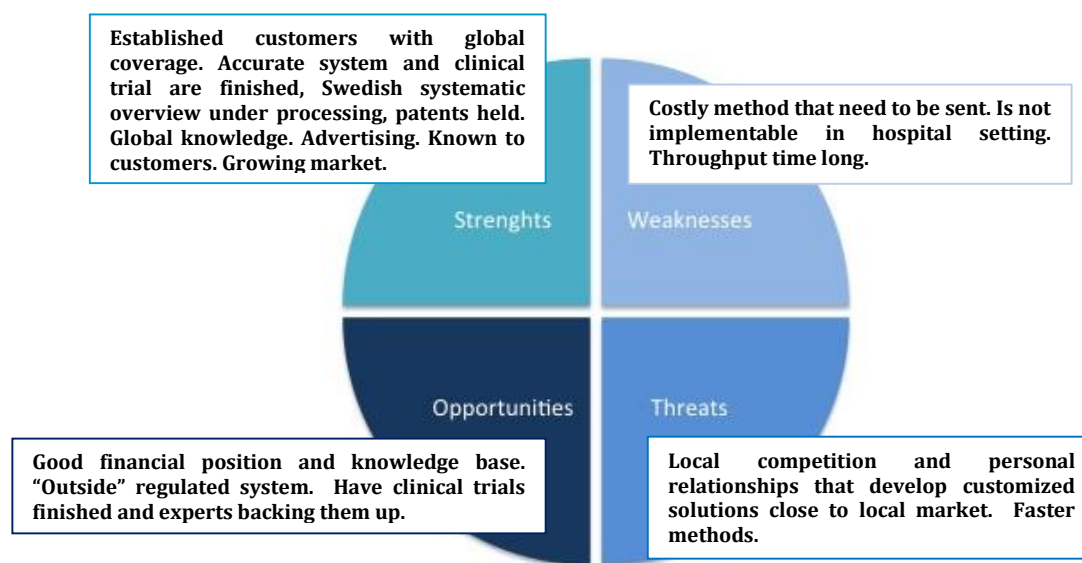


Figure 5.10: Swot analysis on competing solution 2 built on gathered insights

Competing solution 2 is not active on the Swedish market today and tests are sent to other countries when end users chose to perform test that are not supported by Swedish healthcare. A SWOT analysis is performed on competing solution 2:

Strengths are built on established customer, with set customers and service. Globally spread and has knowledge about regulations. The system is accurate. Clinical trials are finished and Swedish systematic overviews are under process. Some companies providing the tests are getting positioned on Swedish market, by sending test abroad. Patents held. Advertising and Internet coverage is growing as well as awareness among customers.

It is a costly method to implement that is carried out manually in many steps, the method could not be implemented in a hospital setting due to the complexity. The method is extremely expensive to perform these days, 700-1200 USD due to the complexity of test. Presented mainly on web which makes it hard to build personal relations and influence end users. Time from sample to answer is about two-three weeks. If tests fail, they are far away and the process will be critically prolonged. Even if the process where to be integrated on a Swedish market it would need more space and time than the innovative test at a higher cost, sample flow would also have to change.

Financial position and a good knowledge base could be considered an opportunity. The competing solution does not have to consider as many regulations, as acting outside the local market. Has knowledge and clinical trials to support solutions and grow awareness.

Local competition and customized solutions that are integrated in a setting where personal relationships might be built. Faster and easier methods could be a threat.

Looking at competing solution 2, it shows that their weakness is that tests probably cannot be implemented in a hospital setting, due to the complexity. Presently tests need to be sent abroad, resulting in long throughput times. Local competition with personal relationships and customized solutions are their main threats. Has strengths built through clinical trials, expert opinions and systematic overviews, strengths that also could be created by the start-up.

5.4.3 Risk analysis

One big threat to the competition is the FTO, freedom to operate, regulated by patents. Regulation, requirements, and other risks, weaknesses and threats are investigated to ensure that risks are managed and that risks with negative impact might be prevented. During the interviews customers was often asked if they saw any problems or risks but they rarely had direct answers. Problems and other considerations were further investigated through analyses as customers did often not have knowledge about regulations and laws.

The main risks identified and communicated are considered to be: patents regulated by freedom to operate (FTO), Venture capital investments, Regulatory risks, market adoption, end users risk and ethics. These are ranked by impact and probability in diagram 5.11 on following side.

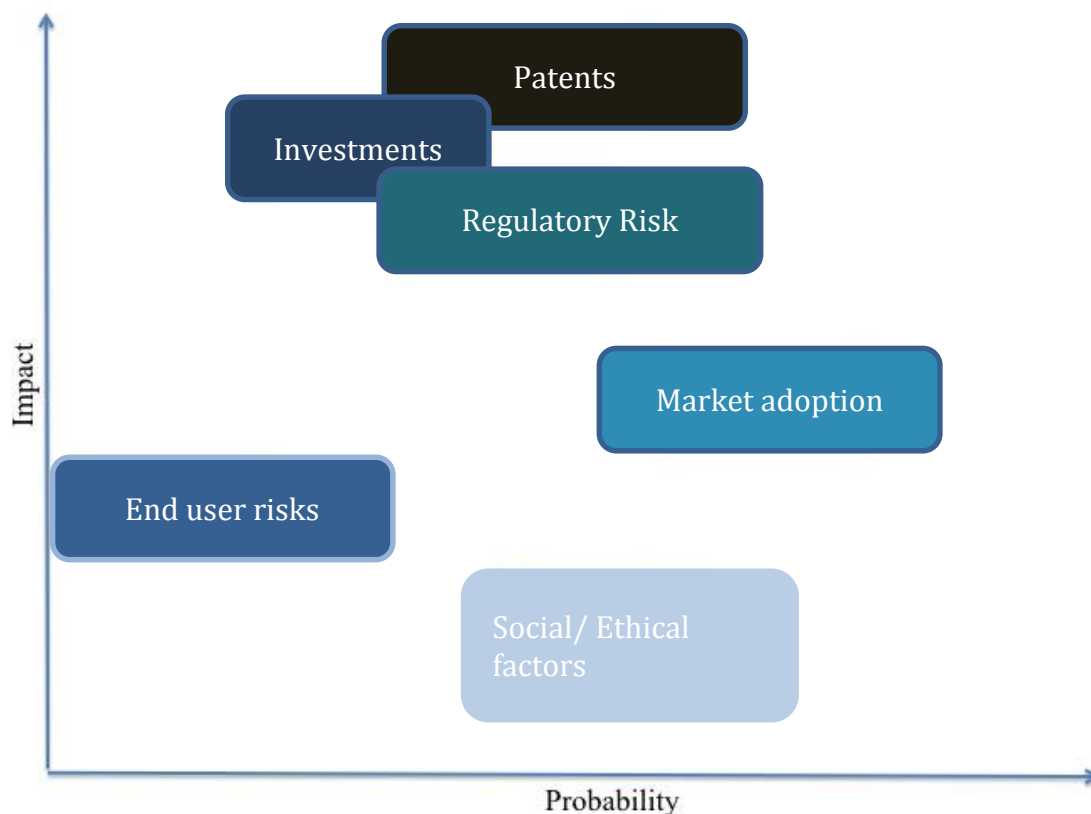


Diagram 5.11: Risk analysis visualizing impact and probability of risks

Litigation is costly and time consuming and should be avoided. If another actor reaches the market with patents on a similar innovation the market space could be blocked and FTO, freedom to operate, limited. The probability is considered medium but the impact would be really high. Time to market is pretty extended due to the purchase process. **The FTO should be evaluated thoroughly and good patents should be created as soon as possible, agile development when placed in customer setting to ensure that all patents are secured.**

Some investors are already actively investing but venture money is needed to keep R&D ongoing. Swedish market is limited and venture capital needs to be handled and collected. **Venture capital might need to be collected globally, investors with personal relationships or regulative knowledge should be preferred.**

Often customers interviewed did not have knowledge about regulatory risks and requirements. Swedish municipalities have local regulations and local differences might occur, making some settings better than others. The local setting for the biggest actor has less patient regulations than the second biggest actors as example, and local regulations should be investigated. Other risks might be built on local environmental regulations or facility regulations and waste handling. **Global regulations, local regulations and facility regulations needs to be met and CE markings need to be explored and met.**

A product market fit, market adoption, should be built trough understanding customer requirements, costs and benefit balance should be clearly communicated to customer. Offers should be built by promoting a product with low complexity, high trialability and observability

building incentives for adoption. This could be done by as soon as possible ensuring that a good MVP is placed in a customer setting.

Expert opinions will be needed, experts within the fields have recently done a review on competitors and these and experts might be interested in the innovated technology. Overviews and systematic reviews might be needed to get markets interests. Clinical studies might be good to strengthen the position and brand identity. The marketing approach should further be investigated and incitements on macro and micro level are suggested. **Present overviews, reviews, studies and cost benefit analyses preferably with experts. Ensure that the MVP is completed and trialability provided. Verify stakeholder requirements and build stakeholder incitements to promote solution.**

End user risks are still occurring, but the reduction from previous method is huge and previous method was implemented. This is indicating that the end user risk will not be considered a problem but probably should be reduced as much as possible.

Ensure a clear overview and investigations that support these numbers is the solution and show that risks are understood and considered seriously.

Customer ethics and social factor might be discussed, and an increasing international mix in Sweden and more religions might influence the perception on the ethics of genetic diagnostics. The method is used a broad and these markets could be used as references. As the solution is similar to competing solution 1 it could in many ways be discussed to already be accepted. **Radio and TV brings up issues like this by participating in discussions earned media might be gained.**

6. DISCUSSIONS

Overview of the methodology used to collect the findings.

To ensure market adoption a product market fit must take place. To understand the factors of adoption the methods presented below have been implemented.

The business model canvas was used as a basis of information, to build understanding about the factors of adoption. The canvas might also be used in-house to promote understanding about customer requirements throughout the team. The cycle of care was implemented to verify the most important stakeholders, many influencers and stakeholders might still be left out but the most important once were interviewed, with open ended questions. The use of the affinity diagram ensured that conclusions implemented in the canvas were converging. Collecting all insights would risk a complicated solution, instead of a MVP.

To really understand the conclusions the knowledge of the disease was found crucial. Understanding the disease made it possible to compare the solution to existing solutions and better understand the competing factors. The cost benefit analysis was built on this knowledge and explored benefits, probabilities and costs to the competition. When gathering these facts it was important to triangulate the information as a lot of information was written by competitors or stakeholder. The cost benefit analysis answers many critical questions, work as a tool to facilitate understanding about benefits and could also be used to set the price. The visualization was improved by the additional decision tree.

The mini HTA was found to be a useful template when exploring the buy-in process as well as factors that would influence adoption. If used wisely the mini HTA could be used as a framework to promote these factors of adoption and verifying the results from the analysis.

It is important to cross the chasm, ensure an overall adoption of the innovation. Gathered result shows a trend among the majority customers and many factors tend to be reoccurring among the price and risk sensitive customers, seen as the majority. Observation was useful to further understand a workflow fit and daily challenges among the users. Market analysis further explored competition on the market and the strategy canvas visualized these insights.

As a case study is done, it is important to further investigate these conclusions by applying the methods to a larger set of innovations entering the market. The need to further understand these factors should be increasing with the growing market. Patents, risks and regulations is also important to investigate further.

7. CONCLUSIONS

Conclusion about factors that can increase the probability of successful adoption, future research suggestions are proposed.

The mini HTA was identified as a basis for buy-in decision, adoption. The mini HTA hold important knowledge about factors that matter to customers; Accuracy, benefits, workflow fit and economy. Mainly the mini HTA was implemented at university hospitals but interviews with customers that had not implemented the mini HTA still verified that the adoption procedure was similar and the same factors were considered as important. Many of these factors are also mentioned during the stakeholder interviews. Stakeholders value is built on; Economy, Service and Quality, factors that converges with the mini HTA.

When stakeholders talk about economy they are referring to the cost they pay to get the benefits. Benefits are mainly brought by reduced end user risks as well as accuracy of the test. A high positive predictive value, low number of false results, is important. Economical safety is communicated to be more important than cost within healthcare and all actors agree that they want clear number presented through a reagent rental agreement, were the instrument is placed in the setting and each tests comes with a cost, to keep costs visual and easy to predict. With a reagent rental agreement it should be in the innovators interest to promote the solution to end users, this should be done by creating good relationships with the stakeholders found within the healthcare setting, educating them about risks and benefits and teaching them how to communicate the solution to end users. Incentives for the healthcare setting to promote the innovation could be used to grow end user adaption. The name of the innovated diagnostics might be of importance, as promoting the idea through internet and media.

Service, mentioned by all users, is expected twice a year, errors are not permitted more than twice a year. Possible problems should be solved within two days from failure.

Quality is once again about the benefits, but also about technological quality and work flow fit. To build benefits it is important to understand other actors on the specific market and weight the factors that build superiority, something that could be done through the cost benefit analysis.

Some factors are mentioned as important to ensure high quality and a workflow fit; A good balance between manual and automatic, where the risks that comes with the human factor is reduced. Human errors are reduced by reducing critical steps, integrating a barcode reader and minimizing pipetting. Steps as manually inserting samples or centrifugation could be performed manually, as risks are low and these steps are convenient to perform.

Overcapacity must be ensured, depending on the nature of the test, and usually 30-100% overcapacity is needed, critical tests need higher overcapacity.

Workflow fit should be created by education, employees should preferably be able to learn their tasks fast and without risks.

Regulations, CE-markings and other critical aspects should have been considered, local regulations are understood. For the company it is also important to understand the freedom to operate and secure patents to secure a market space.

When these factors are considered and the innovation is ready to penetrate the market, a minimum viable product should be put in a customer setting as soon as possible to further improve the product-market fit. One should probably expect a lifelong communication with customers as providing a reagent rental agreement, built on this communication and collected insights continuous innovations might follow.

For further research, as this case study is performed on a globally limited market it would be interesting to further explore these factors more globally, and to understand local trends and regulations better. Brand identity is something that also could be interesting to investigate further, as when creating a brand identity by co-operating with experts and market-professionals. Investors in the business could be seen as a burden, setting demands, as well as a resource providing knowledge and contacts it would be interesting to further investigate how to make use of investors in the best way possible.

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Appendix II Stakeholder comments

Sentences collected from stakeholders, when interviewing about diagnostic in general. Blue marked statements are collected after an NDA and the solution has been shown

Factors identified	Stakeholder statements
Economy (100%)	<ul style="list-style-type: none"> - It is about money, it can't cost more really - Budget is limited and price is the main burden - Most challenging is the cost effectiveness - It is about how expensive it is - If the number of false positives and risks are reduced maybe we could pay more than we are doing today - Costs should always be equal or less than previous solution - Calculate and estimate the benefits as we need clear figures - It is depending on how much it costs - Price is the main burden - The mini HTA is a base for buy-in and shows economy and benefits - Private persons might pay in person if not too expensive - this is similar to previous methods and better, I see no reason that government would not support this.
Cost	<ul style="list-style-type: none"> - RR is nice, we pay per test - 2-3 years RR is usual - For a new instrument RR is safer - Do not want to lease product, stated by most - I personally prefer a fixed price per person - The mini HTA is important for buy-in
Service (100%)	<ul style="list-style-type: none"> - Service is provided and this fast - Within 2 days service should have fixed the problems - They need to work to keep the flow mowing. - Error ok once a year 50% mentions, all agree - Service contract - Preventive service twice a year - Service ok twice a year - Quality, 2 days down per year - Service expected day after
Quality (80%)	<ul style="list-style-type: none"> - Good when one person run instrument from start to stop, no loss of information when switching operator - Quality is when one person starts and finish tests - Quality is the issue - It is not about money, it is about quality and safety for patient - Important with educated employees for quality - Early tests and results are better, it is quality - I do not really like to work with risk score - Good position for us to be early in the market place with this test - The technique provides us a good patient benefit - You can't have a 100% test, this is a really good degree of accuracy - The provided sensitivity brings quality - Better results show that we as hospital/department are going forward - It patient are late today they can't do the test - Do not want to call one person a day to tell them that their test failed, that is not quality - They had to do manual phone calls to follow up, this was a problem - Quality is a test that does not need to be approved by doctors - Quality is the hero of medical devices
Labeling (80%)	<ul style="list-style-type: none"> - Is required, barcode - Labeling and traceability - Barcode needed - Barcode reader is needed - Barcode is needed but employees normally spin samples to position to fit the reader
Manual Automatic (80%)	<ul style="list-style-type: none"> - Manual moments are a source of error 75% - Module systems more easy to use - Automatic pipetting not disliked - Manual, random could be good as random is more expensive - Big batches makes it hard to catch up - Manual moment is a risk - Manual pipetting avoided - Manual pipetting done (small quantities) - Eliminate manual steps when barcode is changed - Manual steps are a source of error - Manual tasks is a source of error

<p>Hands on</p> <p>Sample logistics</p> <p>Overcapacity</p> <p>Throughput time</p> <p>Nigh runs</p>	<ul style="list-style-type: none"> - More automatic steps, less manual steps are never disliked 50% - Manual integration of data is a risk for failure - Prefer batch before continuous processing - Spend time to automatize, avoid manual labor - Prefer automated workflows - To automatic machines takes freedom away from the process and might sometimes be complex. - Manual pipetting is removed - Manual pipetting hurt people - Better a lot of work every second day than some everyday - This workflow is possible - Work hours 7.5 in average - Work hours about 8 hours per day - Good if able to plan the hands on moment freely - Durable reagents makes hands on more free - Doesn't matter if hands-on time is free or not - We already people that could work in this flow - Filling reagents when machine is working - Extra centrifugation is not a problem, x 4 - Workers are hard to find - The cost of workers is small and it is about diagnostics not workers - Usually employees has set tasks at set hours - There are employees around, around the clock working with emergency diagnostics - When asking for extra samples, end users get worried - Logistic can't have double samples, rather call - Glass samples are ok - Take as many samples as you please if they are grown-ups - 30 % overcapacity is needed but we want 100% - As we today run a machine with almost no overcapacity we work weekends as well - It is nice being able to run smaller batches - Secure overcapacity, 100% is good to ensure that a run might be rerun - 2 machines is often a cost issue, sometimes got two to secure overcapacity - Result within 2 weeks would be good enough today, screening - Answer is within one week - Throughput 4 days after arrival - Thursday to Tuesday sounds really good - Result needed depending on illness - We calculate 80% within 3 days - Turnaround time 3 days not a problem - They always ask us, when is the test ready - Turnaround time 2 days not a problem - 3 days turnaround time is not a problem - Friday we got least samples - Good instruments run night - Nights not a problem but weekends are - Night runs is not a problem
<p>Understanding the flow (40%)</p>	<ul style="list-style-type: none"> - Customer flow is important, we haven't got a huge amount of patients needing this but still we got a flow - More end users could benefit from tests - What dimension should we do this in, should we receive samples from others to get volume or how to make use of it if implemented - It is challenging to get this volume - We could include it as an extra service and patients could pay if not government - If we might collect samples to fill the machine it might get less expensive - Our volume is too high, we should at least start with two machines. - Our volumes are too small, would we pay per batch or sample?
<p>Environment</p>	<ul style="list-style-type: none"> - Environment important, substances in smaller quantities. - Facilities has environmental regulations
<p>Extra</p>	<ul style="list-style-type: none"> - In many other countries there are regulations about laboratory centralizations - The central reimbursement around 40USD per test - Could machines and tools included be used for other purposes - Likes machines on bench - A rack in centrifuge would be nice - Space is an issue

	<ul style="list-style-type: none"> - Work with clinics to make product perfect - Get recommenders to consider the product perfect
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Unsolved problems or contradicting sentences	<p>Challenging to get volume, smaller setting. Filling machine, cost savings as employment costs.</p> <p>We would need two machines</p> <p>Weekend runs is a problem</p> <p>Risk scores are disliked</p> <p>Quality occurs when same person follows the test</p> <p>It is a problem to call up end-users when test does not provide answers</p>
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Appendix II *Mini HTA*

The mini health technology assessment developed on questions created by the economic buyer was found to hold important knowledge to understand factors important for customer adoption

1. Who is the mover (administration / business or equivalent / person)?
2. Briefly describe the current methodology. Which patient volumes may be relevant?

Method

3. Is there a systematic review of the literature in the field? Are there results of previously conducted Mini-HTA for this method?
4. What are the differences in outcomes in terms of diagnosis, treatment, rehabilitation or prevention compared to the current method? How big is the difference deemed to be?
5. Are there any known or possible risks, side effects or other unwanted effects created by the method? Available studies / monitoring of sufficient scope and duration for this to be answered satisfactorily in the current situation?
6. What recommendations / advice on the methodology are provided by national authorities or other national / international organizations?

Patient

7. Is the method expected to affect patients regarding quality of life, social situation or work situation, in addition to the above health effects?
8. Does the introduction of the method require any ethical considerations?

Organization

9. What effect will the possible introduction of the method have in terms of staff? Is there a need special information campaigns or training? Impact on working environment?
10. Can the method be introduced in the existing premises?
11. Might the introduction of the method have implications for other sectors or units within the administration, county council or cooperative council within or outside the region? Describe the consequences.
12. When can the method be introduced?

Economy

13. What investments are required for the new method (equipment, any rebuilding, and training)? Does it exist funding / budget plans for the investment?

14. What are the expected additional annual operating costs?

- a. Depreciation / internal interest rates
- b. Personnel costs
- c. Service
- d. Other additional operating costs

15. What revenue methods might be provided? Specify the particular national and regional income. Also calculate net income on county level.

16. Describe the economic impact under question 11

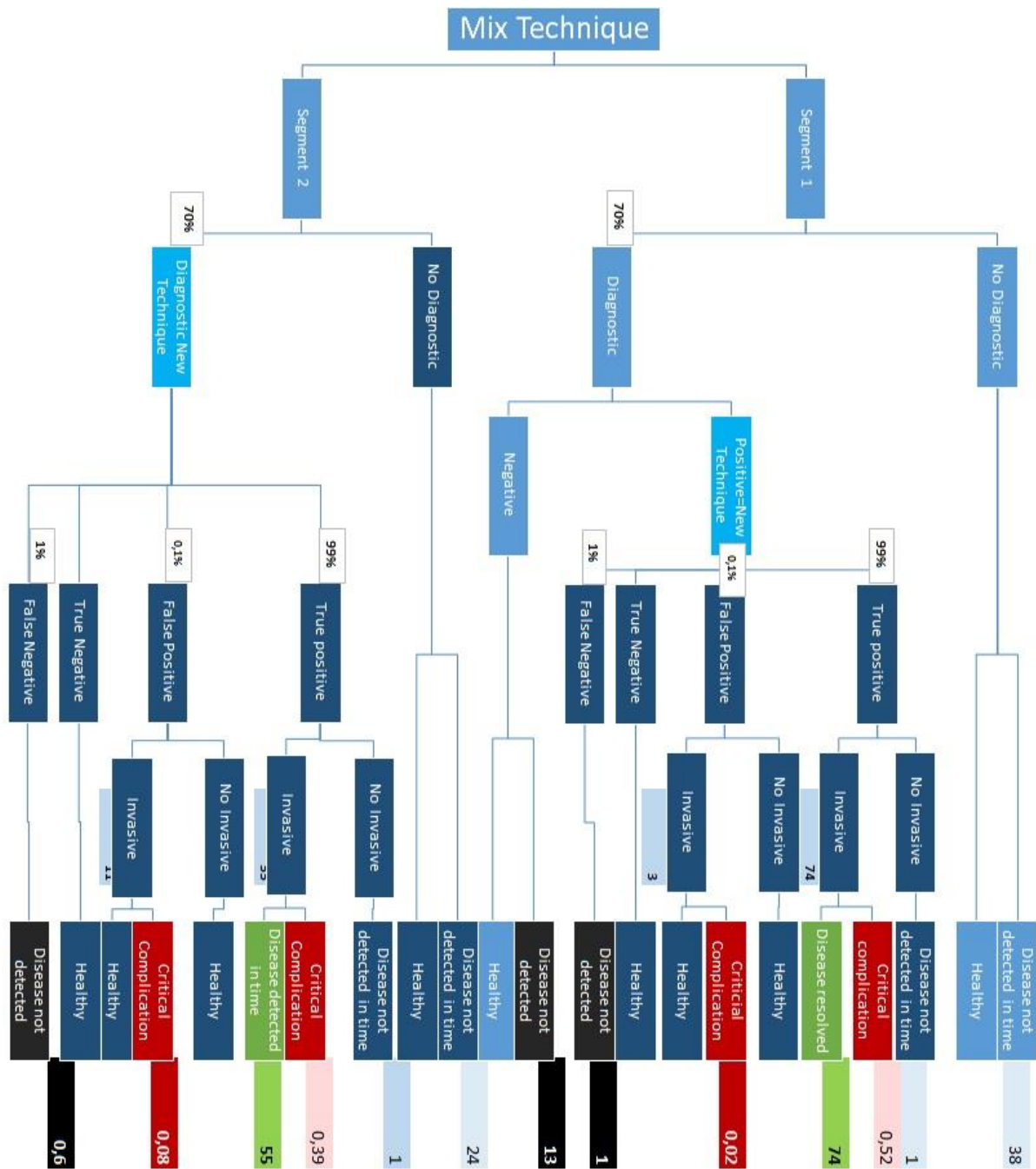
Follow-up

17. If the outcome of the Mini-HTA is that the method should be implemented, how will the results be monitored and reported? Timing? Responsible?

Summary assessment and decision

Appendix III Tree Diagram Comparison- Mix

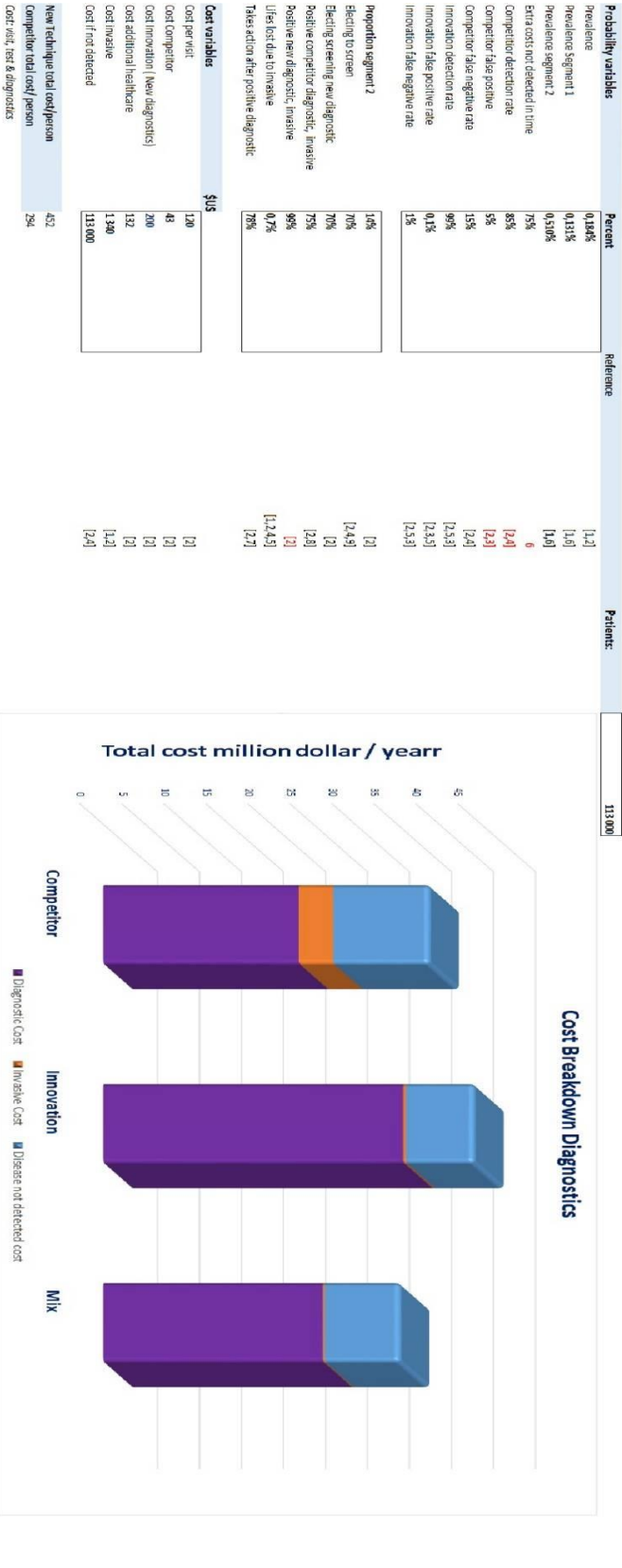
Tree diagram built on 100 000 users and was used in the specific case to further visualize benefits to stakeholders. The procedure is mapped based on prevalence and probabilities total outcomes, positive and negative, are visualized.



Appendix IV *Cost benefit analysis*

The cost benefit analysis for the specific case to further visualize benefits to stakeholders and used as a template for pricing.

Yearly cost breakdown



RESULT QUANTITIES		Positive Diagnostic	Positive Competitor Diagnostic	Invasive tests	Disease detected	Created harm/loss	Disease found/created harm	Percent detected	Positive predicted value	Invasive procedures reduced
Competitor	4 073			3 659	93	21	4	45%	26	93%
Innovation	223			221	143	1	261	69%	64%	93%
Mix	145	3 477		144	130	0	1292	62%	89%	95%

RESULT COST in million \$K		Diagnostic Cost	Invasive Cost	Disease not detected cost	Total	Total/customer	Total cost/ disease detected
Competitor		23		4	11	39	451
Innovation		36		0	8	44	559
Mix		26		0	9	35	447
Break even:	\$US	133					418 094

Income only Innovation, excl costs staff / reagents
Income if Mix

15 820 000
2 925 513

Appendix V Stakeholder Pain, Gain & Jobs

To better understand the stakeholders and also investigate possible influencers in the specific case this table was developed to further understand the complex stakeholder situation for the specific diagnostic tool.

Stakeholder	Primary Gain	Primary Pains	Job to be done	Influenced by
End User: Patient	Accuracy of test and reduced invasive. Fast diagnostics.	False negatives, False positives, Complication due to invasive testing. Information	Need knowledge	Recommender that will recommend diagnostics if adapted by decision maker. Recommender/Influencer as nurses, healthcare, internet.
Economic Buyer:	Total savings and better reputation	Competition, healthcare consolidation and unnecessary costs	Good healthcare to end user	Decision maker
Decision Maker: Clinical Manger	Increased income and patient benefits.	Overall costs, expenses, answer time, competition	Running department and providing best end user solutions	Recommenders, influencers work layout
Recommender: Healthcare setting	Financially advantageous and time saving	Patient communication takes a lot of time, as false positives, transfer and include a lot of data	Communicate diagnostics when needed and drawing blood	Clinical trials Education
Influencer: Clinic Manger	Expansion, lifesaving technology for many patients	costs		Government
System operator	One person needed for running tasks	Manual moments and risks, hard tasks, integrating results	Get test processed	
Doctor	Ensured quality of diagnostic	Opportunity costs, time consuming to look at all tests	Approve results	
Receptionist	Sample labeled and patient info in system	Manually labeling sample	Identify and sending sample	

Appendix VI *Methods applicable to improve the BMC*

Following methods was found to improve the BMC and could be integrated to when only looking at a specific part of the development of the business model.

Key Partners	Key Activities Risk analysis	Value Propositions Cost benefit analysis Compare to competitor Market analysis - Porters - SWOT - Decision tree Crossing the chasm	Customer Relationships Cycle of care	Customer Seaments Cycle of care Mini HTA
	Key Resources Risk analysis		Channels Clinical trials Systematic overviews Mini HTA Crossing the chasm Mini HTA	
Cost Structure Cost benefit analysis Crossing the chasm			Revenue Streams Cost benefit analysis Crossing the chasm Cost benefit analysis, Mini HTA	