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Opportunities for Biotechnology Startups Targeting the Healthcare Industry

A study on how a Swedish biotechnology startup can improve its chances to succeed

Master's Thesis in the Quality and Operations Management Program

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SUMMARY

The healthcare market is dominated by a few key players that are well established and tough for smaller companies to compete with. In addition, healthcare institutions follow strong regulatory processes and are often reluctant to take risks. This creates difficulties for a startup to become a supplier to healthcare institutions even if the product meets all regulatory requirements. Startups generally only have one valuable asset that is their entrepreneurial idea. This can lead to a success story, but it often ends in failure.

The purpose of this research was to examine how a startup can navigate in the healthcare industry in order improve its chances to succeed. To achieve this, the situation of the startup In Singulo Solutions was examined by interviewing their potential customers and other organization that can contribute to their success.

The empirical findings reveal that the competition from large suppliers, laws and regulations and the law of public procurement creates difficulties for startups in the healthcare industry. In order to improve its chances to succeed, a startup should focus on finding a customer need to target, find collaborators within the healthcare and focus on receiving support from innovation programs.

Keywords: biotechnology startups, success factors, healthcare market, innovation, startups as suppliers.

Acknowledgements

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Contents

1. Introduction

This chapter aims to introduce this research project. It presents the background of this study as well as the company in focus, the purpose, the research question and the delimitations.

1.1 Background

The healthcare market is dominated by a few key players that are well established and tough for smaller companies to compete with (Morel et al., 2016; Sanjivan & Onkar, 2020). In addition, the healthcare industry has been largely resistant to change and is still rooted in antiquated practices and systems. As a result, healthcare industry is far behind other industries in adopting innovative technologies and solutions (Chowdhury, 2012).

Chowhury (2012) argues that startups have been a driver of innovation in other industries. However, the healthcare industry is highly regulated and large investments are required to enter this industry. This creates difficulties for startups to enter and isolates the healthcare industry from other areas (Chowhury, 2012). By helping startups with proven technology survive, the advantages of their new technologies could drive the development of the healthcare industry.

Startup companies have difficulties to provide their technologies and become suppliers to healthcare institutions. According to Kazgan (2019), the reason is that healthcare institutions follow strong regulatory processes that create difficulties to adopt new technology. In addition, that healthcare institutions follow rigid procurement processes when they acquire new technologies (Kazgan, 2019). Ying Lim and Andersson (2016) also point out that healthcare providers are often reluctant to take risks, which results in difficulties for a startup to become a supplier even if the product meets all regulatory requirements.

According to Slávik (2019), startups are categorized as an entrepreneurial experiment and a very small business with the opportunity to develop and implement unusual and risky ideas. They can be recognized by rapid growth, experimentation with ideas, high return and the high risk of unforeseen failures. Startups generally only have one valuable asset that is their entrepreneurial idea. This can lead to a success story, but it often ends in failure. Slávik states that 8 out of 10 startups fail during the first 18 months mainly due to not understanding the needs of their customer segment or of profitability problems. Startups usually know who their customers are, but they have trouble reaching them (Slávik, 2019).

Previous research highlights how startups can increase their survival rate and how they can be successful. For example, Qian and Li (2003) describe the importance of maintaining an innovator position, finding a niche market, having market awareness and expanding internationally. This research focuses on how startups can become suppliers for healthcare institutions, especially biotechnology startups in Sweden. The aim of this research was to examine how a startup with proven technology can navigate in the healthcare industry to

improve its chances to succeed. To do so, the biotechnology startup In Singulo Solutions was chosen to be the basis of the research and interviews were held with potential customers and other organisations that could contribute to their success. Potential customers in this study are defined as healthcare institutions that purchase diagnostic instruments and can thus possibly be a customer to In Singulo Solutions in the future. In addition, two other biotechnology startups were interviewed to study practical examples and further increase the understanding of the topic.

1.2 In Singulo Solutions

In Singulo Solutions is a Swedish biotechnology company founded in 2017 after a five-year collaboration between Astra Zeneca and Chalmers University of Technology (In Singulo Solutions, 2020). In Singulo Solutions has developed a completely new technology with potential as a diagnostic method. This technology has several advantages compared to most globally used diagnostic technologies (In Singulo Solutions, 2020). The proprietary technology is a single molecular surface-sensitive microscopy-based method which enables a faster, more sensitive and reliable test. This could result in lower costs, higher precision and the possibility to target diseases that are not being targeted today (In Singulo Solutions, 2020).

In Singulo Solutions is at a stage where they want to use the potential of their proven technology to find a market and a customer base to target. This is a crucial stage of their development and something that many startups go through, which makes their case relevant for research purposes.

1.3 Purpose

The purpose of this research was to understand how a biotechnology startup with a proven technology can achieve success and become a supplier to healthcare institutions in Sweden. This was achieved by examining In Singulo Solutions and their context to explore what they can do moving forward in order to be successful. The issue was investigated mainly from the perspective of healthcare institutions in order to identify what the market demands from startups in order to engage with them. By helping startup companies be successful, their new technologies can contribute to the development of the healthcare industry. The following research question was developed for the study to answer:

How can a Swedish biotechnology startup improve its chances to succeed in providing healthcare institutions with their technology?

1.4 Delimitations

This study is based on the context of In Singulo Solutions. As a result, interviewees were selected with the criterion that they are potential customers of the company in the future or can contribute to the company's success. In addition, this study only focuses on potential customers in the public sector and on the Swedish market. Moreover, this study does not consider issues regarding internal organisation structures and financials of a startup but focuses on strategic decisions to establish a technology in the healthcare industry.

2. Method

This chapter aims to give an overview of the process and elaborates on the different stages of the study. The research design is presented as well as the methods used throughout the study.

2.1 Research Design

According to Schoonenboom & Johnson (2017), one must design a research strategy that fits or adheres to the research questions. Since this study focuses on words rather than numbers, a qualitative approach is suitable (Holme & Solvang, 1997). Further, the relation between theory and data of the study is of a structure where theory is an outcome of the findings, which according to Bell, Bryman, & Harley, (2019) is an inductive structure. As a result, a research strategy with a qualitative and inductive approach was chosen.

Bell et al. (2019) argues that a research design describes a framework for collecting and analysing data. Further, it is appropriate to create a general framework of the research which is illustrated in figure 1. By iteratively forming interviews based on previous research on similar topics, a better understanding of the healthcare industry is created.

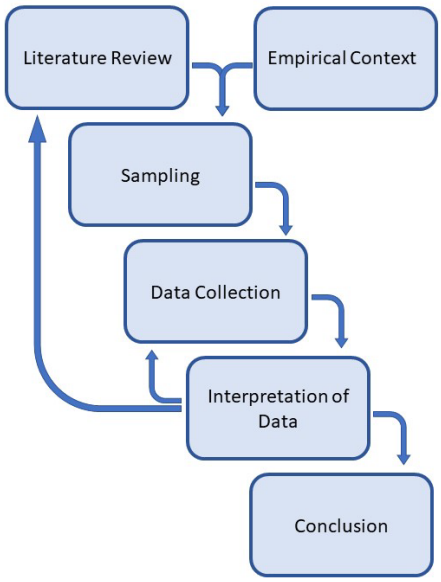

Figure 1: Research Design

Waller, Farquharson and Dempsey (2016) claim that reading existing literature will help to understand and clarify the topic, as well as create the research questions. In this study, the literature review was initially done to create an understanding of the topic and what should be studied empirically. According to Bell et al. (2019), narrative review intends to give the researcher an initial impression and better understanding of the topic area throughout the research process, which was the main focus of the literature review in this study.

The theoretical framework was then developed throughout the research process based on the findings. Further, the literature review guided the sampling and interview questionnaire for the study. The databases Google, Google scholar and Chalmers library was used in order find relevant literature. The key words used were *biotechnology, startups, diagnostic testing, success factors, effectuation, healthcare market, innovation, barriers, public procurement, regulations, startup supplier.*

In order to create an understanding for the context of the study, the empirical context was explored. By researching the industry, the environment of startups targeting the healthcare industry was explained. The research on the empirical context impacted the sampling and interview questions of the study. The databases Google, Google scholar and Chalmers library was used, as well as websites of different companies and organizations in order find relevant data. The key words used were *biotechnology, startups, diagnostic testing, pharma market, MedTech companies, healthcare.*

2.2 Data Collection

According to Bell et al. (2019), researchers often use a purposive sample in qualitative research to be able to select the interview participants. This is done to achieve a sample that is relevant to the study. In this study, the interviewees were selected in consultation with In Singulo Solutions using job title and type of company as the criteria for selection.

The five initial interviews were held with managers with different responsibilities at hospitals and healthcare centres. By targeting experienced interviewees with an overview of the market and operation, the interviews generated an understanding of the industry and for the collaboration between suppliers and customers. Those interviews also provided examples of how a startup can approach customers in this industry. From those interviews, it was discovered that the innovation programs play an important role in promoting innovation and startups in the healthcare industry.

The sampling for the following interviews was made based on the input and referrals from previous interviewees, following the snowball sampling method (Bell et al., 2019). Four of the later interviews were therefore conducted with people working for the innovation programs. The intent of those interviews was mainly to understand how they work with innovation and startups. In addition, what they can contribute to the development of an innovation in the healthcare industry. They also contributed by explaining the difficulties as well as the opportunities for startups trying to compete on the healthcare market.

During those interviews, new leads were discovered which led to interviewing a development manager at a dental clinic, another manager responsible for purchasing and orders at healthcare centres and employees at two different biotechnology companies. The two interviewees from the healthcare centre and the dental clinic were targeted to iteratively examine the process of selecting suppliers. The purpose of interviewing two other biotechnology company was to create a better understanding of the process and different routes that a

biotechnology startup can pursue. A list of the interviewees is presented in table 1.

Table 1: List of interviewees

Interviewee	Employer	Job Title
Interviewee A	Healthcare Centre	Responsible for purchasing and orders
Interviewee B	Hospital	Development Manager
Interviewee C	Hospital	Operations Manager
Interviewee D	Hospital	Operations Manager
Interviewee E	Hospital	Research Department Manager
Interviewee F	Innovation Organization	Responsible for collaboration with companies
Interviewee G	Innovation Organization	Responsible for contracts and financing
Interviewee H	Innovation Organization	Responsible for collaboration with companies
Interviewee I	Dental Clinic	Development Manager
Interviewee J	Healthcare Centre	Responsible for purchasing and orders
Interviewee K	Biotechnology Company	Director of R&D
Interviewee L	Innovation Organization	Innovation Manager
Interviewee M	Biotechnology Company	Finances and External Relations

Semi-structured interviews were conducted to gain information that contributed to answering the research question of this study. Semi-structured interviews give the researchers the freedom to identify and follow interesting side-tracks without deviating from the research question (Ericson, Törlind, & Wikberg Nilsson, 2016). Due to the covid-19 pandemic, all interviews were held online via video conference platforms such as Microsoft Teams and Skype. Furthermore, it is suitable to conduct a pilot study before the real interviews are held (Ericson et al., 2016). Therefore, a pilot study was conducted to ensure quality of the interview framework. The pilot study was performed by interviewing a peer to make sure that the interview questions were comprehensible and served the right purpose.

There were two researchers present at all interviews, with one leading the interview and the other was responsible for the recording. The interviews lasted for between 30 to 40 minutes after which both researchers analysed the answers. The interviews were recorded to make it possible to go back and analyse it again or check for something specific.

In a semi-structured interview, the interviewer asks questions to uncover information on a certain topic and the interviewer has generally prepared a set of questions to ask beforehand. The purpose of the semi-structured interview is to let it evolve into a conversation where the prepared questions act more like a tool for the interviewer to guide the interview to stay on topic (Longhurst, 2003). While the questions vary between different studies and different interviews, there are some types of questions that are commonly used in qualitative research interviews, as presented in table 2 (Qu and Dumay, 2011).

Table 2: Types of questions for semi-structured interviews (Qu and Dumay, 2011)

Type of Question	Purpose of Questions	Examples
Introducing Questions	A way to start the conversation, transition to the main interview.	"Can you tell me about [...]?"
Follow-up Questions	Dig deeper into what was just said.	"Can you explain how that process works more in detail?"
Probing Questions	Making the narratives more complete, get the entire picture.	"Could you elaborate more on that?" "How does that affect [..]?"
Specifying Questions	Get more precise when given a general statement.	"Could you specify in what aspect that was relevant to you?"
Direct Questions	To get specific answers.	"Have you ever worked with a startup as a supplier?"
Indirect Questions	To ask questions projectively	"What other opportunities would you say there are for startups?"
Structuring Questions	Finish the part of the interview and move on the the next.	"If we move on to the procurement process, [...]?
Silence	Give the interviewee a chance to associate and reflect.	
Interpreting Questions	Clarifying and interpreting the answer of the interviewee.	"Is it correct that you experience that [...]?"
Throw away Questions	Could have different purposes.	"Speaking of the innovation programs, [...]"

The interview questions used in this study followed the structure represented in table 2. By combining open questions to start the conversation with direct probing questions, the interviewees spoke freely about the subject but were guided in the right direction.

2.4 Data Analysis

A thematic data analysis was conducted to analyse the data collected from interviews. It is a method well suited to identify patterns or common themes between interview transcripts (Bell et al., (2019)). The purpose of the analysis was to identify themes and connections from interviews that contributed to answering the research question.

The data analysis was divided into different sessions based on the category of interviewee. Separating the analysis allowed for an iterative data collection process to be performed. Once the interviews with the hospitals and healthcare centres were finished, the data from those interviews were analysed in order to identify both findings and new areas to examine. After identifying new areas to examine, new interviewees were approached and interviewed to collect relevant data. This iterative method made it possible to follow the process from a functional technology to a medical instrument in the healthcare industry and to understand the different routes to take as a biotechnology startup.

2.5 Research Quality

According to Bell et al. (2019), researchers suggest two main criterions in qualitative research. These are trustworthiness and authenticity. Trustworthiness is divided into four parts, discussed below.

- The first part is credibility, and it concerns making sure that the research is conducted in accordance with good practice. In addition, that the result of the study is confirmed by the world studied to confirm that the researchers have understood the topic correctly (Bell et al., 2019). To ensure that this study has been conducted in good practice, the researchers have been in constant contact with the research supervisor for feedback and advice. Further, the researchers had weekly meeting with the company In Singulo Solutions to confirm that studied topic was interpreted correctly.

- Transferability concerns whether the findings of the conducted research are applicable in some other context or in the same context at another time (Bell et al., 2019). As this research concerns a specific company it may be difficult to generalize. However, in order to provide the reader as much understanding as possible of the conducted study, the researchers intended to clearly describe the context of the study throughout the report.

- Dependability concerns whether the research is conducted in a manner that is reliable and whether full records of research process are kept and accessible (Bell et al., 2019). To ensure this, all records of the research were documented and described in this report. In addition, this was carefully done in order for the reader to clearly understand the research process.

- The fourth part is conformability, which concerns whether the researchers acted in good faith and did not allow personal opinions affect the research (Bell et al., 2019). To be objective and not allow personal opinions to influence the research is difficult. However, the researchers kept this in mind throughout the entire research process in order to mitigate this issue. In addition, discussions were held continuously with the project supervisor who can be defined as a neutral part.

The criterion authenticity concerns the researcher's responsibility to present opinions in a fair way, to enable research participants to gain a better understanding of their situation and to engage them to change their circumstances (Bell et al., 2019). In this project, the conclusions of the study were shared with the participants to give them the opportunity to understand the key findings and the potential benefits.

2.6 Ethical Considerations

When conducting research, it is important to consider the ethical aspects to make sure that the research is done right and for the sake of the participants (Bell et. al, 2019). In a study like this one, with a lot of interaction both with In Singulo Solutions and with the interviewees, it is important to make sure that the research is conducted in a way that does not harm the participants in any way (Wallace & Sheldon, 2015). The interaction with different parties in this study has been done in a way that ensures that no one was insulted, and the interviews and other interactions have been kept short to avoid preventing participants from doing their job.

This study was conducted during the covid-19 pandemic, which made it very important to make sure that all interactions were done in a safe way for the health of the participants and to not spread the virus. Therefore, even though it would have helped to meet the participants face-to-face, all interviews and most meetings have been held online through different video conference platform. A large part of the participants of this study work within the healthcare system, which has made it even more important to not take up too much of their time during a pandemic. To not stand in the way of their work, the participants have been given the option to choose the time of the interviews.

Bell et. Al (2019) mentions four ethical criteria: harm to participants, lack of informed consent, invasion of privacy and deception. To make sure that this study was conducted in a correct and ethical way, the participants were well informed before the interviews on what was expected of them and what the interview was about before they agreed to it. The participants were also informed that they would remain anonymous to ensure their privacy.

3. Literature Review

The purpose of the literature review is to explore previous research on similar topics and to understand the key factors for success and challenges for startup companies in the healthcare Industry. This chapter presents theory on barriers and opportunities in the healthcare industry and success factors for startups.

3.1Succeeding as a Startup

3.1.1 Effectuation

According to Kitching and Rouse (2020), effectuation is an entrepreneurial logic which follows a process that is dynamic and interactive in order to create new objects. Sarasvathy (2001) describes that new ventures that function according to effectuation has several advantages and are more likely to succeed.

Effectuation is in literature compared to causation, which can be described as the opposite to effectuation and is an entrepreneurial logic which follow a process often learned in business schools (Sarasvathy, 2001). Causation, also called causal logic, takes an approach with clearly defined goals, a detailed strategy and clear description of milestones. The aim is to achieve the defined goals, such as the cheapest and fastest way to the market with highest potential return (Sarasvathy, 2001). Moreover, this logic takes outcomes as given and focuses on using selected means to create these outcomes. This presupposes markets that are given, and entrepreneurs search in the environment to choose the most appropriate way to achieve pre-selected goals (Kitching & Rouse, 2020).

Compared to casual logic, effectual logic takes specific means as given and elaborate on which outcomes entrepreneurs can create with them (Kitching & Rouse, 2020). According to Sarasvathy (2001), effectual logic does not focus on predefined goals but allow goals to emerge over time. Goals emerge by starting with a given set of means and by the imagination and ambitions of the founders and the people they interact with. Kitching and Rouse (2020) claim that all effectual entrepreneurs operate according to five different principles that are described and compared to causal reasoning in table 3.

Table 3: The five principles of effectual and causal reasoning

Decision-Making Principle	Effectual Decision-Makers	Causal Decision-Makers
Bird-in-the-hand	Use available resources and means to pursue aims that are unknown when creating the venture.	Use the resources that fit best to achieve the selected aim.
Affordable Loss	Only invest what you can afford to lose.	Project selection is based on the highest expected return.
Crazy Quilt	Find stakeholders who make precommitments to provide support and expand the resources available.	Analyze competitors in order to find the desired place on the given market.
Lemonade	Use unexpected turns to your advantage, see the opportunities that the changes open up for.	Look at unexpected turns as barriers to overcome in order to reach the given aim.
Pilot-in-the-plane	Create your future in collaboration with stakeholders.	Get ahead of development by predicting future changes and preparing for them beforehand.

Sarasvathy (2001) argues that all entrepreneurs begin with three different means: Who they are, What they know and Whom they know. By using these means, such as taste, education and professional network, entrepreneurs start to imagine and elaborate on what they can create with these means and move into action without planning. In causal reasoning, careful planning is the basis and the work then takes place towards a predefined goal (Sarasvathy, 2001). Moreover, effectual entrepreneurs only invest in what they can afford to lose, build a network of self-selected stakeholders, use unexpected turns as their advantages and create the future in collaboration with stakeholders (Sarasvathy, 2001). In order to describe the differences between the two logical reasonings, Sarasvathy (2001) argues that causal logic can be compared to a great general with the purpose to conquer two thirds of the world. Effectual logic can be compared to an explorer travelling to unknown waters.

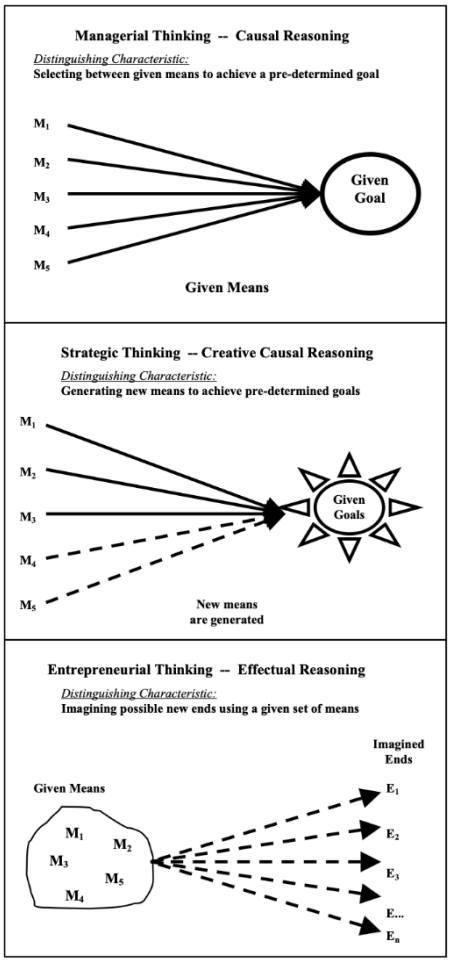

Figure 2. From *What makes entrepreneurs entrepreneurial? (page 3)* by Sarasvathy, 2001.

However, Sarasvathy (2001) states that it is very important to understand that an entrepreneur can use both causal and effectual reasoning depending on the given time and circumstances. Effectual reasoning is more preferred in the early stages of a new venture. Figure 2 visually illustrate the different approaches used in effectual and causal logic (Sarasvath, 2001).

According to Kitching and Rouse (2020), effectual logic provides several benefits to entrepreneurs. Those who use this logic remain flexible, take advantage of environmental changes when they occur, and learn continuously while operating (Kitching & Rouse, 2020). Moreover, Wu, Liu and Su (2019) argues that effectuation can improve the speed of new product development because an effectuation-driven decision logic benefits from the advantages of mutual information with stakeholders and low-cost experiments. In addition, the authors claim that intensified competition may increase the positive effects of effectuation and contribute to increased speed of new product development. This is because entrepreneurs are encouraged to further improve problem-solving speed, provide fast resource solutions and refine process knowledge (Wu, Liu & Su, 2019).

Previous research also highlights negative aspects of effectual logic. Wu, Liu and Su (2019) argue that effectuation's focus on existing resources and no clear objectives, strategy or financial budget may have negative effect innovation efficiency. Excessive focus effectuation may result in more time spent gaining

useful knowledge (Wu, Liu & Su, 2019). In addition, Sarasvathy (2001) argues that effectuation is very dependent on obligations with existing customers and suppliers, which may limit creativity. Moreover, Wu, Liu and Su (2019) describe that excessive focus on effectuation can contribute negatively to a new product's quality. Excessive effectuation often means excessive utilization of obligations in an existing network or focus on short-term plans with too many unsuccessful tests, which negatively affects the quality of new products. However, the authors argue that low to intermediate levels of effectual logic may instead increase the quality of a new product (Wu, Liu & Su, 2019).

3.1.2 Success Factors for Startup Companies

According to Laage-Hellman, Landqvist and Lind (2018), collaboration with customers in product development has several advantages such as providing detailed information about customer needs and problems. These relationships are especially important for startups since they usually have scarce resources. Collaborations with customers are needed to gain access to additional resources that can be used in the company's commercialization of its inventions.

Lazarow (2020) states that there are three different ways startups can increase their chances of succeeding. The first way is a growth strategy where the company tries to take as large a market shares as possible in the initial phase in order to gain a market-leading position. This means that the company is dependent on large investments by external parties due to the large costs. The second way is by having an entrepreneurial idea that is solving a real problem. This leads to a natural demand from the addressed customers. However, often companies with a truly new offering have a long growth path that may include educating the customers. The third way to succeed is to invest in global talent. This means that a startup should employ professionals from all over the world and not just in the local area. This increases the likelihood of recruiting highly skilled people who can contribute to the company's success and growth.

Another success factor for startups, according to Wouters, Anderson & Kirchberger (2018), is to have a customer value proposition that communicates how the offering of the startup is superior to other options. Working with a startup will always bring a certain amount of risk in comparison to an established firm. The value proposition needs to offer a solution to a problem that the customer has or help the customer achieve a certain goal. This makes it very important to create a specific value proposition for each customer and to intrigue enough to convince the customer that working with a startup is the best way forward.

According to the study conducted by Skawińska & Zalewski (2020), there are five factors that affect the success of startup companies in the European Union. The five factors presented are access to human capital, quality and outcomes of institutions and business relations, focus on market situation, business experience and development potential. By analysing data on startup companies from 13 countries, they conclude that these five factors contribute most to competitive potential.

Another view is presented by the founder of a successful pharma startup, Cunningham (2020), who provides three tips to be successful as a startup in the pharma industry. The three tips presented are to have a clear focus, remain agile, and find partners who can support their work. Cunningham also claims that the product or technology is rarely the problem for startups on the pharma market, yet 90% of them fail to get funding. These three tips are meant to support startup companies to succeed in future founding rounds.

3.1.3 Corporate Accelerators

According to Kohler (2016), corporate accelerators can act as an interface between startups and corporations. A corporate accelerator can be described as a program with limited duration that supports a number of startups during the new venture process with education, mentoring and specific resources. The purpose of these programs is to bridge the gap between startups and larger corporations and there are several advantages for both parties with these programs. Kohler argues that the complementary nature of startups and corporations results in corporations receiving support in how to acquire new innovation and startups receiving help to improve executions (Kohler, 2016). Startups can also receive support to improve their products, operations and strategy. Moreover, the authors argue that corporate accelerators can help startups receive sales acceleration, knowledge, skill development, business model development, access to financing and development of strategic partnerships (Gutmann, Kanbach & Seltman, 2019).

Successful programs can result in different future collaborations. For example, the corporation can support a startups pilot project, corporation can become the startups customer, corporation can become a distribution partner, corporation can invest in the startup or the corporation may acquire the startup (Kohler, 2016). In table 4, different corporate accelerator programs and engagement methods are listed and distinguished.

Table 4: Corporate-startup engagement spectrum (Kohler, 2016)

Engagement Method	Description	Distinguishing Characteristics of Corporate Accelerators
Corporate Hackathons	Diverse teams collaborate to solve innovation challenges of a company.	Create longer lasting engagements with participants.
Business Incubators	Flexible workspace that adds value by supporting with legal or marketing matters.	Shorter engagement with startups with very limited equity stake. Cyclical, competitive selection.
Corporate Incubation	Guides corporate non-core innovation to the market.	Reaching out to external innovators when internal efforts do not reach the capability of corporate accelerators.
Corporate Venturing	Gives access to capabilities and insights into markets as well as allows for corporations to participate in innovation.	Instead of focusing on financial investments in external companies, innovation and business development are prioritized.
Mergers & Acquisitions	A fast way to acquire capabilities or technology to solve business problems when entering a new market.	In order to select targets for M&A, a larger number of startups are allowed for selection.

3.1.4 Startups as Suppliers

According to Kurpjuweit & Wagner (2020), startup suppliers can be defined as young and innovative firm that can bring major advantages to buying firms through new sourcing or co-developing new technologies, products or services. Startups are excellent problem solvers, recognized by their ability to make quick decisions and are a source of innovation and of rapid technological change. Therefore, it can be a great advantage to have a startup as a supplier compared to a more established firm. However, startups are struggling with legitimacy and are less likely to be selected compared to more established firms.

Startups face a lot of challenges, such as profitability, scarce resources, lack of established processes and their high failure rate. That makes it difficult for buying firms to evaluate the true value of choosing a startup as a supplier (Reuber & Fischer, 2005). In addition, buying firms usually have predefined criteria and processes when evaluating potential suppliers, such as proven historical track record which often is not suitable when evaluating a young firm. Startups face the challenge of not being identified by their potential customers as many buying firms have a ready-made selection of suppliers to choose from (Kurpjuweit & Wagner, 2020).

Kurpjuweit and Wagner (2020) highlight the four following criteria's that describe how suitable a startup is as a supplier.

- The first criterion, resource and capability fit, is categorized of its management, processes, know-how and financials. Startups with higher quality in these areas are expected to have a higher survival rate that makes them more suitable as a supplier. In addition, the startup's resources and capabilities must to some degree be aligned with the buying firm.

- The second criterion, strategic fit, is described as the fit between a startup's technology and a buying firm's innovation strategy. Buying firms have different strategies for acquiring new technology and some companies are not even interested in having startups as suppliers but want to acquire them instead.

- The third criterion, technological fit, refers to how unique and suitable the technology is for the buying firm. In addition to the fact that technology must suit the company's requirements, the technology often must be much better and more unique than other suppliers to be considered.

- The last criterion is described as market fit, which refers to the importance of convincing the buying firm of the need and demand of the specific

technology, as there are often in-house barriers in choosing startups as suppliers (Kurpjuweit and Wagner, 2020).

3.2 Barriers in the Healthcare Industry

3.2.1 Barriers Between Startups and Healthcare Institutions

According to Kazgan (2019), healthcare institutions follow strong regulatory processes that make it difficult to adopt novel technology. Entrepreneurs need to convince a number of stakeholders that their solution provides value for patient care and the medical experience. In addition, healthcare institutions follow painful procurement processes when they acquire new solutions. They usually require the solution to provide:

- Better quality of life to the patient
- Time savings to clinicians
- Business value and ROI fits into care model
- Easy implementation with almost no cost to entity
- Scalability
- Integration ability into different applications and reporting systems
- Ability to measure outcomes.

The result of this is that healthcare institutions are slow adaptors of novel technology and startups have difficulties to provide their solutions (Kazgan, 2019). Ying Lim and Andersson (2016) argues that healthcare providers are often reluctant to take risks, which results in difficulties for a startup to become a supplier even if the product meets all regulatory requirements. In addition, Ying Lim and Anderson (2016) claim that healthcare institutions operate under high-tech and institutionalized environmental conditions that make change difficult. Threats to norms and methods created by organizational structures, culture, clinical practice and leadership can often create resistance to new digital technology. For this reason, the development of technology in the healthcare has often been slow as decision-makers get caught up in opposing institutional forces that promote but still inhibit change (Ying Lim & Anderson, 2016).

According to Chowdhury (2012), healthcare institutions are far behind other industries when it comes to adopting innovative technology and solutions. While other industries have experienced disruptive change in several areas, the healthcare sector has been largely resistant to change and is still rooted in antiquated practices and systems. The author describes that one driver of innovation in other industries has been startups that conduct rapid and integrative development of small but scalable projects. This means that small prototypes are rapidly built, tested, redefined and finally built up into full-scale products or services. However, the healthcare sector is highly regulated and large investments are required to enter this area, which creates difficulties to access users and isolates the healthcare sector from other areas. In addition, compared to other industries, developers of technology for the healthcare sector are further from the end-users. This results in a gap between the developer and the end user

that can lead to unmet needs (Chowdhury, 2012). Furthermore, Dhainaut, Blin and Herry (2019) argues that startups often lack knowledge about public structures, hospital environment and their constraints. First-time entrepreneurs often underestimate the legal, regulatory, and market complexity of their projects, which creates difficulties for startups (Dhainaut, Blin and Herry, 2019).

3.2.2 Regulations on the Manufacture of Medical Devices

According to Oriel (2019), new regulations on medical devices (MDR) and in-vitro diagnostics (IVDR) went into effect in May 2017. These regulations are far more comprehensive compared to previous regulations that medical device companies in the European Union (EU) operated under. The new regulations create new and stricter quality and transparency requirements for operators in the EU and for operators that import devices to the EU (Oriel, 2019).

The purpose of MDR (2017) and IVDR (2017) is to ensure that the market for medical devices and In-Vitro medical devices in the EU function smoothly and guarantees a high level of health protection for patients and users. In addition, the regulation considers small and medium-sized enterprises. This requires a high standard in the quality and safety of medical devices to ensure the set of safety requirements. The regulations contain requirements on the design, safety and performance characteristics of the devices that are developed in such a way as to prevent occupational injuries, including radiation protection. This means requirements for both the design of the product and the manufacturer (Medical Device Regulations, 2017; In-Vitro Diagnostics Regulations, 2017).

According to Epista Life Science (n.d.), the new regulation has changed the definition of In-Vitro Diagnostics (IVD). This will result in that far more IVD manufacturers will have to certify their device by a Notified Body, for e.g., CE-marking. The author estimates that 80% of all IVD devices need to be certified according to the new regulation. This can be compared to the previous IVD definition when only 20% of the devices on the market were certified (Epista Life Science, n.d.). In addition, Roche Diagnostics (n.d.), argues that IVDR result in that the requirements for performance evaluation, the equivalent of clinical evaluation for medical devices have been significantly tightened. This means that more data and unrelated organizations will be required to assist manufacturers work through sampling, control and certification.

Med-Tech Innovation News (n.d.) describe that the regulations will result in higher costs and longer timelines when developing new products. In addition, they will result in costly new clinical monitoring and evidence generation for certifying products. Another challenging result of the new regulations is the increased clinical testing requirements. The author describes that the new regulations require more complex clinical evidence studies for IVD devices compared to other medical devices and that devices already on the market must be reassessed. In addition, MDR and IVDR require increased emphasis on post-market surveillance, which will require significant additional resources (Med-Tech Innovation News, n.d.).

3.2.3 Accredited Organizations

According to Swedac (n.d.a), accreditation is a competency assessment carried out in accordance with European and international standards. Accreditation is an international system with common legalization within the European Union (EU) (Swedac, n.d.a). The purpose of accreditation is to be able to ensure that calibration, certification, control, verification and testing are done with high quality and good safety for life, health and the environment (Swedac, n.d.b).

Swedac, (n.d.b) describe that EU regulations require that each country must have a national accreditation body designated by its government. In Sweden, it is laboratories, certification and control bodies that assess whether goods and services meet the standard requirements of the legislation. In order to be able to trust that the assessments in Sweden are made in an independent and competent manner, Swedac issues accreditations and supervises them (Swedac, n.d.b).

According to Swedac (n.d.a), it is only organizations that performs conformity assessments that can be accredited. An entire hospital, for example, cannot be accredited, but the laboratory that analyses blood or urine samples can (Swedac, n.d.a). Accreditation is a way to ensure quality and competence and it has positive effects for authorities, purchasers, industry, manufacturers and consumers as it provides several benefits, such as greater security for customers, increased competitiveness and it minimizes the risk of errors (Swedac, n.d.b).

3.2.4 Regulations on Purchasing in the Healthcare Industry

With the purpose of creating an effective competitive environment and ensure that the public sector gets value for their money, the law of public procurement decides how suppliers and customers meet. By having clear regulations on the purchasing made by public actors, potential suppliers are allowed to compete on a fair basis (Edwardsson & Moius, 2009).

Before a public procurement can be made in the European Union, tender documentation must be created stating how the procurement will be done in terms of administrative regulations for that specific process. The tender documentation decides on the regulations and requirements that are specific for the procurement in question, but there are other regulations decided by law that applies to all cases (Molander, 2009).

Public procurements must be announced beforehand, informing potential suppliers about the tender documentation. The same information must be given to all parties interested in the procurement to make sure that they have the same prerequisites to win the deal. Secrecy must be maintained regarding the offers until the deadline for submitting an offer has passed. When all offers are received, everything from opening the offers to making a purchasing decision is done according to the tender documentation, under controlled circumstances and while documenting the process (Molander, 2009).

The complexity of the regulations and demands on the procurement process increases the level of competences and resources necessary to perform the purchase. Having complicated rules that are difficult to understand also leads to

more errors, which in turn means that there are a lot of appeals from suppliers that the procurement was not performed correctly. That process also takes a lot of time and resources, and could be avoided with simpler, more straightforward regulations (Edwardsson & Moius, 2009).

Eriksson (2015) describes that it can be difficult to define and prioritize quality in a public procurement. A common reason is that healthcare institutions find it difficult to define quality in a way that is straight forward and fair. This is not helped by the fact that the process of public procurement is perceived as complicated and rigid. Instead, it causes uncertainty and transfers focus from selecting the best offer to making sure that the laws are followed, and that the process is conducted correctly. Moving focus away from selecting the offer of the highest quality has a negative impact on the development and quality of healthcare. This defensive way of performing a public procurement, aiming at following regulations rather than focusing on what the best option for the operation has a negative impact on the development of new methods and tools. The negative effects are worse for smaller, innovative companies than for the bigger, more established ones. The established companies tend to be perceived as the safer option, and they generally have more legal competence which is helpful during procurements even though the regulations apply mostly to the procuring party (Edwardsson & Moius, 2009).

Intuitively, more offers and more competition should lead to better quality at a lower price. However, not having the resources to consider and test too many offers, the procuring party tends to design the tender documents in a way that excludes some offers. The excluded offers are generally the ones from smaller innovation companies, which in turn leads to a reduction in variety and innovation among offers. The complexity of the regulations leads to the procuring parties not having the resources to consider all offers, reducing innovation in the public sector (Uyarra & Flanagan, 2010).

3.2.5 Innovation in Public Procurement

While there are many factors making it difficult for smaller innovation companies to win procurements, there are measures to be made to promote innovation in public procurement. One important measure is to maintain a close collaboration and dialogue with potential suppliers. This is important throughout the procurement process, but most important for promoting innovation is the communication before the start of the procurement. Communicating with suppliers can keep the procuring party up to date with the new technology and inform them about innovations to implement in their operation. It can also provide information regarding the feasibility and economical aspects of new technology (Reige, 2016).

One of the main reasons that procuring parties within healthcare purchase established products and equipment is to mitigate risks. Purchasing new innovations comes with a risk, as that method or equipment might not be as proven practically. In countries like Great Britain, the Netherlands and USA, there are programs that can be utilized by procuring parties to minimize the risks of purchasing innovation. These programs apply a certain type of procurement with

open competition in several steps. The interested suppliers are tested in these steps to move forward in the process. All candidates that reach a certain quality level get funding to keep developing their solution (Lundvall & von Utfall Danielsson, 2014).

To get the public sector to procure more innovations is not necessarily the main purpose of these programs as a lot of the candidates keep developing their solutions in other ways. The programs are meant to handle the risks that come with procuring innovation by organization (Lundvall & von Utfall Danielsson, 2014).

Another way to promote innovation in public procurement is to adjust list of requirements, which includes requirements on functionality, the supplier and the way to reach the functionality. In order to promote innovation, focus should be on the requirements regarding functionality and with that allow for offers to come from new suppliers with new solutions (Reige, 2016).

A lack of knowledge regarding the needs of the operation is also hindering innovation in the public sector. In most procuring units in Sweden, the people performing the procurement are far from the users of the equipment or service. There is often a lack of feedback regarding what is working and what needs to be fixed or replaced, so the needs of the operation often do not reach the requirements list of the procurement. In USA, they are solving this issue by connecting researchers with both the public and private sector. That is done to map out the needs of the users and inform the procuring unit to make sure that it reaches the requirements list (Lundvall & von Utfall Danielsson, 2014). Lundvall & von Utfall Danielsson (2014) claim that the way that public procurements are performed today hinders innovation. With the formulation of the law, how the procuring units prioritize and how government resources are distributed, it is very difficult for smaller innovation companies to win procurements.

3.3 Innovation and Opportunities in the Healthcare Industry

3.3.1 Success Factors for Biotechnology Companies

Small- and medium sized technology-based enterprises (SMTEs) often struggle with profitability in early stages. In high-tech industries such as biotechnology, there are some challenges that make it difficult to be profitable. With the higher level of technology comes shorter product life cycles, bigger R&D investments, increased competition, and higher uncertainty (Qian & Li, 2003). Previous research has identified important factors to overcome these challenges and succeed as a biotechnology company.

According to Nilsson (2001), what the successful biotechnology firms in Sweden have in common is a connection with academia that allows them to identify the latest findings and turn it into commercial technology. This is achieved by maintaining a leading role in research, having strong connections with other top researchers and having patents protecting the intellectual property of the firm.

According to Qian & Li (2003), there are four factors a SMTE can focus on in order to be improve its rate of success.

- The first is to maintain an innovator position. Since SMTEs generally find it difficult to compete in volume or cost, it is important to innovate continuously and compete through new solutions.

- Secondly, market awareness is an important factor for success of SMTEs. It refers to how familiar the market is with the firm or product. It is important to stay connected to the market and make the customers comfortable with your products and technology.

- The third aim is to find a niche market. With limited financial resources, it is crucial to limit the width of the operations to be able to compete within one field.

- The last thing to aim for is internationalization. As SMTEs often need to focus on a niche market, it might be too small nationally to allow for the firm to be profitable. This means that the firm will have to expand internationally and find the same niche market in other countries to expand their possibilities.

The high-tech industry is difficult for firms in early stages. However, performing well in these four aspects a SMTE can increase its chances of overcoming the risks and seize the opportunities that come with the fast-changing market of biotechnology (Qian & Li, 2003).

For many years, the industry of biotechnology has been approaching a stage where the technological breakthroughs are so frequent and spread out that it is not possible for a single firm to have all the necessary knowledge and capabilities. Instead, networks of collaborations are formed and provide the companies with a way to communicate and share knowledge to everyone's gain (Powell, 1996). While there seems to be a trend towards more global scale collaboration networks, companies generally have networks of a local or regional orientation through the early years. Global networks are more associated with companies that have passed their early years and established themselves on the market (Geenhuizen, M. V., 2008).

3.3.2 Collaboration between startups and healthcare institutions

According to Kazgan (2019), innovation programs are one of the easiest ways for a startup to reach healthcare institutions with its solution. They sometimes work as an accelerator program that enable investors to invest a small amount of money for non-diluted shares in the startup. If these programs are targeted right, they can result in partnerships and pilot studies at hospitals, which provides the opportunity to validate, improve and develop the product or service. Hospitals often have an innovation team with the job to seek for solutions that might not be mature enough to handle the real problems faced in-house. This provides the

opportunity for a favourable investment in terms of time and money (Kazgan, 2019).

Dhainaut, Blin and Herry (2019) describe that a partnership between a startup and a healthcare institution can provide benefits for both parties. For a startup, this could be an opportunity to evaluate and adjust an implemented product with access to healthcare expertise, data and records. Further, this can result in the function of the product or service being publicly proven at a much lower cost compared to if done at a clinical research organization. It would also be more expensive if the startup itself were to carry out the trial without knowledge in specific regulative, technological, methodological and statistical aspects.

Dhainaut, Blin and Herry, (2019) also describe the benefits of a R&D collaboration. Usually this is limited to a specific project with focus on sharing and development of intellectual properties. The healthcare institution gets access to innovative technology while the startup get access to expertise, laboratories, sample data and specific equipment. In addition, these projects can be supported by public funding from actors, such as European future innovation program or association funds.

3.3.3 User Involvement in Medical Device Development

It is crucial to know the needs and requirements of the users when developing medical devices. By considering the needs of the users, the safety of the developed device can be increased while disregarding them can lead to errors in the device which can have bad consequences. Taking the user needs into consideration also impacts the likelihood of success for the medical device. By involving the user in the development process, the chances for the medical device to succeed increases significantly (Shah & Robinson, 2006).

There are several different types of users of medical device technologies (MDTs). They are divided into healthcare professionals, caretakers, patients, elderly people and people with disabilities and/or special needs. All these different categories of people are in different ways users of medical devices, which means that the performance of the device depends on how well it fulfils their needs (Shah, Robinson & AlShawi, 2009).

Shah et al. (2009) further explains that there are five stages of the medical device lifecycle:

- Concept stage (idea generation and concept development)
- Design stage (device (re-)design and prototype development)
- Testing and trials stage (prototype testing in-house and trials in the real field)
- Production stage (device production based on business and commercial rational)
- Deployment stage (product launch and use in the market and post-deployment user feedback)

According to literature, users can be involved in four of the five stages: Concept stage, Design stage, Testing and trials stage and Deployment stage. Users can be involved in the development process in different ways. When choosing the type of user to involve and which method to use, the different development stages should be considered. The most common stage to involve users in is Design stage, after that comes Testing and Trials stage followed by Deployment stage and concept stage (Shah et. al, 2009).

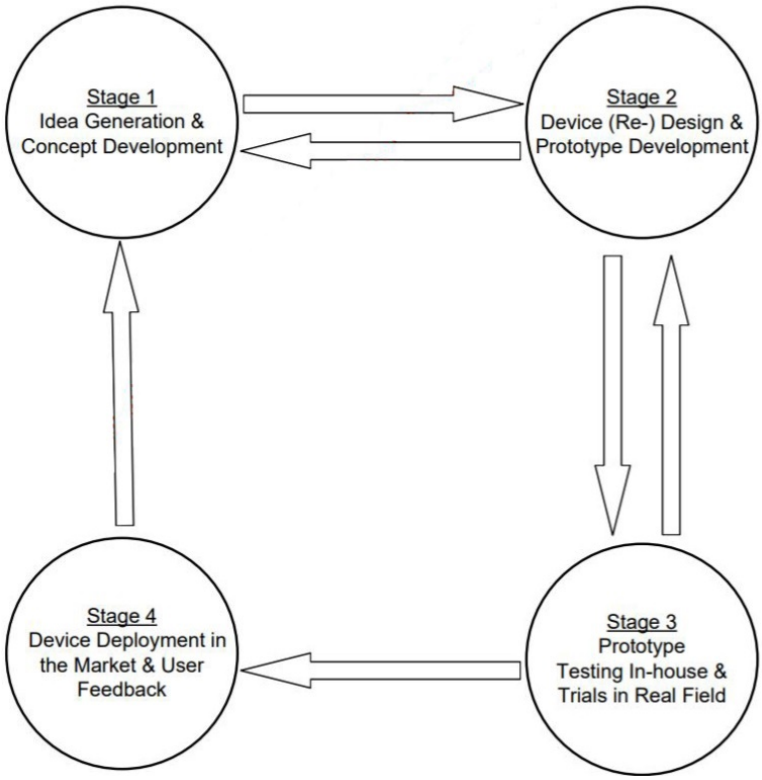

Figure 3. From *Developing medical device technologies from users' perspectives: a theoretical framework for involving users in the development process (page 9)* by *Shah et al. (2009).*

Utilizing close user involvement and frequent feedback is beneficial in product development as it decreases the time-to-market. However, there are factors to look out for when involving the user in the development phase such as matching the time-to-market with the production process. It is difficult to achieve a well-functioning, iterative process of user involvement with the difficult commercial environment and vulnerable users of the healthcare industry (Bridgelal Ram, Grocott & Weir, 2008).

Shah et al. (2009) claim that when developing a medical device that is new to the market, a thorough, iterative process is required from the concept phase until deployment. The process should follow the model presented in figure 3 and involve the user in all the different stages of the process.
Even though user involvement is a requirement for a successful development of a MDT, limited or low user involvement is generally seen in practice. Reasons for the limited involvement could be the difficult circumstances of the market, lack of funds or cognitive, physical or informational limitations of the users (Shah et al., 2009).

4. Empirical Context

To create a deeper understanding of the topic, this chapter presents the context of this study and of In Singulo Solutions. It describes the healthcare and diagnostic testing market and their development as well as a previous case of a company in a similar context.

4.1 The Healthcare Market in Sweden

Over the last 25 years, the healthcare in Sweden has gone from being a public, hierarchal organization to turn into a quasi-market with many different ways of producing and controlling the operations (Andersson, Janlöv & Rehnberg, 2014). Since 2009, the patient is free to choose where to receive care. The way the healthcare funding is distributed varies in different parts of the country, but the most common principle is that the economical means follows the patient to the place they receive care. Private actors are also allowed to enter the market as long as they fulfill the requirements (Axelsson & Sandström, 2016). This creates a certain level of competition within the primary care as the healthcare centers need patients to get funding. The freedom to choose where to receive care for the patient has led to a better sensitivity for what is requested by the caretakers in terms of service and offerings (Andersson, Janlöv & Rehnberg, 2014).

The development seen within primary care in Sweden is shown through an increased level of care utilization and more accessible healthcare for the patients (Andersson, Janlöv & Rehnberg, 2014). The competitive environment also makes patients compare different care givers. This demands the care givers to stay ahead in quality and results to keep their patients and with that their funding. One of the most commonly used parameters for people when choosing where to receive their care is the waiting time. By reducing the time that the patients must wait for an appointment, the chances of being competitive as a care giver increases significantly (Axelsson & Sandström, 2016).

Public financing constitutes a relatively large part of the healthcare financing in European countries. In some countries there is a tradition of mandatory health insurance while others, like Sweden, instead have a system with tax money as the main source of income (Andersson, Janlöv & Rehnberg, 2014). There are two different types of contributions coming from the government, specific and general contribution. The specific contribution is meant for a specific cause, so the municipality cannot decide what to spend the money on. The general contribution is meant for the municipality to spend in the way that serves the operation best in terms of quality of healthcare with the local given circumstances (Axelsson & Sandström, 2016).

4.2 Diagnostic Market Size and Development

The global in vitro diagnostic market was valued at $67,000 million in 2019 and is estimated to reach $91,093 million in 2027 at a CAGR of 4.8% (Sanjivan & Onkar, 2020). According to Morel et al. (2016), the market value in 2016 was approximately $40,000 to $45,000 million, which proves the growth of the market

value. Furthermore, Sanjivan and Onkar (2020), divide the diagnostic market into three different product and service segments: reagents, instruments, and software & services. According to the authors, reagents have by far the biggest market value and will grow at a steady pace as it is a vital part of every in vitro diagnostic test. However, due to new technological development, instruments are estimated to have the greatest growth during the forecast period 2020 to 2027. Furthermore, Sanjivan and Onkar (2020) state by examining the application segments, that infection diseases have the greatest global market potential in the future because of the increasing incidents of HIV-AIDS, hepatitis, and other infection diseases.

According to Morel et al. (2016), the bulk of the in vitro diagnostic market is concentrated in developed countries where the United States, Europe and Japan account for about 80% of the global sales. The IVD market Is highly competitive and the overall IVD market is dominated by key players such as: Roche Diagnostics, Abbott Diagnostics, Becton, Dickinson and Company, Bio-Rad Laboratories, F. Hoffman-La Rouche AG, Qiagen N.V., Sysmex corporation, Thermo Fisher Scientific Inc, Siemens, Johnson & Johnson Medical Devices and Diagnostics, Beckman Coulter and BioMerieux (Morel et al., 2016; Sanjivan & Onkar, 2020).

Sanjivan and Onkar (2020) argues that North America is estimated to be the leading regional market during the forecast period 2020 to 2027. This is due to the higher healthcare awareness among patients, well-penetrated healthcare system and the presence of a large number of IVD key players. However, Asia Pacific is expected to have the greatest market growth during the period, with a CAGR of 6.8%. The reason for that is a huge patient base with chronic diseases that require IVD, the increase of diabetes in the region and the increase of healthcare expenditure (Sanjivan & Onkar, 2020).

According to Hofmann and Welch (2017), new diagnostic tools are being developed combining technological development and available venture capital. New biomarkers are identified with the aim to predict and detect a wide range of diseases. Furthermore, new user-friendly technology that is often connected to mobile devices is being developed to monitor biological parameters. The vision of this development is to transform medicine from being reactive to being more proactive as well as more personal for the specific patient. However, these new diagnostics do not automatically provide improvements in clinical care and population health. They have the potential to help some, but could also increase the frequency of false alarms, over treatment and over diagnosis which may increase healthcare workload.

4.3 The Diagnostic Testing Market Value Chain

As a way to describe and categorize the diagnostic testing market, the value chain was mapped and illustrated as seen in figure 4. The value chain is divided in to three different subsectors: The end users, smaller suppliers and distributors and lastly the big suppliers who can be described as the dominant key players in the market.

Through this mapping of the diagnostic testing market, the different subsectors were analyzed separately which uncovered insights regarding who the potential costumers of startups are and how the companies generally engage with startups on the diagnostic testing market. The mapping of the market was based on the researchers' assumptions and a way to identify potential interviewees for the purposive sampling and is presented in figure 4.

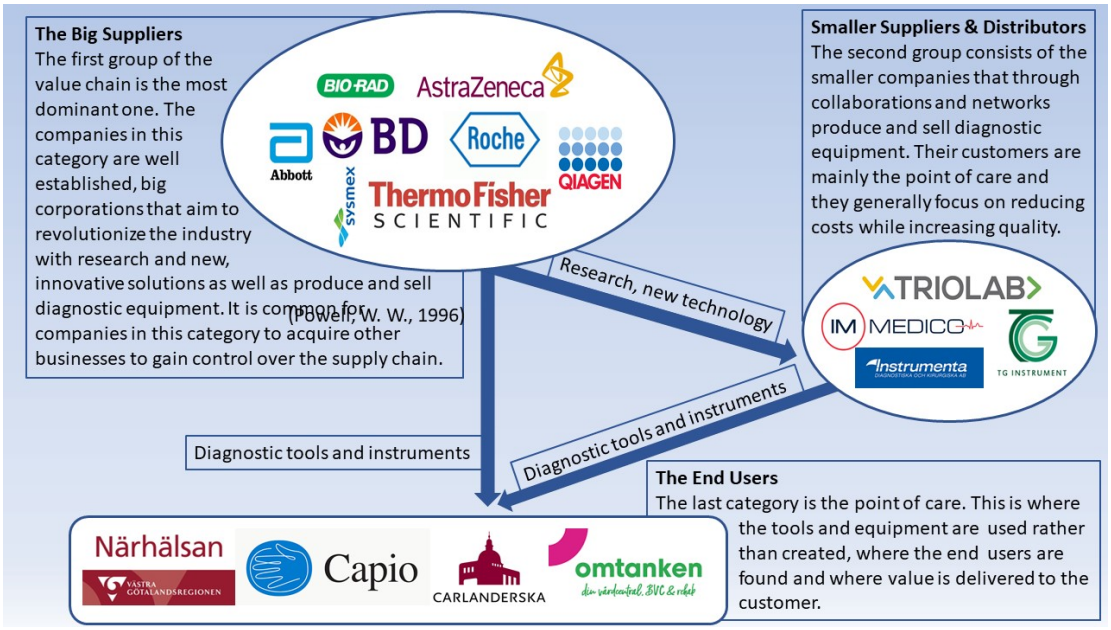

Figure 4: The diagnostic market value chain.

4.4 The Case of Theranos

Theranos is a company founded in 2003 developing a new technology for diagnostic testing. While their technology was later invalidated, they were very successful until that point and raised a lot of money from investors and venture capitalists. Even though their technology does not work the way they claimed, there are things to learn from their success leading up to the invalidation.

One of the key factors for Theranos to be successful was collaboration. They identified the importance of being conveniently accessible for their customers at an early stage, which led to their most important collaboration with the Walgreens drug store chain. By being allowed to place their Theranos Wellness Centres inside the 8100 drug stores, they reached customers in a way that would not be possible without collaboration (Weinstein, Sipala, Turkington & Stromberg, 2016).

Among Americans receiving a recommendation for blood work by a doctor, 40% to 60% choose not to do so. By reducing the cost of blood tests and eliminating the need of a needle for the test and adding the convenience of being situated in the closest Walgreens drug store, the aim was to reach the potential customers that do not want to take a regular blood test. This became Theranos' niche market, as no competitor managed to reach that customer segment (Weinstein, Sipala, Turkington& Stromberg, 2016).

5. Empirical Findings

This chapter presents the empirical findings of this study. The findings are divided into four sections based on the interviewees that provided the data. The first section of the findings shows practical examples of how two different startups have navigated in the industry. In addition, these interviewees describe their experience of how to succeed in the healthcare industry. The following to two sections describes the barriers and opportunities startups face when targeting the healthcare industry. This is based on interviews conducted with healthcare employees. The last section of the findings describes the context of In Singulo Solution and what their strategic ambitions are.

5.1 Startups in the Healthcare Industry

5.1.1 Company Background

Interviewee K explained that Company X started as a research project at a university 15 years ago. Their technology was initially meant to detect breast cancer, but the target usage area later shifted to assessing the condition of the brain to detect strokes and traumas. The company currently has eight employees excluding consultants, about half of them working with the development of the product. Company X just entered the verification phase, and are now conducting tests to verify the functionality, reliability and safety of their product.

Interviewee M described how Company Y started as an idea developed by a doctor and a researcher at a university. They were part of the university ventures program and were initially financed that way. Their technology makes it easier to diagnose respiratory diseases that are otherwise diagnostically complicated, such as asthma or COPD. They are currently selling their instrument to researchers that have an idea on different applications for the technology as they want to find a clinical application.

5.1.2 Collaboration and Testing with Hospitals

Interviewee K described how company X has collaborated closely with an advisory board at a university hospital. The collaboration started through personal contacts doing research at the hospital. At this point, they meet every week to discuss the development and testing of the product with the advisory board. The collaboration has generated a lot of value for company X, initially guiding them to investigate detection of brain condition. Currently, the main purpose of the collaboration is to conduct tests to verify the technology. The tests are done by the hospital but with the interest of company X in mind. Collecting clinical data is crucial to receive a CE-marking.

> "We have a tight collaboration with the hospital and communicate regularly with an advisory board."
>
> Interviewee K, Director of R&D

Similarly, interviewee M described how having a doctor that works at a hospital as a founder has been a big advantage as they have had a continuous contact and collaboration allowing them to conduct tests and explore different options for applications. Interviewee M emphasized the importance of having a contact at the hospital to collaborate closely with and that you are comfortable communicating with, that really cares about the company and innovation.

> "We have always had continuous contact with the hospital and been able to go there anytime to conduct a test"
> Interviewee M, Finances and External Relations

5.1.3 Regulations

According to the interviewee K, CE-marking is a necessity to be able to sell products to the healthcare industry in the EU. Interviewee K added that the CE-marking is not only a way to be able to sell the product, receiving it also increases the chances of getting acquired for a startup with a new technology. The big corporations have in later years tended to wait longer to acquire new companies to mitigate risks, requiring the startups to get the CE-marking on their own first.

The process of receiving the CE-marking can be complicated for some companies, and interviewee K explained that company X has been struggling with regulations regarding their testing. The laws and regulations have slowed their testing process down a lot, as it prevents them from conducting tests on certain patients. In total, they are expecting to receive their CE-marking within a year from starting the verification testing.

Company Y has not started the process towards the CE-marking yet as they need to identify a clinical application for their technology first, as interviewee M explains. The requirements for receiving the CE-marking varies depending on the type of product, so they need to first decide what sort of product they want to develop and then pursue the CE-marking.

5.1.4 Success factors

Looking back at the progress of the company, interviewee K stated that the most important part for startups in this industry is to find a need for their technology. This goes further than noting that there is a gap to fill, you also need to convince the potential users that there is a need. Sometimes that means to challenge the way they think about an issue, which can be difficult if they have worked in the business for a long time.

> "Finding the right market and collaborations is a key to success. Look for people with passion and perseverance."
> Interviewee K, Director of R&D

According to Interviewee K, the most difficult part of succeeding as a startup in the healthcare industry is to survive financially. The steps that you need to go through are so many and each step takes time and has a cost related to it. To make it through all the steps without going bankrupt you need to get funding in some way, but venture capital is not always enough to take you through the process. It is crucial to communicate with stakeholders and shareholders to keep them interested and to be able to get more funding.

Interviewee K summarizes the process by stating that there are two main keys to success in this business. The first one is to find the right market. This includes everything from identifying the initial need for the product to convincing potential customers that it would work and improve the situation. The second key is to find the right collaborations. It is very rare to make it on your own as a startup targeting the healthcare industry, so you need to find collaborations that last and that give you what you need to succeed. These collaborations can vary regarding the purpose of them, ranging from collaborations for economical funding to clinical testing or distribution.

On the other hand, Interviewee M remembers continuously working towards their goal rather than achieving certain steps on the way. The different processes have progressed in parallel, with different challenges emerging along the way. However, there are two areas that interviewee M emphasized to focus on in order to find success targeting the healthcare industry as a startup.

The first one is to manage the finances carefully. Interviewee explained that a startup is very cheap to run initially, and a lot of things can be done before hiring employees and starting expensive processes. By realizing what can be done in the early phase and not rush into advanced processes a lot of costs can be saved, and the company will be more prepared for the challenges that emerge when it enters the next phase. Specific important decisions related to this issue is the timing of listing on the stock exchange and hiring more employees with certain expertise. Another aspect is to find cheap solutions to otherwise expensive problems. For example, instead of spending a lot of money on marketing to gain exposure, Company Y try to attend the right healthcare events. Interviewee M also describes the benefits of these events.

The other area to focus on according to interviewee M is to have a good collaboration with someone who works in the healthcare industry. Interviewee M pointed out two aspects of the collaborator that have been important for Company Y. The first one was that the collaborator has enough authority at the hospital to conduct tests and help Company Y with verifications. It has been very beneficial for Company Y to have a collaborator with that kind of resources. The second aspect is that the collaborator knows the company well and really cares about the success of the company. The collaborator has always had a close relationship with the company and has been willing to fight for their success, which has also helped them a lot through their process.

> Within your niche, find a contact in healthcare. Someone who believes in you that you have a good relationship with.
>
> Interviewee M, Finances and External Relations

5.2 Barriers Between Startups and Healthcare Institutions

5.2.1 Challenges of the Healthcare Market

When asked about the reasons behind the rarity of startups in the healthcare industry, there are some themes in what the interviewees mention as risks or

difficulties of having a startup as a supplier. Interviewee A, B C and D described that large global suppliers dominate the healthcare market, especially more complex services and products, such as medical devices and diagnostic tools. Interviewee B described that it is very rare with startups in the healthcare. The deals that are made in the healthcare industry generally last for a long time. Therefore, it is important for the customer to be able to trust that the supplier will still be there for the duration of the deal to deliver what is agreed on.

Interviewee B described that in the healthcare industry, startups are very often acquired by the big corporations once they have a proven technology and a high potential. If a company would acquire a startup after they reached an agreement with a customer, that would jeopardize the deal and that is a risk that most customers are not willing to take. In addition, interviewee A described that the large global suppliers in some cases acquire startups or small companies with a unique product with the aim of hindering competition and instead investing in their own solution.

"It is difficult for startups in the healthcare industry. The global giants rule the market"
Interviewee A, Responsible for Purchasing and Orders

Another reason for the rarity of startups is the high volumes of the orders. Interviewee A, B, C, D and J stated that once instruments are purchased, they are generally ordered in volumes that are large enough to provide for many hospitals and healthcare centres at once. In order to be able to deliver such an order, an established production line is required. This is not something that most startups and smaller companies have, which makes it difficult for them to close a deal by themselves. Interviewees J and A described that it is much easier to work with a larger supplier because you know what you are getting and can trust that it will be delivered according to the agreement.

When healthcare institutions purchase equipment, a tender documentation is created with the purpose to make the selection of supplier objective. Interviewee C described that to make sure that the documentation is complete and possible to match for the suppliers, the big suppliers are often consulted. While this provides important support for the healthcare institutions in their purchasing decision, this means that the established suppliers can influence the next purchasing decision and keep control of the market. Interviewee A explained that historically, the suppliers approached customers with new solutions to sell their products to hospitals. Nowadays the customers within healthcare attend hearings and congresses to stay up to date with the newest technology and future products. Only the big suppliers present their new solutions at these hearings and congresses, so they get to advertise their products and establish them as the standard on the market.

"The requirements list is formed in collaboration with suppliers. It generally also includes conditions for the procurement agreement"
Interviewee J, Responsible for Purchasing and Orders

Between the deals and procurements, many interviewees explained that they have a continuous dialogue with their established suppliers. Interviewee C described that the big suppliers come visit the site to find new areas to improve and pitch their new products. This dialogue and collaboration allow for the big suppliers to provide solutions before the customers even realize that there is a need for it, making it difficult for a smaller company to anticipate that need and provide a solution first. The interviewee explained that the big suppliers work a lot with innovation and always have new products on the way.

> "The large suppliers often deliver a new product that solves a problem before we even realize that there is a need for it."
>
> Interviewee C, Operations Manager

Several interviewees state that innovation in healthcare institutions is difficult. According to interviewee C, healthcare institutes have few resources for technology development and the employees are very busy with routine activities, which means that it is better for innovation to come externally. Interviewee C also stated that the regulations and the strict requirements for CE-marking hamper innovation. When asked about where innovation in healthcare emerge, all interviewees working in healthcare described that innovation often comes from external parties, such as companies or universities.

5.2.2 The Process of Purchasing Equipment

After interviewing people involved in the purchasing process at hospitals and healthcare centres, it became clear that the process of purchasing equipment in the public sector is complicated. Interviewee B explained that for orders exceeding 500 000 SEK, a public procurement must be done according to the law of public procurement. As long as the price of the order is less than 8 million SEK, the order is financed by the hospital budget. They still must give the suppliers a fair chance by going through the process of a public procurement and creating a specification of requirements. When deciding on a supplier, they very rarely decide to go for a small company. In many cases, they have a requirement of a certain minimum turn over to even consider engaging with a supplier.

When it comes to orders of more than 8 million SEK, the purchase is financed by the municipality which means that the financing decision is made by politicians after the hospital demands money for the investment. To give some structure and illustrate the different processes of purchasing, a description is provided in figure 5.

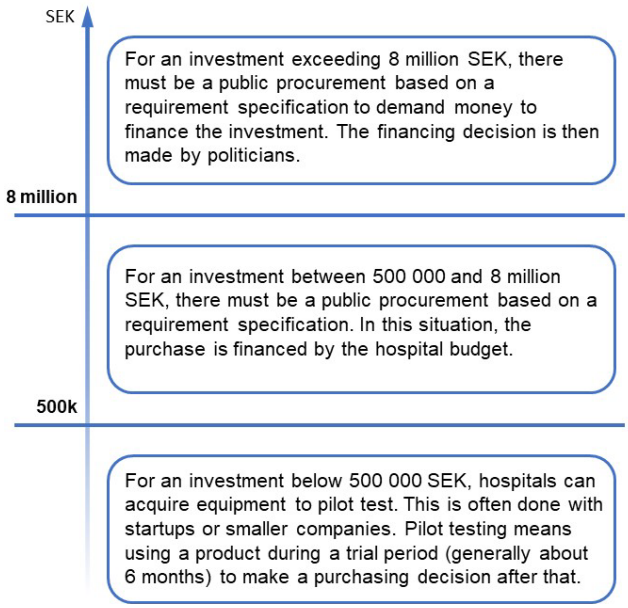

Figure 5: The different purchasing processes for a hospital in Sweden, depending on investment amount

Interviewee J explained that the procurement process is divided into three different phases: the analysis phase, procurement phase and the contract phase. In the first phase, a group of specialists in a specific field are set together to conduct a market analysis. The purpose is to conduct research on available products and the technology development by meeting suppliers and visiting congresses and fairs to obtain as much information as possible. The suppliers are often well-known international corporations. This information then forms the basis for a requirement specification that is created as a basis for the entire process in the procurement phase. These can be requirements on turnover or on a specific historical record, which several of the interviewees describe are locking out smaller companies. During the procurement phase, the procurement is announced. This means that suppliers can submit their proposals, which are then evaluated based on the requirements specification. The supplier who wins the procurement is then included in an agreement that often extends for four years, which interviewee J describes as the contract phase.

Several of the interviewees claimed that the procurement process is very standardized and rigid. Interviewee C explained that it inhibits innovation and that it is not good for competition. Hospitals cannot choose their suppliers because everything must take place according to the standardized process. Moreover, interviewee B stated that the process of public procurement makes it difficult for smaller companies to compete with the more established competitors. Even if a smaller company were to succeed in being picked as a supplier, it is unlikely that

it can produce orders as big as the ones in the healthcare industry. This means that it gets much more difficult for smaller companies to reach the hospitals and healthcare centres once the price of their product exceeds 500 000 SEK.

5.2.3 Laws and Regulations

The healthcare industry is very regulated which creates difficulties for smaller companies. Interviewee D explained that the new medical device regulations (MDR) and in-vitro diagnostic regulations (IVDR) are regulations that has made it more difficult for smaller biotechnology companies to become suppliers. The interviewee described that the new regulations are tougher than the previous ones as it places higher demands on suppliers and urges that you have a close relationship with your supplier.

Moreover, interviewee C described that hospitals are accredited organizations. That means that they have many requirements they must follow, which creates a long way for startups to become mature enough to become a supplier. All interviewees emphasize that there are many innovative solutions on the market, and many come from startups. However, the problem is always the aspect of security and reliability. If a product is to be taken into care, the safety, reliability and precision must be of the highest quality especially due to the new regulations.

> "It is always the safety and reliability aspect that set the limit"
>
> Interviewee B, Development Manager

5.3 Innovation and Opportunities in the Healthcare Industry

5.3.1 Collaborations with Healthcare Institutions

Through research and different projects, the universities are working to drive healthcare development. At the university hospitals there is a lot of collaboration between academia and the practical operations. Interviewee D described that hospitals also stay connected to research, often by having some part-time employees that are also employed at the universities. A lot of experiments and testing are done at the healthcare institutions thanks to these collaborations and that is an important source of innovation in this industry. Through the different tests and collaborations, the universities gain important knowledge contributing to their research and the hospitals and healthcare centres stay up to date with the latest research. Moreover, Interviewee C described that several startups emerge from these collaborations.

> "Universities should be responsible for innovation while we handle the practical operation"
>
> Interviewee C, Operations Manager

Smaller companies and startups can also engage with the healthcare industry to perform pilot testing if the purchasing amount does not exceed 500 000 SEK. Interviewees B, C and D describe that these collaborations are meant to be beneficial for all parties. The company gets to further develop their product and take part of the expertise of the medical staff and patient data. Meanwhile, the hospital or healthcare centre gets a good deal on the new product once it is

finished. Interviewee C said that they have experience from several successful pilot tests with startups that have resulted in procurements. The interviewee explained that a clinic manager at the hospital was contacted by an acquaintance who worked at a startup that offered an innovative solution for storing and finding samples. The product was refined during a pilot test and was then purchased by the hospital because the collaboration was successful. However, according to the interviewee, it is an advantage if you as a startup know someone in healthcare as it can be difficult to get the opportunity of pilot testing otherwise.

"They make it technically possible and we contribute with clinical expertise"
Interviewee C, Operations Manager

Several interviewees described that pilot testing is one of few direct forms of collaboration between startups and healthcare institutions. The experiences that the interviewees have from pilot testing with startups are generally positive, as they see benefits of working with a startups compared to the big suppliers. Interviewee B described that the process of reaching decisions is much faster in startups which makes the communication easier and more efficient. In addition, the fact that the innovations are rarely finished is seen as a positive thing as it allows for changes to be made to fit the needs of the customer better.

"Startups are sources of innovation"
Interviewee C, Operations Manager

According to interviewee I, the impression is generally that startups are more interested in collaborating to create the best possible product for the customer than the big suppliers. However, since the solutions that the startups provide are rarely finished, the time from testing to a functional product is much longer when working with startups. Interviewee J describes that healthcare wants to promote startups and smaller suppliers despite the fact that it is more difficult due to the strict regulations. The interviewee further explained that if a startup has proven the quality of its product in another hospital than theirs, there is nothing to stop them from buying their product. However, it is more common for a startup to sell its product to a larger supplier.

5.3.2 Innovation Programs

Interviewee L describes innovation programs as entities that work to promote and set the terms for collaborations between companies and healthcare organizations. The innovation programs work with all different kinds of healthcare in the region and have three main tasks. The first one is to get as good products and services as possible to the healthcare industry. The second task is to make sure that the collaboration between healthcare institutions and companies is done on a fair basis and that companies are given the same chance to succeed. The third task is to attract life science companies to establish themselves in the region and promote healthcare development that way.

It was clear during the interviews that most people working in healthcare are more than busy completing the day-to-day tasks. There is no room in the budget or in the schedule to work with innovation or try new methods. At the same time, the only way to evaluate innovation is to test it in a real environment to see if it works as intended. Interviewee G explained that in order to make innovation possible without compromising the quality or capacity of hospitals and healthcare centres, the innovation programs work to help companies with new solutions and drive healthcare development.

> "The resources for technology development are scarce. Everything needs to be verified for us to take it in."
> Interviewee D, Operations Manager

All interviewees that work in healthcare described that innovation programs exist with the purpose to help healthcare institutions with innovative solutions to reach hospitals and healthcare centres. Interviewee D described that these organizations act as a bridge between healthcare institutions and innovative companies and that this is where startups should try to get support for an innovative idea. These collaborations can result in pilot tests or information about the needs of healthcare that can help a startup to develop their product. According to Interviewee I, the innovation program is their source of innovation and it helps them to think outside the box and develop.

Interviewee F explained that the innovation programs are not profit-driven since they are in the public sector. Some of the help they can provide startups and other companies is free while the companies need to cover the costs of certain types of help, like clinical testing and other more expensive processes. According to interviewee G, they want to be able to provide more help for free, but they instead refer to other funding organizations as they must treat all companies the same.

The innovation programs work assignment based with the companies. That means, according to interviewee L, that they take on a certain task with a company and help them through that process and then assess the situation again and see if there is another possibility for them to help the company. Interviewee L also stated that it is important to keep a straight and honest dialogue with the company continuously to be able to tell them that they need to go back and keep working on their own before the innovation program can help them.

Interviewee F explained that the innovation programs strive to help the companies find the best way forward. The way they help the company and what they do for them depend on where the company are in the development and what their needs are at that point. Interviewee G described how they work to try and understand the needs of the innovator and help them from there. If the needs do not match with what the innovation program can provide, they try to help by connecting the innovator with the right person whether it is about legal matters, IT, understanding of the business or something else.

According to interviewee L, the way they help companies can be described as giving feedback on products and ideas. It can be anything from usability to basic demands. They do this through simply giving advice, arranging workshops and connecting companies to people that work in the area that is targeted. Interviewee F describes their approach as preparing innovators through counselling, providing contact with incubators and accelerators and helping to understand regulations and requirements.

> "We act as advisors providing companies with contacts in the region. We try to guide them to the best way forward."
> Interviewee F, Responsible for company collaboration

Interviewee H explains that if a company approaches them in an early stage of their technology development, the innovation program can step in as a project manager to guide them in the right direction. They can help with different matters, for example investigating if there is a need for the technology in healthcare. Interviewee G said that the innovation programs can also help companies in the process to receive the CE-marking if they have not received that already.

In the later stages of development, interviewee E said that companies can go through innovation programs to perform clinical tests at the hospitals. Interviewee H explained that they can help by finding suitable patients to conduct the tests with. At this stage, the innovation programs act as a link between the healthcare institutions and companies to promote collaboration between the two and facilitate clinical tests, according to interviewee L.

> "We believe in a form of collaboration between healthcare and companies where the healthcare institution is very active"
> Interviewee L, innovation manager

Interviewee L discussed how the innovation programs in different regions communicate nationally to help each other and to be able to refer companies to other regions if that is a better fit for their product or service. The collaboration between regions is so far limited to communication and some knowledge on what the other regions are currently working on, but the intention is to expand the collaboration in the future to improve their operation.

Interviewee L emphasized that any innovative company targeting the healthcare industry can approach the innovation programs. If a company contacts them and explains their situation and their needs, the innovation program can then assess if they are able to help or if they should guide them to someone who is better equipped to help with the issue in question. Interviewee L said that the only demand they set for companies that contact them is that the innovation cannot be too underdeveloped, because then it is difficult for them to assess it.

> "Anyone can turn to us for assistance. If we cannot help them, we can guide them to someone who can."
> Interviewee L, Innovation Manager

Interviewee H explained that for them to be willing to help a company, the innovation must be something that can help Swedish healthcare. If the innovation is not expected to be able to win a procurement in the future, interviewee H thought the company will have a better chance of succeeding abroad. Interviewee G also stated that the projects that they take in to assist must match the needs of the healthcare industry. They can provide a test bed only where there is a need for it.

It is a very selective process according to interviewee H, and they try to find matches for collaborations in a way that serves the needs of the healthcare industry as well as possible. If there is no underlying need, finding collaborations becomes difficult. All the interviewees from innovation programs agreed on the fact that there must be a need in the healthcare industry connected to the innovation for them to be able to help the company. Interviewee L said that they can sometimes conduct a needs analysis to investigate if there is a need for the innovation by interviewing experts in different areas.

> "We are contacted by many companies but a lot of them do not have projects that lead to a product"
>
> Interviewee H, Responsible for Company Collaboration

Interviewee E explained that a lot of companies do not realize how controlled the process is. There are many companies contacting the innovation programs, but a lot of times their planned process does not match the controlled process or the available resources of the innovation programs. With the large number of companies that approach the innovation programs there is no room or time for them to actively search for companies to collaborate with, according to interviewee L. Interviewee G said that innovators should also consider finding someone that works in healthcare that can help them with tests or monitoring procurements to see if there is an opportunity for the company to win one.

When it comes to the CE-marking, the interviewees from different innovation programs do not quite agree. For example, interviewee G said that they want the companies to have the CE-marking when contacting the innovation organization. Interviewee L also said that verification of the technology and the product is something that the company must handle themselves. On the other hand, interviewee H explained that they can help with CE-marking even though someone at the hospital must take responsibility for the tests. Interviewee E considered it a good idea to go through the innovation programs when pursuing a CE-marking, as it is a good way to gain credibility to be allowed perform the tests. Interviewee H also described that the process to receive the CE-marking is very different depending on the product as well, which affects how the innovation programs can help with the process.

According to interviewee F, a lot of opportunities for new technologies are missed because of understaffing. The number of approaching companies are so many that it is difficult to navigate and

> "We are missing a lot of opportunities because we are understaffed"
>
> Interviewee F, Responsible for Contracts and Financing

validate the different opportunities and select which ones to pursue. Interviewee E made the same point, saying that a lot of companies are denied or referred to other organizations even though their technology or product is very good. Interviewee G mentions personal relations to healthcare as a way in, but also explained that personal connections might not be a very good system to depend on.

5.4 In Singulo Solutions

5.4.1 Background of In Singulo Solutions

In Singulo Solutions technology emerged from a project that was started by a professor at Chalmers University of Technology. In the project, several academics conducted research with the aim of optimizing research instruments with the idea that these tools can be improved and made more efficient. The research project was then taken on to AstraZeneca, where further research was carried out with the help of a doctoral student and a specialist from AstraZeneca.

At the beginning of the project at AstraZeneca, there was an idea to match industrial needs with a new measurement technology. The focus was to target the pharmaceutical industry, but the researchers soon realized that there was great potential for the technology as a diagnostic instrument. Their technology was soon used to help other researchers to measure different proteins, which had previously been difficult. At the end of the project, they realized that they had managed to solve a problem and then began to look at patents and how they could develop the technology further.

5.4.2 The Proprietary Technology

The technology is based on a single molecular surface-sensitive and microscopy-based method, which has several advantages compared to diagnostic instruments used in the healthcare industry today. The technology enables diagnostic test analyzes to be performed faster, with better precision and with a smaller sample. In addition, several analyzes can be performed simultaneously.

In Singulo Solutions is currently conducting diagnostic analysis for research purposes for external organizations that need their expertise and technology. However, the instrument used is only designed for research purposes, which means that it is large and requires a certain amount of competence to control it. The first prototype that was used is owned by AstraZeneca. However, In Singulo Solutions own the technology and has a patent on it. In addition, the company has recently developed the second-generation prototype independent of AstraZeneca.

5.4.3 Strategy

When asked about In Singulo Solutions' strategy, it was explained that the company's current focus is to find a specific need that they can target and design their technology for. Based on the identified need, a strategy will be developed to target this area. To find a need, the company focuses on conducting a market analysis where relevant individuals are interviewed to identify potential needs for their technology. Once a customer need is identified, the company will apply for further funding.

In the long run, the company aims to become a supplier of diagnostic instruments but sees the possibility of being acquired as a possible exit. Furthermore, when asked about the knowledge about regulations and requirements such IVDR and MDR, it was explained that the knowledge is limited, and the employees have no specific knowledge of what these entails.

6. Analysis

In order to analyze the data from the empirical study, the data was compared to previous research to find similarities and differences. This chapter presents the analysis in three parts.

6.1 Startups in the Healthcare Industry

Both the interviewed companies described how they have worked closely with hospitals since the start of their development processes. The interviewees have both seen great benefits from these collaborations, as it has provided a lot of insight and possibilities of testing their innovations. Shah and Robinson (2006) also emphasize the importance of close collaboration with customers in medical device development, claiming that it increases the rate of success significantly. In addition, both companies started at universities. According to Nilsson (2001), what the successful biotechnology companies in Sweden have in common is a connection with academia which allow them to have access to the latest development in research.

It was also highlighted during the interviews that having a personal connection to someone working in healthcare is an important factor for success. It can be a source of information and insight into what there is a need for and help with testing and other resources. Interviewee G also described that the innovation programs also consider having a connection at a hospital as a great benefit for a startup in the healthcare industry. Dhainaut, Blin and Herry (2019) also agree that the connection between startups and hospitals is beneficial for both parties. The authors also claim that it can help a lot in the process of getting the innovation publicly proven.

Receiving the CE-marking was highlighted as a crucial step towards success for both interviewed companies. Interviewee K also described the struggles that Company X has had with the process towards a CE-marking. This can be compared to Oriel (2019) who pointed out that new regulations went into effect in 2017 and are far more comprehensive than previous regulations. Epista Life Science (n.d.) explained that the new regulations make it necessary for more manufacturers to certify their technology. In addition, these regulations will result in more costly clinical monitoring and evidence generation for certifying products (Med-Tech Innovation New, n.d.)

Finding a need for your innovation was highlighted as one of the most important factors to succeed as a startup. This is described as something that should be done early in the process, to be able to adapt the innovation to the intended user. This is confirmed by Lazarow (2020) as one of three ways to succeed as startup. The author argues that solving a real problem will result in a natural need and demand. However, Kitching and Rouse (2020) argue that effectual logic is more beneficial to entrepreneurs in early stages. That means that startups should focus on developing their existing means and keeping their end-goal flexible rather than creating new means to reach a pre-defined goal.

According to the interviewees, it is more important to find a need than to identify a gap that your technology can fill. It also means that you as a startup need to convince the potential customer that there is a need. This is also mentioned as a key to success by Wouters, Anderson and Kirscberger (2018). They emphasize the importance of having a customer value proposition as a startup to communicate the advantages of the product that you are selling. Kurpjuweit and Wagners (2020) also describe the importance of being able to convince stakeholders of the value of the offered technology. According to the authors, this is a factor that determines how suitable the startup is as a supplier.

6.2 Barriers Between Startups and Healthcare Institutions

Both the theory and the empirical findings show that healthcare is a complicated industry for startups and that there are many barriers. It is emphasized in the interviews that the large global suppliers are dominating the healthcare market, especially regarding the more complex products and services. This is in line with Morel el al. (2016) who describes that the diagnostic market is dominated by key players, such as Roche Diagnostic, Johnson & Johnsson Medical Devices and Siemens.

Further, the interviews revealed that the large suppliers often acquire startups, sometimes only to prevent competition. This was considered a risk the interviewees from the healthcare are not willing to take because that would jeopardize the deal between a startup and healthcare institution. To be acquired by a large supplier can for some entrepreneurs be a possible exit. However, the interviews revealed that the acquiring party often requires that the targeted company has CE-marking. According to Med-Tech Innovation News (n.d.), a result of the new IVDR and MDR regulations is increased clinical testing requirements, which makes the process to receive CE-marking more expensive and complex.

According to the interviews, high volumes of the orders are one reason behind the rarity of startups in the healthcare industry. For this reason, it is considered safer to work with large suppliers because they are more established and deliver what is promised. In addition, it is important that the offered technology meets all regulatory and safety requirements. This can be compared to Kurpjuweit and Wagners (2020) study of how suitable a startup is as supplier. The authors describe that a suitable startup supplier should have high quality in processes, management, know-how and financials. In addition, the offered technology must be unique and aligned to the customers' innovations strategy and demand.

The interviews revealed that healthcare institutions and the big suppliers often work closely together. The interviewees describe that healthcare institutions consult only with large suppliers when conducting a market analysis before a procurement. In addition, it is only the large suppliers who present their new products at hearings and congresses. Representatives from healthcare visit the hearings and congresses to gather information about the latest development on the market. This means that the established suppliers can influence the next purchasing decision and keep control of the market. This can be compared to the study by Kurpjuweit and Wagner (2020). The authors argue that many buying

firms have a ready-made selection of suppliers to choose from, which creates difficulties for startups to be identified. Moreover, the interviews reveal that big suppliers visit the healthcare institutions to find new areas to improve. That allows for the big suppliers to provide solutions before the healthcare institutions even realize that there is a need for it. This can create a major barrier between startups and healthcare institutions. It can be interpreted as startups facing an almost impossible task of competing with the large suppliers as they are always one step ahead.

The interviewees revealed that the procurement process is very rigid, complicated and inhibits innovation, which is line with Lundvall and von Utfall Danielsson (2014). According to Edwards and Moius (2019), the negative effects of the procurement process are worse for smaller companies because more established suppliers tend to be perceived as a safer option. Moreover, the interviews revealed that the procurement process creates difficulties for smaller companies to compete with more established suppliers. According to Eriksson (2015), the procurement process causes uncertainty and shifting focus from selecting the best offer to making sure that laws are followed. The result is that more established suppliers are selected before smaller companies, which is in line with the findings of this study.

According to Ying Lim and Andersson (2016), healthcare providers are often reluctant to take risks. This results in difficulties for a startup to become a supplier even if the product meets all regulatory requirements. This theme was also identified in this study as several of the interviewees mentioned that there were often specific requirements for minimum turnover and proven history in procurements, which in many cases lock out smaller companies. Uyarra & Flanagan (2010) also argue that procuring parties tend to design the tender documentation in a way that excludes some offers, generally the ones from smaller innovative companies. One interpretation of this is that startups face the threat of being denied even though they have the best product. Furthermore, there is a risk that a startup will end up in a difficult situation. The startup needs to have a historical turnover to become a supplier but cannot achieve this because they do not have a historical turnover.

Another barrier that is highlighted in the interviews is the healthcare industry's heavy regulations and requirements, which is in line with previous literature. Chowdhury (2012) states that the healthcare sector is highly regulated and large investments are required to enter this area, which creates difficulties to access. The interviewees described that IVDR and MDR, as well as the fact that healthcare institutes are accredited organizations, create a barrier between startups and the healthcare institutions. According to the interviewees and Oriel (2019), these new regulations are far more comprehensive than the previous regulations. This results in a long way and huge investments for a startup company to be mature enough to be able to become a supplier to healthcare institutions. Previous literature argues that the new IVDR and MDR will result in higher costs and longer timelines when developing new products (Med-Tech Innovation News, n.d.). In addition, far more manufacturers must certify their device by notified body for e.g., CE-marking (Epista Life Science, n.d.). According to Dhainaut, Blin and Herry

(2019), startups often lack knowledge about public structures, hospital environment and their constraints. In addition, first-time entrepreneurs often underestimate the legal, regulatory, and market complexity of their projects, which also was highlighted by the interviewees in this study. This can result in that a startup underestimates the costs and requirements required to achieve market success which ends in bankruptcy.

6.3 Innovation and Opportunities in the Healthcare Industry

Innovation and unique offerings were described as the main strengths that startups have during the interviews. Startups were also considered to have the ability to make quick and flexible decisions, resulting in smoother communication between the two parties when collaborating. This is in good agreement with the study by Kurpjuweit and Wagner (2020), which describes that startups are excellent problem solvers and are a source of innovation and of rapid technological change.

The interviewees working in healthcare emphasized that making it in that industry as a startup all by yourself is very difficult. The most important factor in order to succeed as a startup is to have a technology that is targeting a real customer need. In addition, it was stated that collaborations are crucial in order to succeed, which is confirmed by Dhainaut, Blin and Herry (2019). The collaborations can vary in form and purpose, and each startup must form a network of collaborations that serves their needs. By establishing relationships with investors, universities, healthcare institutions or other companies the chances of succeeding as a startup increases significantly. Shah and Robinson (2006) argue that it is important to know the needs and requirements of the users when developing medical devices. For this reason, it is important to collaborate and develop a product together with the customer and user. This theme is also confirmed by, Laage-Hellman, Landqvist and Lind (2018) who claim that collaboration with customers in product development has several advantages, such as providing detailed information about customer needs and problems. These relationships are especially important for startups.

The empirical data collected in this study presents the opportunity to cooperate with the innovation programs. Their goal is to provide healthcare institutions with new technology by helping innovators find their way through the many steps of entering the healthcare market. It is also described as one of the easiest ways to reach healthcare institutions with a new solution by Kazgan (2019). If innovation programs are targeted in the right way, they can result in partnerships and pilot studies at hospitals. That provides the opportunity to validate, improve and develop the product or service (Kazgan, 2019).

The interviewees that work at innovation programs explained that they prefer for the startup to have identified a need for their technology early in the process. Having a clear need for the technology helps the innovation programs as they aim to provide healthcare with new technology that fits their needs. However, Sarasvathy (2001) states that startups benefit from utilizing their given set of means to imagine new ends by using effectual logic and keep the end-goal flexible.

The empirical data showed that innovation programs can help companies by providing contact with accelerators and incubators. The interviewees explained that they refer companies to contacts in the region if they are better suited to help the company. Kohler (2016) argues that corporate accelerators can help startups receive support in improving their products, operations and strategy. In addition, successful programs can result in accelerators supporting a startup's pilot study.

As mentioned above, the law of public procurement is a barrier for startups in many aspects. However, there are aspects of it that can work in favor of startups targeting the healthcare industry as well. Interviewees responsible for purchasing at healthcare institutions pointed out that once the tender documentation is released, the customer must choose the supplier that provides the best offering. This means that the public procurement process can provide an opportunity for a startup that offers demanded equipment to enter the market. While not very common, this was confirmed to be a possibility during the interviews with people responsible for purchasing within the healthcare industry. This was confirmed by the research of Molander (2009), explaining how the tender documentation decides the terms and regulations for the public procurement process. One important measure to make that possible is to maintain a close collaboration and dialogue with potential suppliers. This is most important before the start of the procurement to promote innovation (Reige, 2016).

The interviews revealed that a pilot test can be arranged if the price of the product is less than 500 000 SEK. Pilot testing provides an opportunity for startups to get a chance to prove the safety, reliability and potential of their innovation. This can be an attractive option for the healthcare institutions as well, since they usually get a good deal out of it in terms of a reduced price on the innovation. With the strict regulations that the customers must follow it is very important for them that the technology that they purchase is well proven and certified, which can be achieved through pilot testing. Kazgan (2019) also highlights pilot studies as something beneficial both for startups and healthcare institutions. Dhainaut, Blin and Herry, (2019) describe the benefits of a R&D collaboration. The healthcare institution gets access to innovative technology while the startup get access to expertise, laboratories, sample data and specific equipment. According to Shah and Robinson (2006), taking the user's needs into consideration impacts the likelihood of success for a medical device.

Another advantage described with the pilot testing is the ability to tailor products to the needs of care and the patient. Since a startup's product is rarely ready, the startup can develop the product together with healthcare staff. Moreover, startups were considered more interested in collaborating to create the best product possible compared to larger companies. The importance and benefits of involving the customer in the development of medical devices were confirmed by the study of Shah et al. (2009). Dhainaut, Blin and Herry (2019) also describe that a partnership between a startup and a healthcare institution can provide an opportunity to evaluate and adjust an implemented product with access to healthcare expertise, data and records. In addition, they point out that it can result in the function of the product or service being publicly proven at a much lower cost compared to if done at a clinical research organization.

7. Discussion and Conclusion

This chapter presents a discussion based on the literature review, empirical context, empirical findings and analysis. The purpose of this study was to investigate how biotechnology startups with proven technology can navigate in the healthcare industry to improve their chances to succeed. The company In Singulo Solutions, whose context is analysed in this study, is currently working on the goal of identifying a specific customer need and then develop a strategy to meet this need. In order to answer the research question, the context of In Singulo Solutions is discussed as it is generally applicable for startups targeting the healthcare industry.

The purpose of this research was examined by using In Singulo Solutions as an example, interviewing their potential customers in the public sector and other organizations that could be of assistance in the process. While two other startups were interviewed to capture their perspective, the primary aim was to understand what the market demands from startups to engage with them. That is the reason for not interviewing more startups or other suppliers to the healthcare industry, even though that might have yielded a different result.

The empirical findings of this study are to a large extent in line with previous research. This suggests that biotechnology startups targeting the healthcare industry should act similarly to startups in other industries to increase their chances to succeed. However, there are some areas where the empirical data differ from previous research on startups, which means that some aspects are specific for the healthcare industry.

Conducting the interviews in person and being able to visit the healthcare institutions would have helped to gain a deeper understanding of the topic. However, the Covid-19 pandemic made that impossible. The interviews were conducted via video chat to get as close to meeting the interviewees in person as possible.

RQ: How can a Swedish biotechnology startup improve its chances to succeed in providing healthcare institutions with their technology?

This study clearly shows that there are several barriers in the healthcare industry for startups. For example, regulations and requirements, heavy procurement processes and competition with large suppliers that work closely with the healthcare institutes. In addition, the study shows difficulties for startups to identify specific customer needs to target. The question of how a startup should act and reason in the healthcare industry, which is full of barriers, has probably been asked several times.

According to Lazarow (2020), one of three ways a startup can succeed is by having an entrepreneurial idea that is solving a real problem because it will result in a natural demand. The importance of finding a real customer need to target is emphasized several times in this study. For example, interviewees at the healthcare institutions and innovation programs argued that the most important factor for collaborating or working with a startup is that they can provide a

solution to a real customer need. It can be interpreted that having a real customer need to target is the most important success factor in the healthcare industry, which In Singulo Solutions is currently focusing on finding. This goes beyond the uniqueness of the proprietary technology.

However, both interviewed startups described that their targeted usage area had to some degree shifted over time. Interviewee K described how their technology was initially meant to detect breast cancer, but the target usage area later shifted to assessing the condition of the brain to detect strokes and traumas. In addition, interviewee M described that their technology was developed with purpose to diagnose respiratory diseases, but they are currently selling their product to researchers hoping that they will find a clinical application for it. This shows that it may be difficult to initially find the right customer need to target and a startup should be ready to shift focus over time when opportunities arise. Especially since the close collaboration between healthcare institutions and the large suppliers results in large suppliers always being one step ahead when it comes to finding needs in the healthcare industry.

According to Kitching and Rouse (2020), entrepreneurs can be more flexible, take advantage of environmental changes when they occur and continuously learn while operating by adapting an effectual reasoning. Based on this, one can argue that In Singulo Solutions and other startups in the healthcare industry would benefit from operating according to effectual logic. Especially in the early stages when the startup is searching for customer needs to target and is still developing a product. This means that In Singulo Solutions should focus on their given means, such as their technology, expertise and network and develop these over times while keeping their end-goal flexible until right opportunity arises.

Wu, Liu and Su (2019) argue that effectuation also can improve the speed of new product development. In addition, intense competition, which can be interpreted as present in the healthcare industry, may increase the positive effects of effectuation and contribute to increased speed of new product development (Wu, Liu & Su, 2019). This means that it can be a great advantage for In Singulo Solutions to exercise effectual logic in order to be ready to refine the technology and product when the right customer need arise.

However, as previously discussed, a real customer need creates most of the possibilities for a startup in the healthcare industry. Therefore, it is important to actively search for a customer need to target and not wait for it to appear by chance. When a need has been found, one should invest in this and act according to causal logic to take advantage of the opportunity. However, it is important to maintain flexibility in order to be able to quickly change focus when new better opportunities or unforeseen competition from large suppliers arise.

This study shows that it is extremely difficult for a startup to become a supplier to the healthcare market. Powell (1996) claims that the industry of biotechnology for many years has approached a stage where it is impossible for one single firm to have everything necessary to be successful. Startups like In Singulo Solutions therefore need to find collaborators. According to this study, the best way to do so is through innovation programs.

For example, the interviewees mentioned that the innovation programs can provide a needs analysis which would be very helpful for a startup like In Singulo Solutions. Innovation programs can also be of assistance to startups by helping them with regulatory issues. The importance to get an innovation verified and approved through all the certifications and regulations was highlighted many times in this study. Also, that regulations in healthcare and the process of receiving all the necessary certifications is often underestimated by startups. Therefore, startups like In Singulo Solutions, which often lack knowledge of healthcare regulations, should seek support from innovation programs.

This study shows that pilot testing is a very good method for verifying a new technology. In addition, a successful pilot test increases the chances of winning a procurement significantly according to the interviewees. The possibility of user observations and the collection of important clinical data also enables important improvements of the tested technology. Shah et al. (2009) argue that it is very beneficial to involve users in the testing and trial stage when developing medical devices. Startups like In Singulo Solutions should pursue the opportunity to conduct pilot tests, and innovation programs can help them get there.

If the innovation programs cannot help the company themselves, the interviewees explained how they can provide them with contacts in healthcare or other organizations. Apart from guiding startups to accelerators and incubators, it can lead to a long-lasting connection with someone in healthcare. Those connections can prove to be crucial for the success of the startup, as both the interviewees and Dhainaut, Blin and Herry (2019) state that they can lead to important insights and guidance as well as clinical testing and verification.

To find the right collaborations is highlighted as one of the most important factors for success in this study. Dhainaut, Blin and Herry (2019) also emphasize the benefits that startups can gain from collaborations. Collaborators can be other organizations or healthcare professionals. Establishing a connection with healthcare professionals can provide great advantages to a startup like In Singulo Solutions. The empirical study shows that it can provide insights on user needs, healthcare expertise and access to clinical testing. According to the interviewees, it is an advantage if a startup know someone in healthcare as it can be difficult to get the opportunity of pilot testing otherwise. Startups like In Singulo Solutions should work to establish collaborators in healthcare, as these factors all contribute significantly to the success of a biotechnology startup in the healthcare industry.

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