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# Assessing and Advancing Startup Potential: A Novel Tool for the unlock_ Startup Incubator

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# Executive Summary

In today's rapidly evolving entrepreneurial landscape, startups represent the birth of new ideas and technologies. However, the harsh reality is that most startups fail within their first few years. Common reasons for failure include inadequate business models, poor management, limited funding, and regulatory challenges.

Due to these challenges, startup incubators have emerged as essential elements in the entrepreneurial ecosystem, offering support, mentorship, and resources to increase startup survival rates. One such incubator is unlock_. Originating at the Leiden Bioscience Park, unlock_ is supporting Leiden's local Life Science and Health entrepreneurs. unlock_ is designed to accelerate MedTech, Biotech, and Pharma startups.

This thesis aims to improve and streamline unlock_'s role in startup progression. The focus is on how unlock_ can better keep track of the struggles of startups and, by doing this, can better help them in different aspects. In addition, unlock_'s incubation program could be adapted to specific findings to make it better tailor-made to the struggles of the participating startups. For this reason, we made a tool to help unlock_ achieve these goals.

**The Tool**

The tool designed in this thesis embodies an essential asset for practical application for unlock_. It provides a structured and quantifiable method to evaluate startups. Its ability to capture multiple dimensions of startup progression, including business readiness, market readiness, regulatory compliance, and clinical validation, allows for an extensive understanding of the startup's journey. Each of these dimensions is broken down into specific deliverables that a startup must achieve as it progresses. The tool's deliverables are assigned scores, creating a numerical representation of the startup's progress. This data-driven approach provides a comprehensive and nuanced understanding of the startup journey.

This thesis is focused on utilizing this newly developed tool as a proof-of-concept to answer the central research question: "What is the effect of the unlock_ incubation program on the growth of the participating startups?" As the tool is designed to capture and quantify the different dimensions of startup progression, it presents an excellent opportunity to investigate the incubation program's impact empirically.

**Research Methodology**

The methodology used for this study involved gathering data through semi-structured interviews with 14 startups participating in the unlock_ incubation program. These startups represented different cohorts -the most recent cohort of the program (2023), alumni from the previous year's program (2022), and participants from the program's first edition in 2021.

For data analysis, a combination of quantitative and qualitative methods was utilized. The custom tool provided a quantifiable measure of progress, represented visually in spider charts. At the

same time, a thematic data analysis offered nuanced insights into the startup's challenges and unique circumstances.

**Key findings**

The study's findings indicated a positive role of the unlock_ incubation program on startup progression, with particular success noted in the MedTech sector. Startups in all subsectors faced regulatory hurdles, where it was visible that for Pharma and Biotech startups, this presented a relatively more significant problem than for MedTech startups.

Differences were also noted across the cohorts, with the 2021 and 2022 cohorts exhibiting higher progress scores across all dimensions compared to the 2023 cohort. However, these findings should be interpreted with potential biases in mind – the varying backgrounds of startups, the different stages at which they joined the unlock_ program, and the challenge of comparing different cohorts.

These findings indicate the effectiveness of this tool and show that it gives a good and easily interpretable view. It also shows that this tool could be utilized for multiple goals, like testing the effectiveness of the programs, measuring the current state of a startup, and keeping track of the startup's progress.

**Conclusions**

Despite the challenges and potential biases, the study illustrates the positive impact of the unlock_ incubation program on participating startups. However, the study also highlights universal challenges faced by startups, regardless of their sector. These challenges include securing funds, navigating complex regulatory landscapes, and building a cohesive team. This highlights the need for unlock_ to enhance its support strategies further.

**Recommendations**

Based on the findings, recommendations include increasing fundraising support, implementing a structured regulatory mentorship program, offering more targeted sector-specific support, and continuously refining the developed tool. Introducing a 'Funding Alert System' and workshops on grant-writing techniques and fundraising strategies could help startups better navigate the fundraising landscape. Similarly, startups could greatly benefit from tailored regulatory navigation support and sector-specific strategies. The tool developed in this study could be crucial in tracking these implementations and assessing their impact on startup progression.

By implementing these recommendations, unlock_ can evolve its program to address the specific challenges of startups and ultimately enhance their chances of survival and success in a competitive landscape. This refined approach can further establish unlock_'s reputation as a leader in the incubator market, having a positive ripple effect on the entire startup ecosystem.

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# Introduction: The Life Science and Health Sector: A Landscape for Startups

Life Science and Health (LSH) companies are essential for improving and safeguarding human life (Burke, 2020). This sector includes pharmaceuticals, biotechnology, medical devices (MedTech), and healthcare services. These companies cover a broad structure, from innovation through scientific research to being able to help patients with this new technology (Team, 2021).

The LSH sector is, based on revenue, the biggest market and industry (IBISWorld, n.d.). In addition, it will possess an even more considerable market potential (MarketWatch, 2023). According to MarketWatch, the global healthcare market size was valued at $2235.15 million in 2021-2022 and is expected to exhibit a compound annual growth rate (CAGR) of 21.92% from 2022-2030, reaching $7342.61 million by 2030 (MarketWatch, 2023). This shows that LSH companies play a crucial role in worldwide economic development, in terms of revenue generation but also through job creation.

Innovation is essential for the LSH sector as a significant driver for societal contribution because the standard of care can constantly be improved, resulting in better health outcomes (Hans, 2023). Startups play a vital role as the drivers for this innovation. They bring new perspectives, flexibility, and a risk-taking mentality, something that established companies can be hesitant about (Jabbar, 2022).

However, despite the high potential for innovation and growth within the LSH sector, building a startup is very challenging. According to an analysis in 2019 conducted by the Focused Ultrasound Foundation consultancy group, startup failure rates for medical startups were around 90%; 21,5% of startups fail in the first year, 30% in the second year, 50% in the fifth year, and 70% by year 10 (Carol, 2022). For startups in medical devices, the failure rate is around 75% (Carol, 2022). This alarming data underlines the relevance of this topic and provides a rationale for this research, which aims to understand and improve the chances of success for startups in the LSH sector.

There are multifold problems that LSH startups face that make entry barriers to this sector high: the strict regulatory environment, long product development timelines, and necessary high-capital investments (Danikovich, 2021). Nevertheless, the opportunities are immense, an aging population, a growing number of chronic diseases, the need for less invasive treatment, and a focus on personalized medicine (Mathur & Sutton, 2017).

To ensure that the potential for innovation does not get lost due to these challenges, we need mechanisms that support startups venturing into the LSH sector. This is the point where startup incubators can play a pivotal role in fostering success in this sector. Startup incubators provide essential resources and services to startups (Bhardwaj, 2023). A Sector-specific incubator like unlock_, an LSH-specific startup incubator in Leiden, brings industry knowledge and meaningful connections, significantly enhancing the chances of success. This study aims to shed light on the role and effectiveness of startup incubators in nurturing and growing LSH startups. Furthermore,

it explores the development of a tool designed to help unlock_ better understand a startup's position in the process of building their company, thus enabling them to offer more targeted and effective assistance. The central question we aim to answer through this research is: "How can unlock_, effectively measure the phase in which a startup is operating?"

In conclusion, the LSH sector is a high-risk, high reward. Startups play a significant role in innovation in this sector, bringing new solutions and improving human health. Even though there are considerable challenges, the journey can lead to remarkable achievements with the proper support mechanisms, like those provided by startup incubators. unlock_ is an LSH-specific startup incubator located in Leiden. In the coming chapter, we dive deeper into what unlock_ is and what they do to support entrepreneurs with promising technologies entering this sector.

# Chapter 1: Company Profile

## 1.1 History, Background, and Services of unlock_

The city of Leiden is well known for its thriving hub for scientific innovation and entrepreneurship. With its famous universities and research institutes, Leiden has fostered a rich academic environment for groundbreaking discoveries and technological advancements (UL, 2020). At the heart of this ecosystem lies the Leiden Bioscience Park (LBSP), an area of hundred and ten hectares of land where universities, research institutes, and companies in the biotech sector converge to foster innovation and collaboration.

### 1.1.1 The Origin of unlock_

An essential player in stimulating the entrepreneurial landscape in Leiden is PLNT, a hotspot for passionate and innovative entrepreneurs. PLNT supports entrepreneurs by providing a community, network opportunities, and office space. In addition, PLNT provides knowledge by offering programs to increase startup success. However, as already mentioned, Leiden is primarily known for its life science and health landscape. PLNT did not offer programs and guidance for entrepreneurs in this sector. Building a biotech/pharmaceutical company is highly complex, especially for scientists needing more fundamental business knowledge. To overcome this problem and facilitate the growth of LSH startups, the LBSP Foundation, in partnership with PLNT and several other independent parties in the Leiden bioscience park, developed a specific trajectory for LSH entrepreneurs. In 2019, they came together and successfully applied to the province of South Holland for a grant to support the development of specific programs for early-stage life science & biotech entrepreneurs.

This grant led to the birth of "unlock_ the life science incubator," a project that, while appearing to be an independent organization, was closely tied to PLNT and the LBSP Foundation and operated under the supervision of director Stefan Ellenbroek. With its own branding and positioning, this initiative works on the principle of strengthening what is already there, providing resources where needed, and fostering connections where necessary. It supports and invigorates

the entrepreneurial activity in Leiden's life science and biotechnology sector, marking an essential advancement in the city's entrepreneurial landscape.

### 1.1.2 Mission & Vision unlock_

The mission statement of unlock_ is to support any startup with the potential to make a valuable contribution to a healthier future for humanity. Life Sciences and Health sector startups are working on solutions that contribute to a healthier future that significantly impact our well-being. unlock_ is the key for these startups to access the top Life Science ecosystem in the Netherlands. As the entry point for the LBSP, unlock_ offers the necessary resources and guidance for these entrepreneurs to turn innovative ideas into impactful solutions.

The vision of unlock_ is that entrepreneurs daring enough to think they can make humanity healthier are the ones who do. At unlock_, entrepreneurship is essential for developing the Life Science and Health sector. unlock_ plays a supportive role in the developmental journey of entrepreneurs, providing them with the guidance and resources they need to avoid potential pitfalls and successfully navigate the challenges of the startup world. This way, unlock_ increases the chances of success for startups at the LBSP.

### 1.1.3 unlock_'s Support Trajectory

unlock_ supports startups in different phases with programs and events. The first phase is the so-called activation phase, which focuses on raising awareness and enthusiasm about entrepreneurship and making LSH students and scientists aware that entrepreneurship is a valid career option for everyone with a great idea. In this phase, unlock_, in close partnership with PLNT Leiden, delivers introductory modules and activities on entrepreneurship in studies from the Leiden University and the Leiden University Medical Centre.

The second phase is the pre-incubation phase. The role of unlock_ in the pre-incubation phase is an add-on to the pre-incubation program (Venture Academy) of PLNT. The Venture Academy supports students, researchers, and entrepreneurs during the validation process of their business idea. This support is given through lectures and mentorships by experienced entrepreneurs. During the four months of the Venture Academy, participants are taken along two tracks. The main track supports the participants in building teams, making business decisions, and customer validation. For Life Science, Health, and biotechnology startups, unlock_ supports these startups on essential topics for this specific sector. The main topics covered are IP & brand protection, finance & investment, and balance and budgets. The end goal of the Venture Academy is that the participants have taken the first steps toward becoming an entrepreneur and getting ready for their first round of investment of up to €70.000-.

After the pre-incubation phase comes the incubation phase, it is the main product of unlock_, as it is a 12-month program that is only accessible to Life Science, Health & Biotechnology startups. This incubation program is designed to help overcome the many challenges that Life Science and Health and Biotechnology startups will face in the early phases of building their venture. The program is based on the Healthcare Innovation Cycle, a scientific guidance model for Life Science

and Biotech entrepreneurs (GAITS, n.d.). The goal of the incubation program is to get the participants ready to get investors. The incubation program is divided into two parts:

1. In the onboarding phase (3 months), the startup will follow interactive sessions focused on improving their business structure, making them ready to talk to investors, and learning soft skills like negotiation and pitching.
2. In the tailor-made phase (9 months), the program will be designed to the specific needs of the startups. These nine months include tailored advice, coaching, mentoring, and master classes.

The final phase in which unlock_ provides programs is the acceleration phase. This phase is customized and entirely dependent on the unique needs of a startup at its specific stage of development, resulting in no fixed program structure. Even though every startup has different needs in this phase, at unlock_, companies learn a lot from each other. That is why unlock_ also give some group programs, like the market access and reimbursement program. At the market access and reimbursement program, the startups get insights into creating a market access strategy and finding a reimbursement strategy for their target market.

## 1.2 Culture & structure of unlock_

unlock_ is a relatively new brand and an organization driven by ambition and a strong desire to establish a distinct identity. The culture within the company is a synergy between scientific research and entrepreneurial spirit. unlock_ believes that LSH inventions are created in the laboratory but that a commercial driver is needed to bring these innovations to the people.

At the core of the culture of unlock_ are the characteristics of a market culture, where the organization is oriented towards product development and outwardly focused. In addition to the market culture, unlock_ aspires to foster a brand culture in which the organization makes the vision and brand promise central to actions and external positioning. This organizational culture thrives on inventiveness, innovative leadership, the freedom to experiment, and a flexible work environment. unlock_ understands that fostering a creative and adaptive mindset is essential for driving innovation and staying ahead in the rapidly evolving Life Science and Health sector. On the Competing Values Culture Model proposed by Cameron and Quinn (1999), unlock_ will position itself at the right middle of the matrix (Fig. 1).

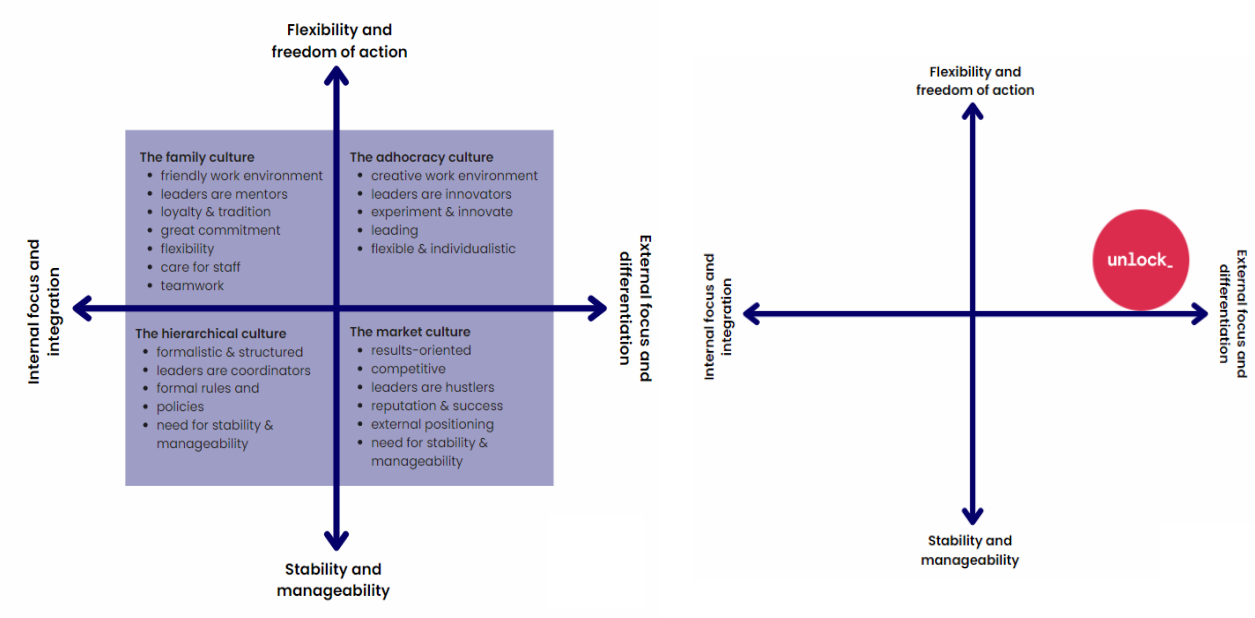


**Figure 1: Cameron & Quinn Competing Values Culture Model, and unlock_'s position in this model.** Figure made by Fieke Koelemij.

At unlock_ continuous learning and development are integral to the culture. The company invests in training programs and workshops to enhance the skills and knowledge of its employees. unlock_ creates a dynamic and forward-thinking work environment by focusing on personal and professional growth. There is an evident inclusive culture that stimulates autonomy and gives room/space to take the initiative and share ideas, also for interns.

The same corresponds to the organizational structure of unlock_, a flat organizational hierarchy that promotes open communication and collaboration. This horizontal structure fosters collective responsibility among the employees. Moreover, unlock_ fosters leadership at all levels of the organization.

## 1.3 SWOT analysis unlock_'s position in the market

A SWOT analysis is performed to understand better the position unlock_ takes in the market of startup incubators in the Netherlands (Fig. 2.).

unlock_ has multiple strengths, making it a valid player in the Dutch startup incubator market. One of its key strengths is that unlock_ focuses entirely on innovative entrepreneurship in the Life Science & Health and Biotechnology sectors. unlock_ differentiates itself from traditional incubators like Utrecht Inc. and YesDelft! by emphasizing specific vital topics for entrepreneurs in this sector, such as regulatory compliance, market access, and financing through (non-) dilutive funds. While Utrect Inc. also addresses these topics, unlock_'s approach is more specialized and focused on addressing these topics in an earlier stage of the startup (UtrechtInc, 2020).

Another necessary strength of unlock_ is the strategic location within the Netherlands. Leiden is a hotspot of scientific discoveries and innovation in the Netherlands and Europe, with its famous

Leiden Bioscience Park. This location provides more than geographic benefits; it immerses unlock_ in a community of successful LSH entrepreneurs eager to mentor new startups and give back to the next generation. This community results in extensive and intensive mentorships for unlock's startups. Thus, unlock_'s location is not only a physical place but a strategic advantage for LSH startups that combine local innovation, LSH community mentoring, and academic collaboration to support the successful development of LSH startups.

However, unlock_ needs to address some weaknesses to solidify its position in the market. unlock_ is a relatively new organization that challenges gaining market recognition and brand awareness. This brings especially challenges for attracting LSH entrepreneurs from outside of Leiden. The lack of visibility could limit the attraction of top-tier LSH startups/Biotech startups. Additionally, unlock_ has limited financial resources compared to more established incubators. Some incubators can attract startups by offering specific seed funding, which could make starting entrepreneurs more inclined to choose one of these competitors.

unlock_ must also be aware of the potential threats. At this moment, unlock_ entirely depends on funding/donations from the LBSP foundation. unlock_'s position would become insecure when this funding stopped. unlock_ would benefit from generating the money (e.g., by offering programs in exchange for equity or a contribution). Furthermore, as already mentioned, there are a lot of competing incubators in and outside of the Netherlands. unlock_ needs to keep track of competition by keeping them in their vision.

Nevertheless, the environment in which unlock_ operates has many opportunities. The LSH/biotech sector, especially Leiden, is rapidly growing in the Netherlands. Furthermore, partners of unlock_ like, the municipality of Leiden, Libertatis Ergo Holding BV (LEH), and Entrepreneurs Association Bio Science Park (OVBSP) actively support the startup ecosystem. unlock_ is already, and can in the future, keep leveraging these opportunities to secure additional funding and strengthen its position.

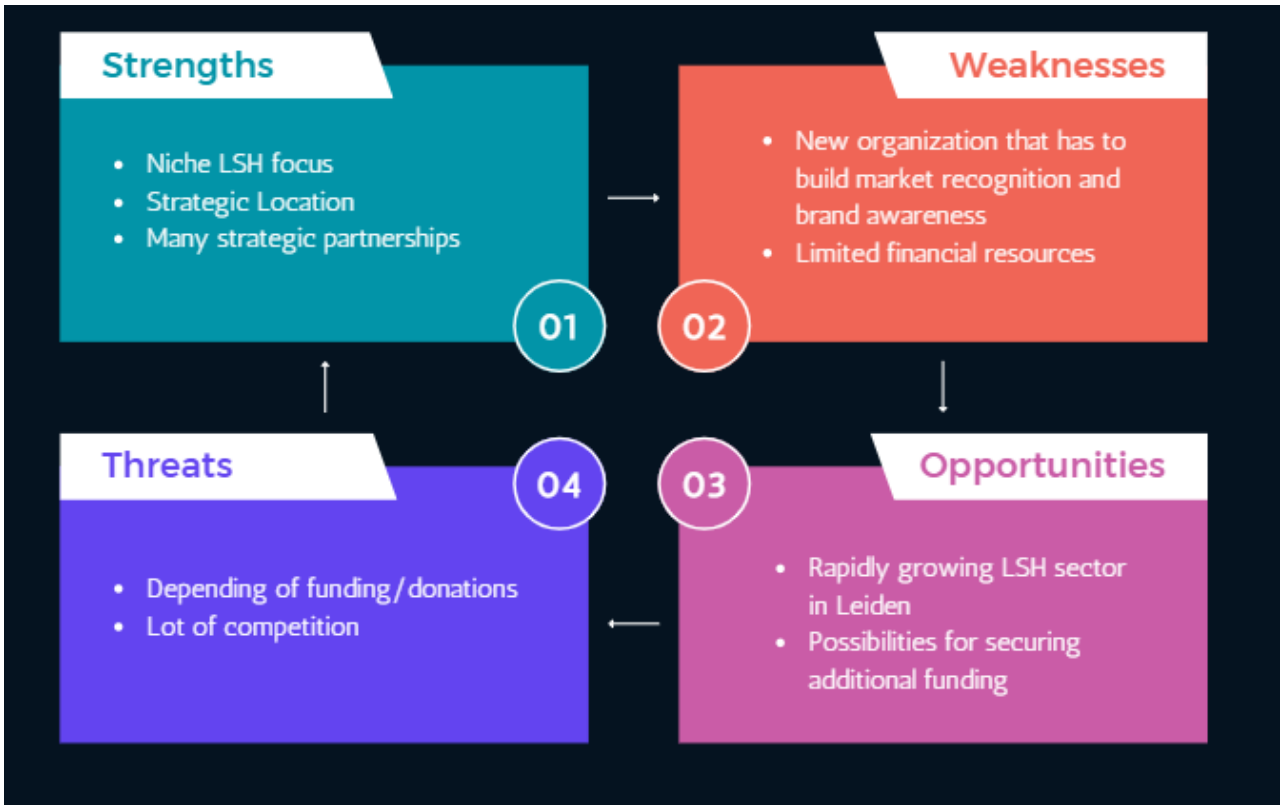


**Figure 2: SWOT analysis on the position of unlock_ in the startup incubator market.Source:** Authors own illustration.

## 1.4 Competitive landscape

Understanding the competitive landscape is crucial for strategic planning and positioning. We will do a comprehensive analysis of the competitive landscape of the LSH startup incubators, focusing on the market in the Netherlands and the broader context of the world.

Our competitive landscape analysis focuses on LSH specialization, network, and partnerships (Figure 3). The LSH specialization aligns with unlock_'s niche and identifies how our focus compares to competitors. Networks and partnerships gauge unlock_'s ability to foster connections, which is vital for startup growth and industry recognition. The criteria not only mirror unlock_'s strategy but help navigate unlock_ towards becoming a leading LSH incubator in the world.

In the context of the Dutch market, unlock_ establishes a formidable position with its unique niche specialization in the LSH sector (Figure 3, The Netherlands). The most direct competitors within the local landscape appear to be UtrechtInc and Yes!Delft. Although relatively new in the incubator scene, unlock_ showcases a competitive level of LSH specialization and network reach compared to these established entities.

On a global scale, unlock_ is charting its course among several strong and experienced players (Figure 3, Worldwide). Nevertheless, unlock_ shows a significant degree of LSH specialization similar to its international counterparts. It is lagging in terms of network and partnerships. This

might be attributed to its comparatively shorter operational history and current stage of brand visibility. The analysis suggests that unlock_ could further enhance its global positioning by investing in strategies to expand its network and partnerships, such as boosting publicity and engaging more actively in the global LSH community.

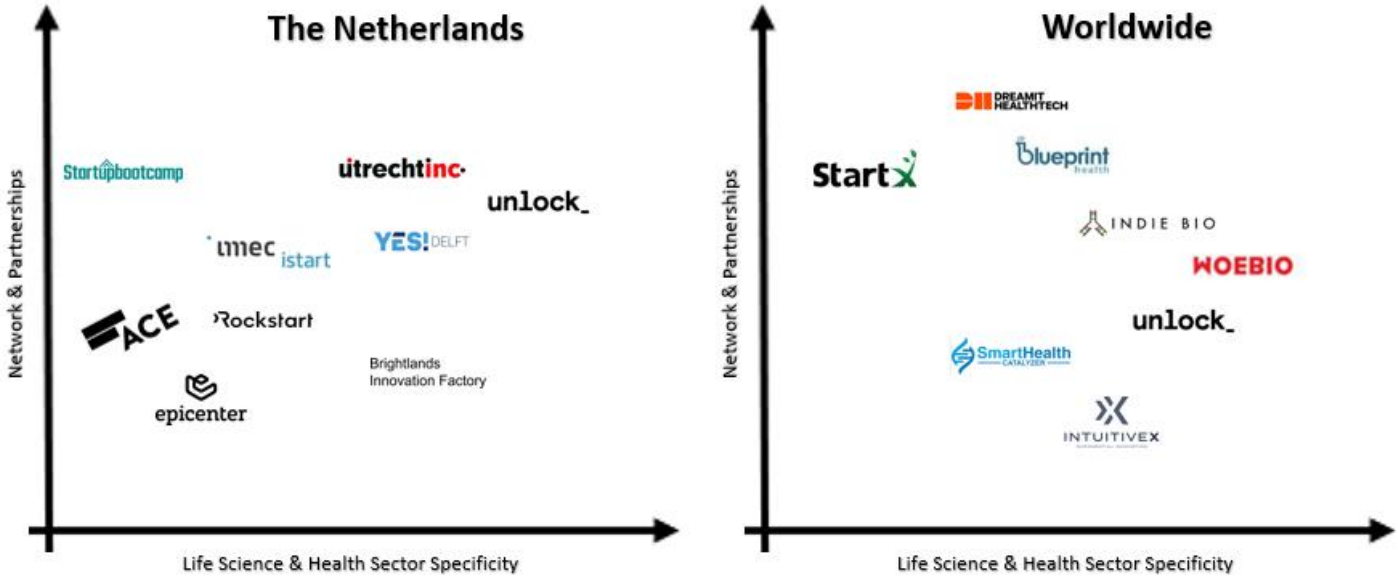


**Figure 3: Competitive Landscape of unlock_ Compared to Dutch and Global Incubators**. This figure presents two matrices demonstrating the positioning of unlock_ compared to other LSH startup incubators in the Netherlands (left) and worldwide (right). Left Matrix: Dutch Incubators: Startupbootcamp (Amsterdam), ACE (Amsterdam), Epicenter (Amsterdam), Imec.istart (Overijssel), Rockstart (Amsterdam), Yes!Delft (Delft), UtrechtInc (Utrecht), Brightlands Innovation Factory (Sittard), unlock_ (Leiden). Right Matric competing competitors around the world: StartX (USA, Palo Alto, CA), Blueprint Health (USA, New York), InuitiveX (USA, Bellevue, WA), Dreamit Healthtech (USA, Philadelphia, PA & Tampa, FL), SmartHealth Catalyzer (India, Hyderabad), IndieBio (USA, San Francisco, CA), Moebio (Spain, Barcelona), unlock_ (Leiden). Source: Author's own illustration, based on data from (Incubator List, 2023).

The competitive landscape analysis provides a comprehensive overview of unlock_'s positioning in the market, both within the Netherlands and globally. It is evident from this examination that unlock_ has carved out a strong niche for itself in the LSH sector. Its key strengths are its high degree of LSH specialization and an impressive network and partnerships for a company of its age. However, the comparison with global incubators suggests that unlock_ might benefit from broadening its horizons and establishing partnerships at the international level, assuming that such expansion aligns with the company's capabilities and strategic objectives

Now we have delved deep into unlock_ as a company, we will continue diving deeper into some practical problems that unlock_ is currently facing. Solving these problems results in a more effective incubator and, eventually, a better position in the market.

# Chapter 2: Problem definition, diagnosis, and proposed solution

In the Netherlands, a country shaped by innovation and entrepreneurial determination, startup incubators are central to the evolution of critical industries (Hisham, 2018). Particularly in sectors as complicated as Life Science, Health, and Biotechnology, the role of these incubators is significant (Holzwarth, 2019) . This is so that scientists, who may have little knowledge of setting up a company, are stimulated and supported to realize their discovered technologies so that society can benefit from this (Holzwarth, 2019). unlock_ jumps into this need by providing an ecosystem of expert coaching, mentorships, specially designed programs, and an extensive network to help new entrepreneurs.

However, even with this comprehensive support system, the diversity of startups in the program makes it difficult to adapt the material to every startup. As observed by unlock_, startups and entrepreneurs differ in structure, goals, and development phases. This heterogeneity complicates making programs useful for all participating startups and tracking their progress. The challenges manifest in multiple ways. First, unlock_ needs help to identify which specific milestones each startup has already achieved in its trajectory, thus making it challenging to provide the appropriate support required at different developmental stages.

Furthermore, although generally positive, the incubation program's impact is not easily quantifiable due to the absence of easy progress tracking. This situation could limit the program's iteration and optimization to stimulate the startups' maximum potential. Finally, the intake process for new startups also poses some challenges. Currently, the intake is done with selection days. However, from these selection days, unlock_ gets limited information about the startups, which needs to be more representative. In addition, the current way of information extraction (cost-benefit technical) is too intensive for a selection process. unlock_ needs a more rigorous methodology to understand each startup's needs fully. A better methodology can also ensure that startups that may be too early or too in the process can be identified, so they can be told they are not the right fit for our incubation program.

The problems are determined from a series of observations within unlock_. Moreover, evaluating the impact of the incubation program on the startups proved challenging due to the diversity. A measurement tool must make assessing the specific effects of the incubation program in general and for each startup easier. In addition, it limits the ability to unlock_ to iterate and optimize its program to get the unlock_ team's maximum potential and the startups.

In light of these identified problems, the core focus of this thesis is to seek a solution to these problems. The first question we aimed to answer is: "How can unlock_ effectively measure the phase in which a startup is operating." In our quest to answer this question, we have designed a tool based on the Healthcare and Innovation cycle principles, a system to measure the progression of health technology and inventions, but wholly customized to the needs of unlock_. This tool consists of a series of deliverables that give a good view of the fundamental steps startups should

typically navigate through at different growth phases (see Appendix). This tool should offer a multi-faceted solution for the struggles mentioned above.

The effectiveness of this tool will not be solely based on literature but will be tested carefully and adapted based on the insights gathered. This testing will be aligned with an important question that unlock_ has and the main research question and the thread of this thesis: "What is the effect of the unlock_ incubation program on the growth of the participating startups?" This testing will involve doing measurements with the tool, collecting data, analyzing the results, and then using these findings to refine the tool. This iterative process aims to ensure that the tool fits the needs of unlock_ as closely as possible.

Data for this research will be collected through in-depth interviews. The founders of the startups will be asked a series of questions that are focused on four main dimensions:

1. Business: These questions aim to get insight into how far they are with their business models, looking into aspects such as their stakeholders, their revenue model, competitors, etc.
2. Market: These questions explore the startups' understanding of their market landscape, unique selling propositions, etc.
3. Regulatory: This topic is crucial for Life Science and Health and Biotech startups, even in an early phase. With these questions, we delve into areas like patents, whether they have the freedom to operate, the regulatory landscape, etc.
4. Clinical: Here, we will ask them about elements like prototype/product development, minimum viable product, proof-of-concept studies, clinical trials, etc.

These four categories are the four pillars of the Healthcare Innovation Cycle and are critical for increasing the change in startup success (GAITS, n.d.).

The interview data will be put into the developed tool for further analysis and visualization. The outputs of this tool will be presented in the form of a spider chart. This chart will provide a clear visual representation of the startups' strengths and weaknesses that can indicate potential threats to their current or future state. This gives an enabling view and understanding of the startup's standing.

The data will be collected from three groups. The first group consists of startups recently started the incubation program (cohort 2023), serving as a zero measurement. The second group consists of the alumni of the incubation program from the 2022 cohort, and the third group is the alumni from the 2021 cohort, providing insights into the program's impact on their growth. This is a biased approach because, ideally, it would be less biased to measure the growth of startups before and after the incubation program. However, this is not possible due to the time constraints of this research. Nevertheless, this 'less biased' approach will be implemented in future research but outside the scope of this thesis.

The obtained data will be handed out to unlock_, with recommendations based on the findings. If the data suggests that, in general, startups are overlooking crucial steps, the recommendations will be focused on how these gaps can be filled within the incubation program. In addition, every startup will receive its results through a spider chart and tailor-made recommendations, allowing them to work on their weaknesses.

# Chapter 3: Theoretical Insights into the Role of Incubation in startup progression

In the intricate world of startups, the route to success is strewn with various influencing factors that either facilitate growth or pose challenges. This chapter delves into these significant elements, such as the entrepreneur's characteristics, the robustness of the business model, team dynamics, the competitive landscape, and the regulatory environment. As each facet contributes uniquely to a startup's journey, understanding them is crucial in informing adequate startup support and incubation strategies.

However, this theoretical exploration serves a dual purpose. It provides a basis for understanding where startups operate and lays the groundwork for developing the tool described in the previous chapter. This tool, which will be detailed later in this thesis, leverages the insights derived from these areas of study to help startups by measuring and understanding the current phase in which they find themselves.

It is essential to have this knowledge when conducting in-depth interviews about elements like Intellectual Property, regulatory pathways, business models, teams, and funding. Moreover, interpreting the deliverables that the tool is based on requires understanding these topics.

The academic research and real-world case studies that follow serve as the theoretical backbone for the tool we are developing. They provide the necessary depth and context, enabling us to create an effective and meaningful tool for unlock_.

## 3.1 Factors Influencing Startup Success

The goal of our tool is to create metrics that we can use to find out what our participating startups need to increase their chance of success. However, that raises the question: "Which factors influence startup Success,  and how can unlock_ use these success factors in our programs and coaching?".

Startup success can be defined in various ways, like profitability, growth, customer acquisition, and user engagement (FasterCapital, 2023). In the world of entrepreneurship, research, and debate are ongoing. A few key factors that regularly come back in literature are the founding team, the business model, product-market fit, funding, and execution ((Cuofano & Cuofano, 2022; AIContentfy, 2023).

### 3.1.1 The Founding Team

The characteristics of the founders are essential for the success or failure of the startup. Research has shown that personal qualities, (industry) experience, and education impact the startup's performance. One of these researches, performed by Unger et al., found a correlation between a founder's level of education and their experience in a specific industry and their entrepreneurial success (Unger *et al.*, 2011). The higher chance of success is due to the better-informed decisions they can make, leading to better outcomes for their startup. In addition, personal attributes like leadership ability, resilience, adaptability, and risk-taking propensity can influence the trajectory of a startup ( Rauch & Frese, 2007). This shows that how a founder is psychologically wired impacts the success of a new venture.

In addition to the founders, the broader team can also play a pivotal role in the success of a startup. Multiple pieces of research, for example, the one conducted by Der Foo et al., showed that functional diversity results in complementary expertise for the startup. When combined, complementary skills become more valuable than individual skills when a shared goal needs to be accomplished (Der Foo *et al.*, 2005). Additionally, a good balance between technical and business expertise is necessary to execute its business plan and handle complex operations. When there is an imbalance, this can cause problems because the team is most likely on a different line (Der Foo *et al.*, 2005). This research shows that building a competent, diverse, cooperative team is critical for startup success and established companies.

### 3.1.2 The Business Model

A business model is a critical element that can influence the success or failure of a startup. A business model is the foundation of how a company creates, delivers, outlines how the company operates and generates revenue (Ovans, 2015).

For multiple reasons, understanding and defining a startup's business model is an essential part of the company's existence (Ovans, 2015):

1. It provides a blueprint on how a company should function, guides decision-making, and determines which resources are needed for executing the plan.
2. A transparent business model helps stakeholders, which includes investors, partners, and customers, to understand what the company can offer each of them. This clarity will also help in attracting investments and fostering partnerships.
3. A business model can help align all parts (stakeholders and actions) toward a common objective, fostering collaboration and ensuring efficiency.

There are many types of business models. For instance, a Software as a Service (SaaS) company, like Microsoft (Office 365), operates on a subscription model where users pay to get access to their services (Patrizio, 2023). Another business model could be a sharing economy model. A well-known example of this is Uber, which connects service providers (the drivers) with customers who need the service and earns revenue through commissions (Ritter & Schanz, 2019). Biotech companies are often built around an innovation model where revenue is generated by developing

and commercializing innovative products and solutions (Murphy, 2022). For LSH startups, a transparent business model is even more crucial, given the sector's complexity, high costs, and regulatory environment (Conrad *et al*., 2019). As an example, consider a biotech startup developing a novel cancer drug. The business model must clearly outline its value proposition (the drug), customer segments (hospitals, doctors, patients), key activities (drug development, clinical trials, regulatory compliance), and revenue streams (sales, licensing deals, partnerships). If these elements are aligned, the startup could be able to get investment and eventually successfully commercialize the drug.

A compelling case illustrating the importance of a robust business model in the LSH sector comes from the example of Galapagos. This company managed to enter the market successfully, not solely based on the quality of its products, but mainly due to its robust business model. This, and many more similar cases like Galapagos in the LSH sector, emphasized that a well-structured business model can often enable market entry, even before developing a top-quality product. This shows that a robust business model can outweigh even the quality of a product (Taylor, 2021).

In conclusion, understanding and developing a robust business model is vital to a startup's success and pivotal in determining market entry. Therefore, investing time and resources is necessary to establish a solid business model.

### 3.1.3 Product-Market Fit

The market potential for a startup's product or service significantly influences its chance of success. When a startup operates in a large and growing market with many unmet needs, they have a higher chance of succeeding (Gruber *et al.*, 2015). Market potential refers to the total demand for a product or service within a particular market. It estimates the maximum sales a company could make to secure 100% market share (MasterClass, 2022). A good evaluation of the market potential is crucial for startups as it helps estimate the target audience's size. In addition, startups that offer innovative products or services that address unmet needs in the market often have greater chances of succeeding. This is especially the case in sectors where innovation is the core of the business strategy, like the LSH sector.

The interplay between market potential and fulfilling unmet needs is at the core of achieving a good product-market fit. Product-market fit is the degree to which a product satisfies strong market demand (Viggars, 2023). Startups that identify an unmet need in the market and create an innovative solution, most of the time, are the ones to achieve this fit (Viggars, 2023).

An excellent example of a successful product-market fit is Flatiron Health. This health tech startup was founded in 2012 and identified that researchers and physicians needed a unified oncology data collection and analysis system. Their platform provided a solution that transforms clinical data into valuable insights, exactly filling the need of their market. Their successful product-market fit led to the acquisition by Roche for $1.9 billion (Herper, 2018).

A startup that failed to find this product market fit is Proteus Digital Health. They developed novel sensor technology for medication adherence, got substantial funding, and got FDA approval.

However, the company did not convince patients, physicians, and insurance of the value their technology delivers. This led to eventually to their bankruptcy in 2020 (Landi, 2020).

These examples show that finding the product-market fit is crucial for startup success and can mean the difference between a billion-dollar company and bankruptcy. This factor should be central to any startup strategy, especially in the world of LSH.

### 3.1.4 Funding

Funding, together with the financial management of the company, are often cited as critical components of startup success. Funding makes it possible for startups to invest in product development, hiring employees, and all the other necessities. Multiple studies confirm that funding is essential for startups. A report by CB Insights (2022) shows that 47% of the startups that failed startups in 2022 resulted from a lack of financing (Hunt, 2023).

High burn rates, where expenses exceed but no new money comes in, can often lead to financial distress. A report by Startup Genome (2022) shows that premature scaling, over-hiring, excessive marketing, and over-optimistic resource allocation are the leading causes of the high burn rates (Startup Genome report, 2023). Startups can prevent financial distress and high burn rates through strategic planning by regularly reviewing and adjusting financial plans in response to changing conditions (Hunt, 2023; Startup Genome report, 2023). Startups, especially in high-risk, high-reward sectors like the LSH sector, often require substantial upfront investments before generating revenue. For these startups, sound financial management is even more critical (Hunt, 2023).

Financial management involves budgeting, cash flow management, financial forecasting, and overall financial planning (Sajjan, 2022). Davila et al. (2003) showed that implementing financial controls positively impacted companies' survival and growth. The study notes that startups implementing financial controls early in the process have a 129% higher valuation in subsequent financing rounds than startups that did not (Davila *et al.*, 2003).

In conclusion, funding is unmissable for a startup to function. However, the burn rates can be manageable with proper financial management control.

### 3.1.5 Execution

A startup can have a great team, product, business model, and much funding, but without the correct and effective execution, it may still fail. Effective execution involves efficiency, adaptability, problem-solving, and resilience (Carmo, 2023).

Because startups usually operate in rapidly changing environments, a crucial part of execution is the ability of the startup to adapt to changes (Carmo, 2023). It is not a wonder that in the entrepreneurial world, the word and concept of 'pivot,' proposed by Blank (2013) in the Lean Startup methodology, is frequently used. Blank encourages the rapid and flexibility of their business model based on market feedback (Blank, 2013).

An example of perfect execution is the company Zipline. This startup started with consumer drone delivery but pivoted its business model to deliver blood and medical supplies because it saw a higher demand and more significant social impact. The flexibility of Zipline is the reason for its success, making it possible for them to become a $1.2 billion valued company (Fortune, 2023).

Moreover, startups face many challenges, and their ability to overcome them is essential for execution. These challenges could be development issues, stakeholder complaints, regulatory hurdles, or internal conflicts. Startups need to have problem-solving abilities to overcome these unavoidable setbacks (Carmo, 2023).

Finally, an underestimated part of execution is consistency. Consistency is maintaining quality and staying true to the company's mission and values. Inconsistency can damage the reputation and trust that the startup has built up (Carmo, 2023).

While the success factors outlined – the founding team, business model, product-market fit, funding, and execution – play a significant role in promoting a robust and healthy startup, they also represent potential pitfalls. Startups may fail if they show weaknesses in any of these crucial areas. Research has shown that a malfunction in these areas are the most common reasons for startup failure (Figure 4) (McCharty, 2017). Therefore, it's crucial for a startup to strive for excellence in these aspects, constantly evaluate their performance, and make necessary adjustments along the way.

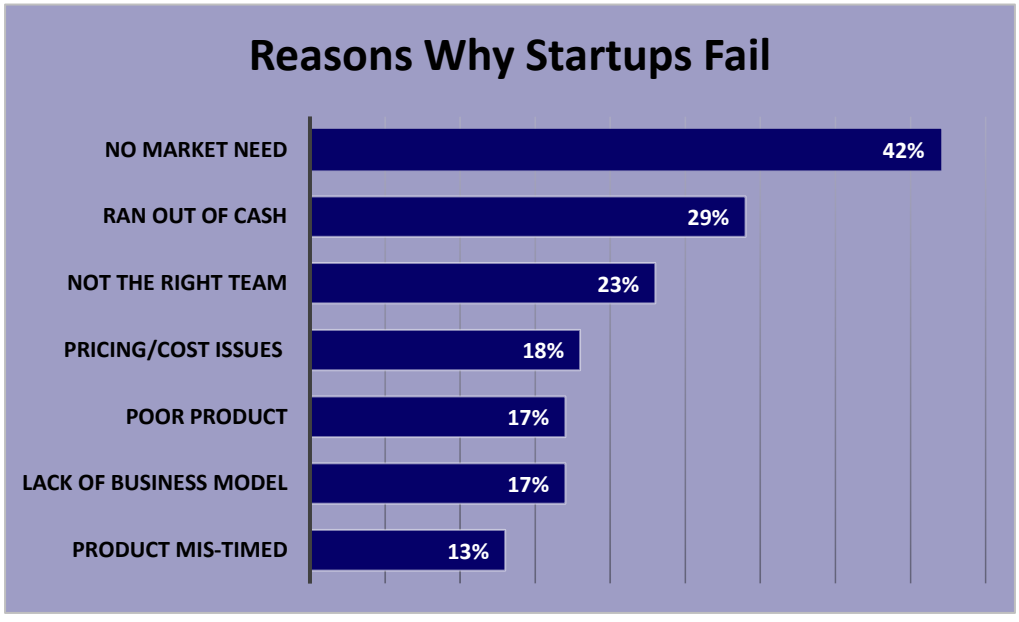


**Figure 4: Reasons Why Startups Fail** - This graph presents the most common reasons for startup failures, expressed as a percentage of total cases studied. Note, the percentages may not sum to 100% as some startups may have cited multiple reasons for their failure . Author's illustration, based on data from (McCharty, 2017).

In conclusion, the road from a startup to success is multifaceted and complex. The founding team, business model, product-market fit, funding, and effective execution are core components that

influence the success of a startup. The interplay of these factors shapes the resilience and adaptability of a startup and can make them unique in its competitive landscape. However, in the LSH sector, more elements are needed to guarantee success. The regulatory environment is a crucial aspect that impacts the trajectory of LSH startups.

## 3.2 LSH Regulatory Environment

The regulatory landscape in the LSH is complex and diverse. This is due to the numerous local, national, and international laws and guidelines. The regulatory landscape exists out of multiple regulatory entities with which startups must comply (FDA, 2018; EMA, 2021).

### 3.2.1 The regulatory landscape

The regulatory landscape is not uniform and can differ across countries and continents. This heterogeneity presents both challenges and opportunities for LSH startups.

For instance, the Food and Drug Administration (FDA) in the USA is known for its strict and comprehensive approach to controlling the safety and efficacy of medical products. When a startup wants a product to enter the US market, it must navigate the complex FDA approval process. This includes pre-clinical testing, a series of clinical trials, and a detailed review of the product's safety, efficacy, and manufacturing process. In addition, if the product is a drug, the startup must negotiate the pricing (FDA, 2018).

In Europe, the European Medicines Agency (EMA) does regulatory approval for drugs. The EMA follows a somewhat different process than the FDA. Even though the standards for safety and efficacy are the same as the FDA, the procedure of the EMA is more streamlined. Unlike the FDA, which takes on all aspects of regulation, the EMA delegates certain responsibilities to Notified Bodies- independent organizations appointed to assess the conformity of certain products before being placed on the EU market (EUC, 2023). The EMA’s central procedures enable companies to submit a single application, which is valid across all EU countries. However, the pricing and reimbursement are handled nationally. Companies must negotiate these points with every country's healthcare system (EMA, 2021).

In Asia, this regulatory landscape is very complex (Tongia, 2018). This is because there are many different regulatory agencies. For example, the China National Medical Products Administration, Japan's Pharmaceuticals and Medical Devices Agency, and Singapore's Health Sciences Authority exist (Tongia, 2018). There is variation between the regulations of these agencies. Startups that want to operate in the Asian market must deeply understand each market's regulatory environment.

In addition to these regulatory bodies, each country has its regulatory agencies (ASM, 2022). Startups must understand the regulatory landscape of each market they plan to enter. In the Netherlands, the Medicines Evaluation Board (MEB) is the regulatory entity that evaluates and monitors human and veterinary medical products (Ministerie van Volksgezondheid, 2019).

Each product's regulations differ, and the landscape varies depending on its specific subsector.

**Biotechnology**

Biotechnology companies, which often develop innovative drugs or treatments based on living organisms, face strict regulations throughout development (Ladakis *et al.*, 2020). Startups in this subsector must comply with Good Laboratory Practice (GLP) during the pre-clinical research and Good Clinical Practice (GCP) during the clinical trials. This is to ensure the safety, quality, and integrity of the research (FDA, 2021).

**Medical technology**

In the United States, the FDA categorizes medical devices into three classes based on risk. Class I devices face the least regulatory constrictions. Examples of Class I medical devices are surgical masks or stethoscopes. Class II medical devices have more regulatory scrutiny than Class I. Class II medical devices could be catheters, pregnancy tests, and syringes. Class III medical devices usually sustain or support life, are for internal use, and by doing this, present a potential risk for illness or injury. These medical devices must comply with strict regulations. Pacemakers and implanted prosthetics are examples of Class III medical devices (FDA, 2017).

In Europe, devices must meet the Medical Device Regulation (MDR) criteria. As part of this, medical devices must obtain Conformité Européenne (CE) marking. A CE mark shows that the devices are healthy, safe, and environmentally friendly and can be sold in the European Economic Area (EMA, 2023).

**Pharmaceutical**

Pharmaceutical companies have to navigate through a complex labyrinth of regulations. The FDA and the EMA closely monitor these regulations. Similar to biotechnology products, pharmaceutical products must adhere to GLP and GCP during pre-clinical and clinical stages. However, they face additional regulations on the manufacturing process. They must comply with Good Manufacturing Practices (GMP) to ensure consistent quality (FDA, 2021).

**Digital Health**

Digital health companies like smartwatches, blood pressure monitors, and sleep trackers face a different regulatory landscape than the subsectors above. The regulatory pathways are less clear because this is a relatively new subsector. Companies that want to go to market with a digital health product have to work closely with regulators to find the appropriate standards for their technology. The FDA has opened a Digital Health Center to guide startups that operate in this subsector (FDA, 2023).

In conclusion, the regulatory landscape in the LSH sector is one of the biggest challenges for startups due to the varying requirements depending on geographical location and subsector. Navigating these regulations can significantly increase a startup's value and reduce risk. A good, well-thought strategy early on can help with this.

### 3.2.2 Regulatory Strategy

For an excellent regulatory strategy, the startup needs to get a clear understanding of the classification of the subsector it is going to operate. The initial classification is crucial because each subsector has unique regulatory requirements, as described above. The next step is to determine which geographical market the startup wants to operate (initially). By doing this, a startup can filter the bulk of information and focus on the requirements of a single regulatory entity (ProPharma, 2020).

In addition to defining an appropriate regulatory pathway, there are several strategies LSH startups can employ to increase their chances of success.

**Targeting Regulatory Jurisdictions**

It could be beneficial to target regulatory approval in one jurisdiction first. For example, some companies aim for FDA approval before EMA approval. This is due to the global recognition of the FDA. This could lead to accelerated procedures at other authorities, such as the EMA. Startups could also focus on markets where they expect the highest demand or fastest approval (RAPS, 2022).

**Early and continued engagement with regulatory authorities**

Regular meetings provide opportunities for clarifying ambiguities, discussing issues, and receiving feedback on proposed plans. In addition, it can foster relationships that benefit the approval process (ProPharma, 2020).

**Regulatory Flexibilities**

A startup can build its technology/product around an addressed unmet medical need or apply it to a rare disease. Sometimes for these cases, regulatory flexibilities are available. This could result in priority review designations and accelerated approval pathways (Sainz *et al.*, 2015). Utilizing these flexibilities can accelerate the approval process and bring the product to the market quicker.

In conclusion, a good strategy can significantly increase the time before market entry. However, regulatory navigation is a piece of the puzzle. In the next part, we go deeper into another crucial component of LSH startup navigation toward a successful company: Intellectual Property (IP) management.

## 3.3 Intellectual Property Management

IP is one of the most valuable assets a startup can have. IP rights provide a competitive advantage and improve the startup's chances of attracting investors (Roy, 2013).

### 3.3.1 The Importance of Intellectual Property for Startups

Securing IP rights gives a startup a monopoly over its innovation, enabling them to exclude others from using it (Roy, 2013). This competitive advantage is one of many reasons IP is necessary for a startup. Having the IP of a particular innovation makes startups significantly more appealing to

investors, particularly venture capitalists, who favor startups with protected IP portfolios (WIPO, n.d.). This is because protected IP assures that the startup has exclusive rights to use the innovation, but also because a patent can validate the novelty and potential utility.

Especially in the LSH sector, IP is even more important due to the nature of the industry (Krauss *et al*., 2021). LSH startups typically are based on scientific discoveries and innovations that often can be patentable. Due to the long time before market entry and the high investments, robust IP protection is essential (Krauss *et al*., 2021). Otherwise, the return on these investments can easily be eroded by (larger) competitors. For LSH startups, it is essential to have a solid IP strategy, not only because it is beneficial but also because it is critical for survival and success.

The importance of IP underscores why startups must understand the different types of IP and develop a strategy that is in line with their business goals.

### 3.3.2 Types of Intellectual Property

**Patents**

When thinking about IP, most people are thinking of patents. A patent is a legal document giving the holder exclusive rights over a specific invention. A patent usually is valid for 20 years after submitting the patent (WIPO, n.d.). There exist four types of patents: utility patents, design patents, provisional patents, and plant patents (Runge, 2023).

- Utility Patents: This type of patent is the most commonly used. Utility patents cover new and useful processes, machines, or systems. Utility patents protect the functional aspects of an invention, which is particularly relevant for biotech startups working on unique methods for drug synthesis or genetic engineering techniques.
- Design Patents: This patent is used to protect an ornamental design. For example, a design patent can protect a particular machine's shape. MedTech startups developing medical devices could use this type of patent in particular.
- Provisional Patents: Provisional patents give startups a 12-month window to assess the commercial viability of the invention. If the inventor fails to file a formal utility patent within this year, he or she will lose this filing date.
- Plant Patents: These cover asexually reproduced, distinct, and new varieties of plants.

Each patent type is geographically limited and only protects the invention in the country or region where the patent has been granted. If a startup wants global protection, it must apply for patents in each target market, which can be complex and expensive (IPR, 2019).

Patents are granted by national or regional patent office's such as the European Patent Office (EPO), the United States Patent and Trademark Office (USPTO), or the State Intellectual Property Office (SIPO) in China (EPO, 2007).

Even though patents can provide protection, they have flaws and risks. The patenting process can be expensive, time-consuming, and it is not guaranteed that nobody will use the technology (Carson, 2020). When filing a patent, the invention is fully disclosed, meaning that the technology

becomes public knowledge. It often happens that technology gets copied in regions with different jurisdictions, like, India or China (Carson, 2020). There is also the risk of infringement litigation, which is costly and can damage the startup (Russkrajex, 2023).

**Trademarks**

A trademark is a recognizable sign or design that distinguishes products or services that identifies the goods or services. Trademarks are essential to a company's brand as they provide a way for customers to identify and associate with a product or service (USPTO, 2023).

A few categories are based on the relationship between the mark and the underlying product (Swensonlawfirm, 2015). These categories are:

- Generic: This is a standard description that does not receive trademark protection. Terms like Smartphone or Fast Food are generic marks.
- Descriptive marks: These describe something about the goods. They are not eligible for trademark protection.
- Suggestive Marks: These hint at a characteristic of the goods and services but do not describe them. Consumers need to use their imagination to understand the connection between the mark and the product. Examples are Netflix and Amazon.
- Arbitrary Marks: These are real words that exist in language but have no connection to the services or goods sold—for example, Apple or Shell.
- Fanciful Marks: Are invented words with no meaning to language. These categories have the highest form of protection because they are invented. Examples are Kodak and Exxon.

When a startup is considering a trademark, it is important to understand these categories and how they can be protected. The more distinctive the mark, the stronger its protection (Swensonlawfirm, 2015).

**Copyrights**

Copyrights are IP that protects original works of authorship. While less prevalent in the LSH sector, copyrights can be essential for digital health startups, particularly those developing software for healthcare delivery or medical research. Copyright protection is automatically granted upon creation of original work and does not require registration (Office, n.d.).

**Trade Secrets**

A trade secret is a confidential information that protects the invention by simply not sharing how the invention works. Trade secrets can range from manufacturing processes, customer lists, formulas and techniques, and software algorithms (FDA, 2017).

For LSH startups protecting trade secrets can be as important as patent protection. For example, a biotech startup might develop a new process that works better than those of competitors. Keeping the process confidential could give the startup a long-term competitive advantage because the competitors do not know to copy it (Linton, 2016).

Nevertheless, the protection of trade secrets can be challenging. A startup must take security measures, like confidentiality clauses, with employees and partners. In addition, unlike patents, trade secrets do not offer protection against the discovery of the same technique or reverse engineering (Linton, 2016).

Trade secrets can be a valuable tool for LSH startups. However, startups must carefully weigh this strategy's advantages and risks.

### 3.3.3 IP Strategy & Potential Risks

Having an effective IP strategy is essential for startups in the LSH sector. A good strategy exists out of several steps (Sandy, 2022).

Firstly, it is crucial to identify the potential IP in the startup. This could be something in the operations, innovation, and branding. Once IP is identified, the next step is securing it. This step involves deciding what kind of IP suits the best (patents, trademarks, copyrights, or trade secrets). In addition, the startup needs to determine in which jurisdiction it wants to operate. Finally, the startup needs to monitor and manage its IP portfolio. This includes looking for potential infringement of their patent and ensuring that the startup itself does not infringe on others' Ips (Sandy, 2022).

However, startups need to know the timelines for securing IP rights. It can take years to make a patent application, and failing to get it around can be extremely costly (Carson, 2022). The first hurdle that most startups face is the high cost of obtaining IP rights. Patent filing fees also can reach thousands of euros. Defending a patent infringement lawsuit can cost millions. Because startups in LSH often operate in innovative and competitive fields, the likelihood of infringing on someone's IP can be high (Staff, 2021). This is why checking on Freedom to Operate (FTO) is crucial. FTO refers to the ability to commercialize its technology without infringing on someone else's IP (Sandy, 2022).

Also, quite often, there are issues with co-ownership. This is especially true when IP is developed in collaboration with academic institutions or other companies. These disputes are complex and can cause significant complications to the startup's growth (Sandy, 2022).

### 3.3.4 IP Case Studies

We look at some cases of successful and unsuccessful companies to get more insights into IP management.

**Genentech**

This company is one of the pioneers in the biotech industry and shows an excellent example of successful IP management. The biotech startup came up with a revolutionizing recombinant DNA technology. They invested heavily in securing the patent rights for the process, knowing that competitors would be interested in the technology. When Genentech got the rights for the patent, it licensed its patent to other companies. This generated substantial revenue (Smith, 2022).

**Research in Motion**

On the other side, the case of NTP Inc. vs. Research in Motion (RIM). RIM found itself in a costly legal battle after being accused of infracting on patents held by NTP Inc. The case led to court, which threatened the shutdown of RIM. RIM finally agreed to pay a $612.5 million settlement. This case shows how vital IP due diligence is to ensure that startups will not infringe on existing patents (Friend, 2013).

IP forms a critical foundation for LSH startups. It offers a competitive advantage and attractiveness to investors. However, managing IP is challenging and risky. These insights into IP management set the stage for our exploration of the funding landscape in the LSH sector in the next part.

## 3.4 Funding Landscape in Life Science and Health

For startups in the LSH sector, funding is a resource that must be constantly flowing. This is due to the long development times, high R&D costs, and many regulatory requirements (Excedr, 2023). It is crucial for LSH startups to understand which types of funding are available so that the startup can keep its head above the water in this long process before making a profit.

### 3.4.1 Types of Funding

**Bootstrapping**

This refers to funding the startup with little capital, relying on personal savings or operating revenue. Bootstrapping is mainly used in the early stages when a startup is still working on its business model and product. LSH startups must find external funding due to the high costs involved (Kenton, 2023).

**Crowdfunding**

This is a method in which funding is collected via raising small amounts of money from many people. Most of the time, crowdfunding occurs online and on crowdfunding platforms. For LSH startups, crowdfunding can be an excellent early validation of their idea. However, crowdfunding may not generate enough money for the large sums needed (Smith, 2022).

**Grants**

Grants are an essential source of funding for LSH startups. This is primarily because grants are non-dilutive, meaning they do not require startups to give up any equity in exchange for funds. This allows the startup to control their company while receiving money. Most of the time, grants are awarded based on societal benefits that they can deliver, which for LSH is the aim to improve health (Dowling, 2023).

Different bodies provide several grants focused on the LSH sector. Here are a few of the most important ones:

- Libertatis Ergo Holding BV (LEH): LEH is an essential partner of unlock_. LEH offers startup loans (up to €70k) and seed investments (up to €1M). LEH is an independent, wholly owned subsidiary of Leiden University that creates, supports and invests in companies related to Leiden University's activities, many of which are located in the Leiden Bio Science Park (LEH, n.d.).
- European Innovation Council (EIC): The EIC is an important funding source for startups within the EU. EIC is a part of Horizon Europe, which has a budget of €95.5 billion for support of startups regarding research and innovation. The EIC supports startups in all stages of the innovation cycle. For LSH startups, the EIC Accelerator is especially relevant because they provide grants (up to € 2.5 million) and optional dilutive equity investment (up to € 15 million) for innovation with high societal impact (EIC, 2023).
- Eurostars: Eurostars supports innovative international projects led by small companies to install technological development. Eurostarts supports the development of rapidly marketable innovative products, processes, and services that help improve people's daily lives worldwide. Eurostarts is relevant for LSH startups because of its focus on innovative startups (Eurostars, n.d.).

**Angel Investing**

Most of the time, Angel investors are individuals with high net worth, investing their personal wealth in startups in exchange for equity. Early-stage funding from angel investors can provide necessary resources for LSH startups and be a bridge to other investment form entities like venture capital firms (Nicastro & Orem, 2022).

**Venture Capital (VC)**

VC firms fund startups with high growth potential in exchange for equity. VCs can provide large amounts of funding, often in the millions or even billions of euros. According to the Annual European Venture Report, €130 billion was invested across an estimated 9.033 deals in 2022, of which 15% was invested in healthcare and biotech (AEVR, 2023). Corporate Venture Capital (CVC) is a subtype of VC. In the healthcare sector, large pharmaceutical companies often have CVC departments that invest in promising startups (Kuisch, 2021).

Each funding type has unique advantages and is suitable for different startup stages. LSH startups, similar to most early-stage businesses, go through several developmental stages. Each phase needs distinct types of funding. The seed stage is usually associated with smaller, riskier investments. Angel investors, grants, or early-stage VC funds often fuel this phase (Peak, 2023). As these startups mature and become less risky, they get toward growth or expansion phases (Series A, B, & C Funding rounds), which involve significant investments. For this phase, funding is coming from VC firms or corporate investors (Reiff, 2023).

### 3.4.2 Funding Case Studies

**Moderna Therapeutics**

Moderna, by now a well-known biotech company, successfully navigated the funding pathway to become a significant player in the LSH sector. Moderna got founded in 2010 and pioneered a novel messenger RNA (mRNA) technology to stimulate the body's cells to produce antigens against pathogens. The startup's initial funding was seed capital from VC firm Flagship Pioneering. This early-stage investment from a VC firm was a form of proof-of-concept for Moderna's mRNA technology. This proof-of-concept investment resulted in further investment, securing $240 million from the CVC department of AstraZeneca in 2013. This did not only result in financial backing but also resulted in strategic collaboration (CB, n.d.).

Because the biotech sector needs high capital, their investment journey continued. It secured a Defense Advanced Research Project Agency grant of $25 million. In 2015 Moderna closed an additional $450 million Series C financing round, which came in the history books as the most significant private funding round in biotech (CB, n.d.).

These vast investments resulted in sufficient growth of their company and the development of their mRNA technology. Moderna has been able to reap the benefits when the Covid-19 pandemic came up. They could develop a vaccine quickly (CB, n.d.).

**Nanosphere**

Nanosphere is a company on the other end of the spectrum. Nanosphere had a good start after being founded in 1998. It went public 2007 and raised $98 million from its Initial Public Offering (IPO). However, Nanosphere struggled to achieve profitability due to high production and operational costs (CB et al.; Intelligence, 2014).

In addition, Nanosphere also made strategic errors in its funding pathway. The company relied heavily on equity funding and less on non-dilutive funding options. This resulted in significant dilution of shares, reducing the value of early investors and making it impossible to raise further funding when Nanosphere was in a downfall. Even with raising over $200 million in funding over its lifetime, Nanosphere could not become financially stable. They filed for bankruptcy in 2016 (CB et al.; Intelligence, 2014).

Even though the result of the bankruptcy is not only due to their lousy funding strategy, this case nicely shows how important finding a suitable funding strategy is to prevent future struggles. It also shows that startups have to be aware that diluting the shares of a company by funding could make additional funding more complicated.

In conclusion, funding is crucial for LSH startups. It enables startups to navigate and keep their head above water during long development times, high R&D costs, and complicated regulatory matters. Funding choice is an important step and must be carefully considered to prevent problems later.

As we go to the next session on Technology Readiness Levels, we will better understand how a startup's progress can be measured by evaluating its product. This is an essential part of the tool for unlock_.

## 3.5 Technology Readiness Level

Startups operating in technology-driven sectors often use the so-called Technology Readiness Level (TRL) framework to assess the progress of the technology. NASA designed the TRL in the 1970s to assess the technological progress of their tools for space missions, but it quickly got used by other sectors as well. The TRL makes communicating, sometimes complex, technologies more accessible amongst stakeholders, investors, and customers. TRL can help startups identify missing parts of their technology, anticipate these potential risks, and improve if necessary. The TRL can be beneficial for talking to investors (AcqNotes, 2023).

There are 9 TRLs in 4 different phases (Figure 5) (twi-global, n.d.):

- The discovery phase (TRL 1,2 & 3)
- The development phase (TRL 4, 5 & 6)
- The demonstration phase (TRL 7 & 8)
- The deployment phase (TRL 9)

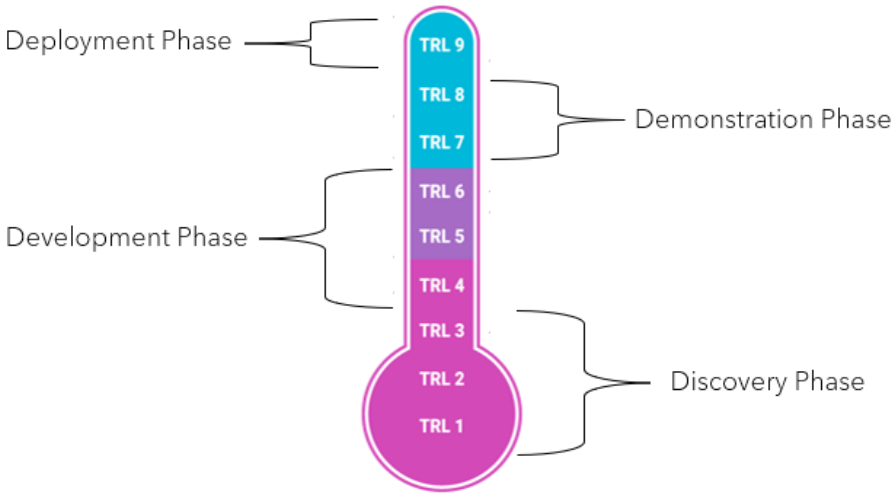


**Figure 5: TRL levels and the corresponding phases (*Large – EU Funding Playbook*, n.d.).**

TRLs have broad applicability across various sectors (twi-global, n.d.). However, it has some unique characteristics in the context of healthcare. In healthcare, the technology is one of many hurdles to overcome (AcqNotes, 2023). Given these healthcare sector-specificities, it is crucial to integrate TRL with extra consideration.

In the context of startups and investors, TRLs play a vital role. Investors often use TRLs to evaluate the maturity of the technology and potential risks. If the TRL of a startup is further in the process, investing in the company is more appealing (Pushpapathan, 2022). This is why for unlock_, which

the main goal is to make the participating startup investible, it is essential to know how far a company is with its TRLs.

While TRLs provide an excellent framework to evaluate the technical maturity of a product, it only covers some essential aspects for attracting investment. This is where Investor Readiness Levels (IRLs) come into play.

## 3.6 Investment Readiness Level

IRLs are pivotal in assessing a startup's amenities for potential investors (Fransen, 2021). This tool evaluates multiple startup aspects that are interesting for an investor. IRLs cover crucial parameters such as financial health, market traction, team composition, business model viability, and exit potential (Fransen, 2021).

### 3.6.1 Definition & Scope of Investment Readiness Levels

The first component of IRL that needs to be understood is the financial health of the startups. This part includes an analysis of revenue and costs, which give an analysis of revenues and costs. In the case of startups that do not have revenues yet, investors look at their burn rate. The financial health of a startup helps investors understand the venture's potential profitability and financial sustainability (Goudt, 2017).

Market traction is another critical component of IRLs. Here investors evaluate the progress and acceptance of the startup in its target market. Critical factors are attracting customers, engagement, and strategic partnerships. Market traction provides evidence of market validation for the startup's specific product (Goudt, 2017).

Another important, as already mentioned, component is the team composition. The team behind a startup is critical, and because of this, it is often said that investors invest in the team rather than so much in the product. Investors like to see a diverse team with a broad range of skills. A diverse team indicates that the startup can overcome challenges and adapt to market changes (Goudt, 2017).

Lastly, the viability of the business model is crucial. The business model must be scalable, have a competitive advantage and a unique selling point, and have a transparent revenue model. A robust business model can demonstrate the potential for high returns (Goudt, 2017).

From an investor's perspective, IRLs provide critical information to understand the company's functioning. This reduces their chance of betting on the wrong horse.

### 3.6.2 Investment Readiness Levels and Technology Readiness Levels as Complementary Tool

IRLs and TRLs are critical to understanding a startup's overall position, but they focus on different dimensions of the business. While the TRLs focus more on the maturity of the technology, IRLs give an investor insights into the business aspects of the startup. Both tools complement each other. However, it consists of two separate tools.

In essence, by interweaving TRLs and IRLs, stakeholders and investors get a more comprehensive picture of the startup's readiness for investment and potential for success. Combining both tools is especially crucial for startups in the LSH sector.

The following section investigates the Healthcare Innovation Cycle (HIC). This tool is designed for LSH startups and combines the TRL and IRL tools.

## 3.7 The Healthcare Innovation Cycle

Traditionally seen and mentioned in many books about entrepreneurship, building a simple company goes through five different phases. These phases needed recognition & ideation, where the initial idea is formulated, development where the initial idea is transformed into a business model and a product to sell, launch where the product enters the market, growth where the company tries to expand its company in the market, and maturity when the company established itself as a stable player in the market (Passaro *et al.*, 2016). For technology-driven companies, the TRLs are an essential framework to use. However, Life Science and Health and Biotech startups have a more complex lifecycle than startups in other sectors. This is due to several factors:

- Regulatory environment: The Life Science and biotech industry has a stricter regulatory system than any other sector. The companies in this sector must comply with specific standards regarding product safety, efficacy, and ethical considerations. Regulatory compliance must already be considered at an early phase of the startup (scale consulting, z.d.; Shaw & Whitney, 2016)4.
- Long development process: Before a product or service in this sector can get on the market, much scientific research and testing must be done. Products must often undergo multiple stages, such as proof-of-concept, proof-of-feasibility, and clinical trials (Paul *et al.*, 2010). Drug development in this industry often takes 8 – 15 years on average (DiMasi *et al.*, 2016). For a startup in the medical device industry, this can be shorter, on average, 3 – 10 years (Zenios *et al.*, 2010). The time can vary depending on the complexity of the technology and the regulatory requirements.
- Significant investments: The costs needed for research and development, clinical trials, and regulatory approval are way higher than in other sectors. The average cost of bringing a new drug to the market can take over € 300 million (Mosi, 2022).
- Complex technology/product: Startups in this sector often involve sophisticated scientific principles and technologies. This means these startups require skilled people with specific knowledge to handle technological development.

Biotech and Life Science and Health startups have more phases than traditional ones in these complex factors. This lifecycle is called the Healthcare and Innovation Cycle (HIC). Because of the complex and time-consuming phases before the technology/product can be launched into the market, the different phases take place pre-launch (Gaits, z.d.). These phases are fundamental to ensure patient safety, so they are inevitable. The distinctive stages of the HIC are (Figure 6):

1. Need recognition & ideation: This phase is the same as in the traditional phases. The need could be a specific disease that lacks effective treatment.

2. Proof-of-concept: This is a critical phase where the proposed idea is verified. It usually entails in-vitro testing to test if the proposed solution is theoretically feasible.
3. Proof-of-feasibility: In this phase, the startups need to look at the practicalities of their solution—for example, manufacturability, scalability preliminary safety.
4. Proof-of-Value
5. Initial Clinical Trials
6. Validation of solution: This phase is mainly focused on testing and validation. This is often through pre-clinical studies and initial clinical trials. The objective is to get as much data as possible on efficacy and safety. However, it is also essential that the tests show that this product has potential advantages to existing standards of care.
7. Approval and launch: When the product gets through the clinical trials, it needs regulatory approval from the involved regulatory bodies for market launch. This involves handing in all the obtained data and responding to requests for additional data. When the regulatory bodies approve the product, it can be launched in the market.
8. Clinical use: The product gets used in practice. Safety and efficiency still get monitored. In this phase also, the market is developed further in the form of patient and clinical awareness.
9. Standard of care: This is the final stage and is reached when the product is a standard treatment or prevention.

Consortia developed the HIC for Improving Medicine with Innovation & Technology (CIMIT). CIMIT has created a roadmap to guide LSH and Biotech through this complex innovation process. They break down the process of each phase into manageable milestones. CIMIT sees the HIC as circular and not as linear, as they note: *"Success is more likely by starting with clinical problems rather than pushing technology solutions and by keeping the focus on the result of improving patient care* (CIMIT, n.d.). The HIC is associated with four dimensions: business, market, regulatory, and clinical (Figure 6). For each phase, CIMIT outlines deliverables within these deliverables. If a startup complies with these deliverables, they minimize current and future risk. LSH & Biotech startups can use CIMIT's Guidance and Impact Tracking System (GAITS), a project milestone and management system (Gaits, z.d.).

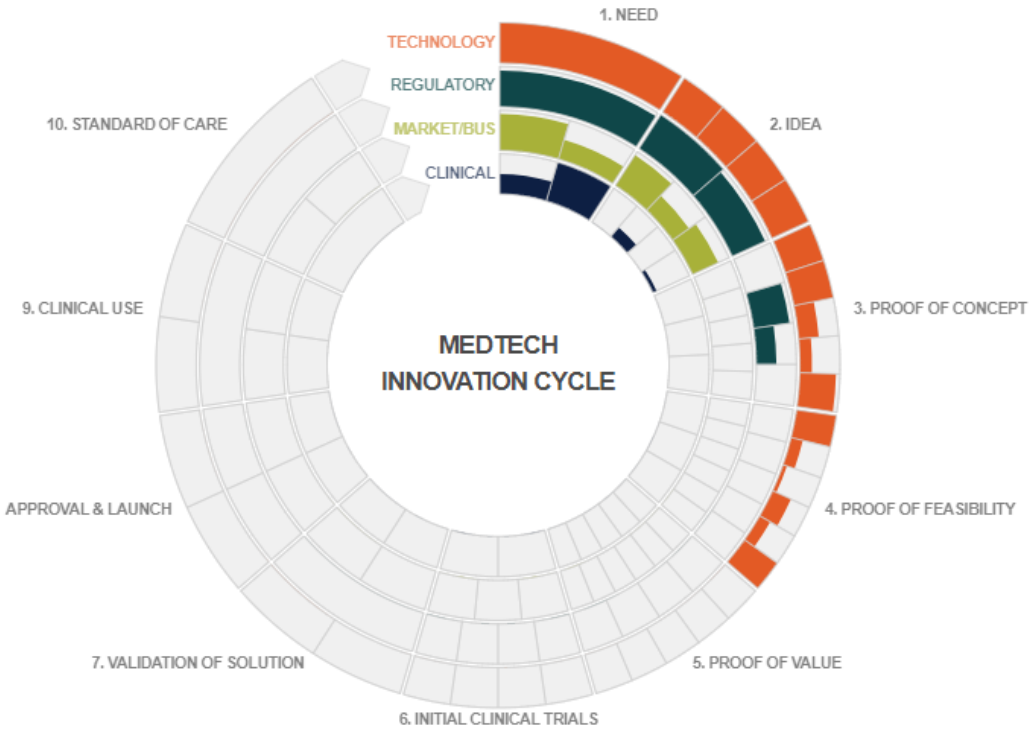


**Figure 6: The MedTech Healthcare Innovation Cycle (*Home - New_Public - GAITS*, n.d.).**

The HIC can be crucial in attracting investors (CIMIT, n.d.). Startups can easily show their systematic progress, adding credibility to the startups. In addition, startups can show potential investors that they know their challenges and can propose a strategy to overcome them. At the end of the unlock_ incubation program, we want the startups to be investor ready. We want them to have an overview of what they already did and what has to be done. This is why the incubation program is based on the HIC. The HIC is also the base for our impact tool. However, because we want a more profound view of the startup's current state, we adapted the deliverables so that we can make a reasonable determination between the different startups in this phase.

Transitioning into the following chapter, we delve deeper into the methodology employed in this study. Central to our approach is the tool based on the HIC, adapted to offer a detailed perspective on the startup's current state and progression. With this, we aim to effectively measure and demonstrate the impact of the unlock_ incubation program on startups.

# Chapter 4: Methodology

## 4.1 Tool Design and Purpose

### 4.1.1 Design of the Tool

unlock_ has a need for a specific tool with which easily can be determined how far a startup is in its process of getting investor ready. The tool's design is primarily devised from the concept of the HIC. This model is recognized for integrating two essential constructs, the TRL tool and the IRL tool, which offer a comprehensive view of startups' progression. However, while the original HIC is a unique tool, it needs more specificity on insights of startups that unlock_ the need to give every startup tailor-made support. This drove the development of a customized tool suited to the specific requirements of unlock_.

The unlock_ incubation program focuses on assisting startups through the phases of proof-of-concept and proof-of-feasibility. To address the gap in the HIC for our specific startup and to get a more refined understanding of a startup's position in these phases, we introduced adapted deliverables at the phases that are most important for these startups at this point, namely, form idea till proof-of-feasibility phase (see Appendix).

The new tool probes various aspects of the startups, including their business model, market position regulatory adherence, technological & clinical progress, and team structure. Each of these elements is scrutinized in depth to yield a more accurate picture of startups' readiness and challenges.

Specifically, in the business and market sections, the tool strongly emphasizes understanding and validating the startup's business model. It explores in depth the startup's knowledge of its stakeholders, the solidity of its revenue model, the competitive landscape in which it operates, and its unique selling proposition (USP). In addition, the new deliverables evaluated the startup's understanding of its total available, obtainable, and serviceable market.

The tool also addresses the critical regulatory aspects relevant to our startups. It evaluates whether startups possess Freedom to Operate (FTO), understands the need for CE marking, have initiated the patenting process, and know the relevant regulatory bodies they must engage with. Moreover, the clinical section focuses on the startup's technical advancement, assessing the existence of a Minimum Viable Product (MVP) and the status of clinical testing.

The interviews also focus on startup teams, a component not in the original HIC. As mentioned in Chapter 3.1.1, the team plays a vital role in the success of a startup, and it is mentioned that investors find a robust and diverse team significant. This tool recognizes this vital section and evaluates the team's role distribution, equity division, and collective skills.

As output, the tool deploys an innovative scoring system. Each startup is scored based on its progress in the specified deliverables, and this score feeds into a spider chart. This chart visually represents the startup's strengths and weaknesses across the four critical areas of business, market, clinical, and regulatory, providing a holistic view of their readiness.

#### 4.1.2 Purpose

This tool can extract in-depth insights into the startup's progress, making it possible to identify the gaps in its portfolio. This, in turn, equips unlock_ with the capability to offer tailored advice to its startups. In addition, this tool is used to get an answer to the central research question: What is the effect of the incubation program on the participating startups? The tool facilitated this by allowing for detailed interviews with startups before the incubation program and with alumni already graduating. The spider charts of these groups are compared and give insights into the program's efficacy.

### 4.2 Sample Selection

In conducting this study, 14 startups participated in the research. Eight startups existed out of the most recent cohort of the incubation program (2023), three were alumni from the previous year's program (2022), and three participants were from the first edition of the incubation program in 2021. This representation provided an opportunity to evaluate startups' progress at different stages of incubation and post-incubation, thereby enriching the depth and diversity of the research.

The 2023 cohort involved two startups from the Biotech sector, four MedTech startups, and one pharma startup. The remaining startup had recently pivoted to a sector outside the LSH sector. Among the 2022 cohort, one startup was active in the Biotech/pharma sector, and another operated at the intersection of the MedTech/pharma sector, with the third startup having pivoted to a non-LSH sector. The first cohort, from 2021, included two Biotech startups and one MedTech startup.

The startups chosen for participation were all part of the unlock_ incubation program without any additional criteria for selection. Given this approach, the sampling can be characterized as convenience sampling. It was an expectation that the participating startups would have at least an idea of an envisioned business model, preliminary market research and validation data, knowledge about their Freedom to Operate (FTO) status, and either an existing Minimum Viable Product or an ongoing effort to create one.

As part of the data collection, 19 startups were invited to participate in the study. Of these, 14 responded and engaged in an interview. Participation was mandatory for the eight startups currently enrolled in the incubation program. However, participation was voluntary for the alumni because they were no longer officially part of the program.

Recruiting alumni from past cohorts posed some challenges. The often busy schedules of these startups resulted in a low number of responses to the initial invitation via email. The issue was resolved mainly by personally reaching out to the startups and by reminders from the program manager, which resulted in more positive responses and participation.

## 4.3 Data Collection

The data collection process for this research was careful and designed to be helpful for the participating startups. The data was collected through a series of interviews, each lasting, on average, 45 minutes. These interviews were conducted mainly in person, although some were conducted online due to location or scheduling constraints. Each interview was recorded with the interviewees' consent to ensure data accuracy and reliability.

A semi-structured interview format was used to obtain a comprehensive and genuine response. This approach was intended to maintain a focus on the pre-established set of deliverables that the interview aimed to assess while also allowing space for unscripted, nuanced discussions. This approach encouraged open-ended conversations and enabled insights into various topics depending on each startup's specific circumstances and focus.

A broad set of critical questions were prepared to act as a guideline for each interview. The questions ranged from asking about the specifics of their technology and business model to the regulatory pathways they needed to navigate. The guidelines also included questions about market size, competitors, unique selling points, and patent requirements. The ultimate goal was to get responses covering multiple deliverables of our tool without making the interview feel rigid or unengaging.

The tool's deliverables were grouped into five categories: business, market, regulatory, clinical/technology, and team. Each category has an average of 3 deliverables per phase of the Healthcare Innovation Cycle (HIC), with 26 for business, 24 for market, 28 for regulatory, 24 for clinical/technology, and 21 for the team. During the interview, responses were input directly into the tool.

To maintain the authenticity of the information collected, efforts were made to minimalize any potential response bias. Startups were reassured that there were no 'right' or 'wrong' answers, aiming for an environment of honesty. The interview design also played a role, with broad questions aiming to indirectly assess the completion of deliverables rather than directly interrogating them. This method allowed for a more nuanced understanding of the startup's progress.

All interview recordings were treated with confidentiality. Non-Disclosure Agreements were signed at the beginning of the incubation program. Startups shared sensitive and proprietary information during these interviews, and to ensure their protection, no transcription of these recordings was made. Instead, the data was directly input into the tool during the interview and cross-verified with the recordings. These recordings were deleted once all data was collected and transferred into the tool. In line with this rigorous approach to data privacy, all collected data was anonymized. This ensured the protection of the startup's confidential information while also providing a thorough understanding of its strengths and weaknesses to facilitate the provision of bespoke, beneficial support.

### 4.4 Data Analysis

In this research's data analysis phase, quantitative and qualitative methods were utilized to generate a comprehensive understanding of the startups' status and progress throughout the incubation program.

**Quantitative Analysis:** The quantitative analysis primarily examined the scores the tool assigned. The tool quantified each deliverable's status across five categories using a two-point scale, thus providing an objective measurement of each startup's progress. The resulting data was represented visually in spider charts for a quick comparative overview of the startups' progress across categories.

**Qualitative Analysis:** The qualitative analysis involved systematically examining the data collected during the semi-structured interviews. Thematic analysis was conducted to identify common themes, challenges, and unique insights among the startups, augmenting the numerical data derived from the tool.

**Dealing with Missing Data and Deviations:** Additional information was solicited via email if any data was missing following the interviews. Special provisions were made when startups had pivoted to a non-LSH sector and thus did not align with the research criteria. One startup from the alumni group was excluded from the study, while others received tailored advice relevant to their unique circumstances.

The methodology describes a custom tool and detailed interviews, thoroughly analyzing startups' progress through unlock_'s incubation program. Quantitative and qualitative approaches revealed objective readiness and insights of the startups. With the research encompassing different cohorts, insights into the effects of incubation were obtained. Moving on to the results section, we will illustrate these findings using spider charts to highlight the program's impact.

## Chapter 5: Analysis of Data

The purpose of this chapter is to present the findings derived from our constructed methodology. This section is divided into two main parts: quantitative results and qualitative results.

First, we will delve into the quantitative results, where startups are grouped based on their specific subsector: MedTech, Biotech, and Pharma. This division allows us to analyze unbiasedly due to subsector deviations, possible similarities, and differences between startups in the same cohort. A similar analysis will be done for startups in the same subsector between cohorts (2021, 2022, & 2023). This method provides insights into growth and development during and after incubation.

The latter part of this chapter will address the qualitative results. Here, the focus is identifying common challenges and success factors among the startups, pre- and post-incubation. The goal is to discern whether startups at different stages grapple with similar problems or if the nature of these problems evolves as they progress through the incubation program. The same principle is

applied to the success factors and common areas of improvement to understand the dynamic nature of startup development.

In presenting the results and to maintain the confidentiality and anonymity of the startups involved in this study, each startup will be referred to using a code letter. This anonymity ensures the protection of sensitive information about the startups, honoring our commitment to their privacy. The code letters for each startup are listed in Table 1.

**Table 1: Anonymized code for each startup in the specific cohort of the unlock_ incubation program and its primary operational area within the LSH sector**

| Cohort 2023 | Startup Code | Subsector |
|---|---|---|
| | A | MedTech |
| | B | MedTech |
| | C | MedTech |
| | D | MedTech |
| | E | Biotech |
| | F | Pharma |
| **Cohort 2022** | I | MedTech |
| | II | Pharma |
| **Cohort 2021** | δ | MedTech |
| | ε | Biotech |
| | ζ | Biotech |

## 5.1 Quantitative Analysis

**MedTech Subsector**

To commence our analysis, we will first focus on the most recent cohort, comprising startups from 2023. By comparing these startups with one another, we aim to identify their respective strengths and areas of improvement. This analysis will also show the similarities and differences between startups in the same subsector and subsectors. We will do this analysis by examination of their spider charts, which provide a visual overview of their current stage across different dimensions.

First, we will examine the MedTech startups from the 2021, 2022, and 2023 cohorts (Figure 7).

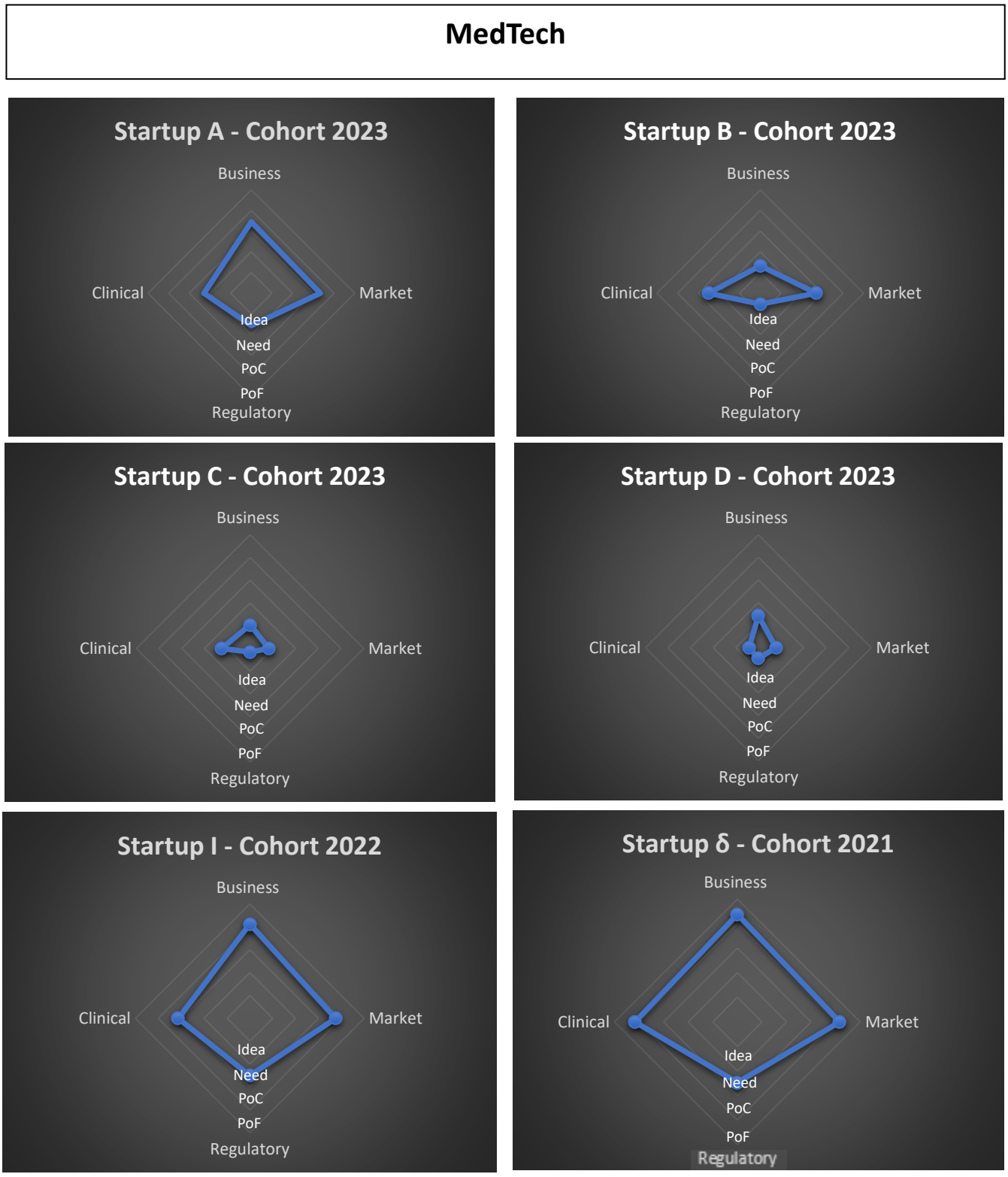


**Figure 7:** Spider charts represent the current progress status of the four MedTech startups (A, B, C, D, I, & δ ) from the 2023, 2022, & 2021 cohort. The plotted points on the chart correspond to scores derived from the unlock_ tool, with startups evaluated across four key phases: idea, need, proof-of-concept (PoC), and proof-of-feasibility. The spider charts visually encapsulate the startups' progress, offering a comparative perspective on their individual journeys towards investment readiness.

### 5.1.1 MedTech Startups Cohort 2023 Analysis

In this portion of the result section, we examine the four MedTech startups from the 2023 cohort, specifically startups A, B, C, and D (figure 7), as we dissect the spider charts representing their current state, diverse trends and differing levels of readiness for investment become apparent.

Startup A stands out prominently, demonstrating a noticeable advantage in terms of progression. Remarkably, this startup is further advanced in business and market, positioning it at the Proof-of-Concept phase. This maturity level differs from the less developed status of the other startups in these categories.

Startup B, while demonstrating an expected level of progression in the clinical and market aspects (around the need phase), lags in the business category, remaining in the idea phase. This discrepancy underlines the diversity in the pace and path of development among these MedTech startups.

Across all four startups, a clear trend emerges in regulatory readiness. Despite their differing degrees of advancement in other aspects, startups A, B, C, and D are all relatively underdeveloped in the regulatory category, lingering in the idea phase. This trend suggests a common challenge for these startups, emphasizing the necessity for increased attention and efforts in navigating regulatory requirements.

As we delve into the results, these initial observations set the stage for further comparative analysis across MedTech startups that participated in different cohorts.

### 5.1.2 MedTech Startups Cohort 2021, 2022, & 2023 Analysis

In this segment of the result section, we extend our comparative analysis by putting the MedTech startups from the 2023 cohort side by side with their predecessors from the 2022 and 2021 cohorts. We aim to identify trends and gain insights into the progression and growth pattern across multiple years of the incubation program.

A clear trend emerges upon visually examining the spider charts (Figure 7). The MedTech startups from the 2022 and 2021 cohorts are markedly further along at all levels than their 2023 counterparts. This difference is especially conspicuous on business, market, and clinical levels. For instance, the 2022 MedTech startup is proximate to the Proof-of-Concept phase in these categories. A notable advance is also observed on the regulatory front, where this startup has reached the ‘need’ phase, surpassing the 2023 startups by one phase.

Further disparities are observed, particularly when comparing the 2021 and 2022 startups to the 2023 cohort’s startups B, C, and D on business, market, and clinical levels. These comparisons possibly underline the growth within the unlock_ incubation program and highlight consistent, albeit slow, progression on the regulatory level across cohorts.

**Biotech Subsector**

After identifying differences and patterns in the development of MedTech startups across 2021, 2022, and 2023 cohorts, our analysis will extend to the Biotech subsector. We compare the Biotech startup from the 2023 cohort against those from the 2021 cohort, aiming to discern possible trends of progression that may have been catalyzed by the incubation program (Figure 8).

## Biotech

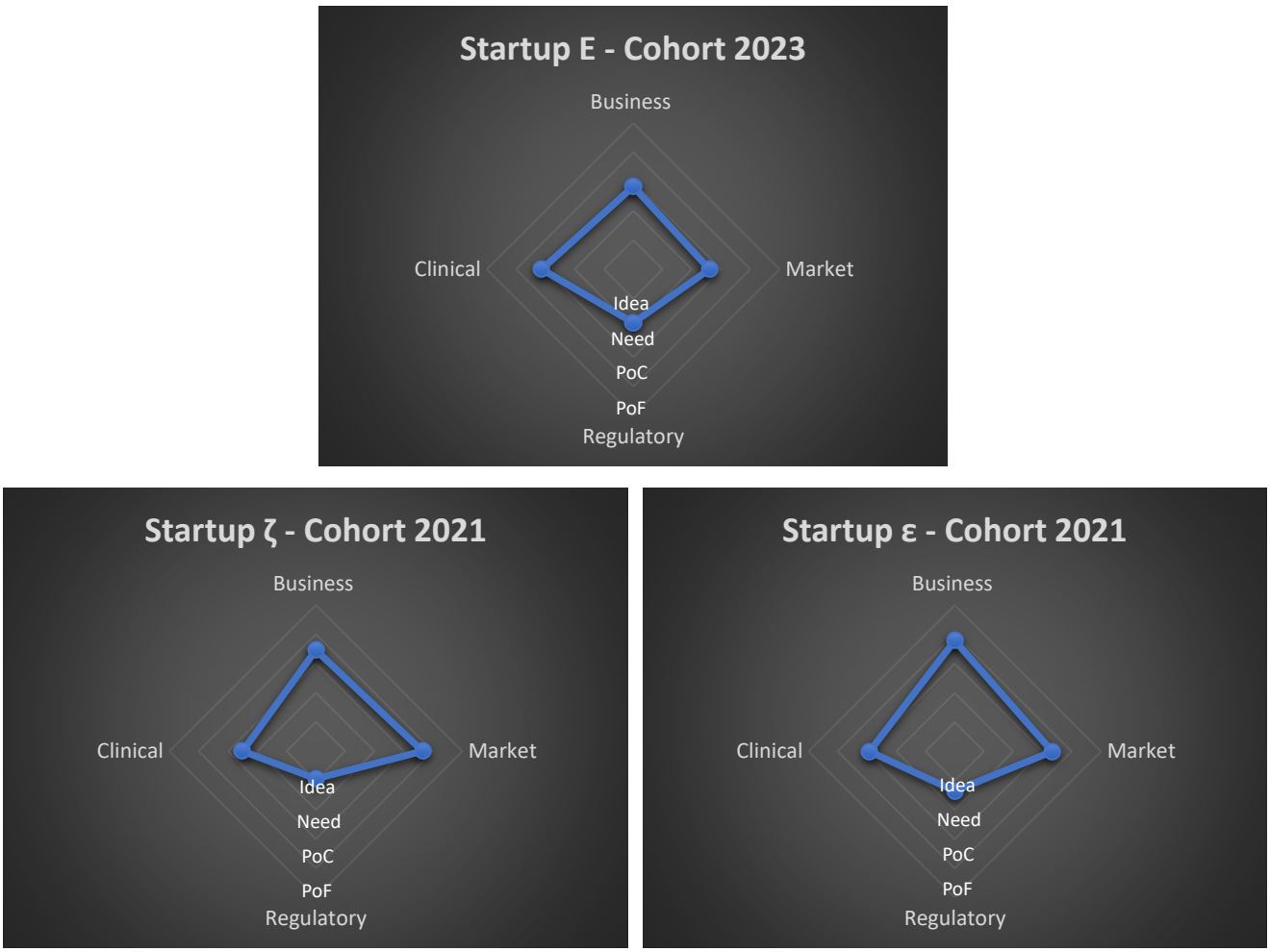


**Figure 8:** Spider charts represent the current progress status of the three Biotech startups (**E**, **ζ, & ε** ) from the 2023 & 2021 cohort. The plotted points on the chart correspond to scores derived from the unlock_ tool, with startups evaluated across four key phases: idea, need, proof-of-concept (PoC), and proof-of-feasibility. The spider charts visually encapsulate the startups' progress, offering a comparative perspective on their individual journeys towards investment readiness.

### 5.1.3 Biotech Startups Cohort 2021 & 2023 Analysis

Upon comparing the Biotech startups across the 2023 and 2021 cohorts, the differences are subtler than those observed among the MedTech startups. On business and market fronts, Biotech startups ζ and ε from the 2021 cohort have progressed to the Proof-of-Concept phase, a step ahead of the 2023 startup E, which remains in the 'need' phase. However, a reverse pattern emerges on the clinical and regulatory level, where startup E stand closer to the Proof-of-Concept phase and 'need' phase, respectively, surpassing the 2021 startups at the 'need' and 'idea' phases. Echoing the trend in Figure 7, Biotech startups also display a lag on the regulatory front relative to the other three categories.

These three Biotech startups have a focus on their business model development and technology, potentially at the expense of due attention to regulatory pathways critical to future technology approval.

**Pharma Subsector**

We will expand this analysis to the startups in the final subsector: Pharmaceuticals. We will compare Pharma Startup F from the 2023 cohort with Pharma Startup II from the 2022 cohort (Figure 9).

**Pharma**

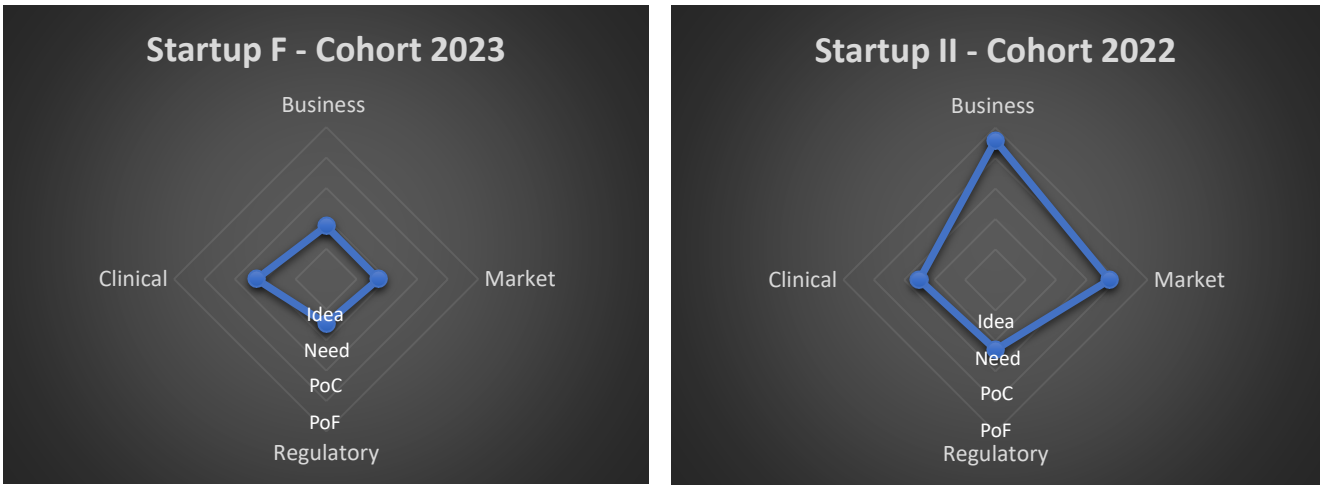


**Figure 9:** Spider charts represent the current progress status of the two Pharma startups (**F & II**) from the 2023 & 2022 cohort. The plotted points on the chart correspond to scores derived from the unlock_ tool, with startups evaluated across four key phases: idea, need, proof-of-concept (PoC), and proof-of-feasibility. The spider charts visually encapsulate the startups' progress, offering a comparative perspective on their individual journeys towards investment readiness.

In assessing the Pharma startups from the 2023 and 2022 cohorts, the differences in their progression are more pronounced. The 2022 Pharma startup, denoted as II, appears considerably further in phases, particularly at business and market levels, which indicates a more profound

business model. Startup II stands in the Proof-of-Feasibility phase on the business front, whereas Startup F from the 2023 cohort is in the 'need' phase. Similarly, market-level comparisons reveal startup II at the Proof-of-Concept phase, contrasting startup F at the 'idea' phase.

Contrarily, the startups are closely aligned on the clinical front, both being in the 'need' phase. This possibly underscores the measured pace intrinsic to Pharma startups in transitioning their products through various phases. Regulatory considerations again showcase a lag: Startup II is in the 'need' phase, and startup F is in the 'idea' phase. However, this reinforces the observation of slower navigation through the regulatory landscape compared to other areas.

Now that we have analyzed all the trends and differences between startups in similar subsectors, we want to zoom out and look deeper into the trends and differences that are not subsector specific.

### 5.1.4 Trends and Differences Across Subsectors

Several intriguing trends and patterns begin to surface. One striking similarity among the MedTech, Biotech, and pharma startups, regardless of their cohort year, is their comparatively slower pace in navigating the regulatory landscape. This trend implies a universal struggle or a lower priority in the area across the different startup types.

Diving into differences, the startups within each subsector exhibit variable paces and priorities. The MedTech startups from the 2023 cohort focus heavily on business and market-level aspects, while their counterparts from the 2021 and 2022 cohorts demonstrate a more balanced approach (Figure 7). Despite being indifferent cohorts, the Biotech startup displays a more consistent trend, concentrating on business, market, and clinical aspects but less on regulatory steps (Figure 8).

In the Pharma startups, progress on business and market levels outpace the clinical level, particularly in the 2022 cohort. While clinical development typically proceeds slowly in this sector, the discernible focus on business and market development indicates a strategic emphasis on these areas.

Despite individual nuances and progress rates, all subsectors share the common challenge of regulation navigation, indicating a shared area of improvement for startups across the LSH domain.

## 5.2 Qualitative Analysis

We presented an extensive quantitative analysis based on the unlock_ tool. However, more than numbers and charts are needed to capture the complete picture. Delving into the qualitative aspect is essential to glean a more nuanced understanding of the startup's journey.

In the following qualitative analysis, we will delve into the core issues. In addition, we will also evaluate the feedback from startups on the unlock_ incubation program, lending us a perspective on the program's strengths and areas of improvement.

### 5.2.1 Challenges and Barriers

The interviews made it clear that building a company is complete with hurdles. The common thread weaved through all startup narratives, particularly those from the 2023 cohort, is the struggle with raising funds. This difficulty was not limited to a single sector or cohort. Startups elucidated that the absence of sufficient funding hampers their ability to commit to their venture fully and slows down or blocks the development of their technology.

Furthermore, a deeper dive into the subsector-specific challenges highlights the intricacies associated with each area. Startups from the Biotech and Pharma subsector consistently vocalized difficulties in understanding and navigating the complex regulatory landscape. On the other hand, MedTech startups, ensconced in a comparatively more straightforward regulatory pathway, expressed lesser concerns. That being said, the data from the spider charts show that MedTech startups navigate more manageably through the regulatory landscape than Biotech and Pharma startups, which showcased that Biotech and Pharma startups were in the 'idea phase' of regulatory readiness, while MedTech startups are one phase further in the need phase. This underlines the importance of tailored assistance for different subsectors, each wrestling with unique challenges.

### 5.2.2 Team Building and Dynamics

Another pivotal facet of the startup's journey is team composition. Startups from the 2023 cohort, still in the nascent stages of their journey, have yet to form extensive teams. A few exceptions to this pattern, namely startups A & B, have already started to assemble their teams. This early commitment to team formation becomes even more prevalent as we transition to the 2022 and 2021 cohorts, with startups I, II, and ε boasting more extensive teams.

Interestingly, the urgency to assemble a team appears more pronounced among MedTech startups, hinting at a subsector-specific trend. This propensity for swift team formation carries challenges, as evidenced by the complexities in managing equity splits. Startups A and B from the 2023 cohort highlighted difficulties in cap table management, a concern that appears to wane as startups evolve and their teams grow more prominent.

### 5.2.3 unlock_ Incubation Program's Contributions

The qualitative feedback on the unlock_ incubation program underscores its value in providing network opportunities. Irrespective of the cohort or sector, startups from 2021 and 2022 lauded the unlock_ community as instrumental in forging new partnerships and alliances. This feedback cements the role of the unlock_ community as an invaluable resource for startups, serving as a potent catalyst in their entrepreneurial journey.

However, the program's curriculum resonated differently depending on the participants' backgrounds. For scientists-founders venturing into entrepreneurship for the first time, the business and market aspects of the program were incredibly enlightening. Conversely, those with prior entrepreneurial experience leaned more toward the clinical aspects. Despite this variance, all participants agreed on the crucial importance of regulatory landscape information. This

uniform consensus indicates the need for continued emphasis on regulatory education in the program's curriculum.

This qualitative analysis has unearthed deeper insights into the challenges, team dynamics, and perceived program benefits for startups across different cohorts and subsectors. These findings complement our earlier quantitative analysis, providing a more rounded understanding of the startups' journey. They also shed light on potential areas for the further evolution and improvement of the unlock_ incubation program.

Through quantitative and qualitative analysis, we have endeavored to comprehend the intricacies of the startup journey across cohorts and subsectors. The next step is interpreting these insights, drawing meaningful conclusions, and translating them into actionable recommendations.

# Chapter 6: Discussion, Conclusion, & Recommendations

In this final chapter of the analytical part of this thesis, we engage in an in-depth discussion of our findings, threading together the various strands of information we have collected. We also try to get an answer to our previously formulated research question: "What is the effect of the inlock_ incubation program on the progression of our startups that participate?"

## 6.1 Discussion

The provided data shows that the unlock_ incubation program has impacted the startup landscape in the MedTech, Biotech, and Pharma sectors. It has assisted startups in progressing through the various phases of their entrepreneurial journey. However, the level of progression varies depending on the sector and cohort.

The analysis reveals that startups in the MedTech sector progress faster and face fewer challenges in understanding their regulatory landscape. This aligns with existing literature findings that indicate that regulatory pathways for MedTech startups tend to be simpler than those for Biotech and Pharma startups(Van Norman, 2016; Liberti *et al.*, 2017. The startups' progression and challenges faced, as evident from the spider charts, reinforce these sector-specific trends.

It is important to note that this study is subject to bias due to the diversity of the startups involved and the timeframes in which they were analyzed. Startups from different cohorts were compared, which may not provide a truly accurate measure of the impact of the unlock_ incubation program. There is much diversity between startups, and it cannot be said with certainty that the startups from previous cohorts were in the same phases as the startups now are. Monitoring the same startup's progress over time would be valuable for a more robust analysis. However, this approach was not feasible due to the limited time frame of this thesis research. Nevertheless, this research will be continued after this thesis.

On the other hand, a comparative analysis of the startups' progression at different stages revealed that, on average, those from the 2021 and 2022 cohorts progressed further in every phase

compared to startups from the 2023 cohorts. This progression suggests that the unlock_ incubation program has effectively aided startups in advancing through the various stages. However, it should be acknowledged that this conclusion is based on the assumption that startups from different cohorts were at roughly similar phases when they joined the program, which might not be the case.

Important to note that the startups from previous cohorts secured additional grants after the program, and one has even managed to acquire their fists customer. While it is encouraging to see these successes, it is essential to consider that the startups that did not participate in this study might have encountered significant challenges or were less successful. This could be a reason for them not to participate, which could give a small amount of a biased view on the success of our startups.

Lastly, an important aspect to consider is the breadth of the deliverables measured by our tool. While this broad approach helps capture various aspects of a startup's progression, it might risk presenting a superficial view of its progress. The relevance of some deliverables can vary between different startups, implying a need for a more tailored subsector-specific evaluation approach.

In a future iteration of this tool, the scoring of deliverables could undergo significant changes. Some deliverables become more critical than others and should carry a higher weight in the evaluation. For instance, a startup that skips specific deliverables but effectively achieves the end goal of a phase should receive higher scores. These scores should be validated in collaboration with experts in the field to ensure the tool's evaluation criteria align with practical realities and offer a meaningful assessment of startup progression.

## 6.2 Conclusion

The unlock_ incubation program is a crucial catalyst for startups in the MedTech, Biotech, and Pharma sectors. Besides promoting progression, the program equips these startups with the necessary tools and knowledge to navigate the often complex and challenging path of entrepreneurship.

The program's instrumental role is highlighted in developing a robust assessment tool tailored to identify these startups' unique challenges and trajectories. The tool has demonstrated its utility and could be used in various critical aspects:

- aiding in the intake process of new startups
- tracking the progression of startups throughout their journey
- assessing the effectiveness of the incubation program
- informing the development of customized coaching and mentorship strategies

Each of these applications underscores the value and potential of this tool in advancing the objectives of the unlock_ incubation program.

Returning to our initial research question: “What is the effect of the unlock_ incubation program on the progression of our startups that participate?” With due consideration of potential biases, we can say that the unlock_ incubation program has a discernibly positive impact on the progression of participating startups. This effect is manifested across four critical dimensions: business readiness, market readiness, regulatory compliance, and clinical validation. Startups, particularly in the MedTech sector, have shown noteworthy advancement along these trajectories after participating in the program.

However, it is crucial to underscore the challenges encountered by the startups. Fundraising emerged as a universal challenge, slowing the growth and development of startups. Understanding and navigating the regulatory landscape was a particularly notable struggle for startups in the Biotech and Pharma sectors, illustrating the complexity of these environments. Additionally, team building posed challenges, indicating the importance of team structure in startup progression.

Now that we have data that suggests some weaknesses and strengths of the unlock_ incubator, we can give, based on these findings, recommendations on how unlock_ can improve its programs resulting in more successful startups from unlock_ and eventually unlock_ can better position itself in the incubator market.

In conclusion, the tool developed and tested in this study effectively addresses the need identified in Chapter 2: "How can unlock_ effectively measure the phase in which a startup is operating." The tool demonstrated its ability to assess a startup's current state and allowed for tracking its progress over time and evaluating the impact of specific programs, such as the unlock_ incubation program. Hence, the tool fills a significant gap in unlock_'s operational framework, providing a concrete, objective method to measure a startup's progress and program effectiveness. Future research will continue to refine and validate this tool, contributing to our understanding of startup development in the MedTech, Biotech, and Pharma sectors and better equipping unlock_ to aid startups on their entrepreneurial journey.

## 6.3 Recommendations

We will now provide a few recommendations related to the just-mentioned weaknesses and shortcomings of the unlock_ incubation program.

### 6.3.1 Enhanced Fundraising Support

A theme from our analysis is the difficulty startups face in securing funds. As mentioned in **Chapter 3.4**, fundraising is a critical aspect that affects the pace and direction of the startup’s progression. In light of this, unlock_ can intensify its focus on enhancing startup fundraising support. This could be done through a two-pronged approach.

Firstly, more frequent and intensive workshops could be incorporated into the unlock_ program, focusing on fundraising strategies and grant-writing techniques. Feedback sessions could further extend these grant-writing techniques.

Secondly, unlock could also consider setting up a 'Funding Alert System.' Given the dynamic nature of the funding landscape, startups often struggle to stay abreast of the latest funding opportunities. This system could provide timely alerts about upcoming grants, competitions, and investment opportunities tailored to each startup's specific needs and stages. This approach would ensure that startups have a clear sight of the opportunities tailored to each startup's specific needs and stages.

### 6.3.2 Tailored Regulatory Navigation Support

Our analysis highlights startups' significant hurdles in navigating the complex regulatory LSH landscape. unlock_ could consider implementing a more structured regulated mentorship program to address this. Here unlock_ could pair startups with seasoned industry professionals who have successfully navigated these complex pathways.

In more complex cases, unlock_ could use some of its budgets to sponsor or subsidize consultations with regulatory experts, allowing startups to receive specialized advice specific to their unique situation.

Lastly, it could be part of the curriculum that startups focus on mapping their regulatory pathway. After doing this, startups can get feedback and advice from professionals on their roadmaps.

### 6.3.3 Sector-Specific Support

It is evident from the study that the challenges faced and the progression patterns of startups differ across sectors. Given this, unlock_ could provide more targeted, sector-specific support. This tailored approach could involve a more detailed understanding of the sectors and their unique needs, resulting in more effective strategies.

### 6.3.4 Utilizing this Tool

unlock_ could emphasize the value of this study and the provided tool. It could be an excellent possibility to keep track of the participants and stay updated on their progress and struggles. Monitoring the participating startups now and then could give insights into what startups need and that particular moment, which makes it possible for unlock_ to offer the support that they need at that moment. By doing this, the unlock_ incubation program could become more dynamic.

# Chapter 7: Self Reflection

Beginning my internship at unlock_, my primary role involved assisting with the program management of the unlock_ incubation program and the venture academy, which serves as a pre-incubation program of PLNT. My duties encompassed aiding startups with pivotal aspects, including refining their pitches, developing regulatory strategies, and designing effective business models. Being scientifically oriented myself, my expertise was valuable because I could understand the technologies of these startups.

The daily exposure to these startups and their numerous unique cases significantly augmented my understanding of the challenges one confronts when launching a company. Considering my ambition to become an entrepreneur, this knowledge is highly relevant.

My involvement continued beyond assisting these startups. I was actively present during the incubation sessions, gaining profound insights into the intricacies of the regulatory pathways within the LSH sector, IP rights, team formations, and equity divisions.

However, the most transformative aspect of my experience at unlock_ was undoubtedly the opportunity to be surrounded by like-minded individuals who are a few steps ahead in the entrepreneurial journey. Observing their unwavering determination and enthusiasm amidst stress and challenges has been an immense source of motivation for me.

The internship also served as a significant networking opportunity. Working with professionals who can contribute to my future entrepreneurial endeavors allowed me to expand my professional network exponentially.

Concurrent with my program management role, I was engaged in research, which mainly involved conducting interviews and developing a good measuring tool. Initially, it was a challenging task, but as I progressed, I evolved and improved significantly. This allowed me to extract more valuable information during the interviews, enhancing the quality of my research.

One of the significant hurdles I encountered was adapting my tool to align seamlessly with unlock_'s requirements. Given my limited knowledge and information at the outset, it was a complex task. Despite some room for improvement, I am satisfied with the progress in refining the tool during my internship.

My initial lack of understanding regarding the complexities of the entrepreneurial journey in the LSH sector, especially concerning regulatory, legal, and clinical aspects, posed particular challenges. However, exposure to many business models and compliance matters during my internship significantly filled these knowledge gaps.

As I reflect on my professional development during this internship, I found a stronger drive to become an entrepreneur and gained much knowledge and an invaluable network. These assets will undoubtedly prove instrumental in my future endeavors. My self-analysis reveals my aptitude for communication and connecting with people as one of my strengths, which significantly

facilitated my research interviews and daily interactions with startups. On the flip side, I need more specific knowledge in some areas, and occasional oversights are areas I intend to work on.

The various courses in the FBE program found practical applications during my internship, be it financial management, strategic management, business research and operations, and entrepreneurship. Applying financial management principles during tasks such as balance sheet preparation and financial calculations, strategic management theories in market analysis, commercialization strategies, and understanding intellectual property rights proved invaluable. The business research and operations course also aided me immensely during interview conduction and data analysis. Furthermore, the foundational entrepreneurship knowledge I acquired from my coursework was instrumental in understanding and addressing startup cases swiftly.

Contemplating my first job, I plan to retain my eagerness to learn and sociability, which served me well during the internship. Whether I embark on my entrepreneurial journey or opt for a managerial or consulting role in a company, the knowledge, and experience I gained during the internship will help me further in the future.

# Appendix

**Deliverables on Business Level**

| | Business | Weight |
|---|---|---|
| **Need** | We have an idea of the envisioned business model for our company | 2 |
| | We have an idea on how we will protect our business model/concept/product from bein copied by others | 2 |
| | We have created an overview of the stakeholders who will be most important for our business | 2 |
| **Idea** | Developed a comprehensive business plan, including market analysis, financial projections, and marketing strategies. | 2 |
| | We have indentified & contacted mentors/advisors who can support us in the development of our business model | 2 |
| | We have an iea of the exchange of value between different stakeholder in our business model | 2 |
| **PoC** | We have indentified & attracted key resources we need to make our business model work | 2 |
| | We know which key partners we need to make our business work model work | 2 |
| | Conducted market validation studies or pilot programs to gather feedback from actual customers or users. | 2 |
| | Secured additional funding or investment to support further development and commercialization efforts. | 2 |
| | Developed strategic partnerships or collaborations to expand market reach. | 2 |
| **PoF** | Achieved significant market traction with a (potential) growing customer base (and increasing revenue.) | 2 |
| | Developed a scalable business model and we know what our revenue model | 2 |
| **Validation of Solution** | We have validated our revenue model concept with key stakeholders in the fi | 2 |
| | We got at least one institutional investment | 2 |
| | Expanded market reach and customer base through strategic partnerships or acquisitions. | 2 |
| | Developed a strong competitive advantage and barriers to entry. | 3 |

**Deliverables on Market Level**

| | Market | Weight |
|---|---|---|
| **Need** | Identified and validated the size of the target market and potential customer segments. | 2 |
| | Conducted market analysis to identify market trends, customer preferences, and competitive landscape. | 2 |
| | We have indentified barreirs to entry for our target market | 2 |
| | We have calculated our TAM, SAM & SOM | 2 |
| **Idea** | Conducted market validation studies, surveys, or customer (talked to 5+ experts or key opinion leaders) interviews to gather feedback and refine the product-market fit. | 2 |
| | We mapped out our competitive landscapen(strenghts/weaknesses from competitors) | 2 |
| | We have indentified what differntiates us from our competitors: our Unique Selling Points | 2 |
| **PoC** | Demonstrated market traction with successful pilot programs, early customers, or initial sales. | 2 |
| | Refined marketing strategies based on customer feedback and market data. | 2 |
| | Conducted competitive analysis and adjusted positioning in the market. | 2 |
| **PoF** | Established a strong market presence with a significant share of the target market. | 2 |
| | Built a recognized brand and reputation as a trusted provider of the | 2 |
| | Identified and pursued new market opportunities and partnerships. | 2 |
| **Validation of Solution** | Established a dominant market position with a strong customer base and brand recognition. | 2 |
| | Expanded into new markets or regions with successful market | 2 |
| | Continuously monitored and adapted to market trends and customer needs. | 2 |

**Deliverables on Regulatory Level**

| | Regulatory | Weight |
|---|---|---|
| **Need** | Conducted initial regulatory research to understand the regulatory landscape and requirements for the technology. | 2 |
| | We have lookoed to see if there are other similar patents available | 2 |
| | We have an idea if we have FTO and if our technology needs to be regulated by ISO | 2 |
| | Started discussions with regulatory agencies or experts to gather feedback and guidance. | 2 |
| **Idea** | Conducted regulatory assessments to identify the regulatory pathway and requirements for the technology. | 2 |
| | We have indentified our preliminary regulatory classification (CE) | 2 |
| | We have done preliminary risk & hazard analysis | 2 |
| | We have created a draft of claims we want to make about our | 2 |
| | Developed a regulatory roadmap and initiated regulatory submissions, if applicable. | 2 |
| | Established a regulatory compliance framework to ensure adherence to regulatory standards. | 2 |
| **Proof of Concept** | **Preliminary regulatory classification:** Regulatory body (FDA in the US) classification of your product based on products or services that work in similar ways. | 2 |
| | **Preliminary regulatory pathway:** The regulatory pathway you expect will be used to approve your solution. | 2 |
| | **Preliminary intended/indications for use:** A description of the way the | 2 |
| | **Preliminary risk and hazard analysis:** | 2 |
| | | 2 |
| **Proof of Feasibility** | | 2 |
| | **Draft essential requirements checklist:** The regulatory pathway will determine what information is required. | |
| | **Submission pathway defined:** An updated version of the preliminary regulatory pathway you expect will be used to approve your solution. | 2 |
| | **Draft product claims:** A draft of the claims that company wants to make | 2 |
| | **Draft instructions for use:** Instructions for Use | 2 |
| | **Institutional approval request(s):** A justification and proposed protocol | 2 |

**Deliverables on Clinical Level**

| | Clinical | Weight | I |
|---|---|---|---|
| Need | Identified the clinical problem or challenge that the technology aims to address. | 2 | |
| | Conducted initial research or literature review to support the clinical need. | 2 | |
| | We have indentified and talked to our user, buyer, and payers | 2 | |
| Idea | Conducted initial feasibility studies or proof-of-concept (POC) studies to demonstrate the technical viability of the technology. | 2 | |
| | Developed a prototype or minimum viable product (MVP) for testing and validation. | 2 | |
| | Conducted early-stage preclinical studies or simulations to gather data on the potential clinical impact. | 2 | |
| PoC | Conducted preclinical studies or early-stage clinical trials to gather data on safety, efficacy, and feasibility. | 2 | |
| | Refined the product design or features based on clinical feedback and user experience. | 2 | |
| | Started building evidence of clinical utility or value proposition. | 2 | |
| PoF | Conducted comprehensive clinical trials to gather robust evidence of safety, efficacy, and clinical utility. | 2 | |
| | Published or presented clinical data in reputable journals or conferences | 2 | |
| | Obtained endorsements or recommendations from key opinion leaders or experts in the field. | 2 | |
| dation of Solu | Generated robust clinical evidence supporting the safety, efficacy, and clinical utility of the technology. | 2 | |
| | Obtained endorsements or recommendations from key opinion leaders or experts in the field. | 2 | |
| | Demonstrated superior clinical outcomes compared to existing solutions or standard of care. | 2 | |

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