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A Comprehensive Case Study on the Provided Support of Dutch Facilitators in the Academic Entrepreneurial Ecosystems for Health-Tech Spin-offs

Master Thesis: Engineering and Policy Analysis

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by

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Preface

K.J. Hogeboom
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To start, I would like to express my gratitude towards my two supervisors during this thesis process, Hanieh Khodeai and Saba Hinrichs-Krapels. During our meetings, I gained valuable insights that are needed to improve the quality of this research continuously. Hanieh particularly aided this project with her quick responses in which she shared crucial knowledge regarding the aim and execution of this study. The implementation of the content analysis and creation of the development framework are direct results of this. I would like to thank Saba for her contributions to enhancing the scientific value of this work and aligning this thesis with the EPA master's program.

In addition, I want to thank all interviewees for participating in this research. Their knowledge and experiences represent the core of this study making the outcomes have scientific and practical implications. I also highly enjoyed the conversations and will use the findings to develop my health-tech spin-off further.

Lastly, I want to thank all my family and friends for their support and trust in me. Their help extends beyond my thesis process and has been valuable during my entire academic journey at TU Delft.

Executive Summary

The COVID-19 pandemic's impact shocked the world, as it affected all elements of our society, particularly our healthcare system. Innovations potentially make the healthcare system more resilient towards these outbreaks and demographic changes (e.g. ageing population). These innovations often originate out of university research and are later transferred by health-tech spin-offs to the market where they create societal value. The Netherlands is no exception to these effects and recognizes the need to support these spin-offs in their journey towards impact. In the early stages of their creation, this support is provided through facilitators within academic entrepreneurial ecosystems. These ecosystems are designed to stimulate the growth of spin-offs by aiding them in overcoming challenges. Some of these challenges are themed bound and uniquely related to the health-tech spin-offs (e.g. clinical regulation). Facilitators of Dutch academic entrepreneurial ecosystems currently assist these groups yet lack knowledge about the effectiveness of their efforts and what enhancements are required for improvements. These knowledge gaps lead to the formation of the main research question:

"How can Dutch academic entrepreneurial ecosystems facilitate the development process for health-tech spin-offs?"

The answer to this question is a result of the three sub-questions that led to an understanding of the current Dutch support system by facilitators of academic entrepreneurial ecosystems and the mismatches in their support towards health-tech spin-offs. The mismatches occur on the factors of tailor-made health-tech programs, clinical validation support, funding demand during product validation, and efficient networking. They form the start of how the facilitators should redirect resources towards a focused support system dedicated to health-tech spin-off needs. The mismatches are also connected as problems with clinical validation can lead to further funding demand. Moreover, facilitators should differentiate on sub-themes such as pharma and biotech to aid the health-tech spin-offs more effectively. Specialised support such as this exists in the Dutch ecosystems (e.g. Unlock & MISO) and should be further stimulated. In the discussion, a short example is given of an existing program of the London Institute of Healthcare Engineering centred around the development of medical devices. These examples can aid in the understanding of how to enhance the support systems.

The findings of this research are the effect of an employed qualitative mixed methods approach combining a literature analysis and interviewing technique. Literature is utilized to generate insights regarding the functionality of academic entrepreneurial ecosystems and the development process of health-tech spin-offs. This knowledge is applied while obtaining qualitative data from facilitators and founders during the use case. A direct example of this is the construction of the development framework, implemented to communicate the interview questions and structure the outcomes. Through a semi-structured approach, a total of 16 interviews were conducted, and recorded for this research, consisting of 9 facilitators and 7 founders. Information from these conversations was highly relevant and analyzed manually by the researcher. Additionally, the development framework was revised into a version better suited to the Dutch academic entrepreneurial ecosystems.

Answering the research question starts by creating an understanding of the key facilitators within academic entrepreneurial ecosystems and the support they offer through literature analysis. Grasping the functionality of the entrepreneurial ecosystems led to the identification of elements that form the building blocks of these ecosystems; Education & Research, Human Capital, Finance & Funding, Government, Support & Networks, and Entrepreneurial Culture. Although related, the academic entrepreneurial ecosystems function differently, thereby covering some of the elements through their facilitator support. The end of this section discovers the types of support, that represent these elements; *Infrastructure support*, *Business support*, *Financial support*, *Social support* and *Legal support*. These support types are later linked to the discovered types of facilitators; Technology Transfer Office (TTO), incubator, accelerator, science park and financial facilitator. This deepens the understanding regarding the functionality of an academic entrepreneurial ecosystem, its facilitators and their services.

This preliminary understanding is then applied to the setting of three Dutch academic entrepreneurial ecosystems during a use case. For each of the ecosystems, Delft University of Technology (TU Delft), Erasmus Medical Centre (EMC) and Leiden University Medical Centre (LUMC), this research determines a list of all facilitators and their support relevant to health-tech spin-offs during their development process. This revealed specialized support areas per ecosystem where TU Delft leads in overall support while painting expertise on high-tech inventions (e.g. biotech). EMC differentiates itself by centring its aid on medical devices whereas LUMC focuses on pharmaceutical-related spin-offs. Moreover, the study introduced sub-forms of support to determine the prioritization of support through content analyses. It was evident that facilitators centred their resources on stimulating social support over other forms.

Lastly, interviews were held with founders to evaluate the current support on their suitability for health-tech spin-offs. This indicated that the effectiveness of support varies between the ecosystems and the type of aid they provide. In general, TU Delft offers the most extensive forms of support while LUMC hosts a dedicated business support program on health-tech spin-offs. EMC lacks on these topics, yet creates impact through their dedicated services to medical device companies (MISO). Overall, mismatches in support occurred on the factors of tailor-made health-tech programs, clinical validation support, funding demand during product validation, and efficient networking.

The discovery of the health-tech spin-off development process, current facilitator support, and the identification of aid mismatches result in the necessary findings for the Dutch ecosystems to fit their support effectively to the needs of health-tech spin-offs. The results carry practical implications as scientific contributions. On a practical level, founders gain more clarity on the operations of support being provided in the Dutch ecosystems. Similarly, facilitators gain knowledge on the development process and entrepreneurial journey of health-tech spin-offs. This in combination with the current mismatch can guide them in shaping their support more compatible with health-tech spin-offs, of which the London Institute of Healthcare Engineering (LIHE) represents a potential example. Scientifically, this research adds to the existing literature by improving the knowledge regarding the similarities and differences between entrepreneurial ecosystems in normal settings and academic ones. In addition, the outcomes contribute greatly to the understanding of health-tech spin-offs in their development. Moreover, relating this to the discrepancies in the current Dutch support offers a novel approach to the established literature. Finally, an interesting finding is the operational focus of the Dutch ecosystems, where each ecosystem specializes in its services.

This thesis executes exploratory research into the mentioned topics. Time limitations and other factors constrain some aspects of it thereby influencing recommendations for future research. To start more knowledge should be obtained on the effectiveness of solutions that resolve the identified mismatches considering the specialized focus of ecosystems. This can be combined by examining the performance of existing support constructions (e.g. LIHE). Given the context of the EPA masters, it is suggested to dive deeper into the Dutch national policies, evaluating their suitability with the discovered mismatches for health-tech spin-offs. Finally, due to unforeseen interest by interviewees, the usability and scientific value of the development framework for health-tech spin-offs should be investigated further. The outcomes of this study provide a starting point for research and practical implications that aid in increasing understanding of how academic entrepreneurial ecosystems should facilitate the development process of health-tech spin-offs.

Keywords: academic entrepreneurial ecosystem, founder, facilitator, health-tech, support, spin-off, development process

Contents

List of Abbreviations

This section explains the abbreviations as implemented in the research

Abbreviations

Abbreviation	Definition
EMC	Erasmus Medical Centre
IP	Intellectual Property
LIHE	London Institute of Healthcare Engineering
LUMC	Leiden University Medical Centre
TU Delft	Delft University of Technology
VC	Venture Capitalist

1

Introduction

The introduction offers an insight into the current research and discussions concerning the support of academic entrepreneurial ecosystems towards health-tech spin-offs. Sequentially it describes the problem statement, research objectives, research questions and the structure of this study.

In March 2020 the world faced the start of a new pandemic resulting from the COVID-19 virus. More than 27 million people lost their lives due to the virus, causing immense societal panic (The Economist, 2021). Experts expect that the COVID-19 crisis is just the start and that pandemics will become one of the leading threats against society (Joi, 2022). With an exponentially growing global population and a strong increase in the ageing demographic, the effects of health-related threats are more impactful than ever. Innovations in health technology (health-tech) enable an affordable and increased level of healthcare contributing to more sustainable healthcare systems, which is named one of the Grand Challenges (Lehoux et al., 2014). The term health technology embraces all inventions related to the healthcare system as seen in the definition by the World Health Organisation ”the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life.” (WHO, n.d.). These health-tech innovations often find their origin in university knowledge and technology. In order for society to benefit from these solutions the innovation is typically transferred to the market through an academic spin-off. A great illustration of this can be seen in the construction of the COVID-19 vaccine by Johnson & Johnson (J&J). The vaccine was created by the department of J&J named Janssen Vaccines, which originated from the Crucell, a former Leiden University spin-off (Invest Europe, n.d.). This spin-off established a deep understanding regarding vaccines for diseases such as hepatitis, fever, typhus and cholera. This knowledge set the groundwork for the coronavirus vaccine by Janssen Vaccines. Moreover, the same vaccine was constructed through a collaboration between Johnson & Johnson and the research department of Leiden University NeCEN (Universiteit Leiden, 2021). In this collaboration, NeCEN provided J & J access to their Titan Krios electron microscopes that is able to detect the right form of spike protein needed for the creation of the vaccine.

The outcomes of these spin-offs can continuously improve the global healthcare systems yet implementation of health-tech solutions remains hard as can be seen in the survival rates. A study in Korea indicates that only 39% of all healthcare startups survive after three years (Lee et al., 2019). This trend is supported by data from the United States with an average survival of 37% (Gupta, 2018). The struggle to survive can be linked to the complexity of challenges faced by health-tech spin-offs during the development stages. Spin-offs have to overcome similar hurdles seen by traditional startups but also those related to the academic entrepreneurial ecosystem. A spin-off operates in a multi-actor environment with customer discovery, finance, legal and technical feasibility challenges. Specialized spin-offs such as those in the health-tech domain face distinctive challenges associated with their domain. A typical example is seen in the medical trials that health-tech spin-offs have to execute in which the effect of their technology on the human body is examined. Academic entrepreneurial ecosystems aim to assist the spin-offs in all of these obstacles through the provision of various facilities. This phe-

nomenon is called academic entrepreneurship, a new focus pillar shared by academic ecosystems. Dutch academic ecosystems are no exception to this, yet specified knowledge is needed to support the health-tech spin-offs effectively.

1.1. Problem statement

New health innovations are needed for the continuation of our global healthcare system. The Dutch entrepreneurial ecosystems are focused on health-tech startups as they represent 31% of all startups in The Netherlands, making it one of the two leading sectors (TechLeap, n.d.). Universities play a vital role in the creation of new technology and are dedicated to providing this service. The results of the efforts as visible as startups within these ecosystems are 3.45 times less likely to quit (Arruda et al., 2014). The survival rate for startups in the last 8 years in The Netherlands was even 85% (TechLeap, n.d.). Still, their impact remains low as after 10 years only 48% of Dutch startups employ more than 10 people, potentially influenced by a lack of proper support (e.g. funding) (TechLeap, n.d.). Supporting specified spin-offs is complex and policymakers search for a general 'secret sauce' method while this concept does not exist (Ziakis et al., 2022; Stam and van de Ven, 2021). To be effective, Miner et al. state that these supportive policies should be specified towards the infrastructure of the universities as they are unique per ecosystem (Isenberg, 2011; Miner et al., 2012). Current literature provides knowledge for academic entrepreneurial ecosystems to construct a base in aiding academic spin-offs. Yet the Dutch universities lack the detailed insights to accommodate fitting support in their entrepreneurial ecosystems for health-tech spin-offs. The absence of the needed knowledge could lead to ineffective support mechanisms and unintended harmful outcomes (Miner et al., 2012).

The knowledge gaps within the current literature relate to several topics. First, many studies are aimed at the entrepreneurial ecosystem in general. In those systems, the academic ecosystem is often taken as one big component while in reality, such an ecosystem consists of various facilitators with its own functionality. Moreover, the startup entities in these ecosystems are spin-offs which operate differently and cannot be directly compared to traditional startups. Both these aspects are examples of why this knowledge is too general for the Dutch use case. More specified literature does include academic entrepreneurial ecosystems focusing on supporting. Studies identify the relevant elements found in the current academic entrepreneurial ecosystems. Furthermore, research focuses on describing the ecosystems' dynamics and which barriers/drivers are influencing them.

These studies provide an initial framework for the understanding of academic entrepreneurial ecosystems and are utilized in the literature analysis of chapter 2.3. Still, there remains a knowledge gap in how well these ecosystems are designed to specifically support health-tech spin-offs. Specialised spin-offs follow unique development journeys in which aid is needed to overcome distinct obstacles. Sequentially, these findings of ecosystems are highly dependent on their geographical & and cultural settings (Tripathi et al., 2019; Ziakis et al., 2022). This means that insights from these studies might not apply to the Dutch academic landscape. Differentiation in the scope and scale implies that employing the findings for policy advice towards the Dutch academic entrepreneurial ecosystems may result in a misalignment and unproductive outcomes. To gain fitting insights into the Dutch ecosystems, this research employs a use case through qualitative research with interviews.

1.2. Research objective

Innovations by spin-offs in health technology can increase the quality of global healthcare. As discussed, many of these spin-offs struggle to thrive due to challenges associated with the typical startup journey, as well as those specific to health-tech ventures. Facilitators within the academic entrepreneurial ecosystem share the common goal to assist the health-tech spin-offs in this development process yet lack the proper knowledge on how to do this effectively.

This study's objective is to gain insights into how the three Dutch academic entrepreneurial ecosystems should design their supportive structures to facilitate health-tech spin-offs. This research contains a use case related to the three Dutch academic ecosystems of Delft University of Technology (TU Delft), Erasmus Medical Centre (EMC) and Leiden University Medical Centre (LUMC). This selection of these academic entrepreneurial ecosystems was based on the innovative drive seen within these ecosystems

and their relevance towards medical technologies (Molema and van Egmond, 2017). The objectives of this research are discussed in the following sections and relate to the implemented methodology which is further explained in chapter 2.

The study's first phase employs a literature analysis to create an understanding of the functionality of academic entrepreneurial ecosystems and the development process of health-tech spin-offs. The first focus elaborates on vital concepts within this research domain leading towards the identification of support types by key facilitators within academic entrepreneurial ecosystems. The other part of the literature analysis, reveals the early-stage development process for high-tech startups, traditional spin-offs and health-tech spin-offs. The insights of these advancement mechanisms influence the listing of the most crucial barriers faced by health-tech spin-offs. All findings of the literature analysis are utilized for the creation of a framework that outlines the development process of health-tech spin-offs, stating the needed actions while linking the relevant facilitators and their support.

This framework is applied during the second stage of the research, evaluating the current support given by the three Dutch academic entrepreneurial ecosystems towards health-tech spin-offs within the various development stages. By gathering qualitative data through interviews with both facilitators and founders of health-tech spin-offs, this research aims to examine the current support while simultaneously identifying potential mismatches in its execution. It creates a perspective on how the Dutch academic entrepreneurial ecosystems perceive the hurdles of the spin-offs and how they design their support to help these ventures overcome those obstacles. The result of this section leads towards the conclusive aim of this thesis containing advice towards the three Dutch academic entrepreneurial ecosystems on how to increase the quality of support towards health-tech spin-offs during the development process. This new approach could form the start of multiple studies evaluating the current ecosystems focused on specialised startups (eg. healthcare, energy). These results lead to a fitting policy that heightens the startup success rate and improvement of resource allocation.

1.3. Research questions

The state-of-the-art research does not adequately provide the Dutch academic entrepreneurial ecosystems with the knowledge needed to enhance the effectiveness of the support aimed at health-tech spin-offs. This study provides insights into how the three Dutch academic entrepreneurial ecosystems can facilitate the health-tech spin-offs within their development stages. This is achieved by examining various academic entrepreneurial ecosystems found in literature and evaluating the alignment between the support of facilitators in the current Dutch academic entrepreneurial ecosystems and the needs of the health-tech spin-offs. This concludes with advice on adjustments towards the facilitators of the three Dutch academic entrepreneurial ecosystems. The found knowledge gaps and this research focus result in the following research question:

MQ: "How can Dutch academic entrepreneurial ecosystems facilitate the development process for health-tech spin-offs?"

To approach the main question, three sub-questions were constructed. Segregating the research into different components through these sub-questions leads to insights needed to answer the main question.

SQ 1: "What are the key facilitators and their support within academic entrepreneurial ecosystems towards spin-offs?"

SQ 2: "What support is given by the facilitators in the Dutch academic entrepreneurial ecosystems toward health-tech spin-offs in the development phases?"

SQ 3: "What is the mismatch between the support given by the Dutch academic entrepreneurial ecosystems and the needs faced by health-tech spin-offs during the development phases?"

The first sub-question functions by providing an understanding of the academic entrepreneurial ecosystems found in the literature through the identification of support by key facilitators. Sequentially, the literature outlines the development process for health-tech spin-offs. Sub-question two investigates how facilitators in the Dutch academic entrepreneurial ecosystems perceive their own support towards the health-tech spin-offs. The final sub-question utilizes the information from the previous sub-questions to conclude the level of mismatch between the needs of the health-tech spin-offs and the current support by facilitators.

1.4. Thesis structure

This thesis research starts with a description of the applied methodologies for the stated research questions in Chapter 2. Next, it executes an in-depth literature analysis leading to the knowledge needed for the construction of the development process framework at the end of Chapter 3. Consequently, using the framework, data is gathered in the use case for the three Dutch academic entrepreneurial ecosystems as described in Chapter 4. In Chapter 5, the insights from the research are used to identify the mismatch in support by the facilitators. Following this in Chapter 6 a revised version of the development process framework is presented based on the findings of the qualitative data. Chapter 7, describes the conclusion of the study which includes the answering of all the research questions. Finally, the discussion, in Chapter 8, provides the implications of the findings, the limitations of the study and recommendations for future research.

2

Methodology

The purpose of this section is to provide an overview of the applied methodology during this research. It starts with a general approach to the research followed by a research design outline. Accordingly, an explanation is given of the used methods per sub-question, followed by an in-depth description of the steps within the methodology.

2.1. Research Design

The research design is tailored to fit the goal of this research on how the Dutch academic entrepreneurial ecosystems can design their support to facilitate health-tech spin-offs. The design of the research employs a qualitative mixed methods process, specifically a triangulation method. This technique uses a combination of methods to form a more comprehensive understanding of a topic or phenomenon (Patton, 1999). In this case, two methods are merged; a literature analysis and an interview technique. These methods are divided into three sections which make up the methodology of this research; *literature analysis, framework creation and use case*. Figure 2.1 provides an overview of the methodology and its stages which are further described in 2.3 and onwards.

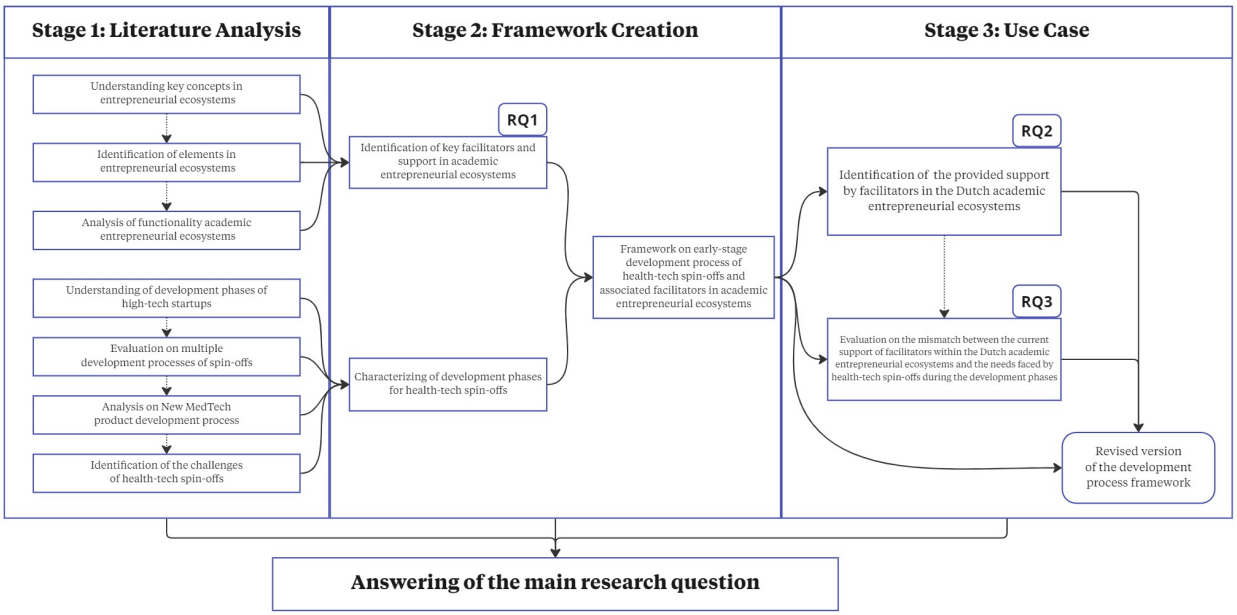

Figure 2.1: Schematic representation of the research methodology (author, 2024)

The research starts with a literature analysis to grasp an understanding of relevant topics needed to answer the research question. This method specifically fits well with the goal of this study as literature analyses are often used in research fields relating to social- and management mechanisms (Snyder, 2019). The literature analysis focuses on two overarching topics: the support towards (health-tech) spin-offs provided by key facilitators and the challenges experienced by the health-tech spin-offs in their development stages. The preliminary understanding from this analysis is input for the design of a framework that captures the needs of the and links them to the associated facilitators found in the literature that offer support on those needs. This framework forms the basis for the second method; interviewing used in the case studies. This technique is widely applied in various research fields as it allows individuals to share their interpretation of the world around them (Knott et al., 2022). This particularly fits well with the type of data needed for this study as these entrepreneurial support systems are based on social structures. The answers to the research questions lie in personal knowledge and experiences. Moreover, this method can help to unravel insights as some of the data needed might not be recorded or sensitive to share on paper.

2.1.1. Methodology per sub-question

The methodology design aids in answering the sub-questions and eventually that one the main research question. For each sub-question, it is stated what methods will be applied, which form of data is needed and how the insights will contribute to the goal of this study.

SQ 1: "What are the key facilitators and their support within academic entrepreneurial ecosystems towards spin-offs?"

Academic entrepreneurship is a rising concept for universities around the world and many studies have been executed on this topic. These insights will be used to identify to most crucial facilitators found in academic entrepreneurial ecosystems. This phase will provide an overview of different key facilitators and a basic setup of the academic entrepreneurial ecosystems. Next, these key facilitators are evaluated on the type of support they offer towards the spin-offs. This helps to understand the underlying dynamics between the key facilitators. More importantly, it reveals the aid the academic support systems find most essential towards spin-offs. This indirectly describes the hurdles faced by the spin-offs in the eyes of the academic entrepreneurial ecosystems. This information is gathered from the literature analysis and the interviews and helps to understand the initial design choices behind the support mechanism for spin-offs.

The insights from this sub-question are used in the construction of the proposed framework. Each development stage in the framework is characterized by specific challenges faced by the health-tech spin-offs. The facilitators are then linked to the stages based on how well their support aids the spin-offs in overcoming the challenges. This leads to a framework that explains the development stages specific to health-tech spin-offs while proposing the facilitators that could offer support. Utilizing the insights from the second and third research questions, a revised form of the framework is created suitable to the Dutch academic entrepreneurial ecosystems.

Research method: literature analysis & use case (qualitative research)

Data: publications, articles, public websites, qualitative data

SQ 2: "What support is given by the facilitators in the Dutch academic entrepreneurial ecosystems toward health-tech spin-offs in the development phases?"

Universities in The Netherlands operate as decentralized structures and will most likely work with different academic entrepreneurial support systems. This question is aimed at getting an understanding of how the three current Dutch academic entrepreneurial systems of TU Delft, LUMC and EMC are designed. Using the theoretical framework and interviews, an overview will be created of the facilitators and the type of support found in the three structures. This data describes similarities and differences between the three Dutch academic systems and those found elsewhere. Moreover, the support will be analyzed using the development stages described in the framework and reveal the facilitator's perspective on the hurdles of the spin-offs and their assumption on the effectiveness of their help in overcoming

these. These insights will be further used to answer sub-questions three and four, associated with the alignment of needs by health-tech spin-offs and mismatch with the current policy of the facilitators.

Research method: literature analysis & use case (qualitative research)

Data: publications, articles, public websites and qualitative data

SQ 3: "What is the mismatch between the support given by the Dutch academic entrepreneurial ecosystems and the needs faced by health-tech spin-offs during the development phases?"

The answer to question two is further examined in sub-question three by determining the mismatch between the provided support and the challenges faced by health-tech spin-offs in the development stages. First, the perspective of the founders of health-tech spin-offs is needed. The initial part of this interview focuses on the proposed development process to see whether they agree with the described stages and the activities that relate to the challenges of the health-tech spin-offs. Next, the interview will emphasize the support they received in their entrepreneurial journey. The findings of these founders will be combined with the perspective of the facilitators to conclude the degree of mismatch of support by facilitators. This analysis provides an understanding of which facilitators in the academic entrepreneurial ecosystems sufficiently provide assistance and which do not, aiding in answering the main research question.

Research method: literature analysis and use case (qualitative research)

Data: publications, articles, public websites, output sub-questions 1, 2 and qualitative data

2.2. Theories

In the various methodology steps seen in this study, there is an underlying application of theories regarding the decoupling/mismatch of support and stages framework. These theories and their influence on this research are described in 2.2.1 & 2.2.2.

2.2.1. Mismatch & Decoupling

Mismatch & Decoupling are two interrelated theories that form the basis for answering the main research question of this thesis research, particularly through sub-questions 3. Mismatch in the effective support given and the challenges of companies is a widely shared problem, that often lies in the lack of understanding by the facilitators of support (Laur and Mignon, 2021). This unawareness by support providers is not the sole reason for the mismatch. Yusuf concludes that this misalignment can be an effect of the shortage of sharing the needs by founders (Yusuf, 2010). The third sub-question tests the concept of mismatch by examining the level of alignment between the support supplied by the facilitators and the need for it from health-tech spin-offs. The outcome of this can be integrated to boost the effectiveness of support in future cases.

The appearance of mismatch is strongly related to the concept of decoupling which Meyer and Rowan describe as "a policy that is formally introduced but not actually implemented and effective" (Meyer and Rowan, 1977; de Bree and Stoopendaal, 2020). It appears in the work context in both an intentional and unintentional manner. The benefits of decoupling, intentionally pursued, are the establishment of legitimacy from stakeholders and the possibility to mitigate conflicts with those stakeholders (George et al., 2006). The occurrence of decoupling is not always a deliberate consequence as stated by (D. Crilly et al., 2012 and Sandholtz, 2012). The lack of consensus in an organisation could potentially result in weak implementation of the policy (Pérezts and Picard, 2015). More practically illustrated in the context of the study, this takes place when an employee of a facilitator does not agree with the policy or feels that it is not suitable or feasible for implementation. This concept directly aligns with the decoupling type of *Policy-Practice* by Bromley & Powell, where this form is depicted as the weak relation between formal policy and daily practices (Bromley and Powell, 2012). This type of decoupling enables facilitators to adopt various, even contradicting, policies under the pressure of external stakeholders in the system. This potentially leads to a loose implementation of the proposed support policy by facilitators. *Means-End* decoupling is the other type and illustrates the weak connection between daily activities and the intended outcome of the policy (Bromley and Powell, 2012). For the setting of this

research, this indicates that facilitators potentially implement policies with the intention of supporting the health-tech spin-offs yet fail to do this effectively. This is a result of the mismatch between the support offered and its fittingness with the needs of health-tech spin-offs. By applying these theories this study aims to capture whether decoupling arises in the policy of the facilitators and the support needed based on the experience of health-tech spin-offs, yet does not include the reasons why this happens.

2.2.2. Stages framework

The concept of stages is widely adopted to define the progress of companies, startups and spin-offs. A more focused form of stages translates to the Technology Readiness Levels (TRL) seen in technology startups. Investors utilize this benchmark to fund startups in a similar stage of development (Pushpapathan, 2022). The Clinical Readiness Level (CRL) represents a variation of this, applied to define the technology progress in the clinical environment (Mejtoft et al., 2022). These concepts and the insights of the literature analysis are inputs for the creation of the proposed framework described in the second stage of the methodology. This framework is an overview of the development stages that the health-tech spin-offs go through, characterised by activities spin-offs are required to execute in order to progress. Furthermore, facilitators of academic entrepreneurial ecosystems are linked to the stages where they potentially can be of the biggest help. This framework is used to guide the interviews by determining the mismatch in the support offered and needed in the Dutch academic entrepreneurial ecosystems. Moreover, it reveals the level of decoupling in the policy of the facilitators and the aid provided in the real-world setting.

2.3. Stage 1. Literature analysis

In the first phase, a literature analysis is executed to form a foundational comprehension of relevant research subjects. These subjects can resemble key themes or previous findings. Abstract B further discusses the methodology applied during the execution of the literature analysis. The literature approach is scoped into two main topics. The first topic focuses on facilitators and their support within academic entrepreneurial support systems found in previous studies. The key concepts are discovered by scoping the literature to conclude with the facilitator and the support. Initially, entrepreneurial ecosystems are analysed to create an understanding of their dynamics and the elements that define them. Next, the literature is narrowed by focusing on the academic entrepreneurial ecosystems. For these systems, the main facilitators are determined and elaborated by describing their aid towards spin-offs. This gains insights into the type of facilitators that are commonly present and the kind of support they provide. This information can later be compared with the Dutch academic entrepreneurial ecosystems.

The development stages of the health-tech academic spin-offs relate to the second study topic. The study starts by examining the development process experienced by companies and startups in general. Later the literature is confined by delving into the development stages of spin-offs and those in the healthcare sector. Gathering information on the needs of the health-tech spin-offs during their development stages could help to understand how the university entrepreneurial ecosystems should design their structures. This can improve the effectiveness of the support while lowering the inefficient use of resources.

The scoping process as described is visualised in 2.1 which entails the databases used, the applied search queries, the search criteria, results and notes on the objective of the search. The searches are primarily centred around the entrepreneurial ecosystems and academic spin-offs, with filters applied to ensure the inclusion of high-quality, recent studies. For example, the first search query in Scopus aimed at the elements that constitute entrepreneurial ecosystems resulted in 284 studies. Additional searches were conducted to identify studies related to academic entrepreneurial ecosystems, development stages of spin-offs, and barriers faced by spin-offs, particularly in health sectors. This systematic approach ensures comprehensive coverage of the relevant literature for the study. The knowledge gained from both literature focuses is used to create a theoretical framework as seen in the second stage 2.4. This framework bridges the hurdles seen in the development stages and the type of support offered by the facilitators. This framework is evaluated in the case studies as elaborated in 2.5.

2.3.1. Method applied in the literature analysis stage

The initial stage of the methodology applies a literature analysis. During the literature analysis, mainly academic sources were utilised to generate an understanding of the topics as the elements of entrepreneurial ecosystems and the development phases of spin-offs. These academic sources are typically found in the form of publications or scientific articles.

2.3.2. Outputs of the literature analysis stage

The outputs of this stage provide insights into the second stage in which the framework for early-stage development process health-tech spinoffs is created. The insights are constructed by understanding the concepts behind entrepreneurial ecosystems, listing the elements that form them and finally analysing how the functionality of these systems in an academic environment. Simultaneously this stage characterizes the development phases for health-tech spin-offs. This starts by examining the development process for high-tech startups. Later information is gathered on various development mechanisms specified for spin-offs. Finally, this scope leads to the evaluation of the New MedTech product development process. The understanding of these distinct innovation processes leads to a list of challenges associated specifically with health-tech spin-offs.

Table 2.1: Literature search overview (author, 2024)

Database	Search queries	Criteria	Results	Notes
Scopus	”entrepreneurial” AND ”ecosystem” AND ”elements”	Filter on highest cited and search setting between 2007-2024	284	Needs to include studies that discuss the process of entrepreneurial ecosystems and elements that create it.
Scopus	”academic” AND ”entrepreneurial” AND ”ecosystem” (AND ”spin-off”)	Filter on highest cited and search setting between 2007-2024 and English and keyword to ”Academic entrepreneurship”	41	Studies that describe the building blocks for academic entrepreneurial ecosystems
Web of Science	”development” AND ”stages” AND ”spin-off”	Filter on most relevant for all years	79	These studies cover the development process specifically for the academic spin-offs
Scopus	”development” AND ”stages” AND ”spin-off”	Filter on highest cited and search setting between 2000-2024	134	These studies cover the development process specifically for the academic spin-offs
Scopus	”barriers” AND ”spin-offs” (AND ”medical” OR ”health”)	Filter on highest cited and search setting between 2000-2024	46	These studies describe the problems spin-off face, sometimes focused on the medical themed ones.

Description:

Table 2.1 provides an overview of the literature search conducted across multiple databases. The table includes the databases utilized, the specific search terms applied, the criteria implemented to filter the results, the number of researches obtained, and any relevant notes.

2.4. Stage 2. Framework creation

The second stage of the methodology includes the creation of a framework that includes the principles captured in the literature analysis. These principles are broadly defined and relate to both the support provided in academic entrepreneurial ecosystems and the hurdles faced by the specialised health-tech spin-offs. The construction of the framework can be divided into three sub-stages; (1) understanding the concepts found in literature, (2) the selection of the key concepts and (3) the identification of the linkages between the key concepts.

The first sub-stage (1) includes the analysis of concepts found in the literature and is covered in the first stage of this methodology as seen in 2.3. In the second sub-stage (2) key concepts are identified for both literature focuses; facilitator support and development stages. Extensive literature is available on both topics thereby underlining the need for correct selection criteria. For the facilitators, this was executed by determining the elements present in entrepreneurial ecosystems. These elements were then employed to examine their occurrence within academic entrepreneurial ecosystems. This approach led to a list of facilitators within the academic entrepreneurial ecosystem that offers the most crucial support aimed at spin-offs in the early stages of development. A similar strategy was applied for the bounding of literature in the context of the development process of spin-offs. Initially, the understanding was created of the development process seen in startups in general. The latter led to the concept of phases in a development process and the characteristics associated with each phase. The concept was taken and tested in the environment of spin-off formation, for both the general perspectives and that of product development. The two perceptions resulted in phases where specific actions were required to be completed for progression. Lastly, the position of the spin-offs in the development process was taken and further framed towards health-tech ones. This revealed, in addition to the overarching challenges, distinct obstacles specifically linked to health-tech spin-offs.

The final sub-stages concentrate on the identification of the connections between the needs experienced by health-tech spin-offs during their development stages and the support offered by the key facilitators in the academic entrepreneurial ecosystem. The framework can be defined as an outcome of these linkages and aims to combine the previously mentioned findings. The goal of the framework is to outline the key hurdles of health-tech spin-offs and propose how the academic entrepreneurial ecosystems can aid the spin-offs through the facilitators. This is then evaluated in the case studies for the ecosystems of TU Delft, LUMC and EMC during interviews with various experts. The lack of availability of the described framework motivated its creation during this study. The framework is a form of graphic elicitation, fitting for qualitative research as it aids in the transfer of information between the interviewer and interviewee (N. Crilly et al., 2006). This study also includes the practical approach of graphic elicitation as stated by N. Crilly et al., 2006. In this process, the visualisation output (framework) is modified after the feedback from the interviewees as seen in stage 3. As a result, the final version of the framework is more fitting to the realistic setting of the support by Dutch academic entrepreneurial ecosystems for health-tech spin-offs and can be applied to improve the effectiveness of the support.

2.4.1. Methods applied in the framework creation stage

The results of the literature analysis stage form the foundation for the creation of the framework. Therefore the framework deploys the method of literature analysis through both academic and grey literature. The grey literature is incorporated to give more accurate background information to the framework such as the size of funding needed per stage.

2.4.2. Outputs of the framework creation stage

The final output of this stage is the construction of the framework for the development process of early-stage health-tech spin-offs. This framework combines the literary findings on both the support side by facilitators and the needs side of spin-offs. The mentioned support side relates to the identification of the key facilitators and their support in the academic entrepreneurial ecosystems. The needs are the results of the discovered development process of health-tech spin-offs and the associated hurdles. The mentioned framework merges the insights by linking the support to the specific needs per development phase.

2.5. Stage 3. Use case

Stage three continues on the previous stages by testing the theoretical framework in the real-world setting of the academic entrepreneurial ecosystems of Delft University of Technology (TU Delft), Leiden University Medical Centre (LUMC) and Erasmus Medical Centre (EMC). This approach has the goal of examining whether the proposed framework aligns with the process seen in the three ecosystems. Findings from the case studies help to identify the competencies of support by the facilitators and more importantly the shortcomings. These insights can be utilized to design support systems more effectively to fit the hurdles of health-tech spin-offs. In addition, resources related to this support can be distributed more efficiently. Moreover, insights derived from the data help to improve the level of implementation of the framework in a practical setting so that it can be adopted by other academic entrepreneurial ecosystems.

Initially, grey literature was utilised to identify the relevant facilitators within the three ecosystems. Similarly, this grey literature helped to understand what kind of support these facilitators provide to the startups/spin-offs. These inside are combined at the start of the use case chapter and form the input for the interviews. The interviews have the goal of collecting qualitative research through conversations with both employees of facilitators and founders of health-tech spin-offs. This technique is widely used in various research fields as it allows individuals to share their interpretation of the world around them (Knott et al., 2022). This particularly fits well with the type of data needed for this study as these entrepreneurial support systems are based on social structures. The answers to the research questions lie in personal knowledge and experiences. Moreover, this method can help to unravel insights as some of the data needed might not be recorded or sensitive to share on paper.

2.5.1. Interviewee sampling

As mentioned data is gathered through interviews which requires the sampling of experts. The defined criteria for the selection of the experts for the facilitators within the three academic entrepreneurial ecosystems are based on the organisation in which they are active, their knowledge of the support offered and their level of seniority and experience. The choice of founders of the health-tech spin-offs was based on the type of health-tech spin-off, their seniority and experience and the age of the spin-off itself. Relating to the latter criterion, there is a preference for longer-existing spin-offs as they are more familiar with the hurdles seen in the development process. For the outcome of this study, it is essential that the experts cover the perspective of the various facilitators as much as possible. This increases the extent to which a conclusive statement can be made about the system as a whole. The same relates to the variety of the founders interviewed, as this can underline known hurdles or highlight new forms. Interviewees were approached through the use of personal contacts and suggestions. Communication with the interviewees and the corresponding was executed through a depicted process seen in 2.5.2. Table 2.2 portrays an overview of all interviewees included in this research.

Table 2.2: Overview of interviewees (author, 2024)

Type of interviewee	Facilitator	Founder
Delft University of Technology (TU Delft)	-	-
Representative of YES!Delft	X	-
Representative of Delft Enterprises	X	-
Representative of Impact Studio	X	-
Founder of MedTech startup	-	X
Founder of MedTech spin-off	-	X
Founder of MedTech spin-off	-	X
Erasmus Medical Centre (EMC)	-	-
Representative of TTO EMC	X	-
Representative of Graduate Entrepreneur	X	-
Founder of MedTech startup	-	X
Founder of MedTech spin-off	-	X
Leiden University Medical Centre (LUMC)	-	-
Representative of LURIS	X	-
Representative of PLNT	X	-
Representative of Unlock	X	-
Founder of digital health startup	-	X
Founder of pharma spin-off	-	X
Kings College London	-	-
Representative of London Institute of Healthcare Engineering (LIHE)	X	-

Description:
Table 2.2 creates an overview of the interviewees categorized by their institution and their role as either facilitator or founder. The ”X” marks the presence of an interviewee with these particular roles. Institutions include TU Delft, EMC, LUMC, and Kings College London. Facilitators represent organizations such as YES!Delft and LIHE, while founders are from various MedTech and digital health startups and spin-offs.

2.5.2. Data Collection process

As mentioned, a semi-structured interview method is applied for the collection of data from facilitator experts and founders. Semi-structured interviews are chosen for this study as they allow the researcher to create a greater understanding of the perspective of the participants rather than grasping the generalized idea of a concept (McGrath et al., 2019). Moreover, semi-structured interviews provide freedom to the researcher to take autonomy during the conversations and steer towards interesting topics for the research (Adeoye-Olatunde and Olenik, 2021). This is simultaneously the reason why a survey-based method was not selected, as it emphasizes the collection of data on a large scale that lacks subject focus.

The structure of the data collection process is divided into three phases. These three phases are constructed as *interview preparation, interview execution, interview interpretation*. *Interview preparation* entails all the activities prior to the interview and includes the sampling of the interviewees, scheduling the interviews, creating the research questions and sending the research questions and consent form in advance. The end of the literature analysis led to the creation of the first version of research questions. These were then sent to the study’s supervisors for feedback and revised accordingly. Next, there is the *interview execution* where the data of the participants is gathered through an MS Teams recording and personal notes. The time of the interview varies between 30 and 60 minutes depending on the schedule of the individuals and the amount of useful knowledge they provide. In the final stage, *interview interpretation*, the data collected is integrated to fit the aim of this thesis study. The applied interview questions are presented in the abstract A.

2.5.3. Interview structure

During the execution of the interviews, a structure is followed to remain consistent and to capture all the needed data. The proposed framework for the development stages is applied as a guide for the conversations and will function as a tool for discussion. This study includes both sides of the spectrum when considering the effectiveness of the support of the Dutch academic entrepreneurial ecosystems. This results in different approaches for the interviews between the facilitators and the founders. This is mostly expressed in the questions asked of the participants. The interview structure for both types of experts remains the same and consists of three components; *introduction, framework review* and *overall vision*. The purpose for each of the components is described and shared with the topics of discussion.

Introduction

The first component is the introductory phase of the conversation and is firstly meant for the researcher and the participant to get acquainted. It also serves the purpose of understanding the perspective of this individual relating to the goal of the organization. This particularly refers to sub-question 4 in the decoupling between the individual's realised support and the facilitator's intended support.

Experts of facilitators

- Basic information on the individual's position in the organization
- Functionality of the position and the organisation as a whole
- Policy definition on the offered support

Founders of health-tech spin-offs

- Basic information on the individual's position in the organization
- Functionality of the position and the organisation as a whole

Framework review

As mentioned, the second component describes the assessment of the individuals on the provided development stages framework. It is interesting to see how the interviewees respond to this framework and to see the level of agreement with it. Both types of interviewees fill different roles in the system, meaning that their perspective on the framework might result in different suggestions (e.g. in the challenges per stage). The facilitators and founders are guided through the stages emphasizing different subjects. The facilitators are asked to share their opinions on the support they offer in each stage and the procedure behind this. In contrast, founders are questioned about their experience with the challenges in the framework and the level of support they received on this.

Experts of facilitators

- Agreement on the development stages framework challenges
- Agreement on the development stages framework linked facilitators
- Information on the support by the facilitator in each stage and the procedure, the collaboration behind it

Founders of health-tech spin-offs

- Agreement on the development stages framework challenges
- Agreement on the development stages framework linked facilitators
- Information on the support offered by the facilitators in each stage
- Information on the crucial challenges in each stage

Overall vision

The final component is the *overall vision* of the interviewees on the functionality of the Dutch entrepreneurial ecosystems as a whole. This continues on the framework and requires the participants to share their personal ideas on the system. The facilitators and founders are invited to share their perceptions on the main issues of the health-tech spin-off. Next facilitators are requested to reflect upon the effectiveness of the support they currently offer while the founders are instructed to advise on more suitable aid from the ecosystems.

Experts of facilitators

- Information on the biggest challenges faced by health-tech spin-offs
- Reflection on the effectiveness of current operations in support

Founders of health-tech spin-offs

- Information on the biggest challenges faced by health-tech spin-offs
- Advise on the improvements of the current support by the Dutch entrepreneurial ecosystems

2.5.4. Ethical considerations

The data assembly through the interview considers the risks involved for the participants. Information shared by the interviewees might be sensible and could potentially harm the interviewee or the organisation they are active in. Moreover, there is a constant threat of data leaks which could similarly harm the mentioned parties. To avoid this a consent form was sent in advance to each participant. This includes the aim of the interview, the potential risks and the mitigation measures. It states that interviewees always carry the right to withdraw from the research. Sequentially, it lists the procedure of data collection through MS Teams and personal notes and the place of online storage. The data collected is strictly used for the purpose of this study and shall be destroyed at the end. The described process was designed with the thesis supervisors and the data steward of the faculty (TPM). Later it was filed in the form of an application and sent to the the Human Research Ethics Committee (HREC) for further approval. This committee checks whether the application conforms with all the TU Delft regulations regarding privacy and data protection.

2.5.5. Interpretation and conclusion

In the final phase of the use case, the findings of the research are shaped into conclusions that answer the research questions. This part discusses what the data meant for the goal of this study and how the reader should interpret the insights. The insights are written as policy advice, specifically for the facilitator within the Dutch academic entrepreneurial ecosystems, on how to improve their support towards health-tech spin-offs resulting in a better transfer of healthcare technology between the Dutch universities and the medical industry. Finally, a discussion is written in which limitations are identified and suggestions for future research are named.

2.5.6. Methods applied in the use case stage

The first part of this stage answers the second research question, which is to identify the support provided by the facilitators of the three Dutch academic entrepreneurial ecosystems. Mainly grey literature was used for the initial understanding of the current active parties in these ecosystems. The websites of the facilitators created the first idea of the support they offer. Additional qualitative data on this support was then gathered through interviews. Eventually, this gave insights into not solely the support of by the facilitators but the functionality of the entire support mechanism behind it. Similarly, interviews were conducted with founders to gain findings on their development process, and their needs for support, leading to the discovery of mismatches in the current support systems. Sequentially this qualitative data was utilized for the adaptation of the framework.

2.5.7. Outputs of the use case stage

The use case stage utilizes the outputs of the first two stages as a comprehension of the existing knowledge and dives further into the case of the Dutch academic entrepreneurial ecosystems. First, the key facilitators within these ecosystems are identified including the support they offer. Qualitative information is then collected to construct more detailed knowledge of the current support provision

resulting in the answer to the second research question. Next, the perspective of health-tech founders on the support is compiled to challenge the viewpoint of facilitators and identify mismatches in the current support mechanisms. Finally, the information on the perception of support in the current Dutch entrepreneurial ecosystems influences the revised form of the framework of the development process of early-stage health-tech spin-offs. This adaptation increases its suitability to the Dutch ecosystems and provides a structured communication tool as was asked by various facilitators.

3

Literature analysis

In this chapter the state-of-the-art literature is examined to create a preliminary understanding of the facilitators and their support found in academic entrepreneurial ecosystems. Sequentially, the study describes the development process seen for high-tech startups, later focusing on spin-offs and eventually health-tech-related ones. In addition, an overview is given of the largest challenges which are closely related to the development process of health-tech spin-offs. These insights are used as input for the creation of a framework that describes the development phases specific to the health-tech spin-offs. This framework provides the activities linked to the challenges of health-tech spin-offs seen in the phases and links them to the facilitators that potentially offer aid with this.

3.1. Entrepreneurial ecosystems

Entrepreneurial ecosystems arose around the 1980s and 1990s to describe the impacts of cultural, economic, social and political effects on the process of entrepreneurship (Stam and van de Ven, 2021; Franco-Leal et al., 2020). An example of this is seen in the research by Dubini where the relationship between the motivation of individuals and the analysis of resources was used to characterize three different entrepreneurial environments (Dubini, 1989). More modern studies build upon this by analyzing entrepreneurial incidents and theories in a broader context (Zahra et al., 2014; Zahra, 2007). The concept of entrepreneurial ecosystems is built upon the Knowledge Spillover Theory of Entrepreneurship (Acs et al., 2013). This theory states that individuals are agents of knowledge and that they will utilize knowledge spillovers to start new endeavours. Its concept is specifically seen in ecosystems where knowledge is available and shared as visible in entrepreneurial ecosystems (Fuster et al., 2019).

Currently, the topic of entrepreneurial ecosystems is a widely used concept in the focus of studies as can be seen by the increase in those studies (Cavallo et al., 2019). This popularity was mostly shared within the economic frame used by policymakers and entrepreneurial leaders. The work of Feld & Isenberg contributed to this through descriptions of how communities and social context influence the entrepreneurial process (Stam and Spigel, 2016). The popularity of entrepreneurial ecosystems led to various definitions for it. Stam's definition is commonly accepted and describes entrepreneurial ecosystems as ”a set of interdependent actors and factors coordinated in such a way that they enable productive entrepreneurship.” (Stam, 2015).

This definition embraces the two different concepts of the term entrepreneurial ecosystem. The ”entrepreneurial” part refers to the process by Schumpeter where the creation of goods and services are explored, evaluated and exploited (Stam, 2015; (Schumpeter and Swe, 2021). Entrepreneurship slightly differs from this definition in the setting of the entrepreneurial ecosystem. Here entrepreneurship is commonly referred to as high-tech startups instead of businesses and specified to ones that perform high growth.

The term ”ecosystem” originates out of ecology and biology where it describes the interaction between living organisms themselves and their environment (Abootorabi et al., 2021; Stam and Spigel, 2016). This is similar to economists that set the ”firm” at the centre stage of the environment (Auerswald, 2015;

Tansley, 1935). Mason & Brown agree with this framing and state that the ecological approach is related to economic gardening (Brown and Mason, 2014). Economic gardening refers to local economic advancements, a process in which certain environments enhance the number of new high-tech startups, including those with high growth (Brown and Mason, 2014). The biological vision of entrepreneurial ecosystems helps to understand the structures and relationships behind those systems (Cavallo et al., 2019). This dynamics within an ecosystem was demonstrated on a broader scale by Autio et al. who concluded that entrepreneurial activity is not independent of itself, it is influenced by several technological, social, policy and organisational factors (Autio et al., 2014). Ecological framing is unique to entrepreneurial ecosystems as they function differently than clusters or business ecosystems (Abootorabi et al., 2021). This difference is particularly seen in the policy written towards those structures as traditional policy won't be effective for entrepreneurial ecosystems (Autio et al., 2018). To understand an entrepreneurial ecosystem is to understand its elements and interactions within.

3.1.1. Entrepreneurial ecosystem models

Entrepreneurial ecosystems are created to function as a hub that facilitates a specific goal. Such a function can be the maximization of the commercial transfer of high-tech startups towards an industry. These ecosystems are constructed on theories that embrace the importance of stakeholders in the systems. The two common ones are the Triple Helix and the Quadruple Helix models.

Triple Helix model

The Triple Helix model is a framework that inspires various entrepreneurial ecosystems. In its essence, it captures the entrepreneurial ecosystem as three main actors; government, university & industry. Each actor fulfils its role in the increase in preferable conditions for the creation of innovation. The government entails the position through its stable influence on the ecosystem through contractual relations. The industry operates as the component for production, while the university is the source of knowledge and innovation (Etzkowitz, 2003).

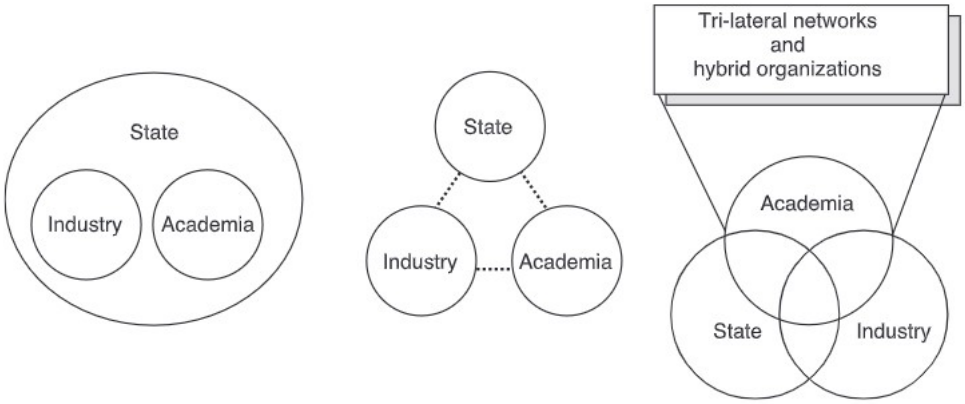

Figure 3.1: A Triple Helix model in various structures (Etzkowitz, 2003)

The Triple Helix model is not bound to a particular interaction process between the three parties. This level of alignment varies per setting and time frame (Etzkowitz, 2003). This aspect can be seen in the development of the Triple Helix model. The development stages are portrayed in Figure 3.1. The dynamic between the actors can take diverse structures depending on the setting of the ecosystem and the development stage they are in. The initial stage is referred to as the Statist Triple Helix. This model was commonly seen in the previous age in several countries such as the Soviet Union. In those countries, companies were predominantly state-owned illustrating the influence of the actor "state" on the industry. Moreover, the state controls the interactions between the other parties and has to take the lead in innovations while supplying the needed resources. In this setup, the academic (university) is seen as a minimalist player with the task of providing the industry with fitting personnel. The industry is the executor of the technological projects and is protected by the state while doing so.

The laissez-faire Triple Helix model illustrates more independent interactions than seen in the Statist Triple Helix. The interactions of individuals are expected to be competitive and not cooperative in the creation of innovation. In this structure, the university (academia) provides knowledge and trained personnel. The goal of interaction between the university and the industry is to maximize the gathering of new knowledge and to provide the industry with sufficient workers. The government is an observer in this system that regulates the market and carries the responsibility to act during events such as market failures (Etzkowitz, 2003).

These two models lead to the final development of the (Hybrid) Triple Helix model. In this system, the parties are equal partners that interact strongly in the promotion of innovation.

Adjustments on the Triple Helix model

The Triple Helix model forms a strong basis for the design of entrepreneurial ecosystems. Iterations are suggested within the scientific community to adjust the model to current needs. The next evolvement of the Triple Helix suggests that elements are taking the roles of the other parties. The industry pursues a role of knowledge creation, initially executed by universities, by setting up R&D departments within companies. Utterback concludes that these efforts are insufficient in the creation of innovation, forcing a more dominant role onto the universities. The universities take responsibility for this by changing their focus towards the commercialisation of their innovations (Ziakis et al., 2022; Rodrigues and Melo, 2013). This concept is known as academic entrepreneurship.

The modern form of the Triple Helix model leads to an environment in which cooperation and competition co-exist. In this system the relations are characterized by the following goals: 1) technology transfer, 2) cooperation and conflict resolution, (3) collaborative leadership, (4) substitution of certain functions, and (5) networking (Varghese et al., 2012). Technology transfer is the main focus between the universities and the industry as can be seen in the development of further organizational formats such as science parks, incubators and venture capital firms (Etzkowitz, 2003; Debackere, 2000).

Marcovich and Shinn continue on the Triple Helix model by offering four modifications related to the main message of adding a fourth element in the model; society. Including a societal element in the model generates a Quadruple Helix model. Society has a broad definition and is seen as the interaction between groups of people, institutions and knowledge (Marcovich and Shinn, 2011). The addition of the societal factor within the innovation process creates a more modern look of the Helix Model. A result of this is the increased sensitivity of the model to the impact of the knowledge on society and its surroundings (Marcovich and Shinn, 2011). Another reason for societal inclusion can be translated from the calls for innovation that often come from a societal perspective as illustrated by climate change.

Budden and Murray extend the Triple Helix model by identifying on a broad scale the most crucial stakeholders in the innovation ecosystem of the Massachusetts Institute of Technology (MIT) (Murray and Budden, 2019). These stakeholders are named as the University, Government, Corporate, Risk Capital and Entrepreneur in which the latter two elements differ from the original Triple Helix model. The recognition of the entrepreneur as a separate component is based on Brad Feld's hypothesis of the "Boulder Hypothesis". This concept suggests that entrepreneurs are the leaders of ecosystem building as they are equally the creators of knowledge (Feld, 2020). Risk Captial represents the involvement of funders of various sorts to increase the efficiency of funding collected by high-tech startups. Singapore is a known promoter of including the funding stakeholders in their entrepreneurial ecosystem (Murray and Budden, 2019).

The adjustments of the Triple Helix model form a basis for the analysis of entrepreneurial ecosystems on a deeper level with a focus on the elements within.

3.1.2. Elements of entrepreneurial ecosystems

Isenberg states that there is no general solution for the creation of an effective entrepreneurial ecosystem. These systems should avoid the direct adaptation of other strategies and start exploiting local conditions and bottom-up processes (Isenberg, 2010). The 9 principles of Isenberg elaborate this approach in more depth (Isenberg, 2010). Although no uniform solution exists for entrepreneurial ecosystems, the precedence of the correct elements is crucial for its effectiveness (Ziakis et al., 2022; Stam and Spigel, 2016).

Stam created a blueprint for an entrepreneurial ecosystem and the processes leading to value creation behind it, seen in Figure 3.2 (Stam and Spigel, 2016). This model is separated into the four layers; framework conditions, systemic conditions, outputs and outcomes. There is circularly dynamic in this model in which the conditions are the causes of the outputs and outcomes. There is a feedback effect in time as the outputs and outcomes influence the conditions. Both the systemic and framework conditions relate closely to the work of Ziakis and the report of Molema & Egmond. Ziaktis et al. summarize the elements of entrepreneurial ecosystem frameworks found in the literature while Molema & Egmond list those specifically relevant to entrepreneurial ecosystem associated with healthcare innovations (Ziakis et al., 2022; Molema and van Egmond, 2017). Leading to the following six elements within entrepreneurial ecosystems: 1) Education & Research, 2) Human Capital, 3) Finance & Funding, 4) Government, 5) Support and Networks, and 6) Entrepreneurial Culture. These found elements are strongly in line with the works of Isenberg and the releases of the World Economic Forum (Isenberg, 2011; World Economic Forum, 2013)

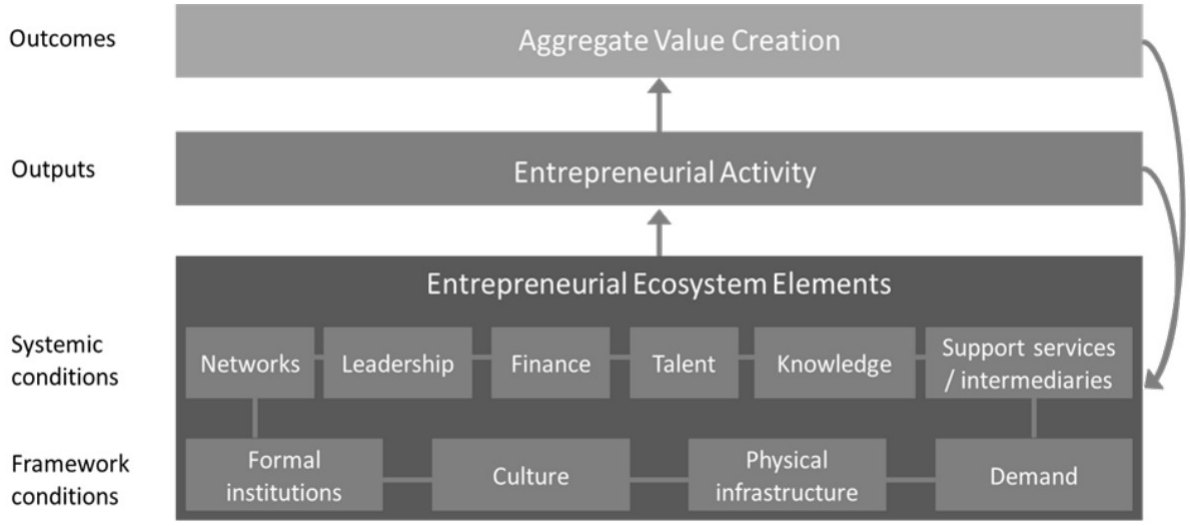

Figure 3.2: Stam and Spigel's design for an entrepreneurial ecosystem (Stam & Spigel, 2016)

The found elements each contribute to the progress of innovation through their unique support. This support type is discussed per element alongside sub-elements that facilitate that support.

Education & Research

Stam's elements: Knowledge

Entrepreneurial education benefits the innovation process within entrepreneurial ecosystems greatly (B. Martin et al., 2013; Ziakis et al., 2022). Education on entrepreneurship stimulates individuals to start new businesses (Galloway and Brown, 2002). Allen and Hall supported this school of thought during their study, concluding that individuals who received higher education are more likely to participate in innovative activities (Allen and Hall, 2008). This directly states the importance of proper entrepreneurial education, specifically at the university level. Moreover, students who received entrepreneurial education are more successful in opportunity identification, benefiting future employers of those students

(DeTienne and Chandler, 2004). Entrepreneurial education is found throughout the entrepreneurial ecosystem. Universities provide courses on the topic for students while incubators and accelerators support them through coaching (Tripathi et al., 2019). While private corporations invest in the creation of knowledge, by R&D departments, education on entrepreneurship remains rare.

Human Capital

Stam's elements: Knowledge, Talent & Leadership

Stam characterizes Human Capital as the most important element within the entrepreneurial ecosystem and is closely related to the Boulder Hypothesis of Brad Feld, mentioned earlier (Stam and Spigel, 2016; Feld, 2020). Human Capital can be defined as the knowledge, talent and skills of individuals to develop innovations (Ziakis et al., 2022; Molema and van Egmond, 2017). Human Capital is highly dependent on workers' education described in the previous element. This is an illustration of the interconnectedness found in the entrepreneurial ecosystem. This element is based upon the foundation of the Human Captial Theory of Ployhart and Moliterno that a higher level of knowledge, skills and various competencies of employers will eventually lead to greater outcomes for businesses (PloyHart and Moliterno, n.d.). Another crucial aspect is the level of employee loyalty, as high-tech startups operate in a high-risk environment (Chorev and Anderson, 2006). As traditionally seen in the Triple Helix model, universities carry the responsibility of generating sufficient Human Capital. Incubators and accelerators contribute to this through knowledge sharing related to entrepreneurship. For this reason, Human Capital does not solely relate to the individuals who receive the knowledge but also to those who share it such as teachers, mentors and experienced experts (Molema and van Egmond, 2017).

Finance & Funding

Stam's elements: Finance

Sufficient funding is crucial for the survival and sustainability of high-tech startups, particularly those with long-term outcomes (Ziakis et al., 2022; Stam and Spigel, 2016). Obtaining these funds is complex as most innovative technologies are often new in their field and financing highly depends on the popularity of a market. The relationship between technology theme popularity and funding is illustrated in the case of Artificial Intelligence high-tech startups (Delipetrev et al., 2020). There are various forms of funding; Venture Capital (VC), Angel investors or public grants (Ziakis et al., 2022). Each form of funding focuses on a specific development level of high-tech startups. Venture Capital predominantly invests in the later stages of development (Festel et al., 2013). Funding does not solely describe financial resources, it also includes the import of Human Capital. This is commonly seen with Venture Capitalists & Angel investors, who provide additional experience and network towards high-tech startups.

Government

Stam's elements: Formal institutions

As mentioned, the government takes a supportive role in the modern Triple Helix model. Its main focus lies in providing an environment in which businesses can flourish (Tripathi et al., 2019). Governments aid in the creation of a stable environment for high-tech startups and their stakeholders commonly provided through a regulatory system. The government sets the stage for legal elements relating to intellectual property, taxes, labour and company formation (Fuerlinger et al., 2015). Moreover, the government can specifically contribute to areas with heightened risk, commonly avoided by the private sector. For instance in funding markets that require steep investments while leading to high societal benefits in the long term (Mazzucato, 2011). Further support also results in the collaboration between the government and private companies such as accelerators and private companies seen in Brazil and Chile (Sainul, n.d.; (Tripathi et al., 2019).

Support & Networks

Stam's elements: Networks, Support services, Physical infrastructure & Formal institutions

Within the entrepreneurial journey, networking is identified as a key element for the success of high-tech startups. Networking relates to all the relations that entrepreneurs make with institutions and individuals (Lechner and Dowling, 2003). This success factor is associated with the quality of the relationships and how well founders are able to exploit resources from these relations (Walter et al., 2006). The strength of these connections is framed in the term Social Capital, which is proven to aid collaborations with partners, which is particularly essential for innovations within global markets (Huang et al., 2012). Furthermore, cooperation with partners or even competitors gains a competitive edge (Gulati et al., n.d.). This element also includes the support offered by various facilitators. Startups are highly complex projects resulting in the need for support on various topics (IP, business development, technological feasibility). Support is not only provided in the form of knowledge but also through access to facilities such as laboratories.

Entrepreneurial Culture

Stam's elements: Culture & Leadership

The final element named by Ziakis represents the social environment in which the entrepreneurial ecosystem operates (Ziakis et al., 2022). This aspect is supported by Budden and Murray's suggestion of the fourth element in the Triple Helix model and relates to the framework condition of Stam named "Culture" (Murray and Budden, 2019; Stam and Spigel, 2016). Performances of entrepreneurial ecosystems are very location-specific and this particularly counts for the element of culture (Tripathi et al., 2019). The element of Culture covers various aspects relating to the term. In (regional) entrepreneurial ecosystems there should be a culture that understands what it takes to create and commercialize innovation and acts on it. This takes leadership from institutions to form programs and grant resources. The culture recognizes the risk associated with startups and does not blame the entrepreneurs for failing yet seeks to assist them. Within these communities, there is a high level of collaboration in which knowledge of common hurdles is shared and success stories are shared to inspire new founders (Molema and van Egmond, 2017). Diversity and language also play an important role in culture as they enable the creation of innovative ideas on which high-tech startups are built (Ziakis et al., 2022).

3.2. Academic entrepreneurial ecosystems

In the traditional Triple Helix model, the university mainly focused on the provision of research and education (Philpott et al., 2011). Currently, a strategy is followed that also includes the development and commercialization of new technologies (Perkmann et al., 2021). In the US this movement was highly promoted by the Bayh-Dole Act of 1980 which triggered universities to patent and license their research outcomes (Guindalini et al., 2021). The broader concept behind this is known as *academic entrepreneurship*. Academic entrepreneurship refers to the creation of a spin-off company by members of the university such as students, faculty and postdocs (Hayter et al., 2018). Various definitions of a spin-off exist throughout the literature. Initially, Shane referred to this entity as a company created by the faculty that holds a technology licensing agreement with the associated university (Shane, 2004). The definition was later expanded through literature by including the companies that weren't necessarily holding a licensing agreement with the universities and with those who were established by individuals other than faculty (e.g. students and postdocs) (Hayter et al., 2017; Fini et al., 2010). This study acknowledges all the definitions described by the literature.

Technology transfer through spin-offs is an essential tool in the advancement of social and economic dimensions (Rothaermel et al., 2007). The economic benefits are shared between the universities and the local communities in which they are located (Hughes and Kitson, 2012; Fuster et al., 2019). Etzkowitz et al. even associate these economic benefits with the definition of an entrepreneurial university (Etzkowitz et al., 2000). It is defined as any university with the focus of undertaking entrepreneurial activities *"with the objective of improving regional or national economic performance as well as the university's financial advantage and that of its faculty."* (Etzkowitz et al., 2000).

This effect motivates the rise of academic entrepreneurial ecosystems. These systems show potential in their support towards spin-offs, as can be seen in the success rates. Between 1980 and 1998 university high-tech startups (spin-offs) had a survival rate of 70% while those outside the academic entrepreneurial ecosystems only had a rate of 25% (Di Gregorio and Shane, n.d.). Yet, the impact of this accomplishment is minimal as only 25% of all inventions are licensed to spin-offs or larger companies (Hayter, 2011).

3.2.1. Principles of academic entrepreneurial ecosystems

As mentioned the pursuit of academic entrepreneurship by academic ecosystems leads to changes in its activities. Traditionally in these ecosystems, the universities carried the task of providing sufficient research to be exploited in commercial ways and qualified personnel to develop it further. These tasks represent the elements of *Education & Research*, *Human Capital* in entrepreneurial ecosystems. An increased effort in academic entrepreneurship results in new activities for academic entrepreneurial ecosystems that cover other elements in the entrepreneurial ecosystems as seen in 3.1.2. This coverage through the activities varies between academic entrepreneurial ecosystems and is described in Philpott's *Spectrum of Entrepreneurial Activity* (Philpott et al., 2011). Academic entrepreneurial ecosystems that are involved in the lower bound of entrepreneurship perform duties such as producing highly qualified graduates and access to consulting (Philpott et al., 2011). Highly focused academic entrepreneurial ecosystems go beyond that by patenting and licensing their innovations and even creating technology parks to support them (Philpott et al., 2011).

The latter form of academic entrepreneurial ecosystems defined their functionality surrounding three principles; technology transfer, university incubation and engagement (Burkholder and Hulsink, 2022). Technology transfer states the patenting and licensing by researchers in the form of innovation or renewal (Philpott et al., 2011). University incubation refers to the creation of new businesses or spin-offs by intellectual property developed by academic researchers and startup firms that utilize venture capital (Hayter, 2011; Shane, 2004; Zhang, 2007). Lastly, engagement includes the interaction of academic researchers with projects that result in societal benefits and collaboration with the industry (Winfield, 2005; D'Este and Perkmann, 2011). These principles are addressed by multiple facilitators within the academic entrepreneurial ecosystems.

3.2.2. Facilitators in academic entrepreneurial ecosystems

The activities associated with the principles (technology transfer, university incubation and engagement) are divided among the facilitators in academic entrepreneurial ecosystems. These facilitators are specialised organisational entities providing a form of support towards academic spin-offs. Hayter states that these intermediaries and their networking play a vital role in the development of spin-offs within academic entrepreneurial ecosystems (Hayter et al., 2018). Khodaei et al. (2020) identify five fundamental types of support as *Infrastructure, Business, Financial, Social and Legal* and are defined as follows (Khodaei et al., 2020):

- **Infrastructure support**: Arrangement of facilities such as working spaces, laboratories, meeting rooms, and (specialized) equipment
- **Business support**: Training and coaching related to skills and knowledge that assist in venture building such as the creation of a business plan or pitch
- **Financial support**: Providing access to financial facilitators such as public grants, venture capitalists & angel investors while assisting in financial planning
- **Social support**: Provision of linkages to industry parties, experienced startups, customers, market experts
- **Legal support**: Assistance on product protection in the form of IP and consultancy on legal agreements (e.g. NDA)

The state-of-the-art literature led to five forms of facilitators found in the academic entrepreneurial ecosystems. Utilizing literature insights, for each facilitator, an explanation is given and linked to the identified forms of support. At the end, a table is presented where the type of support and its definition are connected to the elements of the entrepreneurial ecosystems they cover. In addition, the facilitators who provide these forms of support are incorporated into the table as shown in 3.1.

Technology Transfer Office

Type of support: Infrastructure, Business, Financial, Social and Legal

A Technology Transfer Office (TTO) is a department within the university that focuses on the commercialisation of research. The activities of the Technology Transfer Office differ per ecosystem, yet commonly seen operations are patenting, licensing & equity agreements (Chapple et al., 2005; Siegel et al., 2004; Thursby et al., 2001). These activities can be clustered under legal support as described by Khodaei et al (Khodaei et al., 2012). Some go beyond this by providing support on team establishment, financial assistance, and even technical expertise. (Hayter et al., 2018; Huyghe et al., 2014). Experts within the TTOs need to comprehend the industry's and academic environment's culture and functionality. This knowledge is needed to support the spin-offs effectively and to bridge these worlds in forms of cooperation or transfer of intellectual property (IP) (Powers and McDougall, 2005).

The differentiation of support by the TTOs relates to the change in approach by this part of the university. Figure 3.3 provides an overview of the various IP transfer forms seen between universities and the industry (Swamidass and Vulasa, 2009).

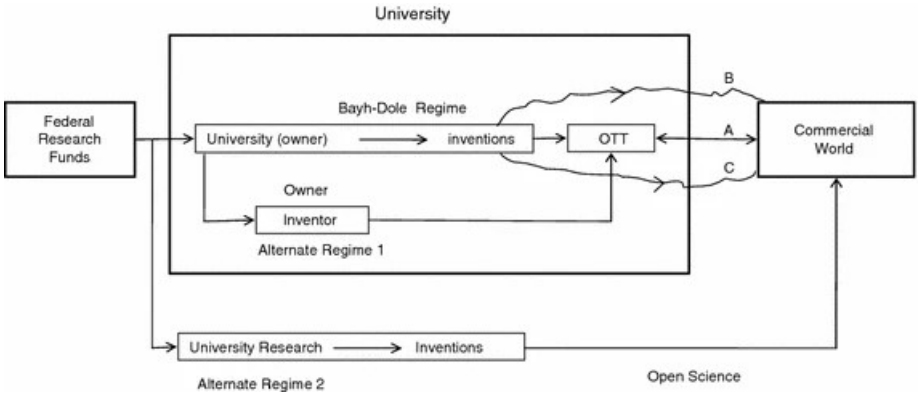

Figure 3.3: Forms of licensing processes (Swamidass & Vulasa, 2009)

Historically, TTOs, or OTTs in the figure, engaged with well-established companies to sell IP to them. The industry players then invested their resources in scaling towards a product or service (Powers and McDougall, 2005). In return the university for financial compensation. A new trend appears in which universities prefer to license the IP through the TTO to academic spin-offs. In return the university obtains shares within those companies or a payment in the form of royalties (Steffensen et al., 2000). Both these methods are described as path A in Figure 3.3. Path B & C visualize the (un)intended leak of patents towards the industry. Regime 1 symbolizes a process preferred by Litan, in which the ownership of the IP is given solely to the inventor and its rewards (Litan et al., 2007). Others such as Kenny and Patton favour Regime 2 where the universities do not patent their ideas yet share them with the commercial players in an open-source environment (Kenny and Patton, 2008).

In both the processes of path A, the TTO becomes a prominent component with extensive knowledge and commodities. Universities enable the TTOs to become more autonomous to increase the output of academic entrepreneurship (Corbett et al., 2014). The increase in support for TTOs by the universities raises the asymmetry in power between the TTO and the spin-offs. This asymmetry potentially leads to an unfortunate outcome for founders of spin-offs with the negotiations over IP. This raises the concern that the TTO's focus could negatively impact the entrepreneurial progress of the spin-offs (Markman et al., 2004). Swamidass and Vulasa even state that the lack of licensees and further entrepreneurial steps are effects of a shortcoming in skills at TTOs (Swamidass and Vulasa, 2009).

Incubator

Type of support: Infrastructure, Business and Social

As the word foreshadows, this entity incubates a spin-off to stimulate its growth. Its objectives are to boost the survival rate of the spin-offs while accelerating its progress (Schwartz, 2013; Mian, 1996). They offer assistance on obstacles regarding funding, networking, team building and business case development (Barbero et al., 2014). Various incubators exist and are often distinguished by their nature for pursuing profit. Non-profit incubators are not rewarded for the success of the spin-offs and aim to promote regional development (Grimaldi and Grandi, 2005). Profit-concentrated incubators benefit from the prosperity and are usually privately owned (Barbero et al., 2014).

Two types of incubators occur within the academic entrepreneurial ecosystems: university business incubators (UBI) and corporate business incubators (CBI). UBIs are constructed tools by universities to further develop their own created IP or research. Shared office space, coaching and funding possibilities are typical services of these incubators. IBIs also offer more university-associated resources with access to laboratories and legal assistance (Mian, 1997). University business incubators are non-profit and are funded by the university to foster academic entrepreneurship (Von Zedtwitz and Grimaldi, 2006).

Accelerator

Type of support: Infrastructure, Business, Financial, Social and Legal

The aid of incubators is crucial for the starting phase of a spin-off. After these companies have progressed in their product, market strategy and team building, they require advanced support (Tripathi et al., 2019). This is provided by accelerators, that offer their services in so-called accelerator programs. In these programs, knowledge is given on the development of business plans, the search towards the product-market fit and networking. Accelerators distinguish themselves from incubators in several characteristics. In contrast to incubators, accelerators do not offer any physical commodities (Miller and Bound, 2011). Moreover, the time frame in which support is provided is significantly shorter than that of incubators and usually lasts three to six months (Tripathi et al., 2019; Cohen, 2013).

Since the first appearance of an accelerator in 1959, these entities differentiated themselves leading to various forms of accelerators (Hausberg and Korreck, 2020). There is a clear separation between those that are publicly funded through their link with universities and the ones that exist in private forms (Byrd et al., n.d.). Specialisation is another discriminating criterion. As mentioned in the research by Hausberg & Korreck, many accelerators accept spin-offs from all industries (Hausberg and Korreck, 2020). Newer forms only select companies with links to specific themes such as bio-engineering and sustainability (Gliedt et al., 2018; Crisan et al., 2021). This close association between the spin-offs enables the accelerator to focus their resources towards industry-related challenges.

Science park

Type of support: Infrastructure and Social

Science parks find their origin in research environments set up by universities to stimulate national innovation (Zou and Zhao, 2014). Their main objective relates to providing physical resources to entrepreneurs and spin-offs (Wright et al., 2008). The young companies require access to office space, laboratories or advanced devices. The science parks also offer intangible commodities; governmental subsidies, suppliers and networks (Wright et al., 2008). These elements' availability potentially boosts the spin-offs' progress. The governments favour this outcome and this leads to extensive support for the science parks (Wessner, 2009). Particularly countries such as China deeply invest in science parks as seen in the Tsinghua University Science Park (Wright et al., 2008; Zou and Zhao, 2014).

Simultaneously the close linkage towards the public institutions comes at a cost. The link potentially entails that its activities are rather scientifically focused than commercial. Moreover, operating within the university context results in slower bureaucratic decisions that could negatively impact the growth of the spin-offs (Clarysse et al., 2005). These environments are also associated with the lack of skills in the commercialisation of innovation, similarly seen with the TTOs (Swamidass and Vulasa, 2009).

Financial facilitator

Type of support: Business, Financial and Social

As mentioned funding is one of the essential elements within entrepreneurial ecosystems and this is no exception for academic ones. Financial resources are needed in all development phases of spin-offs and are characterized by early-stage funding, seed investments and later stages A to D. The form of funding differs from grants and loans to investments and crowdfunding (Tripathi et al., 2019). Each form of funding is related to a different facilitator.

In early-stage funding is relevant for the product and business development of spin-offs within academic entrepreneurial ecosystems (Hayter et al., 2018). Financial support in this phase is commonly seen as grants or favourable loans provided by **public entities**. In this early stage, spin-offs exclusively rely on external funding making it crucial for its survival. This essence was proven by Lockett and Wright in their UK use case, where they identified a correlation between the number of spin-off companies and the height of the R&D funding by universities (Lockett and Wright, 2005). A similar relationship was provided in a case for the US by O'Shea where Federal funding positively affected the entrepreneurial development within universities (Chevalier et al., 2005).

In later stages, funding is utilized for the expansion of the business. This form of funding relates to investment done by non-governmental entities such as **venture capitalists (VC)** and **angel investors** (Hayter et al., 2018). Venture capitalists are firms that invest in high-tech startups with the incentive to maximize. VCs do not solely provide financial resources for further development. By investing they buy themselves into the companies and share its burden and future profits. This leads to managerial assistance in the growth of spin-offs and creates credibility within specified industries (Hayter et al., 2018; Fernández-Alles et al., 2015). Angel investors are described as "wealthy individuals who provide capital for start-up companies" (Morrissette, 2007). These individuals commonly have experience in building a startup and provide besides investment access to specific know-how and a large network in a particular industry.

Linking types of support, elements, and facilitators in entrepreneurial ecosystems

3.1 represents an overview of the support given by facilitators based on the findings in the literature. The table defines the types of support and links them to the elements of an entrepreneurial ecosystem. Next, it indicates which facilitator covers this support in the entrepreneurial ecosystem. For example, for infrastructure support it description indicates that it represents arrangements regarding facilities (e.g. working spaces). This support is connected to the elements of Support & Networks and is provided by facilitators types TTO, Incubator, Accelerator, Science Park.

These table insights are later utilized to draw comparisons with the use case results. This will assess whether the support that is provided by the facilitator as outlined in the literature aligns with the support offered by the facilitators in the Dutch academic entrepreneurial ecosystems.

Table 3.1: Types of facilitator support, their description and linkage to the elements in entrepreneurial ecosystems (author, 2024)

Type of support (Khodaei et al., 2020)	**Description**	**Association to elements of entrepreneurial ecosystems**	**Type of facilitator**
Infrastructure support	Arrangement of facilities such as working spaces, laboratories, meeting rooms, and (specialized) equipment	Support & Networks	TTO, Incubator, Accelerator, Science Park
Business support	Training and coaching related to skills and knowledge that assist in venture building such as the creation of a business plan or pitch	Support & Networks	TTO, Incubator, Accelerator, Financial facilitator
Financial support	Providing access to financial facilitators such as public grants, venture capitalists & angel investors while assisting in financial planning	Finance & Funding, Support & Networks	TTO, Accelerator, Financial facilitator
Social support	Provision of linkages to industry parties, experienced startups, customers, market experts	Support & Networks, Entrepreneurial Culture, Human Capital	TTO, Incubator, Accelerator, Science Park, Financial facilitator
Legal support	Assistance on product protection in the form of IP and consultancy on legal agreements (e.g. NDA)	Support & Networks	TTO, Accelerator

Description:

Table 3.1 outlines the forms of support given by the facilitators of academic entrepreneurial ecosystems such as TTOs. For each type of support, a description is given along with the associated elements of entrepreneurial ecosystems it covers. The last column links the type of support to the type of facilitator that provides it.

3.3. Early-stage development process of health-tech spin-offs

In modern societies, due to the ageing population, healthcare costs have become the highest spending in the gross domestic product as seen in the US and Korea (Lee et al., 2019; Gupta, 2018). The importance of current healthcare technologies cannot be overstated. Many of these innovations rise within the academic entrepreneurial ecosystems in the form of health-tech spin-offs. To support the spin-offs effectively the facilitators and policymakers need to establish an understanding of the development process of these spin-offs in the early stage. A development process is divided into development phases where each phase requires a different strategy and resources to solve them. This study aims to comprehend the development process of health-tech spin-offs by examining the development phases of high-tech startups in general, those of high-tech academic spin-offs and, lastly the specific phases of health-tech spin-offs. The comprehension of the health-tech spin-off development process leads to the identification of the (unique) hurdles associated with the phases. This information is used as input for the activities described in the proposed development framework.

3.3.1. Development process of early-stage high-tech startups

High-tech startups operate as constantly adjusting organisms, as stated in the definition of entrepreneurial ecosystems in section 3.1. The catalyst of change depends on dimensions both internally (e.g. team) and externally (e.g. funding, customers) (Kumbhat and Sushil, 2018). These dimensions are affiliated with a development process characterized by high-tech startups. The Valley of Death (VoD) process is a widely used term for this process (Gbadegeshin et al., 2022). The Valley of Death describes a general life cycle for high-tech startups through the visualisation of cumulative profit/loss over time (Osawa and Miyazaki, 2006). In a traditional pattern, a high-tech startup requires a large investment which translates to a cumulative loss in the beginning. Later the startup gains income through the innovation thereby lowering the cumulative loss and finally achieving profit. This means that the *valley* itself relates to a funding gap commonly seen with companies that require steep investments in research & development (R&D). The height of investment proves to be a dominating factor in the survival of high-tech startups (Gbadegeshin et al., 2022; Mcintyre, 2014). Furthermore, research indicates that the VoD appears to impact life-science high-tech startups the most (Johnson, 2005; Gbadegeshin et al., 2022).

The process described through the process of the VoD is associated with many phases found in literature. Osawa & Miyakazi portray the VoD in four phases that are associated with success in milestones; success in R&D, success in product launch, success as a product & success in a business (Osawa and Miyazaki, 2006). These phases align with the work of Gbadegeshin which entails a clearer structure of the development journey by the identification of three phases; pre-startup, startup and exit/growth (Gbadegeshin et al., 2022; Gbadegeshin, n.d.).

The timeframe of **pre-startup** relates to the R&D executed in the beginning. At this moment all focus lies on the creation of the technology based on the needs of the customers. These needs are found through conversations and result in the value proposition as described by Kumbhat & Sushil (Kumbhat and Sushil, 2018). The high-tech startups operate in a non-professional way where there are enough resources for development. This especially refers to those within the university environment where commodities can be exploited relatively cheaply. Moreover, at this moment the team might still operate without any legal entity. The operations in the phases lead to the initial high costs seen in the Valley of Death.

The **startup** phase marks the start of the steep decrease part of the Valley of Death. This period becomes mature as formal agreements are being made with business partners and customers. Moreover, an official team is established and incorporated with the technology. The startup requires hefty investments as a cause of the professionalization actions and further R&D. This period is marked for around three years and indicates a decisive moment for survival.

When successful, the startup enters the **growth/exit** phase. There is a confirmed product and market fit and the startup experiences its first revenue. This income increases over time thereby sustaining the company and decreasing its debts. This embarks the moment of a long-term strategy through either growth or an exit. When the startup plans to continue on its own (growth), activities surrounding additional services or improved products to customers are considered (Kumbhat and Sushil, 2018). An

exit strategy demands conversations concerning a potential buy-out or merger with industry parties.

As mentioned, the importance of the phases relates to the problems affiliated with them. Kumbhat examines the hurdles behind the phases by matching each phase to various dimensions; objective, customer, and product (Kumbhat and Sushil, 2018). This research however makes the development phases more practical for facilitators and policymakers and aids in identifying whether a startup pursues an unbalanced development process. The dimensions of Kumbhat can be translated into proposed blocks that assist high-tech startups in overcoming the Valley of Death. These blocks are based on the works of Labelle & Goldthau in combination with Ford & Dillard and result in the Buztech Startup model (BSM) (Labelle and Goldthau, n.d.; Ford and Dillard, 2018). The BSM includes; team building, technology development, ecosystem, collaboration, funding, business development, technology management, company building and early marketing (Gbadegeshin et al., 2022). Both the dimension and building blocks provide an initial insight into the problems experienced by high-tech startups in their development process. These findings can be utilized as a start for facilitators in designing their aid towards high-tech startups.

3.3.2. Development process of early-stage academic spin-offs

The development process of early-stage academic spin-offs differs from that of regular high-tech startups as their technology originates out of the academic entrepreneurial ecosystem. For this reason, the proposed steps relating to the Valley of Death are not directly applicable to academic spin-offs. In the academic entrepreneurial ecosystem, the process of academic spin-off development starts with research to create economic value. This process is seen as an ecological one where natural selection occurs, meaning that not all research will be converted into economic value (Hannan and Freeman, 1989; Franco-Leal et al., 2020). Each development journey is unique in its complexity, time and availability of resources. The height of investment costs in R&D is a prime illustration of this, which results in a steeper Valley of Death. These factors influence the growth process and lead to the development phases for early-stage spin-offs.

This part of the study starts with an outline of the development process of early-stage academic spin-offs through a general perspective. This strategy provides insights into the relevant activities of early-stage academic spin-offs. Moreover, it includes the struggles of these young companies and their potential relationship to the academic entrepreneurial ecosystem. This perspective is broadened by including a more practical orientation in the eyes of the spin-offs.

General perspective

Rasmussen et al. (2015) state that academic spin-offs strongly rely on their ecosystem for their performance (Rasmussen et al., 2015). To provide this support effectively universities have been searching for the steps needed to transfer technologies to the market effectively. Ndonzuau et al. performed international research analyzing 15 universities to gain insights into those steps (Ndonzuau et al., 2002). This resulted in 4 phases for development; phase 1: to generate business ideas from research, phase 2: to finalize new venture projects out of ideas, phase 3: to launch spin-off firms from projects and phase 4: to strengthen the creation of economic value by spin-off firms. A similar study was performed by Vohora et al. where the development of academic spin-offs was portrayed using various growth phases (Vohora et al., 2004). Moreover, it describes the process as an iterative non-linear process where the spin-offs need to overcome certain critical junctures to jump to the following phase. These critical junctures are tackled by acquiring the correct resources and performing the needed activities.

Both the works of Ndonzuau et al. and Vohora et al. were used in this study to describe the development process of academic spin-offs (Ndonzuau et al., 2002; Vohora et al., 2004). The process is divided into five phases by Vohora et al. (Vohora et al., 2004). Each phase illustrates the focus of the spin-offs, a set of essential activities they need to execute and their relationship with the academic ecosystem based on the literature of Ndonzuau et al. (Ndonzuau et al., 2002).

Phase 1: Research

The first phase represents the traditional research-creation setting where the scientists focus on the perfection of their findings and the maximization of their publications. At this moment there is no incentive yet to commercialize the potential of the intellectual property.

For a potential spin-off to emerge there needs to be a jump to the second phase resulting in prevalence over the critical juncture of **opportunity recognition**. As the name states this juncture captures the link between the unmet needs of the market and a solution that feels that need (Bhave, n.d.). The first step of commercialization starts with the evaluation of breakthrough ideas. Recognizing such opportunities happens both actively and non-actively and is influenced by specific factors; skills and experience (Vohora et al., 2004; Venkataraman, 2019). This can be achieved by the academics themselves yet demands a change of mindset. This concept is closely associated with the academic culture found in universities. As mentioned, the university framework envisions knowledge as the end product of research that aims to produce publications and provide the best knowledge for its students (Ndonzuau et al., 2002). This can also be seen in the ”publish or perish” mechanism where researchers are incentivised to keep writing new publications instead of pursuing the effects of the research on society. To generate business ideas, the researcher should change the mentality and the associated culture around it. Vohora et al. found through case studies that the universities often lack the skills to make the research commercial attractive to customers and investors. Therefore this aspect strongly influences the success of the spin-off in this phase.

Phase 2: Opportunity framing

The second phase is constructed around the phenomenon of commercial exploitation. This changes the original interpretation of research results where science was considered the end itself and is referred to as *science conception*. In the newer form, *economic conception*, it sees science as a tool in achieving other goals such as the creation of economic value (Ndonzuau et al., 2002). This ties in with the process of the identification and assessment of promising ideas. Academics commonly execute this in collaboration with the Technology Transfer Offices (TTOs) in the academic entrepreneurial ecosystems. This screening involves the gathering of adequate evidence to support that the innovation truly functions both inside and outside the laboratory environment (Vohora et al., 2004). Sequentially, answers must be found for questions such as ”What are the different applications of a given technology?”. This requires conversations with experts within the chosen field to collect practical information. This part relates to the word ”framing” where both the academics and the TTO aim to identify the potential markets, the product application and the establishment of initial contact with customers (Vohora et al., 2004).

The critical juncture of **entrepreneurial commitment** separates this phase from the next one of pre-organization. This principle represents the translation of a vision into the formation of a business and is closely related to the change of mindset by academics as mentioned before. This commitment affects the success of the spin-off in multiple ways. A full-time founder can spend more time, improving faster over time. Nevertheless, the level of dedication also sends a positive message to outsiders such as investors therefore potentially increasing the spin-off’s chance of receiving investments (Vohora et al., 2004). The critical juncture of entrepreneurial commitment describes the conflict between the need for a committed spin-off builder and the inability to find an individual with the correct set of skills. This is derived from four reasons; the lack of role models, prior business knowledge, self-awareness over personal limitations and the incompetence to find and bind skilled external founders. A missing entrepreneurial commitment proves to be a decisive element for progress on various levels and could potentially kill the spin-off when not solved in this phase.

Phase 3: Pre-organization

The pre-organization phase embodies the period where spin-offs start strategic plans for various business elements. These decisions impact the spin-off’s needs for future resources and capabilities. Vohora et al. state that choices in the phase prove to be crucial for the success of the spin-off in the long run (Vohora et al., 2004). Aspects such as time to market entry, loss in revenue and access to Human Capital could potentially be influenced by this moment. Agreements on intellectual property (IP) are another crucial component in this phase. At the start of this phase, there is a presumption about the implications of the technology and its economic benefit. The phase progresses on this idea by creating a more solid venture with a focus on the protection and development of the idea.

The protection of ideas entails the identification of the owners of the research and the actual protection of this research. The ownership of research can be complex as multiple researchers contribute to the work and the ownership can lie between various universities. The agreements of ownership between universities and researchers differ per university. Meaning, in some cases all the research belongs to the inventors themselves and in other cases the ownership is assigned solely to the university. The next step in this process refers to the actual protection of research or intellectual property (IP). Artificial protection is a tool commonly chosen for this preservation of ideas and refers to the translation of research into patents or copyrights (Lowe, 1993).

When there is an understanding of the protection of the idea, the next step focuses on business development. This entails technological and commercial development. *Technological* development relates to the crafting of a prototype to explore the technological possibilities of the invention. Sequentially the prototype showcases the potential of the innovation for partners and customers and makes the proposition more practical. This phase raises the need for material and labour. The achievement of a prototype requires material, man hours and technical facilities for construction. The other element of this phase includes the progress on the *commercial* side. This encloses a strategy on how to get the product to market. Elements that are included are; operational costs, market size and investments needed.

The availability of the resources required for these activities is closely tied to the relationship between the academic entrepreneurial ecosystem and the spin-off. The strength of the relationship can determine the access of spin-offs to the needed resources. These resources are divided into intangible and tangible. **Intangible resources** are translated into Human Capital, one of the elements of entrepreneurial ecosystems. This Human Capital does not solely cover technical skills; it also includes abilities relating to business and management. Management of high-tech companies differs greatly from that of research groups or laboratories. Timmons even concludes that the poor quality of management is a greater influencer of the failure of spin-offs than the lack of business opportunity (Timmons, 1994; Ndonzuau et al., 2002). Human Capital is closely linked to another element in the entrepreneurial ecosystem; Support and Networks. This social capital aids the spin-offs in the collection of the needed resources (Walter et al., 2006). Mian defines **tangible resources** as material and financial commodities (Mian, 1996). Academic entrepreneurial ecosystems play an important role in providing these facilities towards the spin-offs as obtaining this is expensive. Entrepreneurs within the spin-offs aim to minimize the need for these tangible resources as they require financial resources or a loss in equity.

Although spin-offs are independent entities the relationship with the academic entrepreneurial ecosystem remains important. This connection can either be on an institutional level or a personal one. Bray and Lee describe the **institutional relationship** based on three links between the entities (Bray and Lee, 2000):

- universities hold equity shares of the spin-off (financial resources)
- spin-off utilizes a patented technology owned by the university (intangible resources)
- spin-off has access to academic entrepreneurial ecosystem facilities (material resources)

Sequently **personal relationships** could be active between entrepreneurs in the spin-offs and personnel within the academic entrepreneurial ecosystem. The commitment of researchers to spin-off can be out of their comfort zone, especially when they are deeply invested in the institution (Udell, 1990). Nevertheless, this strong relationship potentially benefits the spin-off as it creates an opportunity to utilize academic entrepreneurial ecosystem resources as seen in the institutional relationship.

All business decisions relate to the spin-off's **credibility** as portrayed at a critical juncture. The credibility of spin-offs strongly impacts its ability to acquire resources such as Human Capital and funding, two key elements of entrepreneurial ecosystems. Particularly securing sufficient funding proves to be hard for academic spin-offs and plays a fundamental issue in the transfer of research to economic benefit (Reitan, 1997). Funding facilitators (public & private) demand proof through market insights and business projections. On the other hand, founders require funding to obtain this knowledge leading to a chicken and the egg paradox. This can be resolved by providing funding to spin-offs despite the lack of sufficient evidence or by leveraging (external) business expertise. Vohora et al. state that business experience can improve the decision quality in this phase while enhancing the spin-off's credibility (Vohora et al., 2004).

Phase 4: Re-orientation

After the accomplishment of credibility, the spin-offs own sufficient resources to start on the commercial side by validating the value of their innovation. This process reshapes their original vision of the business case and leads to a re-orientation of their capabilities, thereby identifying new resources that will be needed. This can be described as an iterative process necessary for its correct growth pattern (Vohora et al., 2004). In this phase, spin-offs are constantly adapting their methods and continue to search for information and expertise based on the insights gathered from potential customers, investors and market experts. The change of work processes seems imminent for the spin-offs in this phase yet the ability to coop with it differs per case. This ability is strongly correlated with the efforts performed in the earlier phases. To illustrate, the case studies of Vohora et al. identified that companies that focused dominantly on their technology development, and minimal on market interaction, struggled more with the described change. This is in line with the conclusion that companies who had ”inadequate initial resource endowment, social liabilities lack of entrepreneurial coaching and insufficient business assistance to develop entrepreneurial capabilities” displayed troubling growth (Vohora et al., 2004).

For spin-offs to enter the final phase they are required to overcome the critical juncture of **sustainable returns**. Sustainable returns can be expressed through revenues, milestone payments based on agreements or new investments. It indicates that the spin-off is able to create value for the market through its abilities and resources. The value creation is a result of the team’s flexibility to transform its assets, skills and social capital into needs and information provided by the market. This improvement in internal capabilities proves to be effective and it is commonly seen in larger firms (Galunic and Eisenhardt, 2001).

Phase 5: Sustainable returns

The final phase is portrayed as the sustainable returns period. By this time the spin-offs have tackled numerous uncertainties on both commercial and technological development. As mentioned this is often demonstrated by the company’s first forms of revenue. In addition, new investments are also an indicator of this, as they are utilized for the continuation of the company’s growth. This money is spent on next-generation products/services and the hiring of the needed skills. This rise of also expressed in both tangible gains (e.g. investments, jobs, taxes) and intangible gains (e.g. the reputational rise of the region) (Ndonzuau et al., 2002).

Another important characteristic of this phase is the transformation in the relationship between the spin-off and the academic entrepreneurial ecosystem (Vohora et al., 2004). For the endurance of the spin-off, it is important to distance itself from the academic entrepreneurial ecosystem and start to present itself as an independent high-tech company. This could lead to two potential issues for the academic entrepreneurial ecosystem. First, there is the risk of relocation. As spin-offs experience an expansion of their activities they require additional resources such as specific skilled employees, funding and infrastructure. If not provided in the current geographical location, spin-offs can decide to move away from these academic entrepreneurial regions. Ndonzuau et al. illustrate this by describing the move of two Belgian spin-offs to The Netherlands due to the lack of proper resources (Ndonzuau et al., 2002). Another issue is the change of trajectories by spin-offs to generate alternative funds. Their initial strategy is potentially long-term oriented meaning that they must execute other means such as consulting to survive. This secondary strategy might not bring the hoped economic benefits and social impact visualized by the academic entrepreneurial ecosystem.

The described phases provide insights for the university and other facilitators within the academic entrepreneurial ecosystem on what is needed to develop spin-offs effectively. They can use their influence and resources to tackle those elements which remain sensitive to the survival of the spin-offs. To envision this a more detailed understanding of the challenge faced by the spin-offs from their standpoint is necessary.

Spin-off development through technology advancement

The development phases described in 3.3.2 portray the process as it is envisioned in general. Nevertheless, this approach can differ for the spin-offs that actually experience these steps. This study aims to discuss both perspectives to capture the entire school of thought behind this development journey. The critical junctures are defined on a high level as seen in its terminology; *credibility*. These junctures translate themselves into daily challenges that spin-offs have to overcome, a factor overlooked in the research of Vohora et al. (Vohora et al., 2004). Sequentially, the spin-offs might perceive their progress through other milestones besides the shifts between the development phases. As mentioned by Vohora et al. spin-offs focus primarily on the development of their technology and its achieved capabilities (Vohora et al., 2004). This technological advancement is often found in the literature to demonstrate a company's progress.

Various literature was utilized to illustrate this approach, predominantly the works of Santos et al. and Steve Blank's Lean Method (Santos et al., 2017; Ries, 2011). This method is commonly used by high-tech startups and spin-offs in the creation of their product and business. It describes the link between the design of the product and the success of the business. According to Blank high-tech startups or spin-offs should progress on both product development and business development. Unlike the process of Santos et al., this is a non-linear journey in which high-tech startups undergo several pivoting moments to create sustainable businesses (Santos et al., 2017; Ries, 2011). For the product development process, Blank identifies four phases concept (seed), product development, alpha/beta test and product launch. Wang et al. use these steps as input for a process more suitable for high-tech startups/spin-offs leading to the phases of *Concept, In development/working prototype and Functional/-mature product* (Wang et al., 2016). Blank argues that entrepreneurs will fail when solely using these steps. The provided product development phases should synchronize with business development that happens simultaneously. The business development process is characterised as defining or observing a problem, evaluating the problem, defining a solution, and evaluating the solution. This process should be repeated throughout the product development process to define the true customer and value of the technology. This thesis provides the product development steps of Wang et al. while incorporating the business development mechanism (Wang et al., 2016).

1. Concept (seed)

This concept phase is often referred to as the ideation phase and entails the start of the entrepreneurial path. The founders engage in customer discovery to observe a problem faced by the users. Through conversations more information is provided on the problems and founders use this to design a technology that could potentially solve them. The trick in this phase is to identify the true pain points experienced by users and to see why these have not been resolved by current solutions. Founders can gain many insights into why previous high-tech startups in this specific field have failed in the past.

2. In development/working prototype

The initial outlines for the technology that solves the user's challenges are tested in this phase. The founders return to the users and try to determine whether this innovation aids them. To test this hypothesis founders develop a prototype that showcases the functions of the technology in a basic way. This is better portrayed in the other term for this prototype called the Minimal Viable Product (MVP). The goal of this phase is to diagnose which functions of the product are relevant for solving the hurdles of the users. This will validate the true value that the technology brings.

3. Functional/mature product

A successful completion of the second phase means that a product market fit has been achieved and that initial users are willing to test the technology for a longer period. This requires a more robust form of the product that can be tested in a real-time setting in the form of a feasibility study. After this extensive test, the startup can start expanding its innovation. This results in a final design of the product and brings forth a strategy for sales, marketing and a vision for the business.

Although widely implemented, this approach might not always be as fitting for academic spin-offs. As mentioned, these entities are born out of research by scientists within the universities. This indicates that technology already exists and that the process does not start with detecting a problem and then creating a solution for this. Instead, researchers know the capabilities of their inventions and search

for a problem they can resolve. Nevertheless, the provided steps are still relevant for these cases and require a correct execution of the steps yet simply in a different way. This aspect should not be neglected by the facilitators within the academic entrepreneurial ecosystems.

3.3.3. Development phases of health-tech spin-offs

Using both the general and spin-off perspective this section aims to describe an inclusive approach for the development process of health-tech spin-offs. To do so there needs to be a definition of the health-tech spin-offs. The term health-tech spin-offs is ambiguously used and refers to various forms of innovations that aid individuals in their healthcare. The thesis embraces all the forms illustrated by the World Health Organisation: ”the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life” (WHO, n.d.). The innovations are designed to generate significant value in their specific applications. The creation of new medicine and medical devices is commonly thought of when hearing the term health-tech or Medtech innovations. Of course, these forms are still present in the current fields yet new trends are seen in radioactive medicine, big data analysis and the use of artificial intelligence (AI) (Nguyen, 2019).

This variation in forms leads to differences in the early development phases of health-tech spin-offs depending on the type of healthcare technology they offer. This thesis tries to combine the known methods into a development framework for all health-tech spin-offs. This starts with examining the current methods found in the literature for the process of health-tech spin-offs. The literature dominantly relates to reaching the fourth phase of Vohora et al (2004) *Re-orientation* through the achievement of the critical juncture *Credibility* (Vohora et al., 2004). This work is extended by identifying the main challenges for these spin-offs related to the activities performed in the development process. These insights are used to create the described framework as seen in 3.4. The final framework describes the actions performed by spin-offs in each phase and associates them with the facilitators who can offer assistance.

New MedTech product development process

Health-tech spin-offs operate in a highly complex industry in which they deal with several stakeholders to eventually deliver their innovation to the market. There is a need for product simplicity towards the end-users while maintaining the effectiveness of the product for the treatment or application. Menshenin et al. (2023) discuss two main approaches; design thinking (DT) with a focus on human-centric design (HCD) and systems engineering (SE) (Menshenin et al., 2023). Design thinking relates closely to the approach of Blank to identify and solve problems by creating empathy with the users. Similarly, it sees the journey as an iterative process with the motto of; ”try and fail, fail fast and learn from failures”(Menshenin et al., 2023). This method is beneficial in the search for a correct market fit and particularly helpful in the implementation of the product with end-users. System engineering on the other hand implies an analytical approach to solving problems and closely links with the complex features of a solution. The research combines these methods for the creation of a New MedTech product development process. The process is not particularly constructed for the use by spin-offs. Nevertheless, it offers valuable insights into what is needed per phase for health-tech spin-offs. It exists out of three sub-processes that are discussed in the following sections:

Product strategy definition process

The initial phase defines the heading for the product and the company. It starts with the identification of the problem and the focus on how to solve it. This indicates in which market this product will compete in. An analysis will be executed on the market characteristics such as competitiveness landscape, current solutions and market trends. These insights lead to a definition of business opportunities and eventually the business objectives. These objectives are then translated into metrics which can be used to evaluate the progress. The fifth step, the intended use, is crucial in this phase as it might carry important impacts at a later moment. This intended use is applied as input by the regulatory bodies for the examination of the product’s safety on its users. Following this is the business risk analysis that captures the potential losses and risks relating to this strategy. The end of this phase includes a complete analysis of the entities included in the product life cycle and potential stakeholders. This defines which kind of partnerships need to be established to produce the product. The product strategy definition process output is used as a shared understanding within the team on what is needed and

what they are building (Menshenin et al., 2023). The steps seen in this process relate back to the work done by academics and TTOs in the opportunity framing phase in 3.3.2.

Product concept definition process

In the next phase, the strategy behind the business is conceptualised into a product. This is particularly relevant for spin-offs developing medical devices but can also be broadly applied to bio-engineering projects. The first step in this phase continues on the outcomes of the product strategy definition process. It defines the needs of the users and starts to validate them. This is commonly done through interviews with stakeholders and users with the implementation of methods such as the ”why” questions (Menshenin et al., 2023). This output is used to define the product that the spin-off is creating. These proposed solutions are then rechecked with the same interviewees to validate whether they truly solve the issues. This is done using a Minimal Viable Product (MVP) which is based on the insights of the system requirements. The MVP represents a simple version of the end product to show the potential of the innovation is again validated by the users. The creation of the MVP happens by conceptualizing the MVP, designing it, verifying it in a stable situation and later validating it. This last step will indicate whether the MVP satisfies the users' needs and is used for the creation of concept business approval. This process highlights another synergy between the New MedTech product development process and the general perspective on early-stage academic spin-offs. The activities on the validation of the invention through an MVP are associated with the pre-organization phase.

EMA/FDA drugs development process

In the original New MedTech product development approach the final process relates to the development of drug regulation. Be that as it may, other health-tech propositions might have to follow a similar process. Therefore this research rewrites this part for all health-tech innovations fitting with the inclusiveness of this study. In short, most of these regulations apply to a spin-off when the invention potentially impacts the human body, both directly and indirectly. To illustrate, forms of tools can be labelled as medical devices for internal use (in vitro) which results in a stricter level of regulation. This categorization is based on the intended use of these products as stated in the product strategy definition process. As innovations vary in their features so do their regulatory pathways, specifically to those operating in a new market. The regulatory processes are overseen by the European Medicine Agency (EMA) in Europe or the Food and Drugs Administration (FDA).

The general process is divided into five steps; discovery & development, pre-clinical research, clinical research, EMA/FDA review and EMA/FDA post-market safety monitoring (Health, 2020). In the initial phase, a company spends a lot of resources on the discovery and further development of a drug or innovation. In the academic context, this could already be established during research inside the university. The next step is testing the new invention on animals such as mice which happens in the pre-clinical phase. Following this is the clinical research that exists out of three phases. This is a crucial phase in which the effect of technology on the human body is examined. The phase is divided into three separate phases in which the group of participants grows and a specific subject is relevant. In phase 1 for example the emphasis lies on the safety and doses and is determined on 20 to 100 individuals. The clinical research is closely monitored by the authorities (EMA/FDA).

Although not specifically designed for academic spin-off the New MedTech product development process provides a relevant overview of the necessary steps that need to be taken by a health-tech spin-off. It includes both the elements of the creation of a business and the criteria that need to be covered in the construction of a medical device or drug. The literature is used as input for the development of the final framework presented in the following section.

3.3.4. Challenges of health-tech spin-offs

This chapter aims to outline an inclusive perspective on the development process of early-stage academic health-tech spin-offs. The described steps represent activities that these spin-offs need to execute to realise growth. These activities potentially lead to challenges for the spin-offs during the development process as a result of internal and external factors. This segment identifies the main challenges for health-tech spin-offs when developing their business and technology. A combination of literature is utilized for the construction of four main challenges, associated with the unique characteristics of health-tech spin-offs. It is visible that these challenges are often correlated in their cause. This might also offer opportunities as one solution may solve various problems. The recognition of these barriers aids in the understanding of the journey of health-tech spin-offs and can be implemented by facilitators to fit their support more effectively. The described challenges are dominant during specific phases and critical junctures as illustrated by Vohora et al. and follow the appearance of these events (Vohora et al., 2004). The subsequent challenges include:

Design choices on technology development

The R&D approach of health-tech spin-offs is focused on the achievement of a core invention while minimizing its risks accompanied by this early development phase. The technology development is determined by the *design process* defined as "all the creative and analytical steps by which a given idea is gradually fleshed out into a new product that can be mass-produced and commercialized." (Lehoux et al., 2014). The design process is steered by information on market characteristics such as customer demand, costs of production and competing innovations. Moreover, it aids in the prioritization of the activities found within the design process (Bruce et al., 1999). The approach of the design choices is closely associated with the perspective of spin-offs on the development process as described in 3.3.2.

These design choices are of high importance to the success of the health-tech spin-offs. The initial decisions strongly affect the long-term strategy of these companies and mistakes within this procedure are hard to adjust (Lehoux et al., 2014). These primary choices are strongly influenced by the critical juncture of **opportunity recognition** and the evaluation of commercial strategy as seen in the phase Vohora et al. state as **opportunity framing** (Vohora et al., 2004). There is the risk that a team spends a large amount of time on the identification of the missteps and their resolution (J. L. Martin et al., 2012). This phenomenon occurred in the case studies of Vohora et al., where the concern for its lasting effect is shared (Vohora et al., 2004). The success of health-tech spin-offs is particularly sensitive to these wrong assumptions as these projects are known for their time-consuming, cost-intensive design processes (Lehoux et al., 2014; Metcalfe et al., 2005).

Team capabilities

The lack of resources during the Valley of Death is not the sole reason that spin-offs fail in their journey. Many aspects of their success relate to the team's capabilities in the spin-offs. This competency is often referred to as Human Capital, an element of the entrepreneurial ecosystems, that can be found in the spin-offs. Not all founders are willing to commit full-time even when there are sufficient resources, due to the absence of generated revenue (Oe and Mitsuhashi, 2013). This concept aligns with the work of Vohora et al. where **entrepreneurial commitment** is named as the critical juncture between the second and the third phases.

The team's capabilities prove to be vital in other parts of the development process as well. The **credibility juncture** is defined by Vohora et al. (2004) as the ability of a spin-off team to show progress in order to acquire the necessary resources and expertise (Vohora et al., 2004). These resources are both tangible and intangible and can potentially be realized through institutional or personal relationships between the academic entrepreneurial ecosystem and the spin-off. As named in this section, improving credibility directly influences the challenges of design choices, funding and partnership. In the re-orientation phase, the team's capabilities are tested on another level during the critical juncture of sustainable returns (Vohora et al., 2004). The success in the phase depends on the team's ability to cope with all the market information and to structure its internal processes effectively. In general, the challenge for health-tech spin-offs is to create a team with a diverse set of skills and expertise as this positively impacts the success of a spin-off (Kulkov, 2021; Cantamessa et al., 2018).

Financing

The height of the costs demands large investments to stimulate the progression of the health-tech spin-offs which steepen the Valley of Death as explained in 3.3.1. Kulkov states that in the beginning there is sufficient financing for the academic research which refers to the first phase by Vohora et al. (Kulkov, 2021; Vohora et al., 2004). Later the industry shows interest in innovations by investing in them through private money. The period between these moments relates to overcoming the **credibility** juncture of Vohora et al., characterized by limited resources, where the spin-off struggles for existence (Vohora et al., 2004). This rough period is the effect of two reasons; investor progress demands and medical regulation (Kulkov, 2021). This point occurs just before the market entry of many innovations and results in hesitant behaviour by the investors as they doubt whether the spin-off will become successful. In order to invest financial institutions expect strong evidence of the functionality of the technology and its commercial prospects. The latter relates to the uncertainties surrounding business aspects such as expected sales, cost of production and profit margins (Aspara, 2009).

Part of this proof towards investors is the outcome of the medical regulatory pathways that some health-tech spin-offs are obligated to follow. Passage 3.3.3 elaborates on these pathways that are characterized by multiple testing rounds that examine the effect of the invention on the health of human beings. These medical regulatory procedures are time-intensive and costly as they are overseen by independent authorities, making them a unique additional hurdle to health-tech spin-offs. Jackson argues that public organisations should solve the lack of resources in this period as the outputs of these spin-offs positively impact society (e.g. employment & health benefits) (Jackson, n.d.). This is potentially done through direct investment or access to facilities such as infrastructure for prototype production.

Networking

The challenge of networking is tied to the element of *Support and Networks* in the entrepreneurial ecosystems, and is known as the Social Capital of a spin-off. From the start of their journey, early-stage health-tech spin-offs are required to establish strong relationships with various stakeholders (Lehoux et al., 2014). On one side they have to build connections to future customers and users for the correct decisions on the design choice, as named in the first challenge. Sequentially, the spin-offs need investments for which they need to bond with investors such as venture capital firms (Lehoux et al., 2014). This indicates that the nature of these relationships differ and helps to acquire the demanded resources, skills and knowledge. The achievement of this again has to do with the capabilities of the team as mentioned in the previous challenge. Spin-offs are often led by academics who are sometimes inexperienced in the commercial industry. This results in the need for the construction of a whole new network. This proves to be hard as seen in the cases of Vohora et al. (Vohora et al., 2004). On the other hand, academics could leverage their relationship with the academic entrepreneurial ecosystems to obtain the necessary resources to overcome the critical juncture of **credibility** (Vohora et al., 2004).

Particularly health-tech spin-offs seek assistance in challenges which are highly complicated due to their medical or technical setting. Health-tech spin-offs frequently find their origin in academic medical centres (AMCs) affiliated with a university. Here the AMCs could potentially provide the needed resources and clinical knowledge to the spin-offs. Nevertheless, these AMCs generally miss the correct resources to provide infrastructure to validate the innovation correctly. Facilities such as clean rooms, digital medical records, and patient population data are currently not exploited and this is a missed opportunity (Silva et al., 2018). Moreover, partnerships between the industry and the AMCs could also benefit the spin-offs but these relationships are troubled by ineffective agreements on topics such as ownership of output results (Silva and Ramos, 2018).

3.4. Framework early-stage development process health-tech spin-offs

The literature examined in this study covers several topics relevant to the creation of health-tech spin-offs in the academic entrepreneurial ecosystems such as the facilitators in these ecosystems and their support. Moreover, it covers the development process of general companies and high-tech startups, transitioning to a closer examination of spin-offs and eventually those tied to healthcare technology. This final section combines these insights into the creation of a development phases framework specified for health-tech spin-offs. This approach continues on existing literature as discussed in 2.2.2. It separates the development process into four phases each presenting a specific period with its own dominant needs. These needs are defined into dimensions that are associated with both the business and product development of spin-offs. Based on the literature the facilitators provided support on these dimensions of needs. This thesis couples the facilitators with the needs present in each phase.

The described framework is aimed at the early phases of the development process of health-tech spin-offs. This period offers the highest risks for spin-offs and therefore help is needed the most here from facilitators. Furthermore, during these steps, the relationship is the closest between the health-tech spin-offs and the origin university within its academic entrepreneurial ecosystem. The four phases embrace literature that describes multiple perspectives on the development process. The steps are based on the work of Mejtoft et al. (2022) and strongly align with the process seen in the New MedTech product development process (Mejtoft et al., 2022; Menshenin et al., 2023). Sequentially, it includes the challenges of healthcare technology spin-offs dominant up until the fourth phase of Vohora et al. (Vohora et al., 2004). The obstacles are based on various works found in literature and are translated into activities that relate to one of the four dimensions; business development, product development, clinical validation, and funding. The operations associated with the business & product development are based on the continuous iterative process as illustrated by Blank in 3.3.2. Clinical validation is a dimension designated to health-tech spin-offs and is based on the clinical readiness levels (CRL) to rank the progress of health innovation and works similarly to the indicator Technology Readiness Level (TRL) (Mejtoft et al., 2022). Additional grey literature was utilized to define the funding per phase more practically. The last two rows couple the characteristic activities per phase to the facilitators that provide support on these elements in that particular phase. These insights are based on the works of the literature analysis as illustrated in section 3.2.2. The framework for the development of health-tech spin-offs is presented in 3.4 and each phase is elaborated further in this chapter.

	Conceptualisation	Concept Validation	Product Validation	Product Launch
Key activities business development process (Mejtoft et al., 2022)	- Identification of user problems - Identification of the customer - Setup value proposition	- Value proposition validation - Willingsness to pay validation - Analysis market validation	- Defining commercial path of company - Strategy revenue and costs - Partnership agreements	- Prove of market establishment - Team focus on sales & maintenance
Key activities product development process (Mejtoft et al., 2022)	- Valuation of tech features	- Creation of MVP - Strategy for product protection	- Creation of final prototype - Review of product requirements - Start of the product's technical file - Verification on the subcontractors	- Strategy on production & distribution - Strategy for handling incidents and monitoring legislation changes
Key activities clinical validation (Mejtoft et al., 2022)	- Clinical adoption strategy - Description of intended user and use - Clinical validation to user problems - Risk analysis user risk classification	- Intended clinical application (pre-clinical) - Validation on interaction the user and the innovation interaction	- Validation on functionality final prototype - Execution clinical trials - Reporting on data for health eco analysis - Validation end usability	- Awaiting clinical approval of authorities
Financial pathway (Rutan, 2023 & NWO, n.a.)	- Funding required: max €10K - Public grants/gifts from private relations	- Funding required: €10K - €100K - Public grants or startup competitions	- Funding required: €100K to €1M (Seed funding) - Convertible loans and investments	- Funding required: €1M to €15M (Series A & B) - Private investments
Key facilitators (author, 2024)	- Incubator - TTO	- Incubator - Accelerator - Financial facilitator (public)	- Accelerator - Financial facilitator (public & private)	- Financial facilitator (private)
Offered support per facilitator (author, 2024)	-Infrastructure (Incubator/TTO) - Business (Incubator/TTO) - Social (Incubator/TTO) - Financial (TTO) -Legal (TTO)	-Infrastructure (Incubator/Accelerator) - Business (Incubator/Accelerator) - Social (Incubator/Accelerator) - Financial (Accelerator/public fin-facilitator) -Legal (Accelerator)	-Infrastructure (Accelerator) - Business (Accelerator) - Social (Accelerator) - Financial (Accelerator/public & private fin-facilitator) -Legal (Accelerator)	- Financial (private fin-facilitator)

Figure 3.4: Development framework of health-tech spin-offs (author, 2024)

3.4.1. phase 1. Conceptualisation

The first step of the development is named the *conceptualisation* and entails the transformation of the research into a concept for a business.

Business development

In the conceptualisation phase, business development is highly crucial and starts with the identification of user problems. The problems need to be validated during conversations to determine whether this issue is relevant enough for the users to be solved. This is correlated to the discovery of customers. Customers could be the end-users of the innovation but this is not the norm. The discovery of the needs, users and customers helps to determine where the true value of the product lies, expressed in the value proposition.

Product development

The value proposition is used as input for product development. As mentioned this aspect differentiates for academic spin-offs as commonly innovation is already established out of research. This makes product development less flexible and emphasizes the importance of correct execution of problem discovery. Product development in this phase is understanding which features of the product create value for the user or customer.

Clinical validation

Clinical validation in the conceptualisation phase is indicated by the first two clinical readiness levels. CRL one is the securement of clinical competencies and describes the strategy to accomplish the clinical adoption of a product or method. Moreover, it includes the identification of an intended user that aids in pushing the innovation and an analysis of possible collaboration on clinical validation in later phases (e.g. pre-clinical trials). Sequentially a preliminary intended use is described for the innovation. The second CRL incorporates the verification aimed at whether the product resolves the needs within the healthcare concept and is closely associated with product development. Finally, a risk analysis needs to be executed to state the user-safety classification of the innovation.

Funding

In this first phase, funding is not required in large amounts as the activities mostly demand the investment of man-hours. Potentially financial resources are needed for the compensation of these man-hours, particularly when an external party is hired for this. The first forms of funding are public grants or gifts from private relations such as friends and family. The amount of funding needed is a maximum of €10k.

Dominant facilitators

This phase is aimed at reaching a solid state where there is a customer with a problem and an innovation that can resolve this. To establish this the spin-offs need to revise their business case constantly. *Incubators* provide mentoring on this through programs where founders are introduced to industry networks and are provided with the necessary tools (e.g. business model canvas). Moreover, *Technology Transfer Offices (TTOs)* play a vital role in this phase by discovering technologies through patenting them. Depending on the TTO, support is offered by investing money or access to offices or legal expertise (Swamidass and Vulasa, 2009).

3.4.2. phase 2. Concept validation

In the second phase, the initially suggested concept is validated by searching for the product-market fit. This phase also embarks an important point of iteration. A pivot happens when concept validation fails and the startup has to return to the initial phase. This process is natural for high-tech startups and aligns with the works of Blank (Wang et al., 2016). This is also the moment in which the researchers decide to incorporate the product into a business entity.

Business development

The constructed value proposition is validated by returning to the customers and examining if the features of the product resolve the problems. This moment provides a good situation to test the customers' willingness to pay for the product. When this is not established or the willingness is too low the spin-off might revise its concept and return to the first phase. In addition, the spin-off reviews the market in which it will operate in the future, including an analysis of its characteristics such as size, key players and potential competitors.

Product development

To test the value proposition mentioned in business development the spin-offs turn the concept into a Minimal Viable Product. This is again an iterative process as seen in the New MedTech product development process, where the MVP is adjusted to the features that deliver the value to the customers. The second part of the product development consists of the specification of a strategy for the protection of the product. The discovery of the relevant features creates a unique selling point for the product. These traits need to be protected for the business to compete with other firms in the future.

Clinical validation

In CRL 3 the MVP is tested in a lab or user environment to showcase the intended clinical application to the user/customer. This can be performed in feasibility research or a pre-clinical study. CRL 4 dives deeper into the experience and interaction between the user and the innovation. It is interconnected to business and product development as it verifies the needs of intended users and their perception of the product.

Funding

At this phase, more hours are put into the project as its development progresses which requires financial compensation. Moreover, funding is used for the materials of the MVP to enable testing. This leads to a needed funding between €10K and €100K. This money is often gathered through public grants or startup competitions. The Take-off grants by the Dutch public organisation NWO are examples of funding in this phase (NWO, n.d.).

Dominant facilitators

In the second phase of the development process, the health-tech spin-offs still need coaching from external experts. The expertise depends on the progress the spin-offs have made up until now. In some cases the help of *incubator* can still be beneficial in the search for a product-market fit. When a more developed understanding of this exists, an *accelerator* provides a better fit for the needs of the spin-off. Particularly, when the accelerator is specialised in a specific industry as seen with maritime innovation. Moreover, the progression of the spin-offs requires a higher gathering of financial resources. *Funding facilitators* play a vital role in this phase as further development can be delayed if funding is not achieved. At this moment the risks related to the success of the spin-offs are still high and are therefore often avoided. Public entities fill this gap by the provision of grants that are applied for both business and product development.

3.4.3. phase 3. Product validation

A product, team and business model have been established by now and the spin-off prepares itself for the expansion of the business, so-called ready to scale (Kumbhat and Sushil, 2018).

Business development

The value proposition has been formed and validated with the potential customers, indicating the traction for the product. Future steps include the extension of the business model by defining the commercial path of the company. This results in the definition and strategy for future costs and revenue streams. Additionally, there is contact with potential partners for the construction of the final product.

Product development

The MVP has led to the needed input for the formation of the final prototype, which is tested on its clinical readiness. The requirements for this final product are defined and an analysis is executed on the necessary assets vital for the production of the innovation. Information on the end product is used as input for the protection of the invention. This starts with a review of the product requirements and the creation of the product's technical file. Sequentially, when applicable, a verification on the subcontractors is done and the company prepare for its certification.

Clinical validation

In this phase, the product enters the final levels of clinical validation. In CRL 5 the final prototype's functionality is validated with regards to its stability or repeatability in combination with the medical performance in the relevant clinical surroundings. This process is referred to as a clinical trial and happens in three sub-phases as mentioned by Menshenin (Menshenin et al., 2023). Within these trials, spin-offs need to evaluate the user-friendliness of the end-users and apply for ethical permission from the authority (EMA/FDA), including the relevant standards for the design of the study. It is advised that the spin-offs aim for a high level of evidence level through the implementation of randomized, controlled multicenter studies and potentially a double-blind method using placebo control. Lastly, it is important to notice that the spin-offs should report all the data needed for the health economic analysis. CRL 6 is the final level and validates the end usability of the product with its users.

Funding

In this phase, there is a strong increase in the costs that are made by the spin-offs. This is an effect of full commitment by the founding team, material costs, medical trial costs and of course the incorporation of the company itself. The team should establish contact with investors for Seed funding and public organisations that grant convertible loans. The amount of funding ranges between €100k and €2 million (Rutan, n.d.).

Dominant facilitators

Depending on their programs, *accelerators* can offer assistance to the spin-offs. As several parts of the spin-offs have been established, most of the value that they provide lies in the resources for the next steps such as finding partners for production. In preparation for entering the market, the spin-offs need to cover various costs, growing their demand for additional funding. The costs lie dominantly in the execution of the clinical validation. *Venture Capitalist* and *angel investors* involve themself with the ventures at this point. They start to see the value of the innovation and are open to investing in them.

3.4.4. phase 4. Product launch

In the final phase, the spin-off prepares itself for the launch of the product and the official entry of the market. This phase represents the biggest separation between the university and the spin-off.

Business development

For the spin-off, it is of the greatest importance that a wide network of customers has been built. The company and its investors need to be assured that the product will be sold. This is often proven through a letter of intent in which a company states that it will buy the product when market-ready. Within the team, there should be the construction of a department responsible for the sales and maintenance of the customers. This is to boost future sales and establish long-term customer relationships.

Product development

Product development awaits approval of clinical readiness from the relevant authorities (EMA/FDA) to go into production. Meanwhile, the spin-off develops a plan for the full-scale manufacturing of the product. This does not solely include the necessary machines but also the required agreements with material suppliers. Sequentially, the team awaits the approved documents relating to the protection of the product while focusing on a strategy for the handling of incidents and monitoring legislation changes.

Clinical validation

After clinical approval by the relevant authorities (EMA/FDA) the spin-off is ready to start its operation. It should be noted that the authorities will continue to monitor the impact of the product on human health.

Funding

At this phase, the spin-off is fully funded by investors and goes through various rounds of investing named Series A & B. This leads typically to investments between €2 million and €15 million (Rutan, n.d.).

Dominant facilitators

This phase marks the end of the spin-off's original presence in the academic entrepreneurial ecosystem. The need for support from the facilitators in these ecosystems is decreasing. The spin-offs formed partners and validated the problem, the customers, the business plan and the (clinical) product development. The main interaction is the continued search for financial resources in which *funding facilitators* could potentially play a role. This can both be private money or large amounts of public money in the form of subsidies.

3.4.5. Summary

The literature analysis is separated into the components of the functionality behind academic entrepreneurial ecosystems and the development process of health-tech spin-offs. The understanding of the academic entrepreneurial ecosystems is traced back to the extensively discussed entrepreneurial ecosystems. This concept entails a community of stakeholders to stimulate innovation in an organic structure. This was done by analysing various forms (e.g. Triple Helix model) and later focusing on the elements that shape it. This list of elements including *Human Capital* and *Government* portray the types of support that are covered by the stakeholders. Some of these elements are also active in academic entrepreneurial ecosystems. This type of ecosystem can be visualised as a variant of entrepreneurial ecosystems operating in an academic setting. There are varieties in the involvement of these systems with entrepreneurship which is presented in the principles. This involvement influences the ecosystems' support for innovation. This support is realised through institutions better known as facilitators. The research indicates that there are 5 identified types; *Technology Transfer Office*, *Incubator*, *Accelerator*, *Science park* and *Financial facilitator*. These facilitators are then linked to the support types they commonly provide; *Infrastructure support*, *Business support*, *Financial support*, *Social support* and *Legal support*. Sequentially, the section bridges these support types to the underlying elements of the entrepreneurial ecosystem they represent.

The second component focuses on outlining the development process of health-tech spin-offs. Similarly to the examined ecosystems, the research starts by describing the development process for early-stage high-tech startups. This identified some relevant topics such as the chaotic beginning of these groups during the pre-startup phase and the risks caused by the Valley of Death (VoD). Next, the development process of academic spin-offs is examined through two different approaches. The first one is based on the works of Vohora et al. and Ndonzuau et al. who characterize the process as phases where spin-offs have to overcome critical junctures to develop their companies. The second approach explains the development of the spin-off through technological advancement where all progress depends on the improvement of the innovation. The relevance of the latter approach returns during the last scope of the literature analysis where the development process of health-tech spin-offs is examined. Here the New MedTech product development process is followed indicating similarities to the technological advancement approach. Moreover, this process highlights the unique challenges to health-tech spin-offs crucial to the development process. All knowledge of the various studied development processes is expressed in listing the challenges of health-tech spin-offs and the provided framework that describes the development process. The four challenges are closely related to the stated critical junctures and the unique process described in the New MedTech product development process. These challenges are integrated with the development phases and the facilitators' support to form the framework.

4

Use case

This chapter provides an overview of the facilitators in the ecosystems of Delft University of Technology (TU Delft), Leiden University Medical Centre (LUMC) & Erasmus Medical Centre (Rotterdam). For each ecosystem, a description is given of the origin of the university environment, its facilitators and the support they provide. The end of this chapter examines the support by executing a quantitative content analysis to indicate the preference for support by facilitators. Moreover, the role of facilitators between the literature and the use case is discussed. Finally, a visual overview is provided on the (sub)support of facilitators in each development phase.

4.1. Dutch health innovation system

The creation of health innovation in The Netherlands is closely associated with the functionality of the Dutch national health insurance system. The first national health insurance was rolled out during the Second World War in 1941 and was based on the German Bismarck model. This resulted in public health insurance coverage for 63% of the Dutch population (Tikkanen et al., 2020). By the turn of the century, this model did not fit the current population as it led to inefficiencies and long waiting lists. This gave rise in 2006 to the Health Insurance Act which was strongly influenced by the works of Enthoven and Wynan (Enthoven and van de Ven, 2007). This model combines the public and private insurance markets into one universal market that is characterized by private insurance and mandatory coverage (Tikkanen et al., 2020). In this new approach, all residents paying Dutch income tax are obligated to be insured by private insurers. Every individual is able to select their own fitting insurance package every year and insurers must accept all applicants. Through this high coverage, the costs of health remain lower, creating more financial possibilities for health innovation (Tikkanen et al., 2020). In recent years there has been a new adaption of this model, through the (partial) privatization of hospitals and the rollout of new health insurance schemes. In this new form, hospitals are able to compete in facilities where they are specializing in various forms of expertise. Meanwhile, consumers have more flexibility in their choice of insurance policy in return for lower healthcare contributions. Both these changes empower the professional's and consumer's choice for innovation and the implementation of healthcare, which means that innovation is now directly driven by the needs of professionals and consumers.

The development of the Dutch national health insurance system aligns with the change in the perception of health innovations. In the early 1990s, the concept arose that knowledge was a fundamental resource to the economy, leading to the theory of the National System of Entrepreneurship. This theory illustrated the shift from individual R&D processes to one of an institutional and industrial structure (Ács et al., 2014). This led to the formation of a national policy aimed at creating knowledge and transforming it into a product beneficial for the country's economy. Inventions in healthcare are no exception to this, currently representing the second largest industry among all the national Dutch innovations (TechLeap, n.d.). A continuous race is held on the application of innovation for national benefits and The Netherlands even held the 8th place in the world ranking of the Global Entrepreneurship and Development Index (GEDI) in 2013 (Ács et al., 2014).

Academic entrepreneurial ecosystems play an increasingly important role in the Dutch National focus on healthcare innovations. In the past technology creations were led by big well established corporations. Currently, healthcare inventions are the result of spin-offs or startups that rise from these (academic) entrepreneurial ecosystems (Molema and van Egmond, 2017). This matches with the latest development in the Dutch national health insurance system where end-users determine the course of innovation. This new approach increases the speed and flexibility of the development process for healthcare technology. Dutch academic entrepreneurial ecosystems try to stimulate this process by providing aid to the health-tech spin-offs, offered by affiliated facilitators.

For this use case the three Dutch academic entrepreneurial ecosystems of Delft University of Technology (TU Delft), Leiden University Medical Centre (LUMC) and Erasmus Medical Centre (EMC) were selected due to their relevance to healthcare technologies and their geographical positioning to one another. Each ecosystem is accompanied by a contextual background description along with an overview of the support provided to the health-tech spin-offs by the associated facilitators. This research solely focuses on the early stages of the development process seen for health-tech spin-offs. Information through grey literature, qualitative information from interviews and using the database of Techleap is implemented to identify the relevant facilitators and their support (TechLeap, n.d.). Interviews were held with 7 facilitators across all three Dutch ecosystems. In addition, an interview was conducted with an expert from the London Institute of Healthcare Engineering (LIHE) to gain deeper insights into other support mechanisms. This research included the most relevant facilitators based on their impact towards health-tech spin-offs and their geographical orientation. The aid by the facilitators is linked to the defined support types in 3.2.2. Using the proposed stages in the framework of this study, the support towards the spin-offs is described. This section concludes with an analysis of the provided aid and a comparison of the facilitator's roles as described in the literature and observed in the three Dutch academic entrepreneurial ecosystems. The following chapter uses this input to determine a potential mismatch in the provided support and the needs of health-tech spin-offs.

4.1.1. Difference in terminology

Besides the insights on the support offered by the facilitators, the qualitative research resulted in findings related to terminology applied in the Dutch national entrepreneurial ecosystem. In 3.2.2 the literature identifies various types of facilitators based on the support offered towards spin-offs. During conversations, it became clear that several facilitators were in contact to achieve a more streamlined support process throughout the Netherlands. This also included a change in terminology. To increase the fitness of this study towards the reality of the Dutch ecosystem, the new terminology will be applied henceforth in the rest of the research. This includes the change of incubator to pre-incubator and accelerator to incubator.

4.2. Delft University of Technology (TU Delft)

The Delft University of Technology dates back to 1842 and initially was an academy for civil engineers (TU Delft, n.d.-b). Currently, the university ranks among the top 50 globally, within the top 20 in Europe, and is among the three best universities in The Netherlands. It particularly scores well in areas such as Architecture, Water Resources and Marine/Ocean Engineering (TU Delft, n.d.-c. Today it provides 16 bachelor programs to its students divided over 8 faculties relating to subjects of engineering, science, design and entrepreneurship (TU Delft, n.d.-a).

In line with the National System of Entrepreneurship, the TU Delft adopted a policy in 1998 to support entrepreneurship within its ecosystem that was built on the national Dutch policy called "Technostarters" (Soetanto and van Geenhuizen, 2015). This policy included small loans, accommodations in the facility buildings and if available, coaching. This marked the start of the academic entrepreneurship of the TU Delft. Later in 2005, the TU Delft collaborated with the Municipality of Delft to introduce an incubator program in the incubator YES!Delft. This program included laboratories, secretarial services and the specified entrepreneurial coaching (Soetanto and van Geenhuizen, 2015). The academic entrepreneurial focus of the TU Delft has led to various projects and initiatives over the years to boost spin-off creation and technology commercialization. This is not solely facilitated by the support to spin-off through facilitators such as YES!Delft. This ecosystem provides sub-ecosystems that host experimental environments to test innovations. Examples of these are the Green Village, Robo House and Quantum

Delft (Quantum, n.d.). Moreover, the TU Delft established the Delft Centre for Entrepreneurship (DCE) which functions as a research and education department of the TU Delft, providing education on entrepreneurship for students and researchers (Delft Centre of Entrepreneurship, n.d.).

4.2.1. Delft Enterprises

Delft Enterprises was created in 2008 and is one of the two holdings that are fully owned by the TU Delft. The other holding, TU Delft Services, aids all activities of the TU Delft that are more fitting in a commercial entity such as a B.V. and is done in collaboration with the Finance and Legal Services (TU Delft Holdings, n.d.). Although Delft Enterprises officially is characterized as the holding company of the TU Delft, it also plays an important role in the transfer of technology. For the simplification of this research, Delft Enterprise is stated as the Technology Transfer Office of the TU Delft in which it engages in ”innovative, early stage and technology-based spin-off companies of Delft University of Technology.” (Delft Enterprises, n.d.). Their mission is to translate the TU Delft technologies to impact society through involvement in entrepreneurship, funding, facilities access and knowledge on topics such as Intellectual Property (IP) and partnership agreements. This translation from technology to the market is either created through licensing agreements with a large company/spin-off or through the direct transfer of IP. In both cases, Delft Enterprises receives a reward in return, commonly in the form of shares in the spin-off or royalties with large firms.

Support towards early-stage academic spin-offs

Type of support: Infrastructure, Business, Financial, Social and Legal

Delft Enterprises (DE) is involved in all forms of support, defined in 3.2.2. Delft Enterprises’ is active in the development process before conceptualisation and is named as discovery. This is the phase in which researchers are still fully focused on the development of their technology. Delft Enterprises tries to inspire these academics with the possibilities of entrepreneurship with their inventions. Through this, the academics get involved with Delft Enterprises in the stage of *conceptualisation* where they determine the value of the IP by looking at competitors and market trends, as a process similar to the first stage of Vohora et al. (Vohora et al., 2004). If a potential is found the spin-off moves to **concept validation** where the business development is extended, this work is now primarily done by the spin-off team where DE links the spin-offs to YES!Delft for assistance through their programs. At the end of this stage the IP has been fully transferred to the spin-off and Delft Enterprises becomes a shareholder in the company. From this point onwards, Delft Enterprises has a more passive role in which they aim to assist the spin-offs in their process of gathering the required resources. This resource support is also done in the earlier stages and relates to the support on infrastructure, financial, social and legal. Delft Enterprises is involved in the funding of spin-offs using their own money (e.g. DE Startup Voucher) or through application for external financing (e.g. Take-off 1, TTT Vouchers). The aid in infrastructure is often structured in the IP agreements where the spin-off has the possibility to access university facilities. When needed DE can also offer legal assistance using their collaboration with TU Delft Services. Finally, throughout the whole process, Delft Enterprises aims to provide the spin-offs with a network of various stakeholders to achieve the needed resources in later stages.

4.2.2. YES!Delft

As mentioned, YES!Delft is an incubator and initiative of various partners including TU Delft, Erasmus University and the Municipality of Delft. It initially started on the campus of the TU Delft in 2005 but now also has locations in Rotterdam and The Hague. Their services are not solely focused on the support of spin-offs but on startups and scale-ups in general where more than 250 startups have completed their acceleration program. The organisation believes in the importance of technology’s impact where it is involved in all forms of innovation (e.g. Robotics, AI, Quantum, MedTech and Energy Transition) (YES!Delft, n.d.).

Support towards early-stage academic spin-offs

Type of support: Infrastructure, Business, Financial, Social and (Legal)

The support of YES!Delft spreads over various stages from the framework. The main goal of YES!Delft is to stimulate these groups by offering assistance on team development, funding and networking. In their services, this is translated into predominant support for Business, Financial and Social. In stages

of **conceptualisation** and **concept validation** they offer support in the form of two programs; Co-Lab and Validation Lab. In Co-Lab the single founders of spin-offs get the opportunity to meet their co-founder, relating to the team element. The Validation Lab is a 10-week program where the spin-offs are challenged to find their problem-solution fit, by talking to potential customers and validating their assumptions, much in line with the method of Steve Blank (Ries, 2011). In the following stages of product validation and product launch, YES!Delft provides the Accelerator and fast track to funding programs. In the Accelerator program, the focus lies on the establishment of the spin-off foundation and the acceleration of traction. Over the course of three months, the spin-offs will achieve this goal through workshops, masterclasses and 1-on-1 expert sessions on various topics (strategy, sales & IP). In the fast track to funding program guidance is offered on the financial strategy, making the teams investor-ready. Beyond the early stages of the development framework, YES!Delft aids the groups with strategic funding support and Human Resource (HR) support. These are consultancy services where strategic funding support is focused on the creation of financial lifecycle planning and HR support aids in topics related to team development, talent acquisition and personal conflict resolution. In addition to these programs and services, YES!Delft organizes networking events to stimulate engagement between the industry, financial partners and spin-offs, relating to the support on the Social dimension (Molema and van Egmond, 2017). YES!Delft also grants access to facilities including offices and workspaces for the construction of products, filling the need for support on Infrastructure. Sequentially, YES!Delft indirectly helps the teams on Legal challenges as they link them to corporations specialized in this.

4.2.3. Impact Studio

The Impact Studio was officially launched in 2021 and is a collaborative structure between the Innovation & Impact Centre (TU Delft), Delft Enterprises and the Delft Centre for Entrepreneurship (DCE). It positions itself as a pre-incubator that supports academia and entrepreneurs in their search for the commercial potential of their technology. The goal of the Impact Studio is to prepare the teams as effectively as possible so they can participate in other programs such as those of YES!Delft. They focus on all potential spin-offs that are affiliated with the TU Delft.

Support towards early-stage academic spin-offs

Type of support: Business, Financial, Social

The Impact Studio primarily focuses on the **conceptualisation** stage and in some cases on the **concept validation** stage. In the cases where the academics themselves want to explore the business potential of a technology the Impact Studio offers, twice a year, a coaching program of 6 months for all spin-off themes. Here they aid the groups in the identification of a problem-solution fit for the technology, done through 1-on-1 coaching and peer-to-peer workshops. During this period the groups are able to access study material in the online library. In the situation that academics have limited time or ambition to explore the commercializing of their inventions themselves, Impact Studio offers two solutions. The first one is the Ideation Labs, where researchers get linked to students who will provide this work for them as they are being coached by Impact Studio. The other option is Customer Discovery Support where experts of the Impact Studio will execute a swift market analysis with market possibilities against payment. Sequentially, the Impact Studio assists in Financial support as they assist the spin-offs in grant applications, predominantly done for Customer Discovery Support cases (Impact Studio, n.d.). The dedication related to the programs might not fit the current status of the development process. Due to this, the Impact Studio also holds Open Office Hours, where individuals can discuss their ideas with coaches of the Impact Studio. The Impact Studio aims to be active in Social support through the guidance of groups to other facilitators (Delft Enterprises) or in the past by organizing networking events.

4.3. Erasmus Medical Centre (EMC)

Erasmus Medical Centre (EMC) is an academic hospital that was created as a merger in 2002 between the Academic Hospital Rotterdam and Erasmus University's Faculty of Medicine & Health (Burkholder and Hulsink, 2022). EMC is a hospital that performs daily medical procedures while educating students active in the medical industry. This education is not limited to EMC students alone; collaborations between EMC, TU Delft, and LUMC enable students from all these universities to partake in shared educational experiences, as seen in the Bachelor of Technical Medicine. These shared collaborations

also express themselves in joint research hosted by organisations such as LDE & Delta Medical. Initially, this academic hospital was focused on the provision of education and medical treatment. Recently is expanded its focus by exploring commercial possibilities of technologies that are medically themed. While operated by Erasmus University it now includes education on the entrepreneurial opportunities relevant to the medical environment by the research and education department of Erasmus Centre for Entrepreneurship ("Erasmus Centre for Entrepreneurship", n.d.). Erasmus Medical Centre also hosts two facilities that spin-offs are able to utilize when agreed upon. The first one is the Medtech Innovation Support Office (MISO), which provides spin-off access to medical specialists in the hospital and aids them in their clinical validation trajectory. The other is the Experimental Medical Institute (EMI) which supports the spin-off in the development and design of their invention ("EMI – Experimental Medical Instrumentation - Core Facility - Erasmus MC", n.d.). EMC is broadly oriented on medical interventions (e.g. radiology and nuclear medicine), yet its spin-offs hold a preference for the creation of medical devices.

4.3.1. TTO Erasmus Medical Centre

In their efforts to commercialize the innovations created in EMC, the TTO was created. The initial approach of the TTO was closely linked to the evaluation of the commercial potential of IP. This led to a structure, dominantly aimed at the licensing of the IP to large firms, where the technology could be developed. This approach was recently adapted and the TTO is currently focused on the active construction of its own spin-offs. This resulted in a change of perspective and activities executed by the employees of the TTO. They are working on expanding their support by providing facilities such as workspaces and the creation of an incubator. The goal is to launch the incubator around 2026/2027 where it will host a general program for health-tech EMC spin-offs. Future efforts are aimed at the provision of a tailor-made program, specified for the themes of the spin-offs.

Support towards early-stage academic spin-offs

Type of support: Infrastructure, Business, Financial, Social

The TTO of EMC is mainly involved in the stages of **concept validation** and **product validation**). Before these stages, the TTO engages in informing and inspiring potential entrepreneurs such as researchers and students. This is done through a yearly event named "Entrepreneurial Awakening", which involves a three-day training on what it takes to be an entrepreneur of a spin-off. In the concept validation stage, their efforts are aimed at creating credibility on multiple levels. A business developer mostly executes the business development in this period in cooperation with a coach, both employed by the TTO. On product development, the TTO aids the spin-off in their knowledge of the protection of the IP. Moreover, there are discussions on the use of facilities inside the EMC (EMI, MISO) and offer network opportunities to external partners. Lastly, the TTO believes that funding is needed to create more operational freedom for the spin-off. For this reason, they finance the projects with a grant between €20k and €50k, which is obtained through a successful plan and pitch. In the product validation stage, the focus is set on the realization of a commercial path, the establishment of a team and the potential involvement of external parties. The IP is now translated into patents which are filled and that can be protected. Sequentially, the spin-offs are assisted in their obtainment of seed funding, through networking and business development.

4.3.2. Rotterdam Square

Rotterdam Square is the product of a collaboration between Erasmus Medical Centre and the Municipality of Rotterdam aimed at sharing knowledge in the sector of Life Science & Health innovations. They are not only focused on EMC spin-offs but also welcome spin-offs from existing companies such as Philips.

Support towards early-stage academic spin-offs

Type of support: Social

Rotterdam Square organizes various events to inspire new innovations and to aid the existing spin-offs in obtaining the needed knowledge for progression. They do this with partners such as Innovation Quarter, EMC, TU Delft and LUMC. Their focus lies on specified industries of medical innovations; diagnostics, AI, VR, Medtech & bio-engineering. Rotterdam Square is not specifically fixed on development

but rather hopes to aid in the transfer of knowledge for all spin-offs.

4.4. Leiden University Medical Centre (LUMC)

Like Erasmus, Leiden University Medical Centre is an academic university established in 1996 as a part of Leiden University. Its main goals are the delivery of patient care, research and education (LUMC, n.a.) (LUMC, n.d.-a. At the beginning of the 2000s, there became a higher focus on innovation related to these goals, which resulted in 10 themes for innovation. The scope of the subjects is predominantly aimed at the technologies that have an internal impact on the human body, for instance, pharmaceutical inventions for vaccines or oncology treatment (LUMC, n.d.-b). LUMC is associated with the holding company of the University of Leiden named Libertatis Ergo Holding B.V. (LEH). An important task of this entity is the investment into promising spin-offs through the Enterprise Leiden Fund (pre-seed) in the form of a convertible loan.

4.4.1. LURIS

LURIS functions as a TTO and is divided into two sections where each one represents one of the two universities (Leiden University & LUMC). Initially, they concentrated on licensing agreements to larger firms for the transfer of the innovations to the market. The new focus is set on the creation of spin-offs in which the LUMC IP is utilized. Again this adaption in strategy focus is similar to that of the Erasmus Medical Centre. An element in which LURIS distinguishes itself from other TTOs such as Delft Enterprises is the low amount of propositions they support. They are a medically orientated university, which leads to fewer potential projects. Moreover, the projects they do aid also require a long-term approach and more university resources.

Support towards early-stage academic spin-offs

Type of support: Business, Financial, Social, Legal

Support-wise LUMC is specifically active in the **conceptualisation** stage and in some cases even prior to that period. In this extremely early phase, LURIS emphasizes the importance of entrepreneurial inspiration to correct the misconceptions in this field and to change the ”research mindset” of academics, as mentioned in the first phase of Vohora et al. (Vohora et al., 2004). This concern of research culture is shared with the TTO’s of TU Delft and Erasmus Medical Centre. LURIS tries to achieve this inspiration through talks in the Bachelor of Biomedical Sciences and information sharing through the educational portal. In the conceptualisation stage, LURIS gets approached by researchers who want to protect their research or who foresee commercial potential. Together with the academics will then evaluate the technology based on its innovative power, its potential value to customers and the developments by the competition. When there is a positive result on this, there will be a choice for a spin-off creation or licensing to companies. In cases of licensing LURIS actively scouts for investors and large firms to acquire the IP. With spin-offs, LURIS aims to have an IP transfer deal finished at the end of the conceptualisation stage where the holding company of LUMC will become a shareholder. Meanwhile, LURIS aids in any complications regarding legal issues. To stimulate business development progress LURIS introduces PLNT and the Venture Challenge to the spin-offs. For financial support, LURIS connects the groups to the ELF pre-seed fund or UNIIQ.

4.4.2. PLNT

PLNT operates as an incubator that helps spin-offs in various early stages during their development process. Located in Leiden, PLNT is a widely supported organization with partners including, LUMC, and LURIS, YES!Delft and Leiden Bio Science Park. Although operating in an academic entrepreneurial ecosystem with a preference for medical innovation they are not solely focused on these cases. They do over more tailor-made programs and assistance during specific parts of their programs.

Support towards early-stage academic spin-offs

Type of support: Infrastructure, Business, Social

As mentioned PLNT offer various forms of support towards spin-offs, predominantly during their programs. Similar to the strategy of the TTOs, PLNT tries to inspire academics in entrepreneurship, challenging the academic view upon it with their *Ready to Startup* program. This is also done in collaboration

with LURIS and happens before the **conceptualisation** stage. In the next period, conceptualisation, PLNT hosts the *Startup Play* program aimed at the validation of ideas towards concrete concepts. Insights from this phase are input for *Venture academy*, taking place in the **concept validation** stage. This initiative is described as a pre-incubator, similar to the Impact Studio, that validates the concepts further into products through specialised knowledge by external experts on topics such as IP and HR. During **product validation** the spin-offs have the opportunity to follow the Unlock program. This initiative originally operated as a separate entity yet is now included in the workflow of PLNT and is described later in this chapter. At **product launch** spin-offs often go their own way and this goes beyond the scope of PLNT. They do offer *Sproud*, an open discussion on challenges that the spin-offs are facing. Besides these programs, PLNT organizes many events throughout the year. Show Me The Money is an example of this where the teams get real-life pitch experience for potential investments. PLNT also offers facilities to the groups in the form of offices and laboratories in collaboration with external partners.

4.4.3. Unlock

Unlock is an incubator associated with Leiden Bio Science Park, that offers a support program specifically for spin-offs and startups that are linked to the theme of Life Science & Health (LS&H). Currently, they are located and included in the building and workflow of PLNT to streamline the groups going through the support programs. This choice fits with the mentality of the organisation that LS&H spin-offs should scale fast in order to impact society and be profitable.

Support towards early-stage academic spin-offs

Type of support: Business, Financial, Social

Unlock is mainly active during the **product validation** stage yet also participates in earlier stages. In **conceptualisation** they hold presentations and community events to stimulate academics early on and make them aware of the key questions that need answering (e.g. Who is paying for this?). The 1-year program itself is aimed at groups that are in the stage of product validation and is divided into three months of general training and nine months of tailor-made tutoring. During the general coaching, the groups are informed about various topics related to the journey of an entrepreneur; IP, regulation, sales). During the nine months after there is specific focus on the teams where support is given based on their unique needs. This can be translated into obtaining knowledge through external experts brought in or granting the teams access to courses and events organized by other parties. The end goal is to make the spin-offs investor ready and this is tested during a final pitch.

4.4.4. Leiden Bio Science Park

Formed in 1984, the Leiden Bio Science Park (LBSP) is an ecosystem designed to stimulate innovation in Life Science & Health. The ecosystem hosts facilities of research institutes, large companies and spin-offs all active in the industries of Life Science & Health. The organization of LBSP focus its efforts on access to the pillars of Knowledge, Innovation, Human Capital, Capital and Market (LBSP, n.a.) (Leiden Bio Science Park, n.d.). Based on the progress of the spin-offs, support is provided on these pillars.

Support towards early-stage academic spin-offs

Type of support: Infrastructure, Social, Legal

The support to achieve resources is mostly related to the large network of the Leiden Bio Science Park. Spin-offs typically connect to LBSP for the first time during the **product validation** stage. Their needs associated with the pillars are met through the exchange of knowledge from more experienced companies. LBSP also aids spin-offs in overcoming obstacles related to market aspects through their collaborations with Unlock. Similarly, Unlock is involved on behalf of LBSP with Johnson & Johnson Innovation (JLABS) to assist spin-off in their regulatory journey. Lastly, spin-offs are able to hire the required facilities for further development in the Leiden Bio Science Park. For younger teams, this can be achieved by agreements with Bio Partner and in a later stage with Plus Ultra.

4.5. Interconnected facilitators

The facilitators above are linked to one of the three academic entrepreneurial ecosystems due to their geographical positioning and their regional focus on health-tech spin-offs. Services of other facilitators extend beyond these boundaries, in an attempt to stimulate a larger group of spin-offs, to activate their positive impact on the region. This chapter first describes the overarching organisations that stimulate research and innovations between the universities. Following this, two financial facilitators who are actively investing in health-tech spin-offs are discussed.

4.5.1. Convergence

The convergence organization represents a collaborative link in pushing innovation created between the Delft University of Technology, Erasmus University and Erasmus Medical Centre (Convergence, n.d.). During this partnership, the organization has the goal of smoothing the collaboration between the three universities on numerous topics related to healthcare; Health & Technology and Healthy Start.

Support towards early-stage academic spin-offs

Type of support: Financial, Social

Convergence supports spin-offs in the **conceptualisation** stage of development and in some cases even before that. The projects of Convergence can be seen as research projects where academics from both sides are connected to work on problems that require a technical medical solution. Through these projects, they grant the teams knowledge and funding. Currently, the organisation is also checking how they can support the projects after this conceptualisation stage to stimulate further growth.

4.5.2. LDE & Delta Medical

LDE and Delta Medical provide similar services to those of Convergence yet they represent other universities. LDE is the overarching organisation between Delft University of Technology, Leiden University and Rotterdam University (Medical Delta, n.d.). Delta Medical is a part of this collaboration, representing Erasmus Medical Centre and Leiden Medical Centre with public institutes and science parks, where synergies are created in medically related domains.

Support towards early-stage academic spin-offs

Type of support: Infrastructure, Financial, Social

These two organisations follow Convergence's school of thought, aiming to create innovation through cooperation. Initially, this starts with education and research on themes in which all parties can contribute to the solution. This requires financial resources and in some cases, facilities are offered in the form of living labs. These living labs are connected to specific subjects, and designed to test the innovations in a realistic setting.

4.5.3. Graduate Entrepreneurship

Graduate Entrepreneur was launched in 2021 as an initiative by five founders who studied in Rotterdam and Delft (Graduate Entrepreneurship, n.d.). The goal of this organisation is to specifically support startups or spin-offs of which the founders originate either out of Erasmus University, Erasmus Medical Centre or the TU Delft. They launched two funds (pre-Seed and Seed & Series A) to stimulate the groups financially while offering experience and knowledge. For both these types of support, Graduate Entrepreneur relies on its network of investors and institutes. This network stands at the heart of the organisation, consisting of experienced founders and professionals who are active in various sectors. By leveraging those personal networks and experience they aim to aid the spin-offs. Graduate Entrepreneur includes a wide range of different startups who identify with the themes of Climate Tech, Digital Tech, Deep Tech and Health Tech.

Support towards early-stage academic spin-offs

Type of support: Business, Financial, Social

As mentioned, Graduate Entrepreneurship provides assistance through funding and networking opportunities, in the stages of **concept validation** and **product validation**). In the stage of concept validation, the organisation invests in the teams through a pre-seed fund with investment tickets of

€75k. Through these investments, Graduate Entrepreneurship bind themselves to the spin-offs and try to support them with experience and knowledge through a dedicated mentor. The organisation believes that through this strategy more specialized support can be offered as the needed knowledge differs per theme. Besides this coaching, the teams receive additional tutoring in workshops on relevant subjects (e.g. IP). During **product validation**, the spin-offs receive an additional investment between €500k and €2m from the Seed & Series A ticket. Here Graduate Entrepreneurship deepens its commitment and actively searches what the spin-offs require to make progress. In this later stage, more experienced experts are involved to heighten the chance of success.

4.5.4. Innovation Quarter

Innovation Quarter represents an institute that promotes local economic and social development in the region of Zuid-Holland. They are supported by the Dutch government and collaborate with many large public organisations in the region (e.g. Erasmus Medical Centre, Municipality of Delft and Leiden University Medical Centre). They assist innovative companies in the region through networking, investments and advice on financial strategies (Innovation Quarter, n.d.).

Support towards early-stage academic spin-offs

Type of support: Financial, Social

Innovation Quarter is predominantly active in the phase of **product validation** when a company entity has been established and a commercial strategy has been set. Their assistance depends on the needs of the spin-offs. Innovation Quarter provides access to business developers who can advise on strategy iteration and help the spin-offs achieve partnerships. Innovation Quarter also invests in spin-offs through one of its four funds, which are separated through their theme and the development phase focus. The common ones for health-tech spin-offs are the UNIIQ fund and the Capital fund. The UNIIQ fund invests in spin-offs that require funding to further validate their ideas in the proof-of-concept phase. This investment typically has the size of €350k in the form of a convertible loan. The Capital fund is an investment between €250k and €5m translated into the instruments of equity or a loan. Sequentially, Innovation Quarter, advises spin-offs in the *Market Readiness Program* on their business plan, team and required investments to receive further financial resources.

4.6. Support overview of the three Dutch academic entrepreneurial ecosystems

This chapter provides an overview of the support by the most relevant facilitators within the three academic entrepreneurial ecosystems of the Delft University of Technology, Leiden University Medical Centre and the Erasmus Medical Centre. To further comprehend the aid of the facilitators the types of support are defined into sub-categories. These sub-categories represent the types of support in a realistic setting of the use case. The clarification of the support is incorporated in table 4.1 that visualizes the facilitators per ecosystem, linking them to the type of facilitators and finally, the (sub-)type of support they provide. These results are then further analysed by distributing them under the development phases in which they were provided. This information is portrayed in table 4.2).

Following this, a content analysis was executed to indicate how often the sub-types of support are offered. Table 4.1 represents the outcome of the content analysis. For each sub-type example, quotes are given in combination with the type of facilitators that provide this subform of support. Lastly, the occurrence is tracked to determine the presence of this aid in the overall support that is offered. This content analysis adds a more quantitative approach to the research.

4.6.1. Definition of network facilitator

One of the insights of the use case is the discovery of a new type of facilitator; *network facilitator*). Its primary goal is to assist the spin-offs in building relationships to acquire the necessary knowledge and resources. This can be described as social support that includes all its sub-categories. Examples of these types of facilitators are Convergence or LDE, which are active in multiple ecosystems.

4.6.2. Definition of sub-types of support

The sub-types of support are identified based on the practical assistance by facilitators and the definition provided in 3.2.2). This section describes the definition of both the type of support and its subcategories.

Infrastructure support

Arrangement of facilities such as working spaces, laboratories, meeting rooms, and (specialized) equipment.

- **Workspaces**: Access to workspaces that include offices, laboratories and facilities for technical development.
- **Technical and clinical support**: Assistance as a service of the product development or clinical regulation for the technology.

Business support

Training and coaching related to skills and knowledge that assist in venture building such as the creation of a business plan or pitch.

- **Problem-solution fit assistance**: Guidance in the spin-off process of discovering the problem that the innovation solves.
- **1-on-1 coaching**: Internally organized matching between founders and specialized mentors to share knowledge on commercialization strategies and to stimulate progress.

Financial support

Providing access to financial facilitators such as public grants, venture capitalists & angel investors while assisting in financial planning.

- **Grant provision**: Provision of funding in the form of non-dilutive grant money.
- **Investment provision**: Provision of funding in exchange for interest (loans) or shares (equity seed investments), including convertible loans.
- **Financial application assistance**: Assistance in the application process for the acquisition of funding in the forms of grants or equity investments.

Social support
Provision of linkages to industry parties, experienced startups, customers, market experts.

- **Private network sharing**: Granting access to a network of specialists in various fields, that can share information valuable to the progress of the health-tech spin-offs.
- **Event organising**: Organising events on various themes to aid the health-tech spin-offs in increasing their network.
- **External expertise hosting**: Hosting workshops where external experts aid the health-tech spin-offs in topics related to the progress of the company.

Legal support
Assistance on product protection in the form of IP and consultancy on legal agreements (e.g. NDA).

- **Linkage to IP services**: Directly or indirectly helping the health-tech spin-offs in their process for the protection of intellectual property.
- **Linkage to legal services on contracts**: Directly or indirectly helping the health-tech spin-offs through legal expertise in drafting and reviewing collaboration contracts.

4.6.3. Overview current support by Dutch facilitators

The start of this chapter introduces the background of the various academic entrepreneurial ecosystems and later on presents all the relevant facilitators and their support. Table 4.1 aims to comprehend this information, from grey literature and interviews to construct a structured overview. Here each row describes a facilitator and the ecosystem they are active in. Next, the organisation is classified according to the type of facilitator and linked to the type and sub-type of support they offer. As an example, the Impact Studio operates in the ecosystem of TU Delft and is categorized as a pre-incubator. Through its services, it provides support types Infrastructure, Business, Financial, Social, and Legal. This is expressed in its sub-types such as workspaces for infrastructure support.

In addition, table 4.2 uses the provided sub-types of support and links them to the stages. The combination of these tables outlines the support for the health-tech spin-offs in the various ecosystems and stages. To elaborate the support can shift during the development phase as is seen with Delft Enterprises or it remains the same as can be observed for Rotterdam Square.

Table 4.1: Overview of current support by the Dutch facilitators (author, 2024)

Academic entrepreneurial ecosystem	Name organisation	Type of facilitator	Type of support	Sub-type of support
TU Delft	Delft Enterprises	TTO	Infrastructure, Business, Financial, Social, Legal	Workspaces (Infrastructure), Problem-solution fit assistance (Business), all forms (Financial), private network sharing (Social), all forms (Legal)
TU Delft	YES!Delft	incubator	Infrastructure, Business, Financial, Social	Workspaces (Infrastructure), all forms (Business), Financial application assistance (Financial), all forms (Social)
TU Delft	Impact Studio	pre-incubator	Business, Financial, Social	all forms (Business), Financial application assistance (Financial), all forms (Social)
EMC	TTO EMC	TTO	Infrastructure, Business, Financial, Social	all forms (Infrastructure), Problem-solution fit assistance (Business), Grant provision & Financial application assistance (Financial), Private network sharing & Event organising (Social)
EMC	Rotterdam Square	networking facilitator	Social	all forms (Social)
LUMC	LURIS	TTO	Business, Financial, Social, Legal	Problem-solution fit assistance (Business), Financial application assistance (Financial), Private network sharing (Social), Linkage to IP services (Legal)
LUMC	PLNT	incubator	Infrastructure, Business, Social	Workspaces (Infrastructure), all forms (Business), all forms (Social)
LUMC	Unlock	incubator	Business, Financial, Social	1-on-1 coaching (Business), Financial application assistance (Financial), all forms (Social)
LUMC	Leiden Bio Science Park	science park	Infrastructure, Business, Social	All forms (Infrastructure), 1-on-1 coaching (Business), Private network sharing & Event organising (Social)
TU Delft & EMC	Convergence	network facilitator	Financial, Social	Grant provision (Financial), Private network sharing & Event organising (Social)
TU Delft, EMC & LUMC	LDE & Delta Medical	network facilitator	Infrastructure, Financial, Social	Workspaces (Infrastructure), Grant provision (Financial), Private network sharing & Event organising (Social)
TU Delft & EMC	Graduate Entrepreneur	funding facilitator	Business, Financial, Social	1-on-1 coaching (Business), Investment provision & Financial application assistance (Financial), all forms (Social)
TU Delft, EMC & LUMC	Innovation Quarter	funding facilitator	Financial, Social	Investment provision (Financial), Private network sharing & Event organising (Social)

Description:

Table 4.1 illustrates the support provided by the facilitators of the three Dutch academic entrepreneurial ecosystems. The table includes the Dutch ecosystem, names of the organisations, the type of facilitator, and the type and sub-type of support they offer.

Table 4.2: Overview of the facilitator support per phase (author, 2024)

Name organisation	Conceptualisation	Concept validation	Product validation	Product launch
Delft Enterprises	Problem-solution fit assistance (Business), Grant provision & Financial application assistance (Financial), Private network sharing (Social), all forms (Legal)	Problem-solution fit assistance (Business), Investment provision & Financial application assistance (Financial), Private network sharing (Social), all forms (Legal)	Workspaces (Infrastructure), Financial application assistance (Financial), Private network sharing (Social), Linkage to legal services on IP and contracts (Legal)	Financial application assistance (Financial), Private network sharing (Social), all forms (Legal)
YES!Delft	Event organising (Social)	Problem-solution fit assistance (Business), Financial application assistance (Financial), all forms (Social)	Workspaces (Infrastructure), 1-on-1 coaching (Business), Financial application assistance (Financial), all forms (Social)	Workspaces (Infrastructure), Financial application assistance (Financial), all forms (Social)
Impact Studio	All forms (Business), Financial application assistance (Financial), all forms (Social)	all forms (Business), Financial application assistance (Financial), all forms (Social)	Private network sharing (Social)	-
TTO EMC	Problem-solution fit assistance (Business), Grant provision & Financial application assistance (Financial), Private network sharing & Event organising (Social), Linkage to legal services on IP (Legal)	All forms (Infrastructure), Problem-solution fit assistance (Business), Financial application assistance (Financial), Private network sharing & Event organising (Social), Linkage to IP services (Legal)	All forms (Infrastructure), Financial application assistance (Financial), Private network sharing (Social), Linkage to IP services	All forms (Infrastructure), Financial application assistance (Financial), Private network sharing (Social)
Rotterdam Square	All forms (Social)	All forms (Social)	All forms (Social)	All forms (Social)
LURIS	Problem-solution fit assistance (Business), Financial application assistance (Financial), Private network sharing (Social), Linkage to IP services (Legal)	Financial application assistance (Financial), Private network sharing (Social), Linkage to IP services (Legal)	Financial application assistance (Financial), Private network sharing (Social), Linkage to IP services (Legal)	Financial application assistance (Financial), Private network sharing (Social), Linkage to IP services (Legal)
PLNT	Problem-solution fit assistance (Business), all forms (Social)	Problem-solution fit assistance (Business), all forms (Social)	Workspaces (Infrastructure), 1-on-1 coaching (Business), all forms (Social)	Workspaces (Infrastructure), Private network sharing & Event organising (Social)
Unlock	-	-	1-on-1 coaching (Business), Financial application assistance (Financial), all forms (Social)	Private network sharing & Event organising (Social)
Leiden Bio Science Park	-	-	All forms (Infrastructure), 1-on-1 coaching (Business), Private network sharing & Event organising (Social)	All forms (Infrastructure), 1-on-1 coaching (Business), Private network sharing & Event organising (Social)
Convergence	Grant provision (Financial), Private network sharing & Event organising (Social)	Private network sharing & Event organising (Social)	Private network sharing & Event organising (Social)	Private network sharing & Event organising (Social)
LDE & Delta Medical	Technical and clinical support (Infrastructure), Grant provision (Financial), Private network sharing & Event organising (Social)	Private network sharing & Event organising (Social)	Private network sharing & Event organising (Social)	Private network sharing & Event organising (Social)
Graduate Entrepreneur	-	1-on-1 coaching (Business), Investment provision (Financial), all forms (Social)	1-on-1 coaching (Business), Investment provision (Financial), all forms (Social)	1-on-1 coaching (Business), Financial application assistance (Financial), all forms (Social)
Innovation Quarter	-	Investment provision (Financial), Private network sharing & Event organising (Social)	Investment provision (Financial), Private network sharing & Event organising (Social)	Private network sharing & Event organising (Social)

Description:

Table 4.2 outlines the type of support by facilitators of the Dutch academic entrepreneurial ecosystems across the various development phases. This overview separates the facilitators according to the ecosystems they mainly function in.

4.6.4. Analysis of current support by the facilitators

Both table 4.1 and 4.2 are used for the analysis of the current support by the Dutch facilitators. The results help to distinguish the similarities and differences in provided support towards health-tech spin-offs in the three ecosystems during the development stages. Separation exists between facilitators serving health-tech spin-offs in specific ecosystems and those assisting spin-offs across ecosystems. The latter form, the non-ecosystem bound facilitators, are classified as network and funding facilitators. Their multiple ecosystem focus can be clarified as for network facilitators the network reach increases by not solely focusing on a single ecosystem, creating more potential value for its users. For funding facilitators it can be expected that with the expansion of their coverage, they can fund the best spin-offs in the region. Another distinction is observed in the development phases where the facilitators offer their assistance. Networking facilitators such as Convergence specifically aid the spin-offs in the conceptualisation phases and sometimes even earlier by funding the research that leads to the innovation. In later phases, these facilitators solely provide the teams with the needed contact, primarily to expertise in the medical environment. The funding facilitators concentrate their services on the concept validation phase by supplying funding in the form of convertible loans. The facilitators become shareholders and in return contribute with additional help related to business support and network building.

The ecosystem-specific support by facilitators is affiliated with the university's focus on the ecosystem, generally executed by the TTOs. Interestingly, in the past TTOs centered their services around the process of licensing technology to larger existing companies. ***"For a long time the TTO was very much focused on licensing and did almost nothing with entrepreneurship."*** - TTO EMC. Moreover, within LUMC, there was a zero-tolerance policy, where a researcher was prohibited from owning too many shares in a spin-off. Currently, these TTOs have changed their current focus to the creation of spin-offs.**"In the last years, no startups were formed as the LUMC did not allow its inventors to own shares in start-ups. Fortunately, we have been able to formally change that policy making it possible to create startups from LUMC again."** - TTO LUMC. A major reason behind this choice was the behavioural change of larger firms that increasingly preferred to purchase ideas when further proven (e.g. spin-off form) as mentioned by an interviewee. A possible reason could be the risk aversion of failure by these innovations which is higher through licensing.

The TU Delft has the longest experience with academic entrepreneurship, therefore providing the most advanced forms of support towards startups in general. Evidence for this can be observed in the amount of facilities and programs offered in this ecosystem, particularly by YES!Delft & Delft Enterprises. For many spin-offs, Delft Enterprises becomes a steady partner, as TU Delft becomes a shareholder of the spin-offs. TU Delft depends on the companies' success and therefore assists them in various ways. YES!Delft mainly delivers support through its programs, where the Validation Lab is centred around the conceptualisation and concept validation phases. This provided aid is aligned with the Impact Studio, which supports spin-offs in compatible ways, with a preference for very early cases. Following this, the Acceleration program helps the spin-offs during product validation and the start of product launch.

LUMC & EMC are still in the process of achieving this level of support and trying to do this in their unique way. Particularly, EMC is in the preliminary phase of its support towards spin-offs as observed in the lack of a (pre-)incubator. The differences in resources between similar facilitators lead to different strategies in its support. An example of this is associated with the focus of the TTOs in the ecosystem. While Delft Enterprises (TTO TU Delft) has the tools to facilitate spin-offs in a wide range of themes, LURIS (TTO of LUMC) centres its resources on a lower amount of cases as they are solely health-tech related and require intensive support. This wide orientation of the TU Delft on themes in healthcare technology spin-offs juxtaposes the methods of LUMC and EMC. In these two ecosystems, the emphasis lies on spin-offs within specific themes of healthcare technology where EMC prioritises medical device innovations and LUMC targets inventions surrounding biomedical studies (e.g. vaccines or oncology treatments). Although EMC is the youngest ecosystem in stimulating academic entrepreneurship it is the only ecosystem that provides organized services to promote the development of technology. The services of EMI & MISO are in line with EMC's focus on supporting health-tech spin-offs creating medical devices. As mentioned, EMI aids the spin-offs in the development and design of medical devices while the MISO supports them through the medical regulatory journey. LUMC focuses on projects that offer biological-based solutions to medical issues (e.g. pharmaceuticals). In the early stages, this ecosystem hosts a unique entrepreneurial program named Unlock, which specialises in Life Science

and Healthcare spin-offs. Themed workshops and coaching are included in the program to stimulate the health-tech spin-offs in the best manner. During the product validation phase, the ecosystems assist the spin-offs through specific infrastructure support. By granting access to laboratories and workspaces the Leiden Bio Science Park helps spin-offs create the necessary production set-ups to stimulate further development. This support is mainly supplied in the phase of product validation where the spin-offs need to extend their R&D focus. The analysis indicates that all ecosystems carry the potential for a specialist approach to supporting health-tech spin-offs. Concerning this aspect various facilitators are in connection with each other to promote further collaboration including the transfer of health-tech spin-offs between the programs and ecosystems. This collaboration can potentially result in the handover of medical device spin-off to the hub of Erasmus Medical Centre as support is specifically designed for this entrepreneurial journey.

4.6.5. Content analysis of current Dutch facilitator support

Table 4.3 gives a quantitative analysis of the qualitative data gathered from the interviews with facilitators. This approach creates a more evidence-based perspective on the outcome of this research by counting the appearance of the sub-type of support mentioned during the interviews. Each row in the table illustrates a sub-type of support provided by the facilitators which are monitored and eventually added to the aggregated occurrences of the type of support as described in the last column. To highlight, the sub-type support ”Workspaces” categorized under the infrastructure support has the example quote of ”For a long time we have offered laboratories and offices.” given by the TTO of EMC. This sub-type of support occurred three times during conversations with facilitators and combined with the sub-type of ”Technical and clinical support” was aggregated to a total occurrence of five for infrastructural support.

Table 4.3: Content analysis of support by the Dutch facilitators (author, 2024)

Type of support	Sub-type of support	Example of quote	Type of facilitator	Occurrence	Aggregate
Infrastructure	Workspaces	*”For a long time we have offered laboratories and offices.”* - TTO EMC	TTO, incubator	3	5
Infrastructure	Technical and clinical support	*”We have a separate office that helps the researchers apply for the Medical Device Regulation.”* - TTO EMC	TTO, incubator	2	-
Business	Problem-solution fit assistance	*”We aid in the exploration of scientific innovations to see if and how this can enter the market.”* - pre-incubator TU Delft	TTO, pre-incubator, incubator	7	12
Business	1-on-1 coaching	*”With mentor matching, we are looking for a startup mentor with the right set of skills and network.”* - incubator TU Delft	TTO, funding facilitator, pre-incubator, incubator	5	-
Financial	Grant provision	*”We have a fund to stimulate the startups to the next stage.”* - TTO EMC	TTO, pre-incubator	2	11
Financial	Investment provision	*”We offer €50K to overcome the period before a CLA, to cover private costs and perhaps costs to continue working.”* - TTO Delft	funding facilitator, TTO	3	-
Financial	Financial application assistance	*”We offer in-house market analysis to obtain NWO take-off grant for researchers.”* - pre-incubator TU Delft	TTO, pre-incubator, incubator	6	-
Social	Private network sharing	*”We make connections between researchers and entrepreneurs.”* - TTO EMC	TTO, funding facilitator, science parks, pre-incubator, incubator	6	16
Social	Event organising	*”The event we organise is a great way to get to know the community, so also the other entrepreneurs and of course the investors.”* - incubator LUMC	TTO, pre-incubator, incubator	6	-
Social	External expertise hosting	*”For other expertise such as IP, RVO will give a small presentation.”* - incubator LUMC	pre-incubator, incubator	4	-
Legal	Linkage to IP services	*”For special skills, we have our service partners where we have a party that offers specific support on intellectual property.”* - incubator TU Delft	TTO, incubator	4	5
Legal	Linkage to legal services on contracts	*”We also help through expertise on drafting and reviewing collaboration contracts.”* - TTO TU Delft	TTO	1	-

Description:

Table 4.3 presents an analysis of the types of support provided by Dutch facilitators, categorized into infrastructure, business, financial, social, and legal support. Each type of support is further broken down into sub-types and further explained using example quotes from facilitators to illustrate the nature of the assistance. The table also indicates the occurrence of this sub-type and the overarching support type during the conversations.

4.6.6. Outcomes of the content analysis on Dutch facilitator support

The results of the content analysis outline the differences in support by the facilitators. It indicates which forms are dominantly granted and by which type of facilitator. Using this data, the overarching types of support are discussed to further elaborate on how the support is practically applied and the reasons for this. Information from this analysis is utilized in the following chapter to determine a mismatch in support by comparing the data to the needs and experiences of health-tech spin-off founders.

Social support

These outcomes state that the three Dutch academic entrepreneurial ecosystems provided the most support for social-related needs. This support was expressed in the subcategories of *private network sharing*, *event organising* and *external expertise hosting*, where the first two were mentioned the most. This indicates that the facilitators prioritise the social support over the others. The reason behind this ties in with the dominant perception of facilitators on their role as connectors between the entrepreneurs of the health-tech spin-offs and experts in particular fields or industry markets. Facilitators mentioned that they often lack the capacities or knowledge to support the health-tech spin-offs on their particular theme-based challenges. This can be fulfilled by experts from the field which facilitators try to include in their network with the purpose of later sharing this connection with health-tech spin-offs. The three sub-types of social support are tools to provide this connection.

The importance of knowledge gathering through network relations is shared by many health-tech spin-off entrepreneurs and relates to the *Social captital* as described in the literature. In this same context, entrepreneurs acknowledge the function of the facilitators as network builders for them as illustrated by the following quote: ***"because they have a lot of knowledge, they do make connections with funding organisations or with reviewing those kinds of contracts or of course with the patent."***

Business support

The second most provided form of support is associated with the business part of the development process of the health-tech spin-offs. The facilitators aid the spin-offs in their venture building through problem-solving fit assistance and 1-on-1 coaching. Interestingly these sub-categories are provided following the development process of health-tech spin-offs where initial assistance is aimed at problem-solution fit assistance and is later replaced by 1-on-1 coaching. The problem-solution fit describes the process in which a spin-off discovers the problem which can be resolved using the created innovation. This step implies the first step in the construction of the business case and requires an entrepreneur to interview users and market experts. This procedure is perceived as simple, yet facilitators state that it is one of the largest hurdles for entrepreneurs in the conceptualisation phase. ***"I think that a lot of people already have the idea that they achieved product-market fit."*** - incubator TU Delft. Entrepreneurs of health-tech spin-offs are often academics with a background in the sole creation of research papers. This origin troubles the problem-solution discovery process due to the lack of focus, knowledge, network and social skills. Instead of understanding the problem situation set in a real-world environment, academics assume many aspects and neglect to validate them properly. Facilitators state that in many cases, they perceive the problem primarily from a technical standpoint. In some medical-related cases, academics describe the problem based on the experiences of the patient while it should be dictated by the user's problems. This patient concentration was also mentioned by one of the facilitators; **"This is hard as most researchers are focused on creating something that is aimed at the patients."** - TTO EMC. Vohora et al. and Ndonzuau et al. recognize this phenomenon of academic culture and mindset which is particularly relevant in the first phase of development (Vohora et al., 2004; Ndonzuau et al., 2002). Most (pre-)incubators assist the teams by providing entrepreneurial programs that discuss the needed information to progress on this program. With TTOs, this support is often expressed by a dedicated individual from the TTO who aims to solve this issue either together with the academics or by themselves.

In the following development phases such as concept & product validation, support on 1-on-1 coaching becomes more relevant. Facilitators state that more detailed knowledge of (healthcare) industries becomes increasingly needed for progress. In reality, this sub-type of support is expressed by an organized matchmaking between founders and specialised mentors. This often turns out to be hard as facilitators mention that each spin-off is unique, which means that a truly fitting mentor is often missing.

Financial support

The third most present form is support relates to the provision of financial resources. The initial two sub-types of financial support are associated with the direct transfer of money towards the spin-off, while the last form describes assistance in the acquisition process of money.

Gathering funding is closely related to the stage of progress by spin-offs and it requires an element of proof to gain these resources. Vohora et al. (2004) describe this phenomenon as the overcoming of the juncture of credibility. When credibility is achieved, spin-offs are able to collect the needed resources such as funding. This concept also arose during one of the interviews where an employee of the incubator of the TU Delft described the initial phase of an entrepreneurial journey by an academic. ***"Everybody always enters saying: I need money! Our first response is then: okay but for what?"*** Fundraising is only accomplished when the spin-off has gained the trust of the funding facilitators, through the proof of a sustainable strategy with milestones along the way. Through this proof, the spin-offs communicate their dedication and the risk they take to realize the value of the technology. By providing funding through grants and equity investments the funding facilitators show they trust in the spin-offs and bind themselves to the spin-offs. ***"By making it a grant you force yourself as the provider of the money to believe in the project."*** - TTO EMC.

Not all facilitators have the ability to directly support the spin-off by offering money. Instead, they aid the health-tech spin-offs in the acquisition process of funding by sharing their knowledge on the construction of successful grant applications. In later development phases, these facilitators help to make the spin-off's business case more investor-ready by testing it with the investment criteria of known investors.

Infrastructure support

Infrastructure support relates to access to tangible and intangible resources that are relevant to the development of the product or the hosting of the team. The use case led to the distinction between workspaces and technical/clinical support. Workspaces illustrate the tangible resources and can be translated into areas in which operations can take place; offices & laboratories. This can also relate to the use of equipment such as computers or laboratory devices. For specifically health-tech spin-offs the use of facilities is needed as these setups enable the future technical development of biological-related technology such as vaccines. Facilitators can directly provide access to facilities through IP transfer agreements or in exchange for rent. Other facilitators connect the spin-offs to the facilitators that offer these facilities. In practice, this can also be a combination. ***"We have a certain office capacity meant for the teams. Of course in our sector people need lab space, that is why we also closely collaborate with Leiden Bio Science Park and Bio partner."*** - incubator LUMC.

The other form of infrastructure support relates to the access to services which require specific themed expertise. This was framed in both technical support and clinical ones. Within the academic ecosystem, researchers can access particular technical services to realize a product for further research. This same access is sometimes granted to spin-offs. Another service related to the regulatory journey of health-tech spin-offs. After the use case, it became clear that this department had been specifically designed to support these groups, due to its high level of complexity. This clinical knowledge is not always present in an academic entrepreneurial ecosystem due to a weaker overall link with medical research as seen with TU Delft. In these cases, the facilitators aim to establish collaboration with medical institutions to still fulfil this service.

Legal support

Legal services are highly complicated in the process of innovation creation in an academic entrepreneurial ecosystem. This is due to the ownership of the IP that comes from research. In all the three Dutch ecosystems the IP created through researchers is owned by the universities (particularly the holdings of the universities). Technology transfer is established by either licensing the IP to existing companies or to a spin-off. Predominantly this transfer of IP is done in exchange for shares in the company. ***Otherwise this transfer would be characterized as state aid.*** - TTO TU Delft. As the universities own the IP there needs to be a strong department to protect the interest behind this. The services of this department are also shared with the spin-off to stimulate progression. In practice, this leads to assistance in the construction of IP documents in collaboration with private companies, which are financed by the universities.

In some cases, the spin-offs start to collaborate with existing parties such as research institutions or industry companies. Interviewees described this occurrence in the stages of concept & product validation. It is in both the interest of the universities and the spin-offs to form a collaborative agreement that is fair for all parties. The TTO of the TU Delft aids in this; ***"We have two legal experts that help with the collaboration contracts."*** This support is continuously provided, also after the official establishment of the spin-off company.

Conclusion on the current Dutch facilitator support

The content analysis on the current support by facilitators in the three Dutch academic entrepreneurial ecosystems quantifies the types of support as stated by the facilitators. It provides a clear overview of the occurrence of each (sub-)type of support by facilitators. This occurrence level indicates the dominance of the provided support type in the ecosystems. To elaborate, social support was mentioned the most, suggesting its value in the eyes of the facilitators. The reason for this dominance can be that facilitators truly view this support form as the most critical to the development of spin-offs. Simultaneously the reason for its presence can also be related to the fact that it requires the least complexity and costs to provide. The outcomes of this analysis are later compared with the results of the content analysis by founders to identify possible mismatches in support as discussed in Chapter 5.

5

Support mismatch in the Dutch academic entrepreneurial ecosystems

This chapter provides an overview of the mismatch in support based on the qualitative data from facilitators within the Dutch academic entrepreneurial ecosystems and founders of health-tech spin-offs.

5.1. Definition of support mismatch

The support offered by facilitators and their applicability to the needs of the health-tech spin-offs leads to a potential mismatch in support. In practice, this means that the support is either completely missing or not suited for the problems of the health-tech spin-offs. As discussed this mismatch can either be caused by the lack of understanding by the facilitators, a shortage of sharing their needs by health-tech spin-offs or a combination of both (Laur and Mignon, 2021; Yusuf, 2010). The use case of the three Dutch academic entrepreneurial ecosystems creates an overview of the support offered by the facilitators active in these ecosystems. Although insightful, this represents a single-sided perspective of the support system. Information on the receiving end of support is required to determine whether the support is effectively given to stimulate the progress of health-tech spin-offs. This study conducted interviews with founders of health-tech spin-offs who originate or are active in the three Dutch academic entrepreneurial ecosystems. An initial analysis was executed to illustrate the support perceived by the founders per stage, as presented in table 5.1. To further understand the noted support by spin-offs, a content analysis describes the aid per sub-type using quotes from the interviews, as observed in table 5.2. This information is cross-examined with the facilitator's perspective, as described in 4.1, to determine the level of mismatch in support found in the three ecosystems. This chapter divides the mismatch into subjects that further discuss the challenge faced by health-tech spin-offs and what current support they receive to overcome this based on the analysis of qualitative literature. Sequentially a comparison is executed to determine whether the challenges align with the findings in the literature.

5.2. Perceived support of founders per stage

For facilitators, it is crucial to understand not only which support to offer health-tech spin-offs but also when to provide it. The perceived support per stage in the founder's experience creates the needed insights. Table 5.1 entails the help of the spin-offs received during the four development phases. For each phase, the main support type and its sub-types are stated when experienced by the founders. In total seven founders of health-tech spin-offs were interviewed for this research. The spin-offs originate or are stationed in one of the three Dutch academic entrepreneurial ecosystems. Within the broad theme of healthcare technology, the spin-offs have different focuses varying from software development to medical devices and biotech engineering. Interestingly, the spin-offs all vary in the support they receive during their development phases. While spin-off 1 of the TU Delft experienced many forms of support spin-off 2 merely received some business and social support.

Table 5.1: Overview of perceived support by health-tech spin-offs per stage (author, 2024)

Spin-off name (ecosystem)	Conceptualisation	Concept validation	Product validation	Product launch
Spin-off 1 (TU Delft)	Workspaces (Infrastructure), Problem-solution fit assistance (Business), Grant provision & Financial application assistance (Financial), all forms (Social), Linkage to IP services (Legal)	Workspaces (Infrastructure), 1-on-1 coaching (Business), all forms (Financial), all forms (Social), all forms (Legal)	Workspaces (Infrastructure), all forms (Financial), Private network sharing & Event organising (Social), all forms (Legal)	-
Spin-off 2 (TU Delft)	Problem-solution fit assistance (Business), Private network sharing & Event organising (Social)	Private network sharing & Event organising (Social)	Private network sharing & event organising (Social)	-
Spin-off 3 (TU Delft)	Problem-solution fit assistance (Business), Grant provision (Financial), all forms (Social)	1-on-1 coaching (Business), Investment provision & Financial application assistance (Financial), all forms (Social)	Workspaces (Infrastructure), Investment provision & Financial application assistance (Financial), Private network sharing & Event organising (Social), Linkage to IP services (Legal)	-
Spin-off 4 (EMC)	Investment provision (Financial), Private network sharing & event organising (Social), Linkage to IP services (Legal)	all forms (Infrastructure), Investment provision (Financial), Private network sharing & Event organising (Social), Linkage to IP services (Legal)	all forms (Infrastructure), Investment provision (Financial), Private network sharing & Event organising (Social), Linkage to IP services (Legal)	-
Spin-off 5 (EMC)	Investment provision & Financial application assistance (Financial), Private network sharing & Event organising (Social), Linkage to IP services (Legal)	all forms (Infrastructure), Investment provision (Financial), Private network sharing & Event organising (Social), Linkage to IP services (Legal)	all forms (Infrastructure), Investment provision (Financial), Private network sharing & Event organising (Social), Linkage to IP services (Legal)	-
Spin-off 6 (LUMC)	Problem-solution fit assistance (Business), Grant provision & Financial application assistance (Financial), all forms (Social), all forms (Legal)	Workspaces (Infrastructure), 1-on-1 coaching (Business), all forms (Financial), all forms (Social), all forms (Legal)	Workspaces (Infrastructure), all forms (Financial), all forms (Social), all forms (Legal)	-
Spin-off 7 (LUMC)	Problem-solution fit assistance (Business), all forms (Social)	1-on-1 coaching (Business), Investment provision (Financial), all forms (Social)	Private network sharing (Social)	-

Description:

Table 5.1 provides a summary of the (sub)-types of support perceived by health-tech spin-offs at different phases of their development.

5.2.1. Outcomes on the perceived support per stage

The results described in table 5.1, describe strong differences and similarities in the support the spin-offs received during the development stages. It is immediately clear that none of the spin-offs received support in the final phase as no spin-off made it to this phase yet. The founders found it hard to imagine who will provide additional support in future phases, due to lack of experience and overall clarity on this in the ecosystem. The latter aspect was also mentioned by the facilitators and is further reviewed in the discussion.

Business support

The ecosystem in which the spin-offs operate highly influences similarities in support as founders almost solely seek their support in the ecosystem they operate in. A clear example of this relates to the business support offered in the conceptualisation phase. It becomes evident that the help associated with the problem-solution fit is predominantly experienced by the founders in this stage. In particular, this relates to the ecosystems of TU Delft and LUMC where this support is expressed through the programs of Impact Studio, YES!Delft (Validation Lab) and PLNT (Startup Play). In these ecosystems, similar facilitators provided the business support in the concept validation phase, through the implementation of 1-on-1 coaching. These cases are in contrast to spin-offs located in the EMC ecosystem. Here the founders did not receive any business support from the ecosystem facilitators and had to construct business models own their own. These founders happened to be more experienced, enabling them to perform this. Spin-off 2 confirms the idea that the support is highly dependent on the ecosystem spin-offs operate in. This spin-off originates out of the TU Delft, yet decided to grow its operations outside this ecosystem as fitting health-tech support programs for their specific topic were missing. This explains the limited support in the conceptualisation phase and why only social aid is provided in the later phases.

Legal support

The legal support is in practice characterized by two aspects; linkage to the university and the bounded capacity in later phases. To start, all founders who utilize the transferred IP of the universities encountered beneficial legal support during the starting phases of conceptualisation and concept validation. They specifically mentioned an overall positive collaboration with the TTOs of the ecosystems where it was clear that the TTOs would take the legal responsibilities for the IP, company creation and the possibility of reviewing legal documents. Interestingly, spin-offs that do not employ university IP or where the IP had been gifted by the university had to arrange these aspects themselves through privatized companies. This relation can be explained since the universities are no shareholders in these companies and therefore do not grant access to these legal services. Throughout the interviews, the insight was also formed that the TTOs primarily focus on spin-offs in the earlier phases. This is expressed by the experience of founders who described the support as quite smooth at the start while in later phases there were capacity problems related to the legal support on the TTO side.

Financial support

Financial support is observed as a structure where spin-offs underwent a comparable journey. In conceptualisation, initial funding is commonly acquired through aid in the shape of grant provision. This is then followed by investment provision in concept validation. These investments are in the form of (convertible) loans in exchange for shares and typically relate to the UNIIQ fund of Innovation Quarter or the Take-off 2 loan of NWO. In the case of EMC, the spin-offs went through their conceptualisation phases swiftly raising funding through convertible loans early on. During product validation, the costs become higher as a cause of multiple reasons (e.g. clinical regulation). This demands higher funding through equity investments acquired through agreements with venture capitalists, outside the ecosystems. In this third phase the facilitators solely provide support in assistance on securing this funding but won't provide it directly themselves.

Infrastructure support

Many founders do not broadly experience infrastructure support. Two aspects were found in the qualitative data that define this aid towards the founders. In the first spin-off, the researchers create technology through their work in the laboratories of the TU Delft. While working simultaneously on the spin-off they were able to continue their technical work in the lab. In the later stages, formal agreements were made with the TTO of the TU Delft to continue this way of working. The only other spin-offs that received infrastructure support were the ones located in the EMC ecosystem. Conversations with facilitators and founders made it clear that the ecosystem strives for aid towards spin-offs developing medical devices. After the agreements with the TTO of EMC, both spin-offs were provided with workspaces and the possibility to utilize the support services of MISO and EMI. The spin-offs had a shared view that the workspaces themselves were not specifically important, it was the access it granted to connections in the hospital. Moreover, one of the spin-offs received valuable support from the EMI department to further develop their product. The aid from the MISO department elicited some conflicting opinions. While both spin-offs had positive experiences with MISO, one of them did point out that it was simply

not effective enough or sustainable. Its team members mentioned that the department's activities heavily depended on the efforts and network of one individual. In addition, they said that sometimes the connections to the medical specialised led to no concrete progress.

Social support

Lastly, social support is provided across all phases and ecosystems. The founders acknowledge the importance of this and respond positively to the aid they receive on this matter. They aim to use the various opportunities to strike relations with relevant experts in their theme-focused ecosystems. As mentioned, these are the connections that create the through value for them. Additionally, they are interested in experts on general spin-off topics, such as IP.

5.3. Content analysis on perceived support

Similar to the work in the previous chapter, this section describes the support as the founders of health-tech spin-offs perceive it. A content analysis, as portrayed in table 5.2, evaluates the support by specifying it on the levels of sub-type support. For each sub-type, a quote from a founder is given and later the occurrence of this form of support is summed up. Finally, the last column identifies the aggregated support received per overarching type. For example, the sub-type support of ”workspaces” is characterized by infrastructure support and is elaborated using the quote ”We have access to the lab, while we are spinning out”. This sub-type occurred four times during conversations and contributed to a total of seven times that infrastructural support was mentioned. To gain a reflecting view of the current aid, an equal amount of spin-offs were interviewed per ecosystem.

Table 5.2: Content analysis of support received by health-tech spin-offs (author, 2024)

Type of support	Sub-type of support	Example of quote	Occurrence	Aggregate
Infrastructure	Workspaces	*”We have access to the lab, while we are spinning out.”*	4	7
Infrastructure	Technical and clinical support	*”We started having help from them on the clinical side.”*	3	-
Business	Problem-solution fit assistance	*”The program explained how everything worked, what we can do with the company, with the startup.”*	4	8
Business	1-on-1 coaching	*”In this program you have much more coaching directly with the mentors, who have a very specific experience that you can directly ask the question.”*	4	-
Financial	Grant provision	*”Yes the funding was in the form of grants and gift by competitions.”*	4	15
Financial	Investment provision	*”Then we received the Take-off 2 convertible loan.”*	7	-
Financial	Financial application assistance	*”From RVO we started to get a lot of help especially once we were preparing for these European grants.”*	4	-
Social	Private network sharing	*”Here YES!Delft helped a lot with networking.”*	5	10
Social	Event organising	*”In Leiden in the Bio Science Park what is really nice is that they have these life science cafes.”*	4	-
Social	External expertise hosting	*”They combine the extensive network with the masterclasses and workshops.”*	1	-
Legal	Linkage to IP services	*”For all IP agreements and all the stuff related to your technology you need to talk to them.”*	5	6
Legal	Linkage to legal services on contracts	*”We definitely got legal support review for some of the things.”*	1	-

Description:

Table 5.2 presents an overview of the various types of support perceived by health-tech spin-offs. The support is categorized into infrastructure, business, financial, social, and legal types, with their associated sub-types. These sub-types are further explained using quotes from the founders. Moreover, the table shows the occurrence of each (sub)-type of support during conversations with founders.

5.3.1. Outcomes of the content analysis on perceived support

The content analysis of table 5.2 describes the support as perceived by the founders of the health-tech spin-offs. This research solely includes the support that the facilitators of the academic entrepreneurial ecosystems of TU Delft, EMC and LUMC offer. Juxtaposed to the earlier content analysis, this review will outline which main support forms are observed as the most provided by the facilitators.

Financial support

During the interviews, the founders primarily discussed the support surrounding financial resources. This was divided into the direct access to it by grants, loans, convertible loans and equity investments. Indirect access to funding is provided by assistance on the application for it. Interestingly the founders had a similar journey in acquiring the funding while undergoing the phases in the development process. As described in the framework, the spin-offs received grants in the early stages of the progress. These grants were often the Take-off 1 of NWO or in the form of prize money by winning startup competitions. In some cases, spin-offs linked to the universities received a TTT voucher, which is granted by the unionized organisation of various Dutch universities. Next, the required money was raised through (convertible) loans. Similarly, this funding source was identical for most spin-offs as they acquired the UNIIQ loan by Innovation Quarter or the Take-off 2 from NWO. For the spin-offs that were further in the development process equity investment has been raised through seed-funding by investment companies such as Graduate Entrepreneurship. Although similarities were present in the structural gathering of the funding, differences were also observed. While some spin-offs depended for a longer period on the access of grants, others skipped this phase and directly went for the acquisition of convertible loans. These convertible loans are commonly released when founders are full-time committed to a spin-off. This distinction in funding is therefore potentially influenced by the dedication of its founders which directly relates to the second critical juncture of Vohora et al. *entrepreneurial commitment* (Vohora et al., 2004). When the founders strongly believe in the feasibility of the technology and its future financial returns they are more likely to directly go full-time on the project. Other, more personal, conditions such as the preference for job security might also influence this decision.

Receiving the financial resources was not the only form of support that was provided in these deals. Commonly the spin-offs found the additional support, connected to the funding, equally valuable. An example of this additional aid is access to an industry-specific network, discussed in business support.

Social support

Social support is the health-tech spin-offs' second most experienced form of aid. During the interviews, the founders mentioned that this was particularly expressed through the sharing of private networks and event organising. As newcomers, the founders try to find their way into the industry-specific network present in the overall environment of healthcare innovation. By attending events or through direct relations sharing they increase their network which they find essential to their progress. This was illustrated by one of the founders in the following way: ***"We are really trying to grow our network on the industrial biotech side and the life sciences side."***. For this reason, they prioritize this network building as the founders highlighted that they learn the most from other entrepreneurs. They envision them as equals, understanding that more experienced founders know the struggles of the current health-tech spin-offs, having faced similar hurdles themselves. These relations are not solely utilized for the gathering of knowledge. It also provides a direct way for them to test their hypothesis on technical or market topics with experts. Interestingly, this mentality of resource collection and progression through social relations directly relates to the *pre-organization* phase of Vohora et al. (Vohora et al., 2004). This concept is therefore not unique to the health-tech spin-offs, it aligns with established literature which may explain its priority by founders.

The founders recognize facilitators as entities that hold large resources and connections to the experienced founders. Yet these experienced founders are the ones that carry the valuable knowledge to them. This could potentially explain why private network sharing and event organising were observed the most during the interviews in comparison to the hosting of external expertise. The facilitators noted that workshops on topics such as IP or HR were led by dedicated experts. Although these individuals are knowledgeable on specified topics founders may view these experts as having less valuable knowledge than other, more experienced founders.

In general, founders perceive the facilitators are bridge builders of connections. A founder also noted that this is particularly helpful when a founder is not skilled in creating new social relations. ***"When you are a bit shy to ask for help, and I think a lot of people are struggling with this, an incubator really provides help in this."*** This struggle relates to the shift in personality by academics and was illustrated in the case studies by Vohora et al., further discussed in 3.3.4 (Vohora et al., 2004).

Business support

Overall the business support by the facilitators is perceived as significant to the founders of the health-tech spin-offs. This specifically applies to the programs offered in the concept and product validation phases. The programs in the concept validation were aimed at the discovery of the problem-solution fit. Through workshops in these programs, the founders stated that they were pushed to make their ideas more tangible. As a result, the founders pivoted away from their initial ideas to focus on a more feasible and impactful product. One founder reported: ***"The program is super helpful and it saved a lot of time."*** The programs in this phase are also aimed at developing an entrepreneur on a personal level. A founded noted that the personality change and learning curve in this period had been tough. ***"Our technology was much more developed as for us it was easier to do all technology rather than business as it was not our background."***. This approach to progress on business insight by developing the skills of founders differs from the focus of programs provided in the product validation phase. Here facilitators assume that founders achieved a level of entrepreneurship and concentrate their support on networking. This distinction was acknowledged by one of the founders ***"In the Validation Lab you learn to develop skills while in the Accelerator program, it is all about networking."***

This network is strongly tied to the 1-on-1 coaching form given in the following phases of the development process. Here the founders still received knowledge through workshops but it was combined with the knowledge of a specific mentor. These mentors often had experience themselves as a founder in a similar industry and had access to a large network. The value of this network is discussed in the previous section and illustrated by this quote from a founder: ***"We got connected to a lot of companies which already went through the validation stage and the licensing stage as a medical device and you can directly ask a specific question of how they went through that stage."*** Unexpectedly, this might indicate that the importance of business support by founders is partly the effect of social support. In other cases, founders explained a lack of (specified) programs to provide business-related support. Here the founders indicated that they had to gather the knowledge independently while building their own network. The reason for this was the lack of programs focused on healthcare topics.

Infrastructure support

Infrastructure support is designed to grant spin-offs access to tangible tools (e.g. workspaces) or intangible tools (specified knowledge) which are either structurally provided or flexible based on the needs of the spin-offs. Founders were satisfied with the availability of infrastructural aid and knew how to reach out to the facilitators supplying it. The structured form of this support is commonly translated to the hiring of offices and workspaces. One of the teams operated from the offices of YES!Delft describes the collaboration as pleasant. Another emphasized the availability of the infrastructure by highlighting their option to choose among three locations for setting up their laboratories. ***"We investigated lab space and we weighed the pros and cons. But it made the most sense for the technology we have and the knowledge base to be in Planet Bio because we're close to the faculty here."*** Interestingly it was mentioned that the ecosystem of the TU Delft had the ambition to provide the lab space but couldn't realize it due to the scarcity of resources and the lack of available space for potential growth.

More flexible agreements are made to the intangible tools expressed in the form of services. These types of agreements were usually observed between the TTOs of the universities and their spin-offs. As discussed in the use case, Erasmus Medical Centre hosts two departments related to the development of medical devices; MISO & EMI. MISO assisted the spin-offs by connecting them to the relevant medical specialists that operate in the hospital of which its service is overall experienced as valuable. ***"MISO is a department which we happily collaborate with."*** - founder health-tech spin-off. The connection to the medical experts working in this hospital is also established by being located as a spin-off in the same building. ***"The hiring of the office in the hospital is very valuable as we now have direct ties and are half colleagues of the technical service (EMI) and researchers."***. In some cases, the agreements with the TTOs lead to unique collaborations where the spin-offs are granted

access to the laboratories and in return, they involve students with their technology in the form of projects.

Legal support

In contrast to other startups, academic spin-offs are based on Intellectual Property (IP) created from university research. For this reason, the IP is owned by the university by the implementation of a holding company. The university is 100% owner of this company and thereby indirectly holds the IP. Through agreements the holding company licenses the IP to the spin-offs in exchange for shares, becoming shareholders. The agreements do not solely include the use of the IP, access to additional resources is also included (e.g. funding & infrastructure). The spin-offs consider the TTOs as the providers of IP as they often communicate on behalf of the holding company. Founders acknowledge the TTO's expertise on IP which is lacking within their own team. ***"It were their patents, they took take of the continuity of the patents, so the contacts with the patent lawyer."***. These long-term agreements meant that the spin-offs could theoretically use the legal services of the universities for their own benefit. In practice, this is done on a small scale as the founders experience the limited resources of the TTO's. ***"We would have our biweekly or monthly meetings and say can we look at this together or send something? Yeah. But at the end of the day, there's also like a limit on their resources."*** For this reason, founders search for their own legal services outside those of the TTOs. ***"We work with advisors on many topics, including a lawyer, and a patent office."*** Moreover, a founder mentioned they got help from the RVO patent assistance offices which turned out to be effective.

Conclusion of the perceived support

The results of the content analysis quantify the support perceived by the founders by mentioning it during the interviews. This quantification leads to differences in appearance which may indicate distinction in the prioritization of the support. To illustrate, based on the content analysis, the health-tech spin-offs envision financial support as the most crucial form of help. The ranking of this perceived support might assist facilitators in giving precedence to their offered help. As a result, the founders are better met in their needs, improving the progression of the companies.

5.4. Identification of mismatch in support

This research executed two content analyses to capture a multiple perspective on the current support that is offered towards health-tech spin-offs in the three Dutch academic entrepreneurial ecosystems. Initially, analyzing the occurrence of support sub-types shows which aid facilitators predominantly provide, revealing which sub-type of support the facilitators find crucial for the health-tech spin-off development process. A secondary content analysis captured founders' perceptions of support, highlighting discrepancies between facilitators' and founders' views. A single value of occurrence indicates that the interviewee mentioned the topic at least once during the conversation. This section aims to discuss this disparity further by comparing the occurrence of the sub-type of support as illustrated in table 5.3. This table examines the differences in occurrence for the support forms and their sub-types during conversations with both facilitators and founders. A clear example of this is the sub-type of "Workspaces" that occurred 3 times during conversations with facilitators and 4 times during those with founders. This variety in occurrence can potentially describe mismatches for this specific form of support. This mismatch is then further analysed per stage, table 5.4 and divided into underlying concepts that cause this phenomenon.

Table 5.3: Mismatch identification (author, 2024)

Type of support	Sub-type of support	Definition (sub-)type of support	Occurrence by facilitators	Occurrence by founders
Infrastructure	**Aggregated**	**Arrangement of facilities such as working spaces, laboratories, meeting rooms, and (specialized) equipment**	**5**	**7**
Infrastructure	Workspaces	Access to workspaces that include offices, laboratories and facilities for technical development	3	4
Infrastructure	Technical and clinical support	Assistance as a service of the product development or clinical regulation for the technology	2	3
Business	**Aggregated**	**Training and coaching related to skills and knowledge that assist in venture building such as the creation of a business plan or pitch**	**12**	**8**
Business	Problem-solution fit assistance	Guidance in the spin-off process of discovering the problem that the innovation solves.	7	4
Business	1-on-1 coaching	Internally organized matching between founders and specialized mentors to share knowledge on commercialization strategies and to stimulate progress.	5	4
Financial	**Aggregated**	**Providing access to financial facilitators such as public grants, venture capitalists & angel investors while assisting in financial planning**	**11**	**15**
Financial	Grant provision	Provision of financial resources in the form of non-dilutive grant money	2	4
Financial	Investment provision	Provision of financial resources in exchange for interest (loans) or shares (equity investments), including convertible loans.	3	7
Financial	Financial application assistance	Assistance in the application process for the acquisition of funding in the forms of grants or equity investments	6	4
Social	**Aggregated**	**Provision of linkages to industry parties, experienced startups, customers, market experts**	**16**	**10**
Social	Private network sharing	Granting access to a network of specialists in various fields, that can share information valuable to the progress of the health-tech spin-offs.	6	5
Social	Event organising	Organising events on various themes to aid the health-tech spin-offs in increasing their network	6	4
Social	External expertise hosting	Hosting workshops where external experts aid the health-tech spin-offs in topics related to the progress of the company.	4	1
Legal	**Aggregated**	**Assistance on product protection in the form of IP and consultancy on legal agreements (e.g. NDA)**	**5**	**6**
Legal	Linkage to IP services	Directly or indirectly helping the health-tech spin-offs in their process for the protection of intellectual property	4	5
Legal	Linkage to legal services on contracts	Directly or indirectly helping the health-tech spin-offs through legal expertise in drafting and reviewing collaboration contracts.	1	1

Description:

Table 5.3 compares the types of support provided by facilitators with the support perceived by health-tech spin-off founders, identifying potential mismatches. The table categorizes the support types into the associated sub-types and analyses the frequency in which they occur.

As mentioned, this analysis compares the occurrences of the mentioned sub-types of support during the interviews. This provides insights into the differences in perspectives on the support supplied by the facilitators.

Infrastructure support

Starting from the top there are little differences in the support of infrastructure. Interestingly both sub-types of infrastructure aid are mentioned more by the founders than the facilitators. In addition, the founders emphasized the importance of the correct facilities for the further development of their innovation. This can potentially be explained by the perspective they share that the company's progress is led by the development process of the technology as explained in the literature, 3.3.2.

It is crucial to notice how the ecosystems prioritise the execution of this form of support. The TU Delft ecosystem provides offices through YES!Delft and laboratory space through agreements with the facilities of the university. This approach is similar to that of the LUMC ecosystems through agreements with PLNT, Leiden Bio Science Park and the university. In general, the founders agreed there are sufficient possibilities of granting access to these facilities one of the founders did point out that there were availability issues with laboratory space at the TU Delft. While support in the ecosystems of TU Delft and LUMC is aimed at the providence of laboratory space or offices, EMC centres its aid around services. This specifically relates to the services of MISO and EMI designed to assist the health-tech spin-offs during the setup of their MVP and the strategy for the regulatory pathway. Particularly MISO is a unique service that brings understanding to the whole phenomenon of medical regulation, a topic misunderstood by most in the ecosystem while having a large impact on the spin-off's success.

Reflecting on the infrastructure support this study concludes that there is minimal mismatch in the area of offices and laboratory space. Nevertheless, there is a mismatch discovered in the services of the ecosystems. EMC hosts the EMI and MISO yet it seems to be the only ecosystem to provide these services according to conversations. As a result spin-offs in TU Delft and LUMC miss out on this support, creating a mismatch in support between the ecosystems. This matter is closely linked to the reason why founders value infrastructure support. Founders mentioned that the significance of operating in an office does not lie in its comfort. EMC hosts its offices in the hospital, meaning that the spin-offs can quickly discuss medical topics with hospital employees. Knowledge of these type of conversations is essential raising the need for services such as MISO and EMI.

Business support

Examining the business support leads to larger differences in occurrence mainly caused by the problem-solution fit assistance. Here facilitators underlined their efforts and role in the support of this matter while this was not directly shared by the founders. One of the spin-offs heard from other health-tech founders that the Accelerator program from YES!Delft was not specified enough for medical-related spin-offs, therefore the interviewed spin-off did not pursue this program. Moreover, the spin-offs in the EMC illustrated a complete lack of business support programs, forcing them to learn all relevant aspects on their own. Advanced business support as expressed in 1-on-1 coaching is generally positively received. Founders elaborated that they received valuable information from fitting coaches who have experience in the specified domains. This help is closely associated with the creation of private network and the social support surrounding this.

Analysing the business support between the three ecosystems reveals a large difference. As mentioned EMC provides nearly no assistance on this through the phases. TU Delft on the other hand shows experience in this type of support by offering various programs yet lacking the focus on medical-related startups/spin-offs. LUMC is the only one that does provide a medically-centred program called Unlock. Despite its existence, this program is not able to support all spin-offs that seek its help as it is only active in LUMC. Moreover, it is fixated on groups operating in the product validation phase. This concludes that there is a strong mismatch in business support as the relevant medically-focused programs are missing in the ecosystems.

Financial support

Aid in the gathering of financial resources was dominantly mentioned by the founders in comparison to the facilitators. The founders view the funding as an enabler for their activities and are on a constant run the raise it. Remarkably spin-offs shared a standardized journey in the forms of funding assembled and in the entities that supplied it. This route was confirmed by the facilitators involved in financial support such as TTOs. Another interesting topic here was the aligned opinion of founders and facilitators regarding the needed funding for the execution of the clinical validation and the regulatory pathway connected to it. Facilitators share the concern of founders in raising sufficient funding to start or continue clinical trials, yet doubt whose task it is to support the health-tech spin-offs in this problem. This difference in occurrence between facilitators and founders possibly foreshadows a mismatch on this matter.

Different to other support forms, financial aid is commonly not bound to one specific ecosystem. The facilitators try to service spin-offs of all ecosystems to promote innovation. This might explain the similarities found in the journey of spin-offs to find funding. Still, a mismatch is identified in the financial support during the product development phase. Technology-driven spin-offs require larger forms of funding and this demand increases when clinical validation is needed. During product validation, clinical trials call for extensive forms of financial aid yet this funding is dependent on the results of the clinical trial. This concept turns into a chicken and egg problem which is worsened by the lack of communication and responsibility by financial facilitators.

Social support

Social support indicated another large contrast in the occurrence of stated support. Overall facilitators observe this as the most crucial form of support to offer while the spin-off mentions only specific sub-types of it. The hosting of external expertise outlines the largest distinction and describes the knowledge that is shared by experts on specific topics such as IP. In this research, the true reason for this remains unknown. A possibility could be that the importance of this sub-type was outweighed by the other forms of social support. Founders prioritized the creation of a dedicated network to their technology topic to acquire the necessary knowledge and resources. They primarily utilize the aid of private network sharing and event organising to create this network. The latter support through events was not always received as valuable. A spin-off mentioned that the events centre it's focuses on themes that are less relevant to spin-offs. There is a lack of practical application of the knowledge as it remains on a broad level while only specific knowledge on these topics stimulates progress.

Evaluating the social support between the various ecosystems reveals differences in sub-types of support. Through the business programs, TU Delft and LUMC offer workshops on specified topics (e.g. IP) while this is rarely offered in the EMC ecosystem. Covering the sub-type of *private network sharing* ecosystems seem to fulfil this in different ways. TU Delft utilizes its network of experienced founders while LUMC and EMC are better connected to medical experts who can give insights on practical uncertainties.

Legal support

Comparison between the occurrence of legal support between facilitators and founders results in a minimal difference. Here the emphasis lies on the support for legal protection of the technology created. Facilitators commonly do not provide the services themselves yet have connections to other departments or organisations that have these capabilities. This aid was almost only received by founders when the universities, through TTOs, were shareholders in their companies. YES!Delft is the exception to this as they are an incubator with ties to legal companies offering their services to spin-offs for lower initial prices. Solely one facilitator (Delft Enterprises) stated that they offer additional legal support during collaboration contracts or legal documents. This was confirmed by a spin-off that utilizes these legal services.

5.4.1. Identification in support per development phase

This section continues on the work of the previous analysis presented in 5.3 by examining the provided support of facilitators per development phase. An additional separator is implemented by evaluating the support per ecosystem as the founders indicated that they seek their support in the ecosystem where they operate. The identified mismatch per phase is the difference between the perceived support of founders and the provided support by the facilitators of the three ecosystems. Lastly, the support from the overarching facilitators (e.g. Convergence) was added to the ecosystems in which these facilitators are active.

Table 5.4: Mismatch identification per stage (author, 2024)

Ecosystem	Conceptualisation	Concept validation	Product validation	Product launch
Provided support (TU Delft)	Problem-solution fit assistance (Business), Grant provision & Financial application assistance (Financial), all forms (Social), all forms (Legal)	All forms (Business), Investment provision & Financial application assistance (Financial), all forms (Social), all forms (Legal)	Workspaces (Infrastructure), 1-on-1 coaching (Business), Investment provision & financial application assistance (Financial), all forms (Social), all forms (Legal)	Workspaces (Infrastructure), 1-on-1 coaching (Business), Financial application assistance (Financial), all forms (Social), all forms (Legal)
Perceived support (TU Delft)	Workspaces (Infrastructure), Problem-solution fit assistance (Business), Grant provision & Financial application assistance (Financial), all forms (Social), Linkage to IP services (Legal)	Workspaces (Infrastructure), 1-on-1 coaching (Business), all forms (Financial), all forms (Social), all forms (Legal)	Workspaces (Infrastructure), all forms (Financial), Private network sharing & Event organising (Social), all forms (Legal)	-
Mismatch in support (TU Delft)	Workspaces (Infrastructure)	Workspaces (Infrastructure)	Grant provision (Financial)	-
Provided support (EMC)	Technical and clinical support (Infrastructure), Problem-solution fit assistance (Business), Grant provision & Financial application assistance (Financial), all forms (Social), Linkage to IP services (Legal)	All forms (Infrastructure), all forms (Business), Investment provision & financial application assistance (Financial), all forms (Social), Linkage to IP services (Legal)	All forms (Infrastructure), 1-on-1 coaching (Business), Investment provision & financial application assistance (Financial), all forms (Social), Linkage to IP services	All forms (Infrastructure), 1-on-1 coaching (Business), Financial application assistance (Financial), all forms (Social)
Perceived support (EMC)	Investment provision & Financial application assistance (Financial), Private network sharing & Event organising (Social), Linkage to IP services (Legal)	All forms (Infrastructure), Investment provision (Financial), Private network sharing & Event organising (Social), Linkage to IP services (Legal)	All forms (Infrastructure), Investment provision (Financial), Private network sharing & Event organising (Social), Linkage to IP services (Legal)	-
Mismatch in support (EMC)	Investment provision (Financial)	-	-	-
Provided support (LUMC)	Technical and clinical support (Infrastructure), Problem-solution fit assistance (Business), Grant provision & Financial application assistance (Financial), all forms (Social), Linkage to IP services (Legal)	All forms (Business), Investment provision & financial application assistance (Financial), all forms (Social), Linkage to IP services (Legal)	All forms (Infrastructure), 1-on-1 coaching (Business), Investment provision & financial application assistance (Financial), all forms social (Social), Linkage to IP services (Legal)	All forms (Infrastructure), 1-on-1 coaching (Business), Financial application assistance (Financial), Private network sharing & Event organising (Social), Linkage to IP services (Legal)
Perceived support (LUMC)	Problem-solution fit assistance (Business), Grant provision & Financial application assistance (Financial), all forms (Social), all forms (Legal)	Workspaces (Infrastructure), 1-on-1 coaching (Business), all forms (Financial), all forms (Social), all forms (Legal)	Workspaces (Infrastructure), all forms (Financial), all forms (Social), all forms (Legal)	-
Mismatch in support (LUMC)	Linkage to legal services on contracts	Workspaces (Infrastructure), Grant provision (Financial), Linkage to legal services on contracts	Grant provision (Financial), Linkage to legal services on contracts	-

Description:

Table 5.4 discovers the mismatches in support per ecosystem. For each development phase, the provided support by facilitators of that ecosystem is listed. Similarly, the perceived support by the founders of that ecosystem is mentioned. The next row indicates the mismatches between the support that was perceived by the founders yet was not provided by the facilitators of that specific ecosystem.

Table 5.4 resembles per development phase the provided support by facilitators, the perceived support by founders of health-techs spin-offs and the mismatch in the support. To clarify, the mismatch in support is defined as the sub-types of support that are perceived by the founders yet are missing in the provided support by facilitators of that specific ecosystem. For example, facilitators of the TU Delft ecosystem mentioned that they offered support in the form of problem-solution fit assistance, grant provision etc. Founders of that same ecosystem listed that they perceived support in workspaces, problem-solution fit assistance etc. In the end, there is a mismatch in support regarding the workspace (infrastructure). This indicates that this support is crucial to the development of the spin-offs from the perspective of the founders although this is not always offered by the facilitators of the three Dutch ecosystems. In these cases, the founders were able to obtain support through other organisations outside the identified facilitators in this use case. This analysis discusses the mismatch per phase, implying the similarities and differences between the various ecosystems. As was stated before, the founders of the spin-offs were not able to describe their perceived support for the final phase as they had not yet reached this phase. Therefore no comparison could be made in support mismatch.

5.4.2. Conceptualisation

For conceptualisation, the ecosystems distinguish themselves in the support mismatch. In the TU Delft ecosystem, one of the spin-offs mentioned that they were able to use laboratories of the TU Delft to develop their technology further. This form of support is not officially offered by one of the facilitators in this phase and is a clear example of the benefits of a strong relation between a spin-off and an origin university as discussed in the literature 3.3.2. In the EMC ecosystem, there is a misalignment relating to the investment provision. Spin-offs received funding early on from private investors outside the ecosystem to stimulate their progress. This form of support is not yet provided by the facilitators in this phase. Lastly, for LUMC there is a mismatch in the support in legal services relating to contracts. This is a rare case, where the spin-off received support from both the LUMC and TU Delft ecosystem, meaning that aid on this legal service was now granted by TU Delft facilitators.

5.4.3. Concept validation

In the concept validation phase, the same mismatch is seen in the infrastructure aid for the TU Delft ecosystem. No mismatch was seen in this phase and the following ones were for the case of the EMC ecosystem. In the LUMC ecosystem, spin-offs perceived access to workspaces even though this is not accessed through the LUMC facilitators. Similarly, grants were provided in this stage through startup competitions organised by other organisations. In conclusion, the same mismatch is seen during the conceptualisation phase regarding legal aid.

5.4.4. Product validation

In the third phase, product validation, a mismatch in assistance through grant provision in the TU Delft ecosystem. One of the spin-offs mentioned that they received funding to aid in the form of international grants targeted at spin-offs in this later phase. This similar grant provision support mismatch was seen for the LUMC, as a spin-off stated it received prize money from startup competitions, characterized as grants. Again this ecosystem experiences support mismatch relating to the legal services on contracts.

5.5. Factors for mismatch in support

This section identifies and discusses the topics of mismatch in the support by the Dutch facilitators and the needs of the founders of health-tech spin-offs. These mismatches were observed by analysing the occurrence of support as presented in table 5.3 and the mismatches in support during the development phases illustrated in table 5.4. The outcome of this was that in general many forms of help are made available to the health-tech spin-offs. The real issue however lies in the focus of this support on the specific themes of healthcare technology spin-offs. This section identifies four mismatches based on the stated analyses and discusses them using the content analysis on both perspectives of facilitators and founders, as illustrated in 4.6.5 & 5.3. The four mismatches relate to the following aspects; specific health-tech programs, clinical validation support, funding during product validation and efficient networking. Each mismatch is examined by evaluating the affiliated need of the health-tech spin-offs, and the current support that is provided on this.

5.5.1. Tailor-made programs for health-tech spin-offs

The first mismatch in support is found in the entrepreneurial support programs and their missing link towards health-tech cases. This study identified all the major programs offered towards spin-offs in the three academic entrepreneurial ecosystems. These programs are predominantly focused on the period of conceptualisation and concept validation. The programs are designed to aid the spin-offs in their entrepreneurial journey by discovering the market suitability of their technology. In reality, this translates to having conversations with potential users and customers to understand the underlying problem and determine whether it gets solved by the suggested invention. This is a general development process that is often influenced by technological advancement as described by Steve Blank in 3.3.2 (Ries, 2011). In the phases of conceptualisation and concept validation, problems may arise in defining the correct problem-solution fit for the invention. This is associated with the challenge of design choices as illustrated in 3.3.4, where critical decisions are made that carry a long-term impact on the company's success.

In general, the founders experienced overcoming these struggles and elaborated that they valued the established programs in their support of this. Nevertheless, they missed the applicability of these programs towards cases in the medical industry. As described in the literature analysis of this study health-tech spin-offs go through a general spin-off early-stage development process and one that relates to their unique linkages to the medical industry. This particularly relates to the development process described in the New MedTech product development approach in 3.3.3. Obstacles that occur regarding the general development process are in most cases covered by the existing support programs. Medical-themed problems however are barely tackled by the facilitators except for the Unlock program. Challenges related to the medical industry are not solely focused on the clinical validation of technology but also relate to market characteristics of the medical industry. This means information on reimbursement processes of health insurers or procurement decision procedures in hospitals.

The lack of health-tech specialisation resulted in founders choosing to join programs that had this expertise (Unlock) or deciding to gather the necessary knowledge by themselves. The latter case appeared to be dominant in the entrepreneurial ecosystem of Erasmus Medical Centre, where there was even a lack of these "standard" entrepreneurial programs. Another example of the need for such programs was illustrated during the interviews where one of the founders stated that they had contact with another health-tech spin-off who previously followed the Accelerator program of YES!Delft and didn't recommend it to them as ***"The program was not specified on healthcare meaning it is too general for them."***. In such cases, the founders progressed using their skills and network. This however can potentially delay or avoid the succession of the health-tech spin-offs.

A program such as Unlock is shown to be well-known and valued by founders who completed it. This program leverages its network by attracting knowledge from experienced founders in themes of healthcare technology and expertise on specific topics (e.g. IP). This technique is shared by another helpful institution on this matter named Graduate Entrepreneur. This funding facilitator uses its network of investors as their market experts on specialised topics such as healthcare technology. Both these organisations prove to be an example of the missing specified programs for health-tech spin-offs.

5.5.2. Clinical validation support

Similar to the findings of the literature, the founders stated their strong focus on the clinical validation of their technology and the required regulation associated with it. An insightful aspect is the moment when this becomes relevant. In the proposed framework the clinical validation starts in the phase of conceptualisation, yet in reality, the founders expressed that this procedure became relevant at the end of the concept validation phase. The reason for this was the absence of clarity on the product strategy. In the first two development phases, there is no absolute idea about who the customer is, what the functionalities of the product are and what the final product design will be. This uncertainty phenomenon is associated with the challenge of design choices as discussed in 3.3.4. Having a robust idea of the design of the MVP positively influences the reliability of the product. This aspect is crucial for clinical validation and regulation as mentioned by one of the founders: ***"The big thing is consistency and reproducibility. And this relates also to the clinical validation side."***

The final product design and its intended use steer the process of clinical validation and the regulatory pathway. Interviews with both facilitators and founders indicated that these journeys are unique for every spin-off. For cases where a new technology enters an existing market, the regulatory pathway is more structured in which the new inventions have to meet the standards of the existing equipment. Depending on the spin-off this can be beneficial as it is clear what the regulatory path is and what is expected in terms of quality performance. On the other hand, it can cause an extra threshold for cases where the new technology is hard to compare with the current inventions. For innovations in upcoming markets, this pathway is unclear resulting in the freedom to set these regulatory standards. In this situation, regulatory bodies are unfamiliar with new forms of technology, creating an extra hurdle for obtaining regulatory approval. Fortunately, the regulatory authorities are aware of this, remaining open to new technologies. ***"It's also of interest for the FDA or the EMA to be challenged by novel concepts."***

The uniqueness of this pathway makes it difficult for the spin-offs to determine what the next steps should be. In addition, almost no facilitator provides support on this topic meaning that in close to all cases the spin-off has to set out this process completely on their own. The complexity and uniqueness of each case make it hard to support which potentially leads to avoidance of assistance on this topic. The conversations offer insights that support is mainly needed on clinical regulation which requires intensive knowledge, a rare skill in the labour market. To solve this issue, spin-offs either hire someone, learn it themselves or pay private companies for advice. The TTO of EMC is the exception as they grant access to the Medtech Innovation Support Office (MISO). This department is knowledgeable regarding the processes behind regulation while simultaneously providing a network of medical specialists. One of the incubators is aware of its unfamiliarity with specialised knowledge regarding these processes as becomes clear from the quote:***"We do not have the knowledge of what goes on in a hospital and what it needs."***

The incubator acknowledges that this is not their role and resolves the issue by collaborating with medical institutions, such as Reinier de Graaf Hospital. Through this connection, the facilitators aim to simplify access to practical clinical knowledge. Whether Reinier de Graaf is able to support the spin-offs in the documentation for clinical regulation effectively remains unknown. Support for this clinical regulation continues to be hard to implement as the processes are complex and knowledge is scarce. Even in the cases where there is support (e.g. MISO), the goal of effectively aiding the spin-offs is hard. Founders described that the current help from MISO is mainly carried by one individual who connects the spin-offs to the correct technical specialists.

Another aspect is the specific focus of this clinical regulation support, as individuals link this to the legislation regarding medical devices, as expressed in the Medical Device Regulation (MDR). One of the founders mentioned that the majority of the aid on this matter is designed for this purpose yet neglects the other forms of healthcare technologies which also require regulation. ***"There are a lot of programmes and things running like TTT Med tech. But our process is totally novel. So there is a limit to what people can help you with."***

To conclude, stakeholders in the three ecosystems currently offer very little support towards health-tech spin-offs during their process of securing clinical regulation. Some facilitators are aware of this and try to address the issue by providing aid either directly (e.g. MISO) or indirectly as can be observed in the case of YES!Delft. In addition, it is crucial to consider that this help is organised proficiently while

including all forms of healthcare technology, as this is currently missing.

5.5.3. Funding demand during product validation

As discussed, the health-tech spin-offs follow a similar journey in the gathering of the necessary funds during the development phases. These findings indicate resemblances in the funding possibilities as described in the framework of this study. Through all phases, the demand for necessary funding increases and is collected through different organisations. In the first two development phases, conceptualisation and concept validation, funding is respectively acquired through grants, startup competitions and (convertible) loans. These grants are either publicly available ones such as the NWO Take-off 1 grant or are directly provided through the facilitators. Grants like Convergence and MedTech TTT are directly offered to the spin-offs when the universities are stakeholders in the spin-offs. In concept validation, larger financing is needed for the creation of a team and to cover increasing costs in product development. Commonly these financial resources are (convertible) loans received from Innovation Quarter, NWO or Rabobank. In both phases, facilitators assist in writing the application forms needed to secure funding.

In the third phase, product validation, there is swift in funding possibilities and in the sources that provide them. At the start of the product validation phase, there is a clear idea about the problem of the customer, what the solution brings and what the MVP should achieve. Building forward on this the health-tech spin-offs start their clinical validation on a larger scale, in combination with the required clinical regulation. Product validation is associated with the steepest point of the Valley of Death, section 3.3.1, as it requires the highest sum of costs, mostly related to clinical validation and regulation. The financing of this phase is done by assembling the funding from private investors such as venture capital firms. This leads to two obstacles for the spin-offs in this phase, access to the right facilities and gathering sufficient funding. The first issue is discussed in the previous section and is intertwined with the challenge of raising capital. The effect of funding on the facilities is clearly mentioned by one of the founders: ***"That just really helped us be able to say, OK, now we can start to set up our own lab. Yeah, we could hire a full-time fermentation scientist."*** This school of thought is supported by the results of the comparison in content analysis in 5.3, where financial support was dominantly mentioned by founders. This potentially indicates its importance to the founders, enabling them to progress on various dimensions (e.g. clinical validation).

Founders outlined the relationship between funding and clinical validation/regulation as a paradoxical situation where they were attempting to secure investments to finance their clinical validation yet the investors required them to present clinical data on their progress. This becomes a chicken and egg dilemma where funding is needed to create clinical data while this data is needed for obtaining the funding. Investors aim to use this clinical data to determine the progress and potential success of the spin-off, as they prefer companies with a low risk of failure. This mechanism is inefficient, demanding intensive focus from the spin-offs and leading to delays in the development process. These delays in itself lead to even more costs, intensifying the process for securing the funding. The paradox is structural and vicious, resulting in a large barrier to health-tech spin-offs. Facilitators are aware of this issue ***"Between phase 1 clinical trials and phase 4 clinical trials there is such a large drop-off. This is for someone who has invested his whole wealth a very large risk."***

Through its Capital fund, Innovation Quarter aims to break the paradox by providing easier access to funding in the product validation phase. In practice, a founder states that this does not solve the discussed issue. ***"Private funding says let's have this gap filled by public funding. Public funding, in the case of Innovation Quarter, says we lack the knowledge so let's partner up with a VC (venture capitalist). Yet the VC is not there for €400k, they only go for larger tickets when you have clinical data."*** Here the founder explains that within the ecosystem it is unclear who should provide the financial support to the health-tech spin-offs in the phase of product validation: ***"This is a mismatch and also a growing misinterpretation of each other's societal role."***

The mismatch in the financial support during product validation becomes a bottleneck for the development process of health-tech spin-offs. This challenge was found and discussed in the literature, in section 3.3.4, and applies to the cases of the three Dutch academic entrepreneurial ecosystems. Facilitators are aware of this problem, yet struggle to solve it due to responsibility distribution and the availability of knowledge and resources.

5.5.4. Efficient networking

Literature and the executed use case conclude that networking is one of the cornerstones of success for spin-offs. In literature, the concept of networking is categorized under the entrepreneurial ecosystem element of *Support and Networks*. It relates to both the creation of relationships and the ability of spin-offs to exploit these and is often referred to as Social Capital. A strong network aids the spin-offs in their mission of acquiring the needed resources to stimulate their companies. This process is associated with the credibility juncture described by Vohora et al. (Vohora et al., 2004). These resources are both intangible and tangible and are obtained through both institutional and personal relationships. During the interviews, the founders particularly mentioned that strong relations with the TTOs of the universities helped them immensely.

Insights of the literature indicated that in general facilitators acknowledge the network strategy spin-offs take to gather the resources and aim to support them in this. As a result, all described types of facilitators provided social support. This study recognizes the awareness of facilitators on this matter and similar behaviour in support policy are observed in the use case for the three Dutch ecosystems. A clear example of this is witnessed in the occurrence of social support in the content analysis of facilitators as presented in table 4.6.5. The collected qualitative data leads to a distinction between three forms of social support that the Dutch facilitators provided; *private networking sharing, event organising and external expertise hosting.* At first glance, private network sharing would relate the most to network building, yet the other two sub-types influence this process similarly as the individuals present at these events or workshops hold large networks. Moreover, other forms of support such as financial or business are often closely accompanied by networking. This was confirmed by one of the founders describing the social-related support of Graduate Entrepreneur; ***"They thought we will offer access to very important people in very large firms and combine that with the training of the entrepreneur and workshops, masterclasses and funding."***

While some facilitators include the social partly in their support policy, others dedicate the purpose of their organisation towards this aid. This particularly relates to the overarching facilitators that operate in multiple ecosystems, such as LDE & Medical Delta. Here their main focus lies on connecting academics to initiate joint research that requires a collection of expertise. This is executed in combination with providing workspaces and grant provisions. Their focus for support is primarily aimed at the phase before conceptualisation and conceptualisation. During the interviews, the founders affirm their appreciation for aid surrounding social capital. Nevertheless, they share their concern regarding the efficiency of this help, particularly during later development phases when more specialised knowledge is required, which is obtained through these connections. One of the founders described that facilitators do not always understand the needs of the health-tech spin-offs as they organise events on topics that are too general or not applicable to their case. While the inevitability of these events not applying to every health-tech spin-off is recognized, the founder points out that a solution to this social mismatch is rather simple. ***"It would be very valuable if we had a meeting place for coffee and some drinks, to share knowledge. Knowledge needed to get from this point to the next is shared among peers."*** This fits in with the school of thought mentioned by many founders that they gain insights from other founders.

Facilitators deeply recognize social support as a crucial component for the success of spin-offs and focus their resources on enabling this. Similar to the mismatch in business support, currently social aid is too widespread to assist the spin-offs in their needs effectively.

6

Revised development framework

This chapter provides an adjusted version of the development framework of health-tech spin-offs earlier presented in this research. First, the initial application is reviewed, followed by a discussion on the updated version reflecting the changes made for each development phase.

6.1. Application of initial development framework

Due to its exploratory nature, this research utilizes qualitative data from facilitators and founders to answer the research questions. The gathering of this data was obtained by conducting interviews with semi-structured questions. This led to the creation of the development framework described in section 3.4. This development is solely literature-based, using the results of facilitator roles, the development process of spin-offs and their challenges. During the interviews, the framework communicated the development phases and the activities executed within them. This aids in constructing a shared understanding of this research setting between the researcher and the interviewee. It became evident that this framework held additional value as some interviewees expressed interest in adopting it for their own use. This caused the formation of this chapter that revises the development framework to enhance its suitability to the support mechanisms and development process of three Dutch academic entrepreneurial ecosystems. For the modification of this framework, the feedback from both facilitators and founders was used. This resulted in the final design for the framework as presented in 6.2.

6.2. Revised version of the development framework

As mentioned, the adjustments to the framework are based on the comments of the interviewees. This two-sided perspective increases the applicability of the newer version as it is based on experience while being specifically designed for the three Dutch ecosystems. The revised version of the development framework for the health-tech spin-offs is represented in 6.1. This model still describes the development process on a broad level, as there should first be an understanding of this stage before delving into detailed work. Nevertheless, the interviews led to a deeper comprehension of this precise advancement process. A founder indicated that its spin-off tracked its development process through a self-designed monitoring dashboard. This dashboard outlines the development process for health-tech spin-offs for the ten development phases of *Need, Idea, Proof of Concept, Proof of Feasibility, Proof of Value, Initial Clinical Trials, Validation of Solution, Approval & Launch, Clinical Use, Standard of Care*. It defines these phases by describing the goals that need to be reached in the four dimensions of *Clinical, Market/Business, Regulatory and Technology*. This dashboard was strongly influenced by two existing templates; Innovation in Healthcare by EIT and the Guidance And Impact Tracking System (GAITS) (EIT Health, n.d. GAITS, n.d.). The framework for Innovation in Healthcare provides four different approaches set to the sub-themes of healthcare innovation; MedTech, Digital Health, Biomarker Diagnostics, and BioTech. While outlining the ten development phases broadly, it quantifies certain activities and provides a more detailed description of the regulatory elements. GIATS applies the same 10 development phases and four dimensions as the EIT framework, yet functions more as an interactive tracking system for progress. All the frameworks provide information from the perspective of founders

on the development process of health-tech spin-offs. This perspective aligns with the development of spin-offs guided by technological advancement as described in the literature in 3.3.2. Understanding this perspective can help the facilitators to fit their support more effectively to the needs of health-tech spin-offs. Abstract C further describes the adaptive process for the updated version of the framework.

	Conceptualisation	Concept Validation	Product Validation	Product Launch
Key activities business development process (Mejtoft et al., 2022)	- Identification of user problems - Identification of the customer - Setup value proposition	- Value proposition validation - Willingsness to pay validation - Analysis market validation -Unpaid pilots	- Defining commercial path of company - Strategy revenue and costs - Partnership agreements -Paid pilots	- Prove of market establishment (sales) - Team focus on sales & maintenance
Key activities product development process (Mejtoft et al., 2022)	- Valuation of tech features	- Creation of MVP - Strategy for product protection	- Creation of final prototype - Review of product requirements - Start of the product's technical file - Verification on the subcontractors	- Strategy on production & distribution - Strategy for handling incidents and monitoring legislation changes
Key activities clinical validation (Mejtoft et al., 2022)	- Clinical adoption strategy - Description of intended user and use - Clinical validation to user problems - Risk analysis user risk classification	- Intended clinical application (pre-clinical) - Validation on interaction the user and the innovation interaction	- Validation on functionality final prototype - Execution clinical trials - Reporting on data for health eco analysis - Validation end usability	- Approval clinical regulations
Financial pathway (Rutan, 2023 & NWO, n.a.)	- Funding required: max €50K - Public grants (Take-off 1, MedTech TTT, MIT feasibility)	- Funding required: €50K - €500K - Public grants/startup competitions and (convertible) loans (UNIIQ, Take-off 2, innovatie lening)	- Funding required: €500K to €2.5M (Seed funding) - Convertible loans and equity investments	- Funding required: €2.5M to €15M (Series A & B) - Private investments
Key facilitators (author, 2024)	- Pre-incubator (Impact Studio/PLNT) - TTO (Delft Enterprises, EMC, LURIS) - Financial facilitator (NWO, 4TU, RVO) - Network facilitator (Rotterdam Square)	- Incubator (PLNT/YES!Delft) - TTO (Delft Enterprises, EMC, LURIS) - Financial facilitator (IQ, NWO, Rabobank, GE) - Network facilitator (Rotterdam Square	- Accelerator (Unlock/YES!Delft) - TTO (Delft Enterprises, EMC, LURIS) - Financial facilitator (IQ, NWO, Rabobank & VC/Angel investor) -Science park (LBSP) - Network facilitator (Rotterdam Square)	- Accelerator (Unlock/YES!Delft) - TTO (Delft Enterprises, EMC, LURIS) -Financial facilitator (VC/Angel investor) -Network facilitator (Rotterdam Square
Offered support per facilitator (author, 2024)	-Infrastructure (Pre-incubator/TTO) - Business (Pre-incubator/TTO) - Social (Pre-incubator/TTO/network facilitator) - Financial (Pre-incubator/TTO/financial facilitator) -Legal (TTO)	-Infrastructure (TTO) - Business (Incubator/TTO) - Social (Incubator/TTO/network facilitator) - Financial (Incubator/TTO/financial facilitator) -Legal (TTO)	-Infrastructure (Accelerator/science park) - Business (Accelerator/science park/financial facilitator) - Social (Accelerator/TTO/network facilitator/ science park/financial facilitator) - Financial (Accelerator/TTO/financial facilitator) -Legal (TTO)	-Infrastructure (Accelerator/science park) - Business (Science park/financial facilitator) - Social (Accelerator/TTO/network facilitator/ science park/financial facilitator) - Financial (Accelerator/TTO/financial facilitator) -Legal (TTO)

Figure 6.1: Revised development framework (author, 2024)

In general, the initial version of the framework was received positively by all interviewees. In most cases, the described activities aligned strongly with the performed tasks executed in reality by the founders. Sequentially, the facilitators agreed with the activities and described the support they offered in each phase that corresponds to these activities. Regardless, the construction of a completed framework, including all possible facilitators and factors remains hard. Health-tech spin-offs vary in their development process, which translates to the contrast in the progress of the four dimensions. To illustrate, a group might have achieved strong growth in product development whereas business development has been minimal. Similarly, facilitators are not bound to the set boundaries of the development framework, possibly offering support between two development phases. In addition, there is uncertainty surrounding the definition of the development phases. Incubators United utilize the definition of TechLeap, characterizing the phases into sub-phases (Incubators United, n.d.). Although different in their set-up the TechLeap template indicates strong resemblances with the development framework of this study. This aspect in combination with the implemented feedback, increases the suitability of the revised framework. The following sections will further elaborate on the adjustments made for each development phase.

6.2.1. Pre-conceptualisation

One of the insights regarding the proposed development framework was the discovery of the pre-conceptualisation phase. This period happens before the conceptualisation and marks the start of the entrepreneurial journey for founders. It is defined as the research sub-phase in the TechLeap model, describing the rise of innovation through research. This indicates similarities to the *Research* phase as described by Vohora et al. where opportunity recognition defines its critical juncture in reaching the next phase (Vohora et al., 2004). Current efforts by facilitators in the Dutch ecosystems are precisely aimed at tackling this issue. The role of TTOs starts here as they organise events to inspire academics to pursue entrepreneurship. Additionally, they perform active scouting of IPs and researchers. The network facilitators (e.g. Convergence) are also vital in this phase as they facilitate the creation of over-

arching research between ecosystems, to evoke innovation with synergies between healthcare and technology. Some of these facilitators continue to provide social support throughout all development phases.

Although relevant the revised framework does not include this phase in the development framework as it is primarily aimed at the facilitators and does not include activities for spin-offs applicable to the dimensions.

6.2.2. Conceptualisation

In conceptualisation, the activities remained the same as the original approach. Changes were made in the financial pathway as the maximum required funding was set to €50k instead of €10k. The original amount seemed too low in the eyes of facilitators given the height of the available grants that vary between (€20k and €40k). In addition, the framework now portrays the names of these available grants as they were mentioned by the founders during interviews. Sequentially, the conceptualisation phase represents the first adjustments made regarding the key facilitators. In the revised framework, some facilitators are linked to the phases in which they provide support. For example, the facilitators that offer business support through programs are listed in this phase (e.g. Impact Studio). The Impact Studio and PLNT were also categorized as pre-incubators, a definition set by facilitators.

6.2.3. Concept validation

In concept validation, a change was implemented in the dimension of business development. Founders emphasized the importance of including unpaid or in some cases even paid pilots, as it is direct proof of their advancement. Next, the necessary funding was increased to €500k as the founders stated they received higher financial resources in this phase, mainly at the end of this phase. Related to this, the type of funding besides grants and startup competitions now also includes (convertible loans). These we obtained through the mentioned financial facilitators under the row of key facilitators (e.g. Graduate Entrepreneur (GE)).

6.2.4. Product validation

Similar to the adjustment in concept validation, in this phase the business development is further defined by paid pilots. This is observed by the founders as their first customers and makes this project more practical as founders now have to create the associated partner agreements. In the financial pathway, the phenomenon of high demand for funding is now incorporated by increasing the max to €2.5 million. Interestingly, advice for this change was mentioned the most by both facilitators and founders. As discussed a gap occurs here, characterized as the Valley of Death, enabled by misalignment in responsibility between public and private funders. In the row of key facilitators, these private funding facilitators are simply referred to as VC or angel investors. Health-tech spin-offs follow a unique path which results in specialized investors. Including specific VCs would not be suitable for all cases. On the other hand, this same category does include the ecosystem's distinct accelerator programs and Science Park.

6.2.5. Product launch

The product launch entails more than simply introducing a first product to the market, it also signifies the pivotal moment when spin-offs typically disengage from their hosting ecosystem. Spin-offs will scarcely lean on the support of the facilitators and increasingly receive help from investors. In addition, there remains a void in uncertainty regarding the effectiveness of support as facilitators of the academic entrepreneurial ecosystem disregard this phase in their focus. Universities through the holdings of the universities, will continue to act as stakeholders in the spin-offs.

7

Conclusion

This chapter concludes by addressing the main research question, providing comprehensive answers to each of the corresponding sub-questions.

7.1. Approach to answering the main research question

In our battle against potential future healthcare problems, technological advancements are needed. Many of these originate out of universities in the shape of academic spin-offs and are therefore supported by facilitators in academic entrepreneurial ecosystems. Nevertheless, these academic entrepreneurial ecosystems struggle to facilitate this support effectively. The reason for this potentially lies in underlying misunderstandings related to the specific needs of health-tech spin-offs. The Netherlands is no exception to this and through a use case this study is aimed at tackling this problem by answering the main research question:

"How can Dutch academic entrepreneurial ecosystems facilitate the development process for health-tech spin-offs?"

The process for answering the main research question is outlined in the research methodology as presented in chapter 2. Here the research design describes the answering of the main question through the provision of solutions to the sub-questions. The first sub-question is set to create an understanding of the key facilitators found in the academic entrepreneurial ecosystem as described in the literature. The perception of these ecosystems and the functionality of the facilitators within them aids in answering the second sub-question focused on the support by facilitators for three Dutch academic entrepreneurial ecosystems. Within these sub-questions, there is a specific concentration on the support towards health-tech spin-offs during their development phases. The provided support in the use case is utilized for answering the last sub-question where the mismatch in support is determined. This includes a comparison between the provided support by Dutch facilitators and the founders of the health-tech spin-offs. Insights from these three focuses lead to the final statement of how the Dutch academic entrepreneurial ecosystems should facilitate the development process of health-tech academic spin-offs.

7.2. Answering of the research sub-questions

"What are the key facilitators and their support within academic entrepreneurial ecosystems towards spin-offs?"

Tackling the main research question requires an understanding of the key facilitators found in academic entrepreneurial ecosystems and their support. This understanding starts by analysing the more general entrepreneurial ecosystems. This study does this by identifying the elements that define these systems: *Education & Research, Human Capital, Finance & Funding, Government, Support & Networks, Entrepreneurial Culture.* These elements describe the support that is offered by these ecosys-

tems towards innovative companies such as startups. The next literature search was aimed at these entrepreneurial ecosystems in an academic setting leading to academic entrepreneurial ecosystems. These ecosystems operate differently as the origin of the technology they support is founded in the research of the universities. The basis of their process surrounds the licensing of their technology in the form of IP towards existing companies or academic spin-offs. This study focuses on the latter case by zooming into the support that academic entrepreneurial ecosystems provide spin-offs in the creation of their company. This study found that the support can be categorized into 5 forms; *Infrastructure, Business, Financial, Social* and *Legal*. All forms of support contribute to the development process in their unique way and are applied throughout the study to classify the aid by facilitators. Moreover, these support forms provided by the facilitators in academic entrepreneurial ecosystems represent the identified elements of entrepreneurial ecosystems. These definitions and relationships are portrayed in the overview communicated at the end of this literature analysis.

Through these support forms, the study discusses five types of facilitators, namely: **Technology Transfer Office (TTO), incubator, accelerator, science park and financial facilitator**. The literature indicates that the types of facilitators distinguish themselves through their operational process and concentration on support. A clear example of this is the TTOs where the existing literature positions them as the main stakeholder in the creation of spin-offs. Their precise responsibilities and roles differ per ecosystem and are highly influenced by their IP transfer processes. Within each type of facilitator, subforms exist that are classified under the overarching terminology. These subforms vary in their offered sub-type of support and the development phase at which it is provided. A clear example of this relates to the financial facilitator that captures both public and private organisations that allocate grants and equity investments.

These defined types of facilitators are then utilized at the end of the literature analysis where an overview of the support structure is provided. This overview links types of support to the types of facilitators who provide them. In addition, it links the forms of support to the elements of entrepreneurial ecosystems they cover. This overview directly answers the sub-question 1 of this research. In addition, the classification of the facilitators and their support is later utilized for comparison to the qualitative data gathered for the Dutch use case.

"What support is given by the facilitators in the Dutch academic entrepreneurial ecosystems toward health-tech spin-offs in the development phases?"

The second sub-question builds forward on the knowledge obtained in the first one by applying it to the use case for The Netherlands. This use case analyses the academic entrepreneurial ecosystems of Delft University of Technology (TU Delft), Erasmus Medical Centre (EMC) and Leiden University Medical Centre (LUMC). The main focus is to comprehend the existing support by the facilitators of Dutch academic entrepreneurial ecosystems aimed at health-tech spin-offs. Dutch facilitators centre their assistance on specified forms provided during various development phases. In order to understand the current support by Dutch facilitators, this study initially constructs a knowledge basis on the development process of health-tech spin-offs. This basis is grounded in literature and resembles the second part of the literature analysis. The analysis revolves around the early-stage development process of health-tech spin-offs. It solely includes the early stage development phases as the facilitators of academic entrepreneurial ecosystems are primarily relevant in this period of time.

This part of the research starts by examining the development process of early-stage high-tech startups. This section identifies an overall valid concept of the *Valley of Death*, illustrating a pattern of increasing debts due to high uncertainty. This concept is relevant to all tech-related companies and provides a simple understanding of the general development process. Following this, the development process of early-stage academic spin-offs is expressed through a general perspective and one that is led by the advancement of technology. These perspectives are included during the final scoping that outlines the early-stage development phases specifically for health-tech spin-offs represented in the *New MedTech product development process*. This final approach incorporates steps on product strategy as a pathway for clinical regulation making it specifically suitable for health-tech spin-offs. The development process for health-tech spin-offs is realized through activities which carry risks when not successfully executed. This leads to challenges during the advancement process and is defined as *design choices*

in technology development, team capabilities, financing & networking in 3.3.4. Together with the New MedTech product development process, these challenges are combined in the constructed framework for the development process of health-tech spin-offs. This framework is missing in current literature and functions as an enabler of communication during interviews with facilitators and founders.

For all three ecosystems in the use case, the analysis of the current support starts by discussing the original academic focus of the ecosystem, followed by listing the related facilitators and their support. To create a further understanding, the support is categorized into sub-types portrayed as follows; **Workspaces & Technical and clinical support (Infrastructure), Problem-solution fit assistance & 1-on-1 coaching (Business), Grant provision & Investment provision & Financial application assistance (Financial), Private network sharing & Event organising & External expertise hosting (Social), Linkage to IP services & Linkage to legal services on contracts (Legal)**. These sub-types are involved in the evaluation of facilitators' aid represented in two analyses. First, a table overview illustrates the support by the various facilitators and the type of facilitator they represent. The help is then explored in depth by discussing it per the development phase. Here, it was found that the support is highly bound to the focus of the ecosystem on specific fields within healthcare technology. EMC has prioritised their aid towards medical device spin-offs while LUMC aims to facilitate pharmaceutical-related ones. TU Delft shows longer experience in academic entrepreneurship through its vast availability of support programs and the size of its network. The support however is generally focused therefore, EMC and LUMC try to differentiate themselves through more tailor-made assistance. EMC grants spin-off access to the Medtech Innovation Support Office (MISO) whereas LUMC supplies a medical-themed incubator program for spin-offs (Unlock). The ecosystems also show alignment in their support systems. The facilitators in the ecosystems predominantly underline the importance of business support. This particularly is expressed through the variety of business support programs throughout the identified development phases. Moreover, the ecosystems acknowledge the importance of a streamlined support process between the different ecosystems. This led to the rise of Incubators United which aims to optimize the difference in support so that programs can differentiate their aid to assist spin-offs better.

These outcomes are followed by a content analysis employing a quantitative approach to indicate the ranking of offered aid. The analysis reveals a preliminary focus on social support as facilitators acknowledge its importance. Facilitators position themselves as enablers of relation builders, an opinion shared by founders. Here facilitators lean on the concept of Social Capital as discussed by Vohora et al., 2004. in the literature. This is based on the idea that facilitators do not necessarily see themselves as the provider of resources but aid the spin-offs in achieving credibility through social connections. The insights of this sub-question are harnessed to compare with the findings of the founders in answering sub-question three.

"What is the mismatch between the support given by the Dutch academic entrepreneurial ecosystems and the needs faced by health-tech spin-offs during the development phases?"

The previous sub-question characterizes the current support offered by the facilitators of the three Dutch academic entrepreneurial ecosystems. The qualitative data from facilitators resembles a single perspective of the support. Therefore similar interviews were conducted with founders of health-tech spin-offs operating in at least one of the three ecosystems. This information is presented in the mismatch chapter through an overview of perceived support per development phase, along with the perceived support identified in a content analysis. These results indicated that perceived support strongly depends on the ecosystems spin-offs are active in. Similar to the information of facilitators, TU Delft and LUMC were deeply invested in the providence of business-related support programs. EMC on the other hand, shares this ambition for the future and centres its current aid on practical services for medical devices. An insightful finding is the dominant occurrence that financial support was mentioned by the founders, potentially foreshadowing its importance from the founders' perspective. Another relevant aspect is social support, a form structurally important to the founders for gathering the needed resources. Founders acknowledge the overall support on this, particular relations with specific partners such as TTOs aided them in receiving other support forms (e.g. legal, infrastructure). Lastly, no thoughts were shared on the last development phase as none of the spin-offs reached this point. Sequentially this phase fell out of the scope of most facilitators in providing support.

The qualitative data obtained from facilitators and founders were utilized for the analysis of the potential mismatch in support. Similarly, this analysis includes an overview of the occurrence of support from both sides and the difference in aid through all development phases. The comparison of support occurrences mentioned during interviews highlights potential perspective differences in the importance of various support types to the progress of spin-offs. Significant varieties in values are observed for the social support, particularly for the hosting of external experts. Founders seem to acknowledge the relevance of this support yet mention that the recent execution of this aid is not fitting to the needs of the health-tech spin-offs. For the health-tech spin-offs, the true value lies in the specialised knowledge of experienced experts. Moreover, there appears to be a preference of founders for infrastructure support, relevant to the product development and clinical validation of spin-offs. Sequentially, the mismatch in support was examined throughout the development phases.

The mismatch here was constructed as the support perceived by founders yet not provided by the facilitators of that particular ecosystem, meaning that founders received it elsewhere. This analysis led to minimal mismatches for each ecosystem. The TU Delft ecosystem lacks in offering infrastructural assistance in the conceptualisation and concept validation phase. EMC ecosystem showed solely mismatches in investment provision during conceptualisation as this was financed by private investors. Lastly, for LUMC's ecosystem, the evaluation revealed a mismatch of linkage to legal services on contracts during all development phases.

Both discussed analyses, executed on the occurrence of support and during the development process, resulted in a minimal mismatch of support in all ecosystems. In practice, the true support misalignment relates to the fitting of current aid towards the characterized needs of health-tech spin-offs. This study identified four factors of mismatch regarding; **tailor-made health-tech programs, clinical validation support, funding demand during product validation, and efficient networking.** The support lacks correspondence to the specific needs of health-tech spin-offs throughout these topics. As an example of the first topic, Unlock is the sole business program fit for the needs of health-tech spin-offs, while this was mentioned to be essential to these spin-offs. Support mismatch for clinical validation is caused by the differentiation of health-tech-themed spin-offs from other spin-offs/startups. Health-tech-themed spin-offs are often required to clinically validate their technology while simultaneously applying for regulation. The majority of the facilitators lack the knowledge and the resources to guide the spin-offs effectively on this matter. The spin-offs now often assemble parts of this information from different parties with uncertainty regarding its applicability. The third mismatch occurs as the clinical validation and regulation steepen the Valley of Death for spin-offs thereby requiring the need for more funding. The existing financial support system fails to fund the groups efficiently to survive the third development phase. The reason behind this is the unclarity of responsibility between various facilitators concerning the financial aiding of the health-tech spin-offs. Currently, there is simply no answer to the question of whether support needs to be provided by public or private financial facilitators. Lastly, the founders appreciated the current efforts on social support yet noted that it often shortfalls the fittingness to the needs of health-tech spin-offs. Current events fail to effectively help startups. In response, a founder proposed an informal occasion where ideas and experiences are shared. Unfortunately, this request has not been realised.

This study concludes that current support mechanisms by facilitators are sufficient in aiding the health-tech spin-offs in overcoming general challenges. The true mismatch of support lies in the suitability of this support to the specific healthcare technology-themed desires. The findings of this sub-question are input for addressing the main research question.

7.3. Answering of the main research question

"How can Dutch academic entrepreneurial ecosystems facilitate the development process for health-tech spin-offs?"

Using the use case of TU Delft, EMC and LUMC, this study investigates how the Dutch academic entrepreneurial ecosystems can facilitate the development process specifically for the needs of healthcare technology spin-offs. The first sub-research question uses literature to identify the key facilitators of the Technology Transfer Office, incubator, accelerator, science park and financial facilitator. Each of these facilitators covers elements of the (academic) entrepreneurial ecosystems, essential to effectively support startups/spin-offs. The use case tried to examine how this literature applies to the three academic entrepreneurial ecosystems of TU Delft, EMC and LUMC. By mapping the provided support of facilitators and perceived support of health-tech spin-off founders, potential mismatches were revealed on four topics. These mismatches function as a beginning for further improvements.

An effective form of support suitable for the needs of health-tech spin-offs requires an understanding of their complex development process. These companies experience unique challenges that demand tailor-made solutions. While many programs exist for business support, only one (Unlock) is designed for life science & health groups during product validation. Facilitators offering these programs should introduce more of these programs covering all development phases. These programs should incorporate knowledge dedicated to themes within the broad concept of health-tech spin-offs. To clarify, a spin-off providing software within the medical industry has a different development journey than that of medical devices used for surgery. This particularly links to the preparation and execution of the clinical validation and the associated regulation. The research indicated that the struggle to prove clinical impact and thereby obtain regulation found in literature also applies to the Dutch health-tech spin-offs. The discussed programs carry the potential to assist the spin-offs during their preparation for clinical validation and the associated regulation simultaneously. Departments such as MISO should be stimulated and replicated across the ecosystems to provide continuous support for clinical validation and regulation.

The paradox of securing sufficient funding to execute clinical trials while needing clinical data to acquire this funding leads to a negative spiral, risking potential failure. This is reinforced as facilitators lack the knowledge, resources and responsibility to resolve this. This responsibility aspect aligns with an overarching problem of communication between facilitators within the same or different ecosystem. Founders mentioned it was hard to envision the possibilities of support as many facilitators operate independently. Facilitators should align their support mechanisms to cover all necessary needs by health-tech spin-offs. This includes the business-related programs and the provision of funding during the product validation phase. Sequentially, there should be a stronger relationship between the existing facilitators and the public and private funding organisations.

Fortunately, facilitators are aware of this issue resulting in the rise of Incubators United, an initiative to stimulate cooperation among facilitators Incubators United, n.d. Improvements in collaboration between the facilitators and the various ecosystems show prospects to leverage the differences in focus of the ecosystems into specialised health-tech support. The ecosystem of TU Delft holds the experience to advise the ecosystems of EMC and LUMC on the structural organising of their support mechanisms. In addition, the ecosystems should continue to position themselves as specialised hubs on specific health-tech topics. EMC shows promising potential to host spin-offs developing medical devices whereas LUMC centres its aid on pharmaceutical technologies. Meanwhile, TU Delft maintains its role supporting strongly tech-based innovations which the collaboration with DSM on biotech is a prime example of. The establishment of hubs creates the possibility for the ecosystems to exchange their spin-offs based on their needs. As a byproduct, facilitators can design social support more effectively to purely serve the knowledge demands of the health-tech spin-offs. This would resolve the final identified mismatch in current support.

These suggestions aid the Dutch facilitators on how to structure their support to effectively facilitate the development process of health-tech spin-offs. Thereby transforming the three ecosystems into a unified single-purpose functioning ecosystem that enables a seamless natural support process towards health-tech spin-offs, embodying the ecological element of entrepreneurial ecosystems

8

Discussion

The discussion starts by listing the knowledge gaps of existing literature which this study tried to fill through its scientific contribution and practical implications. Next, the research limitations are addressed and followed with the recommendations for future research. The last section covers the relevance of this study within the Masters of Engineering and Policy Analysis (EPA) and the reflection of the researcher.

8.1. Scientific contributions on the knowledge gaps

Healthcare technologies strengthen the Dutch healthcare system by increasing its quality while lowering its costs. These innovations dominantly originate out of university research and are transferred to the commercial market by academic spin-offs. Supporting these groups benefits the universities and their regions both socially and economically, contributing to the development of academic entrepreneurial ecosystems. For facilitators operating in these ecosystems, it is essential to understand the needs associated with the development of health-tech spin-offs to provide support accordingly. Current support is offered to spin-offs yet facilitators lack knowledge of whether the current support fits these needs and what adjustments are necessary to enhance its quality. Functioning as the primary motivation for this research, these knowledge gaps are introduced in 1 and further discussed with the gained insights of this study.

The majority of the existing literature is fixated on the dynamics of entrepreneurial ecosystems. These theories describe a larger ecosystem where the university is set as a single component. In reality, this component is defined by various facilitators operating in an academic entrepreneurial ecosystem, specifically designed to support academic spin-offs. Therefore the derived knowledge of entrepreneurial ecosystems is not directly applicable as the settings differentiate. The scientific contribution of this research is expressed through various findings of this research. First, the described knowledge gap is answered through the literature analysis, structuring existing information regarding the functionality of (academic) entrepreneurial ecosystems. Using the entrepreneurial ecosystems as a starting point the research dives further into the academic entrepreneurial ecosystems and their support relationship towards academic spin-offs. Numerous sources were used to conceptualise the relationship between regular support for startups by entrepreneurial ecosystems and the aid in the growth of spin-offs through academic entrepreneurial ecosystems. This part concluded with an overview where the types of support, that cover elements of entrepreneurial ecosystems, were provided by characterized types of facilitators, found in academic entrepreneurial ecosystems.

A second knowledge gap relates to the variation of spin-offs in their development journey to that of regular startups. The latest literature discusses the advancement process of these groups yet fails to include the unique pathway of health-tech spin-offs. The development process of health-tech spin-offs results in distinctive challenges such as clinical validation. These unexplored areas of expertise are crucial to the current Dutch facilitators.

In the second part of the literature analysis, this study particularly outlines the development process

unique to health-tech spin-offs. This was realized by evaluating the development process of startups and regular spin-offs to finally scope it down to the unique growth journey of healthcare technology spin-offs. These insights were used to identify four main challenges related to the development process of health-tech spin-offs. The understanding of the development process of health-tech spin-offs was combined with the challenges to construct a novel framework that describes the development process of health-tech spin-offs in the early stage. The framework includes four development phases defined by dimensions (e.g. product development) and was applied as a communication tool during the interviews. Later, feedback from facilitators and founders was utilized to create a revised version of the framework. The final version integrates the current active facilitators with the necessary activities of health-tech spin-offs per development phase. The evolution-building method for this framework and the content of the framework itself can potentially be utilized by others to obtain similar data and compare it to the Dutch ecosystems.

Lastly, findings relating to these types of ecosystems are highly dependent on their geographical and cultural setting and can therefore not be directly applied to the Dutch academic entrepreneurial ecosystems (Tripathi et al., 2019; Ziakis et al., 2022). This research includes three use cases representing the academic entrepreneurial ecosystems of TU Delft, EMC and LUMC. Information on these cases is therefore directly applicable to the listed ecosystems. Moreover, compared to the existing literature the use cases potentially carry a higher level of applicability to the other Dutch academic entrepreneurial ecosystems. The results outline the dynamics between the ecosystems and their specified focus on sub-themes within health-tech spin-offs. The discovered characterizations add to understanding these ecosystems and can be harnessed by comparing them to other ecosystems. The use case also reveals on a practical scale the support provided by the facilitators and those experienced by the founders. The employment of several analyses deepens the understanding regarding the prioritization of the (sub-)types of support from both perspectives. Moreover, this entailed that in general the support is perceived by founders as sufficient yet the real discrepancy lies in how well the support aligns with the distinct needs of health-tech spin-offs. Sequentially, this research highlighted the four potential mismatch subjects, which can serve as an example of inadequate support observed in other ecosystems focused on aiding health-tech spin-offs.

8.2. Practical contributions

8.2.1. Founders

Generating the findings of this thesis required data obtained through conducting 16 different interviews. This process results in a high level of practical implications for the outcomes. Starting with the implications for the founders, this research aids the spin-offs by offering an initial overview of the support provided during the development phases by the three Dutch ecosystems of TU Delft, EMC and LUMC. The clarity on this matter addresses the urgent need of founders for information on which facilitator offers what type of support during what development phase. One of the founders summarized this in the following way; ***"We weren't sure what kind of value they were bringing. whether we were too early or too advanced, it was unclear at which stage we were in order to apply for that."*** In addition, the research provides an overall idea of what the facilitators offer the spin-offs and whether this was effective in the opinion of other health-tech founders. This helps the founders to better understand the support mechanism, thereby increasing the chance for them to choose a facilitator that best fits their interests.

8.2.2. Facilitators

The tangible insight on this issue is expressed in both the summarising table of 4.1 and in the revised development framework of 6. These insights simultaneously carry application possibilities for the facilitators. As mentioned, facilitators are aware of the uncertainties regarding the structure of the provided support between all facilitators. At present these parties are involved in a collaboration initiative named Incubators United, to streamline the aid towards spin-offs and startups between the various ecosystems (Incubators United, n.d.). The revised version of the framework and outline of the development process of health-tech spin-offs can potentially support the facilitators in their efforts. Particularly the framework represents a new medical-themed perspective on an existing framework used by Incubators United to communicate their support. In addition, this research underlines other miscommunications in

support regarding the funding aid during product validation and uncertainty of general support centring the product launch phase.

The findings concerning the mismatches in support are expected to have the largest implications for facilitators in the three Dutch ecosystems. To start it not only provides an initial understanding of the effectiveness of their own support, but this thesis also makes recommendations on overcoming these mismatches. During the interviews, the founders did not solely mention the flaws of the current support mechanisms they also shared ideas on how to improve them. Specifically, the founders of medical device spin-offs suggested a support mechanism, that is deeply involved up until the moment of in-human testing. ***"An experimental basis aimed at the first in human testing under the scope of the hospital. Because you develop it internally, it saves costs, you know your capabilities and you can select your innovations on that."*** This aligns with another founder who recommends a specialised medical academic entrepreneurial ecosystem with its main purpose to ***"Facilitate but don't control."***

8.3. Policy implications

This study identifies four subjects of support mismatches present in three Dutch academic entrepreneurial ecosystems of TU Delft, EMC and LUMC. The policy recommendations are directly influenced by these mismatches and include current efforts on progression observed during the interviews. In general, the founders state that they observe an insufficient commitment to specific aid towards health-tech spin-offs. Therefore the overall policy recommendation is that facilitators should devote more time and assets to this matter while distributing the responsibilities related to this.

8.3.1. Tailor-made support for health-tech spin-offs

The current support misses its link to the specific needs of health-tech spin-offs. In at least one of the cases, a spin-off did not participate in a support program due to this lack. The absence of these programs can potentially increase the likelihood of failure for these companies. Unlock represents an example of a business support program, specifically designed for health-tech spin-offs. Nevertheless, it operates out of the LUMC ecosystem and focuses on spin-offs during the product validation phase. Fitting support is needed in all ecosystems during all development phases. Following this advice, the ecosystems should pursue the aim of specializing in their services towards themes within healthcare technology. Given the current status, this means that EMC will continue to focus its efforts on medical devices, LUMC will support pharmaceutical-based solutions and TU Delft will assist biotech companies. This support does not solely include the introduction of business programs but also the provision of suitable infrastructure and expertise.

8.3.2. Clinical validation support

Support on clinical validation can be perceived as a part of the proposed tailor-made support for health-tech spin-offs, yet requires the most resources and knowledge to execute effectively. EMC started this development with the introduction of the MISO department, where medical device spin-offs are aided in the clinical validation and regulation process. However, this study does not perceive the current form of MISO as sustainable or fully effective. Ecosystems should dedicate time and assets to this matter as it is one of the largest challenges in the development phase of health-tech spin-offs. This support should again be tailor-made to the focus of each ecosystem, as each theme and each company has a unique clinical validation journey and corresponding regulation.

8.3.3. Funding during product validation

As mentioned, the product validation phase is characterized by clinical validation/regulation and the related shortage of funding accessibility. Here the gap exists between public funding through grants, convertible loans and private investment in exchange for equity. Innovation Quarter is one of the facilitators acknowledging this issue and attempting to resolve it by investing in this phase. In reality, this process does not achieve full productivity, thereby leaving part of the problem unaddressed. New policies should be created that state which facilitators are responsible for this issue. This demands a higher level of governance in collaboration with the universities on the ecosystem level. This mismatch in financial support carries effects on a national degree, therefore the Dutch National government should

play an active role in providing a solution to this problem. This demands a national-orientated policy extended to the work of Innovation Quarter which operates within the province of Zuid-Holland. A national policy can simultaneously overcome this obstacle for similar spin-offs operating in another part of The Netherlands.

London Institute for Healthcare Engineering (LIHE)
The described ecosystem by these founders fits in with the effort of Kings College in the creation of the Londen Institute for Healthcare Engineering London Institute for Healthcare Engineering, n.d. This research interviewed an expert on this establishment, leading to more insights into the functionality of this medical device-oriented ecosystem. This organisation shares the ideas of the Dutch founders, by underlining the importance of all parties being hosted under one roof. These parties are medical specialists, entrepreneurs, students, regulatory experts and private companies. Here spin-offs are guided through programs in which they receive ongoing active support from professionals on various topics to reduce time and raise the success rate. The ecosystem of EMC shows a start in this by hosting the MISO department, to support spin-offs in the medical regulatory aspects. By managing the development process in-house LIHE supports startups/spin-offs intensively in almost all aspects to stimulate the development process effectively. Examples such as these can help to discover whether these ecosystems have application possibilities in the Dutch environment.

8.4. Research limitations

This study is characterised by its exploratory focus on the functionality of the three Dutch academic entrepreneurial ecosystems. This exploratory aspect was necessary as very little literature exists on the current support of health-tech spin-offs in The Netherlands. This orientated approach leads to limitations surrounding the execution of the research and the impact of its results. The first limitation relates to the mentioned lack of available literature on various topics such as academic entrepreneurial ecosystems and health-tech spin-offs. The search strategy was extended to include all relevant sources. Nevertheless, it remained hard to substantiate the found insights with multiple sources. Sequentially, with the limited amount of sources, it becomes challenging to contextualise found ideas in the setting of this research. For example, how does the development process of health-tech spin-offs apply to the Dutch academic entrepreneurial ecosystems?

To continue, this study has the aim of representing the dynamics in support of multiple ecosystems, as they are connected through relations and overarching facilitators. While describing three important Dutch academic entrepreneurial ecosystems no claims can be made regarding the direct applicability of the results to other Dutch ecosystems. These ecosystems possibly operate differently leading to a contrast in the support and its mismatch. In addition, the research discusses the operations of one of the three Dutch ecosystems on a large scale meaning that it is hard to analyse the functionality of the support mechanism in depth, for example per business support program. This lowers the underlying comprehension of the process of how this aid is provided. This knowledge would have been valuable for further scientific understanding of the academic entrepreneurial ecosystem. Both these limitations are caused, among other factors, by time constraints associated with this thesis.

This research identifies the mismatch in support but does not describe how these were caused in the first place. Obtaining insight into the rise of these mismatches might potentially foreshadow a more effective solution for resolving them. Moreover, the founders suggested solutions to the mismatches which were combined with the proposal of the discussed support ecosystem of LIHE. The research outlines these examples while not mentioning how they should be implemented into the existing three Dutch academic entrepreneurial ecosystems which would enhance their relevance to the main research question.

In addition to this, the research solely identifies the mismatches in support between the facilitators and the health-tech spin-offs, yet fails to include mismatches between other relevant parties. An example of this could be the mismatch between the Dutch National policy associated with the existing support systems and the needs of the health-tech spin-offs. Insights into this topic are not only valuable to understanding the entire Dutch innovation system but can sequentially explain the cause for the discovered mismatches in this research.

Finally, research limitations occur in the applied methodology of this master thesis. In the chosen methodology, a qualitative analysis was selected to gather the needed data on a practical level. This approach is highly sensitive to subjective data which lowers the overall applicability of the results. Relating to this, the author of this research found the interviewees through social connections which can potentially contribute to the level of biased information. This research tried to tackle this issue by using semi-structured interviews with a large group of interviewees (16) to extract unanimous conclusions. Nevertheless, this problem is maintained for this type of methodology. Furthermore, on a practical level, founders often found it hard to determine what they were missing in support during the various development phases. This complicated the comparison of data between the facilitators and founders eventually lowering the quality of the outcomes.

8.5. Recommendations for future research

The recommendations for future research are based on expanding knowledge using the results of this study as a foundation. One of these extensions relates to the identified mismatches in support of the three Dutch ecosystems. The academic segment on the academic entrepreneurial ecosystems designed for health-tech spin-offs would benefit from an approach where the cause for the mismatches is further investigated. The creation process for these mismatches can be utilized to prescribe new solutions, fitting on an ecosystem level. In general, it is advised to aim future research on this scale to further comprehend its effectiveness in support over time. This is particularly interesting for ecosystems specialising in supporting specific-themed health-tech spin-offs. Similar existing support systems such as LIHE can function as an example of this by identifying its components to mimic them in the Dutch academic entrepreneurial ecosystem. The development of EMC on medical devices can serve as a testing ground for these innovations. For further comparison between ecosystems, it is suggested to combine these types of analyses with quantitative data on success rates. This quantitative aspect was named by a facilitator as an aspiration for the future to gain insights into its own progression.

Additionally, associated with the EPA master program, it is worthwhile to pursue studies reviewing the current Dutch national policy on supporting health-tech spin-offs or spin-offs in general. This reveals the distribution of responsibility in support of the private sector and the public entities. This directly relates to the mismatches seen in financial support during the product validation and the general aid provided around the time of product launch and afterwards. Moreover, it can possibly describe the cause for the found mismatches in support between the facilitators and the health-tech spin-offs.

Lastly, during conversations, interviewees expressed value in the development framework of this research. This motivated the creation of an additional chapter 6, where the original framework was revised to increase its suitability to the Dutch ecosystems. It is suggested to further iterate on this approach, thereby heightening its usability for future research. A first possible adjustment could be the addition of the row, team, as stated by one of the interviewees. This could include the team's diversity, size, and commitment (e.g. part-time). This element was not incorporated in this research due to a lack of time and the availability of literature. Expanding on this, it is advised to include more quantitative data which can be utilized to show improvements in support over time while simultaneously comparing the progression to other ecosystems. These results could help to deepen the understanding of the conditions influencing an academic entrepreneurial ecosystem's success rate.

8.6. Relevance to EPA

This thesis research is affiliated with the Engineering and Policy Analysis (EPA) as its results contribute to a resilient policy solution against global health, one of the global grand challenges. Academic entrepreneurial ecosystems can be defined as complex social structures in which facilitators operate as stakeholders and influencers. Each facilitator carries out its own policy expressed in the shape of support towards spin-offs. This thesis arranges these stakeholders while describing their functionality and the dynamics of the ecosystem in which they operate. By answering the main research question this research provides insights into the potential policy implications set to resolve the mismatch in support towards health-tech spin-offs.

8.7. Researcher reflection

For this study, a researcher's reflection is required as the researcher is partially involved in the ecosystem it examined. For the last few years, the researcher has been working for the pre-incubator Impact Studio and is the co-founder of a health-tech spin-off. This motivated the interest in the research and aided in acquiring the number of interviews with facilitators and founders. Due to the link to the ecosystem, the researcher strongly focused on remaining independent by acknowledging to interviewees that the mentioned information would remain anonymous, encouraging them to speak freely. Nevertheless, answers could have been unknowingly influenced, particularly those relating to the works of the Impact Studio. To limit the biases the researcher focused on interviewing as many individuals as possible to obtain a multi-perspective view. In addition, the semi-structured questions were designed to be relatively open so that the interviewees were free to share their thoughts on the topics. The intention behind this was not to force the answers of individuals in a certain direction which would happen with questions such as; "What were the best aspects in the support of YES!Delft/Impact Studio". Moreover, the intention of the research was not the validate in detail the quality of each support form by facilitators but rather to get an overview of the entire functionality of support mechanisms in the ecosystems. The researcher tried to be as critical as possible, as he believed that this would eventually benefit the quality of the research and its potential impact on the ecosystems the most.

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A

Interview questions

This section of the abstract presents the questions applied during the interviews with facilitators and health-tech founders in the three Dutch academic entrepreneurial ecosystems.

A.1. Semi-structured interview approach

This thesis research implements a semi-structured approach to obtaining qualitative data through interviews. This approach creates flexibility for the researcher in discovering the most valuable insights. Moreover, it divides the interview into three stages; *introduction, framework review*, and *overall vision*. This method aligns with the proposed development framework, clearly outlining the development process of health-tech spin-offs. The following sections provide the questions applied to this thesis.

A.1.1. Facilitators

Introduction

- *Could you please state your name and your position in the organization?*
- *What would you say is the main function of your position?*
- *What is the goal of (name organization) in aiding the health-tech spin-offs?*

Framework review

- *When looking at the development process in which stages would you say (name organization) offers the most support?*

Per stage ask:

- *Do you agree with the required activities for the health-tech spin-offs in this development stage?*
- *Do you agree with the facilitators that are linked to this stage and why?*
- *What support is offered by (name organization) to the health-tech spin-offs in this stage?*
- *Why do you consider the support in this area important (e.g. funding)?*
- *Do you engage with other facilitators in this support?*

Overall vision

- *What would you say are the biggest challenges for the health-tech spin-offs in each stage and in general?*
- *In what way could (name organization)/academic entrepreneurial ecosystem (TU Delft/LUMC/EMC) improve their services to support the health-tech spin-offs better in the future?*

A.1.2. Founders

Introduction

- *Could you please state your name and your position in the organization?*
- *Could you briefly describe what the spin-off does?*

Framework review

- *Do you agree with the development process as it is described in the framework?*
- *What stage are you currently in?*

Per stage ask:

- *Do you agree with the required activities by the health-tech spin-offs in this development stage?*
- *What support is offered to the health-tech spin-offs in this stage?*
  - *If so, which facilitator offered you that support?*
  - *If so, how did they offer you this support?*
  - *If so, how did they get in contact with you?*
  - *If so, do you consider this support sufficient given the challenges?*
- *Why do you consider the support in this area important (e.g. funding)?*

Overall vision

- *What would you say are the biggest challenges for the health-tech spin-offs, in general, per stage?*
- *In what way could the academic entrepreneurial ecosystem of (Delft/Leiden/Rotterdam) improve their services to support the health-tech spin-offs better in the future?*

B

Methodology behind the literature analysis

Abstract B elaborates on the methodology implemented during the literature analysis.

B.1. Literature analysis methodology

The methodology of the literature analysis relates to the search strategy applied to discover the relevant literature. By employing the search strategy, various knowledge gaps were outlined that motivated this research and simultaneously influenced the literature analysis's structure. These knowledge gaps are further illustrated in the section 1.1. The literature analysis includes two overarching topics; the functionality of academic entrepreneurial ecosystems and the development process of early-stage health-tech spin-offs. Similarly, these concepts describe the methodology of the literature analysis. The following section divides the topics into the relevant steps followed during the methodology.

B.1.1. Functionality of academic entrepreneurial ecosystems

The first part of the literature centres around the concept of academic entrepreneurial ecosystems and the functionality behind them. This initial understanding of these ecosystems is needed to further analyse them in a practical setting during the use case of the three Dutch academic entrepreneurial ecosystems. This knowledge is gathered in two described steps.

Definition of entrepreneurial ecosystems

Primary searches in the literature indicated that entrepreneurial ecosystems are a widely discussed concept. They capture an overarching system to outline the rise of innovation through the support of various stakeholders in an organic dynamic. In the Scopus search engine the queries of ”entrepreneurial” AND ”ecosystem” were used to find the necessary information. Later the search was extended with the words ”functionality” AND ”innovation” AND ”system”. The latter terms are used as well to explain entrepreneurial ecosystems. The literature outcome of this strategy led to knowledge of the direct definition of these ecosystems, foreshadowing their purpose. Sequentially, it resulted in theory illustrating the various structures in which the entrepreneurial ecosystems are observed. These structures determine the role of the stakeholders active in these systems simultaneously characterizing the elements of support covered. For this topic, the search queries of ”entrepreneurial” AND ”ecosystem” AND ”elements” were used. The highly qualitative works of Isenberg, Ziakis and Stam proved to be particularly helpful in collecting the necessary insights. This eventually contributed to the construction of the list of entrepreneurial ecosystem elements; *Education & Research*, etc. While being informative, this step of the literature analysis also discovered a knowledge gap. A large number of sources are focused on the entrepreneurial ecosystems yet simplify the academic component. This motivated the following step to further investigate academic entrepreneurial ecosystems.

Academic entrepreneurial ecosystems

The structure concepts behind the entrepreneurial ecosystems identified the university as one of the key stakeholders. This section dives deeper into this knowledge by investigating the operations of an entrepreneurial ecosystem in an academic setting. The methodology utilized the words ”academic” AND ”entrepreneurial” AND ”ecosystem” to find the definition of the term and its principles. The term ”spin-off” was additionally applied as it strictly relates to this kind of innovation system. The principles portray a university's involvement in innovation creation and entrepreneurship support during the process. This support is provided by specialized facilitators operating in the academic entrepreneurial ecosystems. The following section identifies these facilitators, illustrating their purpose and linking them to the support they provide. This extended the search strategy by implementing the terms ”facilitators” and ”support parties”. The chapter ends by combining the elements of entrepreneurial ecosystems, the types of support and the facilitators found in academic entrepreneurial ecosystems. Sequentially, the methodology discovered that facilitators, although relevant are strongly underrepresented in literature. The majority of the literature is aimed at the barriers or influences that influence the ecosystem's innovations, ignoring the support mechanisms.

B.1.2. Development process of early-stage health-tech spin-offs

The second part of the literature analysis includes the development process of health-tech spin-offs, specifically during the early-stage ones. A similar approach was utilized as seen in the first, by examining more generally applicable information and later scoping it to the mentioned subject. This resulted in three steps each elaborating on a different kind of development process.

Development process of high-tech startups

Research into the progression of growth by high-startups led to the identification of three phases; pre-startup, startup and growth/exit. Literature was found through the implementation of the words ”high-tech” AND ”startups” AND ”development” AND ”process”. The stated are linked to the notion of the Valley of Death, extensively discussed in sources. High-tech startups however follow a different path in development compared to spin-offs as the innovation is created in another way. This identified another knowledge gap that required a more dedicated search on the development phases of spin-offs.

Development process of early-stage spin-offs

By employing the words ”development” AND ”stages” OR ”phases” AND ”spin-off” in the search engines Web of Science and Scopus, a more extended evaluation was conducted on the advancement of spin-offs. Useful insights into this approach were dominated by the works of Vohora et al. who describe the development process of spin-offs through the use of critical junctures (Vohora et al., 2004). This procedure was later compared to a more design-centred system of development. In general, the knowledge regarding this area is limited particularly with the focus on health-tech spin-offs. This issue represents another knowledge gap that motivated this research. Measured against regular spin-offs, health-tech spin-offs overcome unique hurdles influencing their progress. Therefore this study executed a final focus during the literature analysis aimed at the development process of early-stage spin-offs.

Development process of early-stage health-tech spin-offs

This section stretches the previous search by including the words ”medical” OR ”healthcare” OR ”health-tech”. This mostly resulted in the finding of the New MedTech product development process. This process indicates similarities with the design approach illustrated in the development process of spin-offs. The steps indirectly portray obstacles that need to be overcome to succeed in progression. Therefore the search was combined by linking it to ”obstacles” AND ”hurdles”. The findings of this search in combination with the previous insights led to the listing of 4 crucial obstacles for the health-tech spin-offs during their early-stage development process. Eventually, this list was then again utilized with other gained knowledge from the literature to create the framework.

C

Adaptation process of the development framework

Abstract C describes the iterative process behind the adjustments of the framework for the development process of early-stage health-tech spin-offs.

C.1. Semi-structured interview approach

The framework constructed in section 3.4 was initially intended to serve as a communication tool during the interviews with facilitators and founders. Moreover, it aided in structuring the support per development phase deepening the understanding of the current situation for the Dutch academic entrepreneurial ecosystems. During conversations with facilitators, unexpected interest was shown in the framework itself. Facilitators are prioritising the alignment in external communication by creating one design for the development process of startups/spin-offs. The created framework for this study can potentially contribute to the final version by the facilitators. The framework was revised based on insights gathered during the interviews with facilitators and founders. The main factors for these adjustments are discussed in the following sections.

C.1.1. Terminology

One of the reasons for the facilitators' creation of a single framework is the harmonization of the terminology used. Throughout the various forms of support, different words are used to describe the same context which confuses facilitators and founders. One of the issues relates to the naming of the facilitators using the term *incubator*. Multiple facilitators made it clear that this word needs to be used for the facilitators offering business support during the concept validation phase. Facilitators providing this support in the conceptualisation phase are named as *pre-incubator* and the ones in the product validation phase are referred to as *accelerators*. This change in terminology was implemented in the newer version of this framework. Similarly, new a type of facilitator was added to the framework; network facilitator. The literature analysis did not include this new facilitator type; however, it needed to be included to complete the characterisation of all facilitators found in the ecosystems. During the interviews and the examination of grey literature, various phrases were also found to describe the different development phases. To illustrate, Incubators United labels the conceptualisation phase; *ideation* (Incubators United, n.d.). This distinction in terminology also applies to the frameworks of Innovation in Healthcare by EIT and the Guidance And Impact Tracking System (GAITS) (EIT Health, n.d. GAITS, n.d.). For this study, it was decided to not include this change in the revised framework as it would potentially cause too much confusion during reading, thereby undermining the cohesion of the research.

C.1.2. Funding per phase

A second element that was incorporated in the updated version of the framework was the height of the funding required per phase. The need for this modification was strongly supported by various founders and facilitators. They underlined this thought by mentioning that health-tech spin-offs require higher investment due to the need for clinical validation and regulation. This led to a significant increase in the required funding per phase, based on the comments of the interviewees. In addition, examples are provided per phase of funding possibilities commonly used during this period. For example, for public grants, the Take-off 1 grant by NWO is generally applied during the conceptualisation phase.

C.1.3. Naming of the key facilitators and their support

In the initial version of the framework, the row stating the key facilitators solely included the types of facilitators found in literature fitting to the development phase. The latest framework validates this setup further by not only linking the types of facilitators but also stating the facilitators active in the three Dutch academic entrepreneurial ecosystems. Sequentially, in the last row, the offered support by these facilitators was corrected. Per type of support, the type of facilitators is associated.