AN INVESTIGATION OF THE ENTREPRENEURIAL BEHAVIOUR OF A GERMAN MEDTECH START-UP WITH A FOCUS ON DISRUPTIVE INNOVATION

ROBERT BAUSTEL

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It always seems impossible until it is done - Nelson Mandela

ABSTRACT

German MedTech start-ups with a focus on disruptive innovation operate with increased entrepreneurial risk in rapidly developing niche markets and have to overcome a number of hurdles before they are allowed to market their products. Although there is a constant demand for technology and product innovation from their customers, the doctors and patients, hurdles such as the resource constraints of start-ups, the impact of disruptive innovation brings and regulatory restrictions make these ventures a very vague business model.

This research project focuses on entrepreneurial behaviour, in particular on the organisational design, corporate strategy and organisational culture of German MedTech start-ups with a focus on disruptive innovation, in order to investigate the specific behavioural characteristics that can overcome these hurdles in the long term.

To answer the research question, an inductive research setting based on an interpretivist epistemological and a subjectivist ontological approach is chosen: “How is disruptive innovation in medical devices possible for German MedTech start-ups, and what is the appropriate entrepreneurial behaviour to overcome the high market barriers?” Based on the mono-methodological qualitative setting of a mini-ethnographic case study, semi-structured interviews will be conducted with employees of a German MedTech start-up to explore in depth their understanding and experience of the underlying phenomena. The thematic analysis of the rich data collected leads to themes and patterns of entrepreneurial behaviour. The latter findings are discussed based on the basis of the results of the extensive literature review, which have been synthesised into a comprehensive conceptual framework that theoretically identifies the contemporary best-in-class behavioural characteristics of a MedTech start-up.

The final findings of the discussion show that there is a large gap between the theoretical and practical characteristics of entrepreneurial behaviour. The most important findings are the lack of entrepreneurial knowledge about the specific theoretical issues related to disruptive innovation, as well as the lack of risk-taking and the formulation of an explicit innovation strategy. The underlying social research project and its findings contribute to the expansion of theoretical knowledge in this niche area of business administration. On the one hand, a new conceptual framework was developed that encompasses the characteristics of the three most important pillars - start-up organisation, corporate strategy and innovation-oriented culture - and thus leads to practical advice for German MedTech start-ups planning long-term success in dealing with disruptive innovations. On the other hand, the thematic analysis of the data obtained by conducting the mini-ethnographic case study and the subsequent discussion based on the obtained ‘should’s’ from the academic literature leads to a clear gain in theoretical knowledge and also represents a unique gain in practical contribution.

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LIST OF ABBREVEATIONS AND ACRONYMS (IN ALPHABETICAL ORDER)

AI	Artificial Intelligence
B2B	Business to Business
B2C	Business to Consumer
BCD	Business Culture Design
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte/German Federal Institute for Drugs and Medical Devices
BMBF	Bundesministerium für Bildung und Forschung/German Federal Ministry of Education and Research
BMG	Bundesministerium für Gesundheit/German Federal Ministry of Health
BVMed	Bundesverband Medizintechnologie/German Medical Technology Association
CE	Conformité Européenne/European Conformity
CEO	Chief Executive Officer
CVM	Competing Values Model
EEA	European Economic Area
EPO	European Patent Office
ERP	Enterprise Resource Planning
EU	European Union
EudaMed	European Database on Medical Devices
GDPR	General Data Protection Regulation
HCP	Health Care Professional
HR	Human resources
IPO	Initial Public Offering
IPR	Intellectual Property Rights
IVD	In Vitro Diagnostics
MBO	Management-by-Objectives
MD	Medical Device
MDD	Medical Devices Directive
MDR	Medical Devices Regulation
MedTech	Medical Technology
OECD	Organisation for Economic Co-operation and Development
OKR	Objects and Key Results
QDAS	Qualitative Data Analysis Software
QMB	Qualitätsmanagementbeauftragter/Quality Management Officer
R&D	Research and Development
RPV	Resources, Processes and Values
SME	Small and Medium-sized Enterprises
SOP	Standard Operating Procedure
UDI	Unique Device Information
UK	United Kingdom
US	United States
VAT	Value Added Tax
ZLG	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten/German Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices

LIST OF APPENDICES

University of South Wales
Prifysgol De Cymru

GRADUATE SCHOOL
YSGOL GRADDEDIGION

CANDIDATE DECLARATION

This is to certify that, except where specific reference is made, the work described in this dissertation is the result of my own research. Neither this dissertation, nor any part of it, has been presented, or is currently submitted, in candidature for any other award at this or any other University.

29 December 2022

Robert Baustel

1 Introduction

Culture eats strategy for breakfast!

This deliberately exaggerated statement, attributed to Peter Drucker, asserts in a very simplistic way that organisational culture plays a far more important role in day-to-day corporate behaviour than corporate strategy (Campbell, Edgar and Stonehouse, 2011, p. 263). Much quoted and debated, there is still no clear evidence as to whether this statement is true, but there seems to be a tendency that it is. For the present research project, it serves as the core hypothesis and thus as the starting point for an investigation of the entrepreneurial behaviour of a German 'Medical Technology' (MedTech) start-up with a focus on disruptive innovation.

The introductory chapter of this dissertation provides the framework for the underlying research project, explains the context in which the topic was chosen and identifies relevant research gaps. It also presents the research design, which includes the sequential research question, the research aim and the research objectives. Based on these core objectives of the dissertation, the underlying research philosophy and the chosen methodological approach are presented. The following sections provide an overview of the structure of the dissertation as well as the contributions and possible future research in this topic area.

1.1 Research framework

As the title suggests, this research project relates to a very narrow business area: the specific entrepreneurial behaviour of a German MedTech start-up with a focus on disruptive innovation. This section sets out the research framework to provide an overview of the scope and context of this specific 'research endeavour'.

Entrepreneurial behaviour

Corporate or, more specifically, entrepreneurial behaviour ultimately consists of all the written or lived policies in a company and can be adapted relatively quickly. It can be divided into internal behaviour (internal relations) and external behaviour (external relations). This research project focuses exclusively on the internal relations of companies, in particular the key areas of organisational design, corporate strategy and organisational culture, which together influence individual corporate behaviour.

Organisational design is the basic framework for a company and includes all decisions about the use of the company's 'human capital' that best serve the company's (innovation) success. This research project examines the specific elements of the organisational design of start-ups, how it has evolved over time and how it differs from the designs of established companies.

Corporate strategy is the formal core statement of any company and can include ideas, plans and a vision that a company has defined for its future business activities. Strategic goals are more likely to be achieved in the long term. Together with the company's culture, it is the most important lever available to managers.

Organisational culture, as the more elusive lever, encompasses all the beliefs and ideas a company has, the way it does business and the way its people behave. Because culture is neither tangible nor written down, it is harder to describe and understand than corporate strategy. Organisational culture is subject to the perceptions of different employees, but also to the perceptions of outsiders.

German MedTech Industry

In 2021, the German MedTech Industry generated an industry sales of EUR 36,4 billion and value added of EUR 15.5 billion (Beeres, 2022, p. 9). At 93%, 'Small and Medium-sized Enterprises' (SMEs) – including start-ups – are the most common type of company in the German MedTech industry. An SME-driven, highly

innovative (9% of turnover is reinvested in 'Research and Development' (R&D)) and export-strong sector (export ratio around 66) of the 'German Mittelstand' (Beeres, 2022, p. 9). Although the global covid pandemic has affected the global economy and the health sector in particular, the 'MedTech Innovation Climate Index' of the German Medical Technology Association (BVMed) has not declined (Beeres, 2021, p. 41). According to the German Federal Ministry of Education and Research (BMBF, 2022), the German MedTech sector is a very attractive market of about 1,300 SMEs that form the innovative backbone of a highly innovative and high-growth sector of the German healthcare industry. Innovations in medical technology offer great potential for the healthcare of the future and at the same time, great opportunities for start-ups and SMEs in Germany. However, the process of researching and developing medical technology solutions is becoming increasingly costly (BMBF, 2022).

Corporate Innovation

Business innovation, i.e. the invention of new products or the improvement of existing ones, has always existed in the history of the modern economy and has always been associated with the destruction of previous existence. The German philosopher Friedrich Nietzsche, with his '*Übermensch* Entrepreneur' and Zarathustra's 'creative destruction' (Reinert and Reinert, 2006), already stated in the late 19th century that "whoever is a creator always annihilates" (Nietzsche and Kaufmann, 1968, p. 59). The German sociologist and economist Werner Sombart, who appears to have been most influenced by Nietzsche's theories, first introduced the concept of 'creative destruction' into economics (Reinert and Reinert, 2006). In the early 20th century, Joseph Alois Schumpeter, an Austrian-born economist and professor at the Harvard Business School, linked the phenomenon of 'creative destruction' to innovation management. Later, the term 'creative destruction' became almost Schumpeter's trademark. In his book "The Theory of Economic Development", published in 1911, he examined, inter alia, the circular flow of economic life, entrepreneurial profit and the business cycle, and identified innovation as the crucial dimension of economic change (Pol and Carroll, 2006).

For Schumpeter, economic change is closely linked to innovation, entrepreneurial behaviour and market power (Pol and Carroll, 2006).

Disruptive Innovation

Clayton M. Christensen, former professor of business administration at Harvard Business School, first described the theoretical considerations and models behind 'disruptive innovation', a special type of innovation that leads to products penetrating lower market segments or even creating entirely new markets, in 1997. Since its inception, the theory of disruptive innovation has been studied and described in many industries, resulting in a growing number of studies and publications. However, there are still gaps in knowledge as not every dot on the map has been discovered. Hogan (2005, p. 21) describes disruptive innovation as exciting, releasing "products that challenge the status quo of an existing market". In addition, Hogan (2005) describes the challenges for a disruptive firm to bring order to 'chaos' in order to increase its chances of survival as it grows.

An initial rough literature review during the development of the research proposal for this dissertation resulted in the following figures, shown in Figure 1 below.

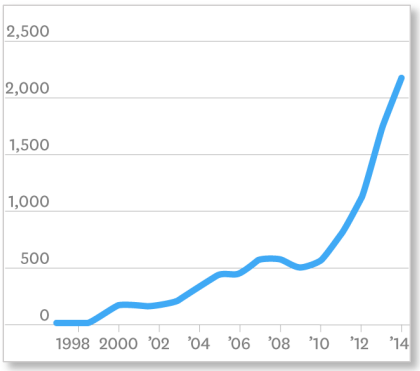

Figure 1: Number of articles in which the term 'disruptive innovation' has been used (Christensen, Raynor and McDonald, 2015, p. 50)

According to this, the total number of published articles using the term 'disruptive innovation' was quite low during the last century, but started to slowly increase since 2000, and then a dramatic increase in scientific papers published since 2010

(Christensen, Raynor and McDonald, 2015, p. 50). According to Yu and Hang (2010, p. 435), “a number of interesting research directions deserve further examinations within the disruptive innovation domain”. This highlights the obvious importance of further research and theory development, including in the more specific area of disruptive innovation in the MedTech industry.

Criticism

Recent medical device scandals in Europe, e.g. faulty hip implants, pacemakers and breast implants leading to thousands of injured patients and many deaths, have filled numerous newspapers in recent years (Reuß, 2018; Schirer and El Mokhtari, 2018) and have been discussed in research papers (Cohen, 2012a, b; Godlee, 2016; Horton, 2012; Korzillus, Zylka-Menhorn and Gießelmann, 2018; McCulloch, 2012; Watson, 2016). This has sparked a debate about whether there is still a need for further innovation in the MedTech sector and whether greater patient protection, e.g. in the form of stricter market regulation, is needed. These and other critical discussions are justified and are presented in detail in the literature review section, based on the latest evidence.

Research context

With a strong academic background in commercial law and business administration, and having worked for more than half a decade in the life sciences practice of a large international law firm, handling various medical device product liability cases, the question of how far regulation can go in the interests of patient safety before it stifles life-saving innovation in medical devices kept coming up. The German Federal Ministry of Health (Bundesministerium für Gesundheit (BMG)) recognised the dilemma and addressed it in a publication on the market access requirements for medical devices in Germany following the introduction of the ‘Medical Device Regulation’ (MDR), stating that the aim of this regulation is not to hinder innovation and rapid access to innovative products for patients, while at the same time ensuring the safety of the products and their benefits for patients at a uniformly high level (Bundesministerium für Gesundheit, 2022). Reflecting on this

dilemma led to the recurring question: Are disruptive innovations in medical devices even possible? And if so, how can start-ups – as the companies most exposed to entrepreneurial risk –market these products profitably, given the very limited availability of financial and human resources? These questions will be fleshed out in the next section when it comes to the explicit research design.

Research gap

The in-depth research in the specific areas of start-up entrepreneurial behaviour and disruptive innovation is incomplete and lacks coherence. The following citations found in the literature highlight the apparent research gap.

In their paper, McAdam and Cunningham (2019, p. 7) highlight the need to advance research on entrepreneurial behaviour to better understand "how entrepreneurs create, develop, sustain and grow new organisations". In relation to organisational culture, Hogan and Coote (2014, p. 1609) note that "the existing literature does not sufficiently document the characteristics of an organisational culture that supports innovation". Pöllänen (2021, p. 117), in her recent study of start-up culture, found that there is a lack of academic research "on organizational culture in small, newly founded innovative companies such as startups". This in line with Denison, Haaland and Goelzer (2004), who point out that although researchers have developed an integrative framework for organisational culture, there is little consensus on a general theory. Jassawalla and Sashittal (2002, p. 42) call for "the voices of managers involved in real-life product-development processes and concrete illustrations of existing conceptual developments and research findings about the culture-innovation linkage", as currently available theories offer little help to innovation-oriented managers. In her article on ‘future literacy’, Bendig (2021) poses the question: “How can we plan for an uncertain tomorrow?”. The faster society changes, the greater the present bias, the higher the risk aversion, the worse our ability to read the future and translate it into behaviour. She goes on to apply these societal phenomena to companies and their managers, who remain stuck in hierarchies and lack long-term strategies, "the small amount of imagination that

remains is then lost in pure discourses of fear and risk" (Bendig, 2021). By reflecting, discussing and provoking our ‘thinking box’, our limits, beliefs and premises for action in the light of possible futures, out-of-the-box futures become conceivable and feasible. The latter findings provide an important glimpse into the future and thus point to possible emerging gaps that should be further considered.

In publishing his paper ‘The Ongoing Process of Building a Theory of Disruption’, Christensen (2006) called for further debate, research and analysis of the impact of new technologies on organisations and customers so that the knowledge gained would further improve his theory of disruptive innovation. Although Christensen has spent his entire life researching disruptive elements in healthcare, he has not focused on disruptive product innovation in medical devices.

Zien and Buckler (1997, p. 276) add to the ‘list of gaps’ by claiming that all innovative companies probably share the same ‘key’ and principles, but that each company’s “implementation ‘formula’ is particular and specific to the company”. The latter suggest that there is a 'DNA' for start-ups and that needs to be deciphered.

Haines (2016, p. 176) describes the need for ethnographic research in start-ups in particular because, although there are ‘design thinking’ approaches that have been incorporated into start-ups, “ethnographic research is not known or understood within the startup world”. She refers to the dilemma that start-ups are inherently “cash-strapped and scrappy by nature” and therefore do not have the resources to employ ‘dedicated researchers’ (Haines, 2016, p. 187).

A thorough search for relevant academic research on the internet platform ‘EThOS’, where more than 600,000 dissertations can be found, revealed a similarity between the present research topic and the dissertation of Heiss (2017). Heiss’ research project examined strategic factors for the internationalisation of German MedTech SMEs and found that “the impact of research in the specific field of German MedTech SMEs is relatively poor”. In his master’s thesis on the characteristics of

disruptive innovation in the medical device industry, Berlin (2011, p. 2) found that there is “limited body of work related to innovation within the medical device industry”, “specifically, literature that examines the application of the principles of disruptive innovation to the medical device industry is limited in scope and quality”, and called for further research in this area.

The non-exhaustive list of citations illustrates the numerous knowledge gaps in research on start-up entrepreneurial behaviour and thus the importance of this specific research project, which explores the areas of disruptive innovation and entrepreneurial behaviour, including organisational design, strategic planning and innovation-oriented culture, and combines current theoretical knowledge with practical findings to contribute to the current pool of theoretical knowledge. The research design that follows in the next section will pave the way for answering the overarching research question through an empirical mini-ethnographic case study.

1.2 Research design

This section presents the underlying design of this research project, including the research question that defines the research aim and objectives, the overarching research philosophy and the research method ultimately chosen.

1.2.1 Research question

Following the previously defined research framework and context, the explorative research question of this dissertation is formulated as follows:

> How is disruptive innovation in medical devices possible for German MedTech start-ups at all, and what entrepreneurial behaviour pattern is appropriate to overcome the high market barriers?

1.2.2 Research aim

The research aim is set in order to answer the research question through empirical social research. While the research aim specifies 'what' is to be studied, the research objectives are concerned with 'how' the research aim is to be achieved. Based on the research question, the research aim is:

> To investigate whether disruptive innovations in medical devices also lead to specifically disruptive entrepreneurial behaviour among German MedTech start-ups.

1.2.3 Research objectives

The aim of this research project, as described above, was summarised in the following three research objectives:

(1) To assess whether disruptive innovations in medical devices are at all possible for German MedTech start-ups and, if so, to identify favourable and unfavourable factors influencing the entrepreneurial behaviour of German MedTech start-ups with a focus on disruptive innovations.

(2) To combine the most favourable components of organisational design as well as the crucial corporate, strategic and culturally modifiable 'human factors' that influence the entrepreneurial behaviour of innovative German MedTech start-ups into a comprehensive conceptual framework.

(3) To test this conceptual framework using empirical methods and to derive recommendations for the organisational design and corporate strategic and cultural orientation of German MedTech start-ups with a focus on disruptive innovations.

1.2.4 Research philosophy and methodological approach

Looking at the research question, the aim and the objectives, it quickly becomes clear that the research field is limited to a small group of potential German MedTech start-ups dealing with disruptive innovations. The appropriate research philosophy and method must be adapted to these circumstances.

In discussing the various philosophical assumptions related to social research, the research underlying this dissertation will be based on constructivism, a subjective ontological standpoint that is best suited to achieve the research objective. The research will focus on social actors as they have the capacity to think creatively and bring their thinking into existing processes. From a subjective epistemological standpoint, social constructionism advocates the creation of evidence by a participant observer who collects rich data from which ideas are derived from a small number of specially selected cases.

Social constructivist philosophy, which adopts an interpretivist approach to theory development with an inductive strategy, fits perfectly with the research objectives outlined and will provide sufficient data that can be analysed and interpreted to extend the knowledge gathered in the literature and potentially provide new insights.

Consequently, the latter assumptions lead to the conclusion that the underlying research is subject to the interpretive paradigm, which is characterised by the attempt to understand the world as it is, in order to understand the fundamental nature of the social world at the level of subjective experience.

From a social constructivist philosophical perspective, this research will use the qualitative method of a mini-ethnographic case study to best achieve the set research objectives, incorporating individual aspects from both worlds. The validated blended method combines an ethnographic approach for detailed and systematic study of cultures with a case study protocol for, inter alia, detailed investigation of a situation to explore and uncover complex issues.

1.3 Outline of the dissertation

Based on the research question, aim and objectives, the first theoretical part of this dissertation will investigate whether disruptive innovation is possible in the German MedTech sector and, if so, which restrictions exist. With a focus on the entrepreneurial behaviour of German MedTech start-ups that intend to innovate and market medical devices according to the theory of disruptive innovation, the second part of this dissertation will then examine the entrepreneurial behaviour of these very specific disruptive innovators with practical means.

Figure 2: Outline of the dissertation process

An explicit roadmap for this project has been developed, which divides the project into two parts. The 1st part, the literature review of chapter 2, is intended to provide an in-depth insight into the German MedTech industry, the areas of disruptive innovation and entrepreneurial behaviour, and to serve as the theoretical basis for this research project. Section 2.2 summarises the key aspects of the German MedTech industry, which is based in a promising, thriving MedTech market. This is followed by section 2.3, the introduction to the characteristics of (disruptive) product innovation in the MedTech industry. Finally, section 2.4 on entrepreneurial behaviour lays the foundation for a conceptual framework developed from the previous as well as the now added theoretical insights in the areas of start-up organisational design, corporate strategy and innovation-oriented culture. On the basis of the defined thematic focus and the research aim and objectives, the results of the literature review are used to combine the crucial organisational, strategic and cultural factors of start-ups in the German MedTech sector that develop and market disruptive innovations into a comprehensive theoretical framework.

The results of the literature review are essentially needed to carry out the 2nd part of the dissertation, the empirical social research, which is based on knowledge gained through experience. According to Yin (1994, p. 12), “empirical research advances only when it is accompanied by logical thinking, and not when it is treated as a mechanistic endeavour”. Following on from the findings of the 1st part, empirical social research should be used to investigate in depth the entrepreneurial behaviours mentioned above, using the carefully discussed and finally selected methodology and methods. The empirical research should (in the best case) validate the proposed lessons with scientific methods and add something new to the existing body of knowledge in the field of the German MedTech industry. The overall methodology and methods that will lead to the best possible results from this research project still need to be defined by logical conclusions.

The philosophical journey begins in chapter 3 with an in-depth look at the research methodology that underpins all social science research. The different ontological and epistemological positions are presented and discussed, the most appropriate philosophical positions for this particular research project are selected, and the most appropriate research design and methods are chosen to best achieve the research aim and objectives. Balancing all philosophical positions with the underlying aim and objectives, the research follows the social constructionist approach. A comprehensive ethnographic case study with long-term observation and cross-case analysis could not be carried out due to a very limited sample size of suitable companies, scarce resources and a limited research period. Therefore, a focused mini-ethnographic case study following an inductive social constructionist approach is the preferred method to best answer the research question with the available resources.

Finally, the findings of the case study are analysed and discussed with the results of the theoretical literature review in chapter 4. Section 4.4 presents the findings of the discussion that contribute to the body of knowledge. The dissertation concludes with chapter 5, which presents the contribution to theoretical knowledge and

practice, summarises the limitations of the research and provides an outlook for possible further research.

1.4 Contributions and further research

The research findings are intended to help market participants to accumulate knowledge in the area of entrepreneurial behaviour and to gain market advantage by applying the – yet to be validated – 'game-changing' critical skills. As the underlying research is very specific to the German MedTech market in direct relation to the innovation and/or distribution of disruptive medical devices, the concrete findings can only be transferred to other markets or industries with great caution. The final findings are explicitly intended to help German MedTech start-ups adapt their corporate strategy and culture in order to strengthen their position vis-à-vis competitors and established companies in the (white space) markets in which they operate or in the niche markets they create through the distribution of their disruptive medical devices.

The findings will be useful for both academic and professional platforms as they examine the entrepreneurial behaviour of start-ups in the German MedTech industry and provide new theories for academics and guidelines for managers and professionals.

This study has made an important key contribution to theoretical knowledge in three ways: it has introduced a new perspective on entrepreneurial behaviour, provided a unique conceptual framework and validated the findings empirically. The empirical investigation of the theoretical antecedents of disruptive product innovation to finally gain insight into the possibility of a 'disruptive pattern' in entrepreneurial behaviour adds another piece to the knowledge puzzle.

This study also makes a practical contribution by providing an up-to-date and uniquely comprehensive list of characteristics, summarised in a conceptual framework that prescribes a ’disruptive pattern’ of entrepreneurial behaviour and serves as a kind of blueprint for the entrepreneurial behaviour of start-ups in the German MedTech industry that focus on disruptive innovation.

Further research could be a more comprehensive multi-case study, for example focusing on several start-ups in the MedTech industry, to improve and substantiate the findings (Yin, 2018). The latter would meet the requirements to introduce quantitative methods and thus provide statistical evidence. In addition, future research could pursue a combination of qualitative and quantitative data collection and use a mixed methods research design to compensate for the weaknesses of specific qualitative or quantitative methods (Robson, 2002; Stake, 1995).

2 Literature review

2.1 Introduction

The literature review was conducted to provide a sound contextual and theoretical basis for answering the above research question, aim and objectives. It is mainly based on information from professional journals as a solid, peer-reviewed academic source. In addition, the review draws on legal texts and standards, as well as studies, scholarly books and conference papers, which can be considered as the most reliable academic sources. Where non-academic books are cited, they have been selected to provide important insights from a practical perspective that meet the specific requirements of a professional doctorate on which this dissertation is based.

The review is divided into three parts, starting with the most important contextual aspects of the German MedTech industry, in order to provide an accurate overview of the external aspects affecting start-ups in this specific industry sector in the light of this research project. Furthermore, the theoretical aspects of disruptive innovation will be presented and their impact on the previously presented MedTech industry will be shown. Following on from the core theme of this dissertation, the third section presents the entrepreneurial behaviour of start-ups operating in the aforementioned MedTech industry and engaging in disruptive innovation, in particular organisational design, corporate strategy and organisational culture, in its theoretical contours and practical implications on the basis of the available literature. Finally, the results of the literature review lead to the development of a unique conceptual framework that bundles and illustrates the most important characteristics of the areas of organisational design, corporate strategy/innovation strategy and innovation-oriented culture. This conceptual framework is then further used in the 2nd part of this dissertation to test it in a mini-ethnographic case study and to gain new theoretical insights.

2.2 Key aspects of the German MedTech industry

2.2.1 Introduction

In order to understand the totality of this research project, it is essential to understand the context in which the start-ups studied operate, to define the term ‘medical device’ and to examine the facts and binding laws, rules and regulations – the boundaries – as well as ethical considerations of the German MedTech industry as the target market on which this research project focuses. A look at the current market figures will also underline the importance of this research project in a steadily growing market.

2.2.2 Definition of medical devices

Medical devices play a crucial role in the diagnosis, prevention, monitoring and treatment of diseases (European Commission, 2017). Article 2 No. 1 of Regulation (EU) 2017/745, the so-called ‘Medical Device Regulation’ (MDR) of the European Parliament and of the Council of 5 April 2017, legally defines medical devices in the European Union (EU) as follows:

> ‘Medical device’ means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
> - diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
> - diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
> - investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
> - providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by

> pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
>
> The following products shall also be deemed to be medical devices:
>
> - devices for the control or support of conception;
> - products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point (European Parliament and Council of the European Union, 2017, p. 15).

The German Federal Institute for Drugs and Medical Devices (BfArM) has published a detailed list of medical devices on its website:

> Implants, products for injection, infusion, transfusion and dialysis, human medical instruments, medical software, catheters, pacemakers, dental products, dressings, visual aids, X-ray equipment, condoms, medical instruments and laboratory diagnostics. Medical devices are also products containing or coated with a substance or preparations of substances which, when used separately, are considered to be medicinal products or constituents of medicinal products (including plasma derivates) and are capable of exerting an effect on the human body in addition to the functions of the product (BfArM, 2022).

With the exception of in vitro diagnostic medical devices and active implantable medical devices, the MDR, Annex VIII, divides medical devices into three classes according to their specific level of risk. All low to medium risk medical devices are grouped in ‘class I’ and represent rather innocuous medical devices such as medical apps, reading glasses, wheelchairs, gauze and thermometers. All medical devices with a medium to high risk are grouped in ‘class IIa’, e.g. dental fillings, X-ray films, hearing aids and ultrasound devices, and in ‘class IIb’ medical devices, e.g. intraocular lenses, condoms, X-ray devices and infusion pumps. Class III medical devices are those with a high-risk potential, such as hip and knee implants,

cardiac catheters and breast implants. It goes without saying that the level of education/training for the correct use of a medical device increases with the above classification (European Parliament and Council of the European Union, 2017, p. 141 ff.).

Medical equipment used to treat patients is very sensitive. Any malfunction of a device can lead to a failure of therapy for a patient. In the worst case, a patient may even be harmed by the incorrect use or malfunction of a medical device. For this reason, the EU and the national (health) authorities have adopted laws, rules and regulations to best protect patients from misuse or malfunction of medical devices and to ensure optimal health protection.

These regulations limit the ability of companies to develop and market medical devices. Therefore, medical device innovation is hampered by many rules, laws and regulations. A further analysis of the negative impact on medical device manufacturers and the impact on innovation is provided in section 2.2.6.

2.2.3 Characteristics of the European MedTech industry

According to Vlckova and Thakur-Weigold (2020), there is no single definition of ‘MedTech’ in either academic or industry literature. MedTech Europe (2022, p. 4) describes medical technologies as “products, services and solutions used to save and improve people’s lives […] from prevention to diagnosis to cure”. They can be divided into three categories: ‘Medical devices’ (MDs), ‘In vitro diagnostics’ (IVDs) and ‘Digital health’ (MedTech Europe, 2022, p. 4).

As Germany is a founding member and integral part of the European Economic Area (EEA) and the EU since its inception in 1957 and 1958, it is necessary to analyse the overall market conditions as well as the laws, rules and regulations of the EU market, as these are superior and binding for the German market.

Medical devices are the essential foundation for health and quality of life in our society. As the healthcare sector faces challenges such as societal/cultural changes (e.g. the ageing of European society, which will lead to several 'tsunamis' in Europe over the next two decades (Yanguas et al., 2017)) and the foreseeable global shortage of health professionals in the future (World Health Organization, 2016, p. 44), increasing patient expectations (e.g. reducing health inequalities in the EU (Mackenbach, Meerding and Kunst, 2007)) and the demand for increasing quality of care (Legido-Quigley et al., 2008), as well as the emergence of new medical technologies (e.g. e-health technologies, telemedicine and minimally invasive surgery) (European Commission, 2010). To address these challenges, the members of the 2010 exploratory process decided to further develop 'efficiency-based medicine', i.e. "innovative technologies that improve the efficiency and quality of public health management programmes around patient safety and productivity of healthcare systems" (European Commission, 2010, p. 7). It was also decided to "improve the development and use of clinical, economical and societal evidence for medical devices" that "should increase the use of appropriate screening and early-diagnosis programmes to both improve patient outcomes and drive efficiency" (European Commission, 2010, p. 7). Mechanisms should be put in place "to ensure a robust evaluation and rapid access to market for innovative products and services with added value" (European Commission, 2010, p. 9), the latter meaning that disruptive innovations are excluded from this initiative as they explicitly consist of lower performance (see section 2.3 ff. for a detailed definition of disruptive product innovations). Furthermore, "the dissemination of valuable developments in other sectors into the medical device sector should be facilitated" (European Commission, 2010, p. 9).

Nevertheless, the EU is the largest global market for medical devices after the United States (US) (European Commission, 2010, p. 8). The sector has become increasingly important for the healthcare of EU citizens and influences spending. In the EU, the MedTech sector is a major employer, employing around 800,000 peoples (MedTech Europe, 2022, p. 16). Total turnover in 2021 will be

EUR 150 billion, generated by more than 34,000 MedTech companies, of which around 95% are SMEs (MedTech Europe, 2022, pp. 20, 26).

The attractiveness of the EU as a market for innovative medical devices is reflected in the number of 15,300 MedTech patent applications filed with the European Patent Office (EPO) in Munich in 2021 (MedTech Europe, 2022, p. 12). Patent applications from EU countries account for 41% of the total, with 59% coming from other countries, including 38% from the US (MedTech Europe, 2022, p. 12). The long-term study shows a significant increase in MedTech patent applications (see Figure 3). While the number of MedTech patent applications has increased almost continuously, the number of biotechnology and pharmaceutical patent applications are stagnated (see Figure 3).

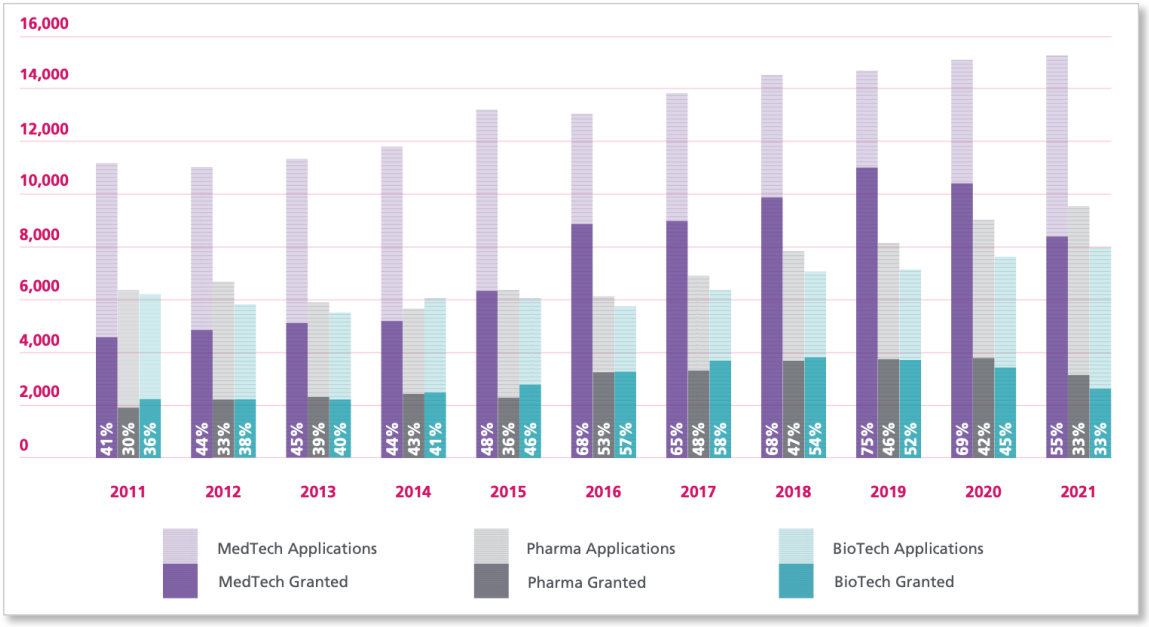

Figure 3: Evolution of European patent applications to the EPO by technical field (MedTech Europe, 2022, p. 14)

The largest markets for MedTech/devices in 2021, based on manufacturer prices, will be Germany with 25.8%, France with 14.3%, the United Kingdom (UK) with 10.4% and Italy with 9% (MedTech Europe, 2022, p. 27). Globally, the US leads the medical device market with 43.5%, followed by Europe with 27.3%, China with 7.2% and Japan with 5.6% (MedTech Europe, 2022, p. 29). These figures underline

the attractiveness and positive development of the MedTech market in Germany/Europe, also in comparison with the large competitive markets of the US, China and Japan.

This section has provided an insight into the status quo of the European MedTech market and its attractiveness, as the figures indicate a positive future development of the market. There is still a lack of information on theoretical considerations of how the European MedTech industry, to which the German MedTech industry is also linked, will change in the coming years.

2.2.4 Medical device innovation

By its very nature, the global health sector consists of countless medical researchers in medical schools and teaching hospitals, generating new and improved knowledge every day. This new knowledge will enable further technology-based research and development, which will lead to new technological inventions and ultimately product innovations. As a result, new business opportunities are constantly being created. This demand-led approach to medical device innovation has been analysed by Mokyr (1998). According to Mokyr (1998), the evolution of medical devices follows the models of blind variation with selective retention (the models associated with the Darwinian paradigm). This was extended by Ramlogan and Consoli (2008) who stated that the history of medicine demonstrates that there are theoretical, methodological and philosophical issues that influence the selective retention of technologies and prevent the selection of a particular research path in a particular medical field. Ramlogan and Consoli (2008) argue that medical innovation is a long-term process based on two factors: The growth in the ecology of knowledge forms and the creation of coordination mechanisms within different knowledge forms and different fields.

Dosi (1988), concerned with the technical and procedural understanding of knowledge, claims that the growth of knowledge is a path-dependent process. Based on Dosi's notion of the path-dependent nature of medical innovation,

Langlois and Savage (2001) claim that the main reason for medical innovation is the accumulation and recombination of accumulated knowledge based on the social understanding of the origin of feedback. Metcalfe, James and Mina (2005, p. 1292) state that “medical innovations should be seen as trajectories of improvement sequences in which procedures are progressively refined and extended in their scope of application”. Mina et al. (2007) argue that the process of medical innovation is neither random nor fully organised, following Dosi’s view that medical innovation is path-dependent and constrained by people’s awareness of the problem. Ramlogan and Consoli (2008) conclude that the accumulation of medical knowledge is the result of change pathways (sequences of innovative ideas). Blume (1992) confirmed the finding that most innovation studies of medical technologies focus on the nature and development of these technologies and insist on the path-dependent and evolutionary nature of medical innovation. While most studies of medical innovation focus on decisions to adopt existing technologies, Ramlogan and Consoli (2008) point out that much of the literature seems to downplay the process that leads to the creation of new medical technologies. While most scholars take an evolutionary approach to medical innovation, the importance of discontinuous and disruptive innovation in the development of medical knowledge is completely ignored. This suggests that the adoption of new medical innovations is an immature area in the field of medical device innovation and that further research is needed.

It is also clear that health insurers and national health systems have a strong interest in cheaper products that have almost the same functionality as their predecessors or that significantly reduce the cost of medical treatment, which drives innovation in disruptive medical devices.

Consoli et al. (2005) argue that it is mainly the dynamic relationship between the development of scientific knowledge and the application of techniques in clinical practice that leads to continuous innovation trends in medical technology. According to Murray (2002) and Thune and Mina (2016), the role of hospitals as the

main source of active feedback in medical innovation systems should be considered (see Figure 4).

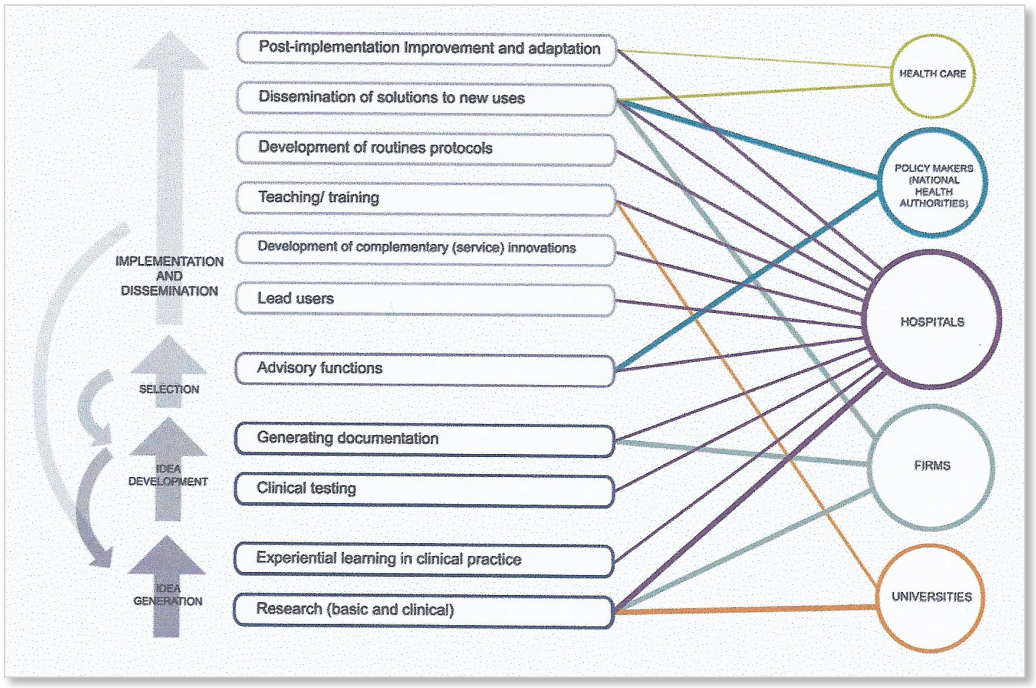

Figure 4: The role of hospitals in innovation (Thune and Mina, 2016, p. 1547)

Fuchs and Sox (2001) argue that the different nature of MedTech objects and problems can lead to uneven knowledge production in MedTech (Rosenberg, Geljins and Dawkins, 2005). However, the collaboration of different key stakeholders such as physicians, scientific researchers and hospitals is needed to balance the unevenly produced knowledge through the mutual interaction of scientific knowledge and applied technologies (Consoli et al., 2005; Consoli and Mina, 2009).

Blume (1992) and Gelijns and Rosenberg (1994) have highlighted the interactive relationships of a wide range of disciplines, agencies and institutions between business, clinicians and academic scientists. Different scholars have developed different conceptions of the medical device innovation system. According to Rosenberg (1976), medical innovation is demand-intensive, which implies the existence of technological capabilities (Gelijns and Rosenberg, 1994).

In contrast, Mokyr (1998) argues that the cliché ‘necessity is the mother of innovation’ is absurd. According to him, innovation arises in an unstable situation as a result of frequent exogenous changes in pathogens in a medical setting. Following Rosenberg (1976), Gelijns and Rosenberg (1994) added that the biological demand for medical innovation is more important than the social demand brought into play by Gelijns, Zivin and Nelson (2001). This leads to the assumption that biological technology has a greater influence on medical innovation than social needs (Mina et al., 2007).

2.2.5 Market barriers

Despite the above positive facts about the medical device market and medical device innovation, there are also obstacles to overcome for innovative companies in the medical device sector. Due to the sensitivity of medical devices, manufacturers have to overcome several hurdles before a product can be marketed in the EU. Patient safety is the keyword and is underlined by several laws, rules and regulations at EU and national level, which are also hurdles for manufacturers to overcome. Bergsland, Elle and Fosse (2014) summarise the barriers to medical device innovation as follows:

(1) Medical practice patterns and education;
(2) Market size and penetration;
(3) R&D and device failures;
(4) Regulatory limitations, and approval processes;
(5) Intellectual Property Rights (IPRs), patent limitations, and publication issues;
(6) Reimbursements, pricing, and payments; and
(7) Ethical considerations (Bergsland, Elle and Fosse, 2014, p. 206).

The list illustrates the variety of barriers faced by companies trying to sell their medical device innovations in a market. Regulatory restrictions as the main barrier

to bringing medical devices to market and their impact on medical device innovation are presented in the following sections.

2.2.5.1 EU conformity declaration

Before they can sell their medical devices on the EU market, manufacturers must obtain the 'CE marking' (CE stands for 'Conformité Européenne' / 'European Conformity') for each of these products, indicating conformity with health, safety and environmental standards for products sold within the EEA. The CE marking should not be confused with a quality mark. The CE marking indicates that a product complies with the applicable EU directives and regulations, which means that the product can be marketed in 28 EU countries (including the UK). CE marked products meet the specific standards of performance, quality, safety and efficacy for the type of product. The legal manufacturer of medical devices is solely responsible for complying with the legal requirements and ensuring the CE marking of its medical devices, regardless of whether you outsource any or all components of your manufacturing process. Due to the different risk classifications of medical devices established by the European Parliament and the Council of the EU in Annex IX of the MDR (European Parliament and Council of the European Union, 2017), medical device manufacturers have to apply different rules depending on their specific classification (see section 2.2.2) before they are allowed to affix the 'CE mark' to their products and sell them on the EU market. The more a product can harm the human body or 's health, the stricter the rules to be applied. For both start-ups and established companies, risk classification is a potential barrier to market entry, as they must ensure that all the laws and regulations are complied with and met before a new medical device can be placed on the market. In order to meet all conformity requirements, an approved third party ('notified body') must be involved in the conformity assessment procedure or in the establishment of a production quality system, the level of involvement depending on the level of risk. On the contrary, once the CE marking procedure has been successfully completed, manufacturers do not have to fear as many competing manufacturers as, for example, in a market with fewer laws and regulations (e.g. consumer/electronic

products), as competing manufacturers have to assess the feasibility of placing a new medical device on the market due to the conformity assessment hurdles.

2.2.5.2 Incident reports

In addition, all national health authorities in the EU evaluate so-called incident reports. These reports relate to medical devices on the market that have recently caused an incident, such as a death or a deterioration in a patient's health. These incident reports are submitted to the authorities by the treating doctors or hospitals, but also by the medical device manufacturers themselves. Depending on the seriousness of the incident, the health authorities will publish warnings on their websites and send warning letters to the persons/patients affected by the incident. If the medical device in question needs to be modified, the health authorities will also make a recommendation to the manufacturer to modify the affected product. In Germany, for example, the state authorities are also informed, as they are legally empowered to force the manufacturer to modify the product in order to restore patient safety.

2.2.5.3 Clinical trials

Clinical testing of medical devices is another hurdle that manufacturers must overcome. Whenever there is no clinical data available from the literature and clinical experience, or clinical trials are inadequate, clinical trials must be conducted. These clinical trials need must be approved by the national health authorities and are conducted on volunteer patients to gather data on the safety and/or performance of the medical device, which can only be verified in clinical trials.

2.2.5.4 Limitation of demand

Another barrier is the natural limitation of demand for medical devices. As most of these products are not subject to the emotional purchase decision of customers, but to the rational medical diagnosis of treating physicians, there is a natural limit to the quantity of medical products needed in a market segment. Not all segments of

the healthcare sector are characterised by the same demand. As there are variations in pathologies, the manifestations of these varies. Therefore, the demand for products needed for different pathologies is highly dependent on these.

In general, a distinction must be made between medical devices that can be purchased directly by patients (consumer medical devices) and medical devices that are used by doctors in their practices or in hospitals and that patients cannot to take home or even buy (professional medical devices). Both categories are subject to the same laws and regulations as the above-mentioned medical devices. Consumer medical devices can be advertised and benefit from an open business-to-consumer (B2C) market. However, business-to-business (B2B) professional medical devices are regulated by national health insurance schemes and associations, which partly fund the products and therefore have a strong control over the market. These regulated markets do not encourage manufacturers to enter the market without a high risk of failure due to non-compliance before a single product is sold.

2.2.5.5 Ethical aspects

There are also ethical reasons that may create barriers to the sale of medical devices. As defined in section 2.3 ff., a disruptive product innovation is based on selling products with inferior technology/features compared to established products, but also at a significantly lower price. This raises the question of whether it is ethically justifiable to treat patients' illnesses with products that have inferior functionality to products already on the market, but at a significantly lower cost. Health insurers and associations may demand lower-priced products, but is it still ethical to treat patients with medical devices with inferior features? Christensen, Grossmann and Hwang (2009) analysed the healthcare industry and found that there is likely to be a conflict of interest. On the one hand, we are currently overserving many patients who will never accept a service that is less promising than the one we have today. On the other hand, the healthcare system is demanding cost-sensitivity and, therefore, disruptive innovation in the medical

device sector. Christensen, Grossmann and Hwang (2009, pp. 317-318) list several examples of how medical procedures have changed over the years, while disruptive technologies have changed them in a sustainable way. These medical procedures – presumably to cure the patient's disease in a more common way – and many other examples cited in their book demonstrate the existence and therefore the need for disruptive innovation in the medical device sector, despite all the ethical issues surrounding this topic.

2.2.6 Impact of Regulations on Medical Devices Innovation

In May 2017, the European Council, the European Commission and the European Parliament adopted the new MDR (European Parliament and Council of the European Union, 2017), which replaces the existing Medical Devices Directive (MDD) from May 2021. The new regulation has far-reaching implications for medical device manufacturers, inter alia, but also for Notified Bodies, which play an important role in the certification process of medical devices.

2.2.6.1 The primary paradigm of patient safety

Rosentreter (2017) mentions that the definition of patient safety "contains the moral implication of protecting patients from harm in the context of curative treatment and thus touches the ironclad medical principle of *Primum nihil nocere* – the imperative of no-harm" (Rosentreter, 2017, p. 102; translation by the author), known from the fundamental tenet of medicine, the 'Hippocratic Oath'. Ensuring patient safety is therefore always at the forefront of innovation and the introduction of new medical devices. According to Mattox (2012, p. 60), any malfunction of a medical device that results from an error, accident or an unintended event that could lead to patient injury should be strictly avoided. The European Commission (2017, p. 1) noted that "problems with diverging interpretation of the existing rules as well as certain incidents – e.g. with breast implants and metal hips – highlighted the weakness of the current legal system and damaged the confidence of patients, consumers and healthcare professionals in the safety of medical devices". As a result, a process was launched to rethink and ultimately replace the previous directive with the new

regulation. These changes raise the question of whether the new regulation has only positive effects on patient safety. According to Mattox (2012, p. 60), various studies have shown that the development of healthcare technology does not automatically improve the corresponding product quality or patient safety.

2.2.6.2 Newly implemented regulation

The amendment merged the former MDD (Council Directive 93/42/EEC), which dates back to the 1990s, into the MDR. Unlike EU Directives, EU Regulations are directly applicable and legally enforceable in all Member States, which underlines the importance of the new Regulation.

Various changes have been made to the new Regulation which, according to the European Commission (2021a, p. 32), will "ensure better protection of public health and patient safety". The Regulation contains some significant changes for customers and medical device manufacturers. These include:

- better protection of public health and patient safety. In particular high-risk devices are going to be subject to stricter pre-market control. Certain aesthetic devices (such as coloured contact lenses or equipment for liposuction) presenting high-risk to consumers and practices such as reprocessing of single-use devices are included in the scope of the new Regulations and made subject to a stricter and more harmonised regime. Rules on clinical evaluation and clinical investigation (and, for in-vitro diagnostic medical devices, performance studies) are generally strengthened and stricter requirements on the use of hazardous substances are introduced.
- a comprehensive EU database on medical devices (EUDAMED) that will contain a living picture of the lifecycle of all products being available on the EU market. A large part of the information will be made publicly available, including a newly introduced summary of safety and performance for all Class III and implantable devices. The Commission is

required to set up the database by spring 2020 and to maintain it thereafter.

- a new device identification system based on a unique device identifier (UDI) that will allow easier traceability of medical devices.
- an 'implant card' for patients containing information about implanted medical devices that will make information easily available and accessible to the particular patient.
- a robust financial mechanism to ensure patients are compensated in case they receive defective products. The Regulations require manufacturers to have measures in place to provide sufficient financial coverage in respect of their potential liability. Such financial coverage shall be proportionate to the risk class, type of device and the size of the enterprise. This should allow patients to be rapidly and effectively compensated, also in case of financial bankruptcy of the relevant company (European Commission, 2017).

The new MDR has replaced the former MDD in 2021. During a transition period starting in 2017, manufacturers were required to change the approval process for their products, assess any gaps in the new approval processes, and switch to these processes to meet the requirements for clinical trial processes, as well as planning and reporting obligations to the new EudaMed-/UDI database system.

Beeres (2021) presented the results of an online survey of BVMed member companies conducted in autumn 2020 on the topic of possible obstacles to MedTech development in Germany:

- Additional requirements due to the MDR (81%)
- Obligation to provide comprehensive clinical data due to MDR (71%)
- Longer conformity assessment periods (62%)
- Anti-innovation attitudes of health insurers (40%) (Beeres, 2021, p. 39; translation by the author).

The above-mentioned key responses from this survey clearly show that the companies concerned see the newly installed MDR, with its additional requirements, as an obstacle to MedTech development in Germany. More resources are needed in MedTech companies to comply with the 'innovation-hostile' Regulation, which causes major problems for start-ups and SMEs in particular.

2.2.6.3 Impact of regulation on innovation

The European Commission (2017, p. 3) emphasises that the new Regulation will achieve "a consistently high level of health and safety protection for EU citizens using these products", while noting that it will also have "a potential boost to SMEs active in this sector". Although they predict that the simplified administrative procedures, the increased legal certainty and the enhanced credibility and reputation of the overall system will have a positive impact on the industry, there are critical voices from German officials and association representatives, such as from the BMG, the German Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) and the BVMed. As Germany is home to the largest number of medical device manufacturers in Europe, these bodies are planning to set up a national support initiative for SMEs, which they see as disadvantaged by having to deal with more regulatory processes than before, even though the registration process for medical devices is to be simplified at EU level. They state that the new certification of products already on the market will be an additional burden for SMEs. Furthermore, the MDR requires manufacturers to appoint a "person responsible for regulatory compliance" to oversee the manufacturer's quality management and post-market surveillance system "in a manner that is proportionate to the risk class and the type of device" (European Parliament and Council of the European Union, 2017). Although SMEs are not required to employ regulatory compliance managers, they must have such a person 'at their disposal' on a permanent basis.

A closer look at the structure of the European medical device market - in its role as the world leader in this sector - reveals that there are currently over 500,000 different medical technologies available to consumers (MedTech Europe, 2022, p. 5). The majority of these medical devices are innovated, developed, manufactured, and sold by SMEs, which currently account for 95% of the medical device market (MedTech Europe, 2022, p. 20). It should be obvious that global incumbents with up to 65,000 employees (e.g. the leading global healthcare company Siemens Healthineers states on its homepage that it will employ more than 66,000 people in 2022) can more easily adapt their human and financial resources to the new regulatory requirements than SMEs with their limited resources due to their limited company size. Most incumbents have separate business units dedicated to regulatory requirements to ensure that new products meet the regulatory standards and can be sold in the most time and cost efficient way. SMEs and their high potential to innovate new products - which is higher than the innovation potential of highly organised incumbents (OECD, 2011) - and sell them on the EU market are therefore disadvantaged as changes to the regulatory framework increase their costs and strain their limited resources.

Outdated medical device Regulations in Europe have led to the need to rethink and amend the current regulatory framework to ensure a state-of-the-art level of patient safety. The newly amended Regulation should pave the way to achieve this goal. Nevertheless, further innovation is needed in this research-intensive area of healthcare to better serve the medical needs of patients in the future. While it is right to promote a high level of patient safety through a revised regulatory framework, it is also important not to forget the need for a high level of patient healthcare, which will lead to the availability of even better healthcare solutions through medical device innovation. Finally, the proliferation of regulations leads to an explicit dilemma: it is difficult, if not impossible, to increase patient safety and innovation potential at the same time. Therefore, new Regulations should always be carefully assessed for their impact on innovation. Possible future amendments to the Regulations must address issues arising from the dilemma that SMEs will suffer from the implementation of

many of the restrictions imposed by the new regulatory framework. The end result could be a globally excellent level of patient safety in the EU, but a very limited product portfolio in the medical devices market, as SMEs are likely to avoid the extensive pre-market certification process. The worst-case scenario would be that more effective medical devices would only be sold in markets outside of the EU due to more manufacturer-friendly regulatory requirements in these markets.

According to the BVMed's online survey (Beeres, 2021), the most important health policy demands in Germany are:

- MDR: Simplification of recertification for existing products (56%)
- Shorten the duration of the evaluation procedure (40%)
- Support programme for SMEs to implement the MDR (36%)
- Generally reduced VAT for medical devices (33%) (Beeres, 2021, p. 40; translation by the author).

2.2.7 Key results

Analysing the historical data of the European MedTech industry, it can be concluded that this is a vital market with a lot of potential for future growth. As the market consists of almost 95% SMEs, it should be very interesting for start-ups and entrepreneurs to enter the market and gain market share. However, as lucrative as the market appears to be, there is an obvious need for MedTech manufacturers to comply with many laws and regulations before they can sell their product in the market. They also need to understand the needs of patients and their willingness to buy their products, which are intended to cure them.

Aware of all barriers mentioned in section 2.2.5, many bodies in the EU, including the European Commission, are working together to reduce barriers in order to support "the competitiveness of the EU medical devices sector (e.g. research & development, clusters, intellectual property, regulatory and trade aspects) with particular emphasis on creating a favourable environment and practical support for

SMEs" (European Commission, 2010, p. 6). Nevertheless, manufacturers have to face the current laws, rules and regulations and cannot rely on possible future improvements. Learning from fraudulent incidents will increase the focus on patient safety and lead to stricter laws and regulations, which will require more time and resources from companies. They will also need to address industry-specific and ethical issues before they can successfully bring their medical device to market. The impact of EU market regulations on the innovation potential of SMEs is a key finding of this section and is taken into account in the development of the conceptual framework, as start-ups need to address these regulations strategically and act accordingly (see Figure 5).

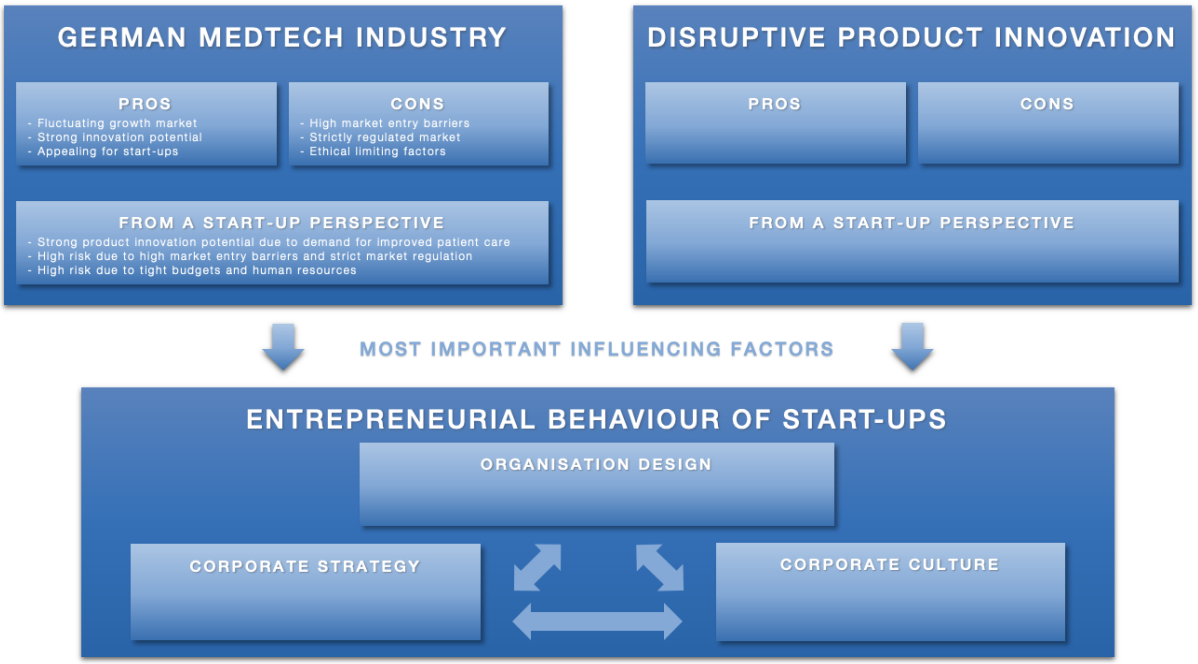

Figure 5: Key aspects of the German MedTech industry

The preceding contextual literature review on the German MedTech industry forms the basis for the further theoretical literature review in the following sections. Based on the collected facts that affect start-ups in this very specific industry, the theoretical assumptions about disruptive innovation and entrepreneurial behaviour need to be defined and illuminated in this specific context.

2.3 Disruptive product innovation

2.3.1 Introduction

Disruptive innovation is a recent theory that has emerged from innovation management theory, with the first research findings dating back to the 1980s. In order to understand the broad theory of disruptive innovation, it is important to examine its origins in the field of innovation management as well as the criticisms that have arisen as the theory of disruptive innovation has become more respected and commonly used to analyse current business cases.

2.3.2 Innovation management

As part of business theory, innovation management has been defined by the Organisation for Economic Co-operation and Development (OECD) in its recent 'Oslo Manual' as "the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations" (OECD/Eurostat, 2005, p. 46). Ahmed (1998, p. 31) describes innovation as "the engine of change", a "pervasive attitude that allows business to see beyond the present and create the future". Schumpeter (1942) identifies five forms of innovation:

(1) the introduction of a new good
(2) introduction of a new method of production
(3) opening of a new market
(4) conquest of a new source of raw materials or semi-finished goods
(5) introducing of a new form of organisation

More pragmatically, Pisano (2015, p. 46) defined a firm's 'innovation system' as a "coherent set of interdependent processes that dictates how the company searches for novel problems and solutions, synthesises ideas into a business concept and product designs, and selects which projects get funded".

In this research project, which focuses on the area of product innovation, this particular type of innovation has been defined as “the introduction of a good or service that is new or significantly improved with respect to its characteristics or intended uses. This includes significant improvements in technical specifications, components and materials, incorporated software, user friendliness or other functional characteristics” (OECD/Eurostat, 2005, p. 48).

There are several different approaches to segmenting innovation management in the academic literature. In order to show the diversity of innovation forms that exist for an organisation or company, the four dimensions of the ‘Innovation Space’ introduced by Tidd and Bessant (2013) are helpful to consult (see Figure 6).

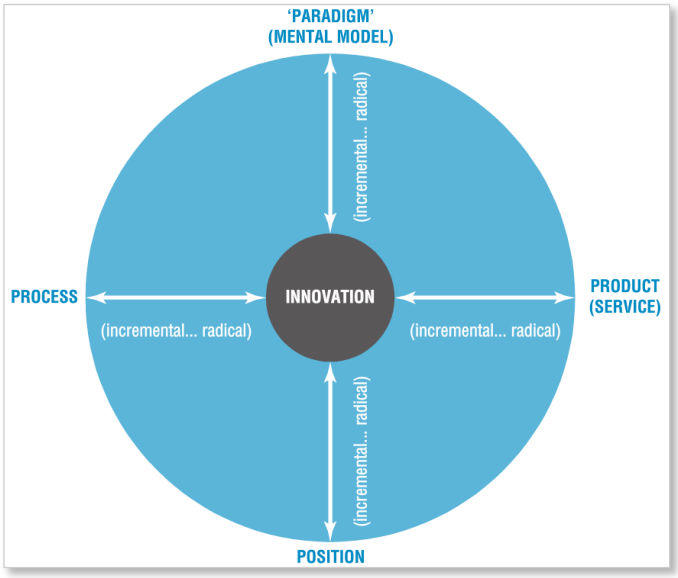

Figure 6: Innovation Space (Tidd and Bessant, 2013, p. 25)

The ‘4Ps’ of the innovation space stand for the ‘Product (service)’ that a firm offers, ‘Process’, which describes how the products are created/delivered, ‘Position’, which describes the context in which the products are introduced, and ‘Paradigm’, which is the “underlying mental model” of a firm (Tidd and Bessant, 2013, p. 24). This research project focuses on product innovation. The degree of novelty in this can be described as ‘incremental’ for a more conservative change to an existing

product ("doing what we do better") or 'radical' for a major change to the product ("new to the world") (Tidd and Bessant, 2013, p. 41).

Following the mainstream studies of Florida and Kenney (1990), Morone (1993) and Utterback (1994), technological innovations can be divided into two categories: revolutionary, discontinuous, breakthrough, radical, emergent and step-function technologies, or evolutionary, continuous, incremental or 'nuts and bolts' technologies. The different names for the same meanings unfortunately dilute a unified definition of innovation theory.

For an overview of the concepts of different types of innovation, Henderson and Clark's (1990) schematic is very comprehensive (see Figure 7).

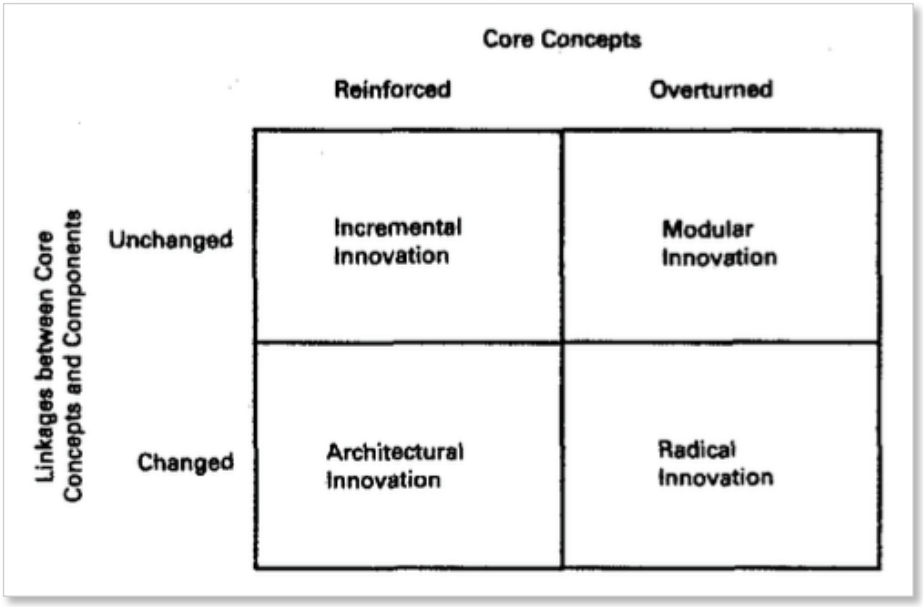

Figure 7: A framework for defining innovation (Henderson and Clark, 1990, p. 12)

Henderson and Clark (1990) visually illustrate the connection between the four quadrants based on the level of impact of architectural knowledge (core concepts) and the level of impact of component knowledge (linkages between core concepts and components).

Gary Pisano (2015), a professor at Harvard Business School, describes the importance for a company or organisation to develop an individual innovation strategy “that’s closely linked to a company’s business strategy and core value proposition” (Pisano, 2015, p. 48). He characterises innovation in terms of two important dimensions of a company: the business model and the technical competencies, and divides the different emerging categories of innovation into a so-called ‘Innovation Landscape Map’ (see Figure 8).

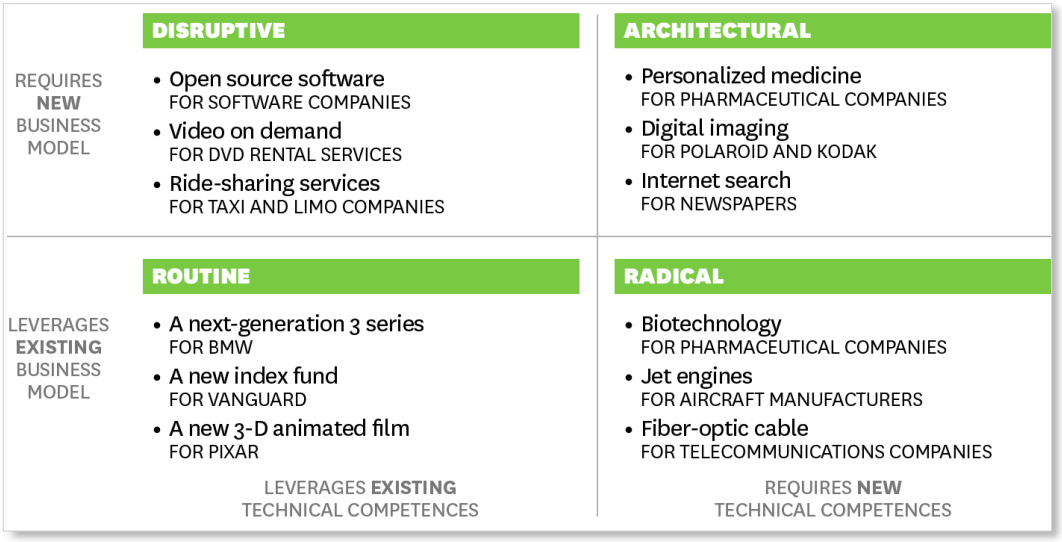

Figure 8: The Innovation Landscape Map (Pisano, 2015, p. 51)

On the one hand, a company must decide whether to use the existing business model or whether there is a need for a completely new business model. On the other hand, the company must decide whether to leverage the existing technical competencies or to develop new technical competencies. The Landscape Map divides the emerging categories into four quadrants (see Figure 8). Names of companies that fit well into these categories are given as examples on the map. According to this, the category of disruptive innovation - the focus of this research project - requires a new business model and the use of existing technical competences (Pisano, 2015, p. 51). In doing so, companies challenge or disrupt the business models of other companies (Pisano, 2015, p. 50). The development and further theoretical details of disruptive product innovation are presented in the

following sections, the influence of corporate strategy on innovation in section 2.4.4.1.

2.3.3 Disruptive Innovation

Before introducing disruptive innovation in its theoretical entity, the term 'disruption' needs to be examined. A simple definition of the word 'disrupt' is "to interrupt the normal course or unity […] [or in] business: to cause upheaval in an industry" (Merriam-Webster, 2022a). According to the Cambridge Dictionary (2022a), 'disruptive' is defined in business terms as "changing the traditional way that an industry operates, especially in a new and effective way". Fox (2014) notes that "the word has become a mark of forward-thinking decisiveness". Jean-Marie Dru, founder and chairman of the global advertising agency network TBWA, is the inventor of TBWA's DISRUPTION® method for developing business-changing ideas. According to Dru, "its name implies the idea of rupture, of nonlinearity, a before and an after in the life of a brand" (Dru, 1996, p. 15) and that "discontinuity is at the heart of disruption" (Dru, 1996, p. 33).

Disruption is part of several business areas such as technology driven innovation management, creative driven marketing and advertising methodology (Dru, 1996, p. 15). In the 1990s it emerged mainly in the advertising industry. According to Dru (1996, p. 54), "disruption is about finding the strategic idea that breaks and overturns a convention in the marketplace, and then makes it possible to reach a new vision or to give new substance to an existing vision". Businesses should create new worlds and constantly do, undo and redo. To do this, they "must adopt a mind-set of anticipation" (Dru, 1996, p. vii) because "disruption is about displacing limits" (Dru, 1996, p. 55). The theoretical details of disruption in the context of (product) innovation are explored in the following sections.

Joseph Schumpeter's work influenced and developed theories of innovation management. He argued that "economic development is driven by innovation through a dynamic process in which new technologies replace the old"

(OECD/Eurostat, 2005, p. 29). In doing so, Schumpeter (1942) introduced the notion of 'creative destruction', showing entrepreneurs how to sustain long-term economic growth. New market entrants must be radically different, ensuring a fundamental improvement over the incumbent's product. He even argued that the quality of innovation resulting from creative destruction is the reason why capitalism is the best economic system (Schumpeter, 1942). The theory of disruptive innovation was further developed from 1986 by Foster (1986; Foster and Kaplan, 2001), Henderson and Clark (1990), and Moore (1991). From 1992 onwards, Clayton Christensen further developed the theory of disruptive innovation and popularised it through the publication of several academic papers and books (Christensen, 1997, 2006; Christensen and Bower, 1996; Christensen and Raynor, 2003). Pisano (2014, p. 2) defines disruptive innovation as "innovation that fundamentally transforms the way value gets created and distributed in an industry".

As with any theory, there is a flip side to disruptive innovation. In developing the theory of disruptive innovation, Christensen also discovered the 'innovator's dilemma' (Christensen, 1997). Well-managed, established companies face a difficult choice between the sustainable development of their existing product and the development of disruptive technologies. The innovator's dilemma is discussed in more in detail in section 2.3.7.

Due to the fact that "core concepts have been widely misunderstood and its basic tenets frequently misapplied" (Christensen, Raynor and McDonald, 2015, p. 46), Christensen has already warned that disruptive innovation theory will become "a victim of its own success" (Christensen, Raynor and McDonald, 2015, p. 46). Therefore, it is inevitable to refer to Christensen's definition of the process of disruptive innovation:

> a form of innovation that creates new markets (market disruption) by discovering new categories of customers. It does this partly by harnessing new technologies but also by developing new business models and

> exploiting old technologies in new ways. The innovative products are low cost/easier to use and they enter the lower end of the market. Not to forget that disruptive innovation is not linked to any business success (Christensen, 1997).

He later added that “disruptive technologies are typically simpler, cheaper, and more reliable and convenient than established technologies” (Christensen, 2016, p. 192). Further to Christensen, Sood and Tellis (2005), Utterback and Acee (2005) defined technology, firm and demand disruption as three domains for a given disruptive innovation. It is important to distinguish well and not to confuse disruptive innovation with disruptive technology. Markides (2006) further separated technological innovation from business model innovation, as a finer categorisation is needed within the theory of disruptive innovation.

Christensen (2016) makes a precise distinction between sustainable and disruptive technologies. Sustainable technologies are found in most new technologies that have improved product performance. Sustainable technologies can still have different characteristics, such as radical, incremental or discontinuous (Christensen, 2016, p. xix). Disruptive technologies, on the other hand, are characterised by inferior product performance, such that they perform significantly worse than established products in mainstream markets. In order to create some certain customer value, they are likely to have other features that the established products do not have, thus creating new product categories (Christensen, 2016, p. xix). According to Christensen (2016), every new market created is the result of a disruptive innovation. Considering value as an important goal of active companies, we can say that sustainable innovation is based on a historical value proposition, while disruptive innovation creates a new value paradigm. Table 1 summarises the definitional criteria for disruptive product innovation presented in this section.

Criteria for defining disruptive product innovation		
Year	Author	Criteria
1942	Schumpeter	"Economic development is driven by innovation through a dynamic process in which new technologies replace the old"; introduced the term '**creative destruction**', drawing the way for entrepreneurs to sustain long-term economic growth; **new market entrants need to be radically different** by ensuring that **fundamental improvement is achieved in comparison to incumbent's product**
1996	Dru	"Discontinuity is at the heart of disruption"; "disruption is about finding the **strategic idea that breaks and overturns a convention** in the marketplace, and then makes it possible to **reach a new vision or to give new substance to an existing vision**"; "disruption is about **displacing limits**"
1997/2016	Christensen	Christensen developed theory of disruptive innovation from 1992; "a form of innovation that creates new markets (market disruption) by discovering new categories of customers. It does this partly by **harnessing new technologies** but also by developing new business models and **exploiting old technologies in new ways**. The innovative products are **low cost/easier to use and they enter the lower end of the market**"; "disruptive technologies are **typically simpler, cheaper, and more reliable and convenient than established technologies**", disruptive technologies are characterised by **poorer product performance**, they perform significantly worse than established products in mainstream markets, to generate a customer benefit, they are likely to **have other features that the established products do not have**, thus **creating new product categories**
2014	Pisano	"Innovation that **fundamentally transforms the way value gets created and distributed** in an industry"

Table 1: Criteria for defining disruptive product innovation developed for research (emphasis by author)

2.3.4 The S-curve theory

To understand the theory of disruptive innovation, one needs to internalise the so-called 'technology S-curve theory' - a forecasting tool - introduced by Foster (1986). Christensen (1992) called it "a centerpiece in thinking about technology strategy" and examined the S-curve framework used at the industry level for corporate managers planning the development of new technologies. He defined technology "as a process, technique, or methodology – embodied in a product design or in a manufacturing or service process – which transforms inputs of labor, capital, information, material, and energy into outputs of greater value" (Christensen, 1992).

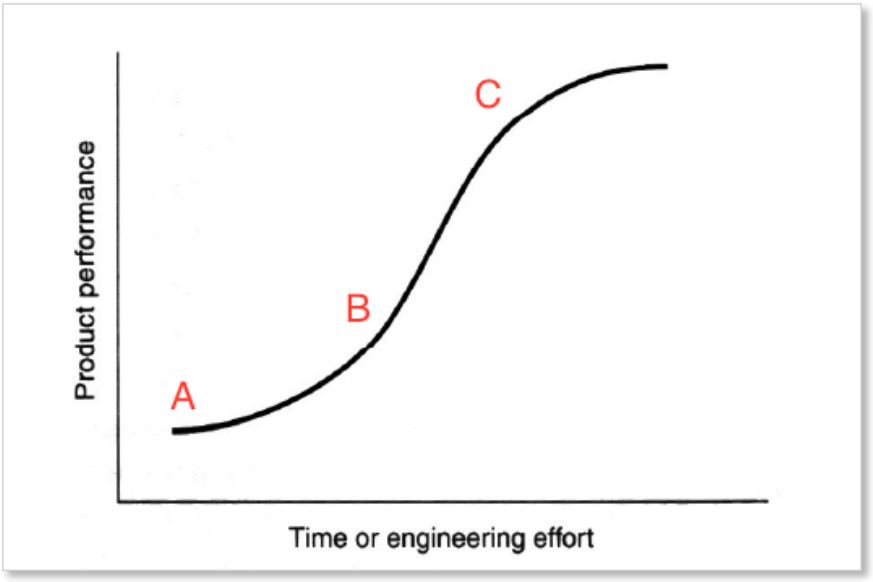

Figure 9: The technology S-curve (Christensen, 1992, p. 335), edited by the author

Christensen's S-curve shows how the performance of a technology develops slowly in the beginning (see Figure 9, 'A'). Over time, a breakthrough occurs and performance improves rapidly (see Figure 9, 'B'). The end of the S-curve marks the point where the technical effort finally reaches the scientific (natural or physical) limits. The performance of the technology no longer increases much; without additional effort it would tend to decrease (see Figure 9, 'C'). This is also the point at which an established technology becomes increasingly vulnerable to replacement technologies. To prevent the technology from being attacked by a competing technology, new technologies must be well planned and developed in a certain order. Scholars such as Becker and Speltz (1983) and Foster (1986) saw the S-curve as having strong prescriptive value for strategic management and developed a strategy based on their findings (see Figure 10).

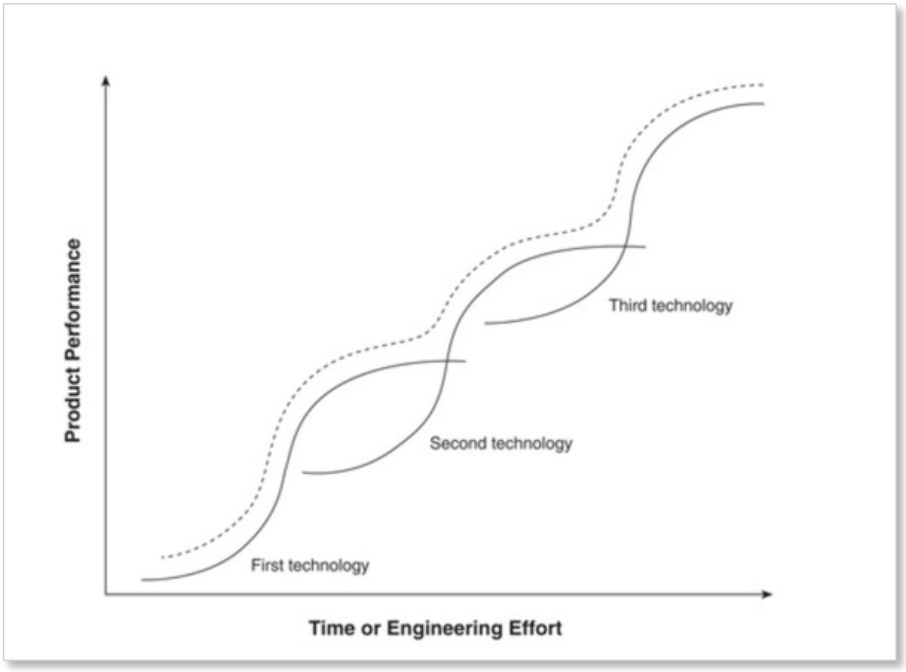

Figure 10: The prescriptive S-curve strategy (Christensen, 1992, p. 340; 2016, p. 40)

The prescriptive S-curve strategy describes the identification of new sustainable approaches/technologies when the currently developed technology has “passed its point of inflection” (Christensen, 1992, p. 339; 2016, p. 39). As shown in Figure 10, subsequent incremental technologies do not have to wait until the performance of the current technology declines. The strategy works best if the follower technology is introduced when the performance of the follower technology increases the most (see Figure 9, ‘B’) and outperforms the predecessor technology when its performance declines (see Figure 10). This works perfectly even though the initial performance of the new approach/technology is worse than that of the successor technology. On the contrary, the initial lower performance does not attract the attention of potential attackers who invest early. The ultimate goal of the prescriptive S-curve strategy is for the firm’s technological performance to follow the dashed line (the high performer’s path) in Figure 10 (Christensen, 1992, p. 339). If firms fail to develop and adopt new technologies in a timely manner, this may be the reason why firms fail in the market and may lead to an advantage for attacking firms (Foster, 1986).

In order to apply technology S-curve theory to disruptive technologies, it is necessary to be break it down into the different markets that the technology is likely to penetrate.

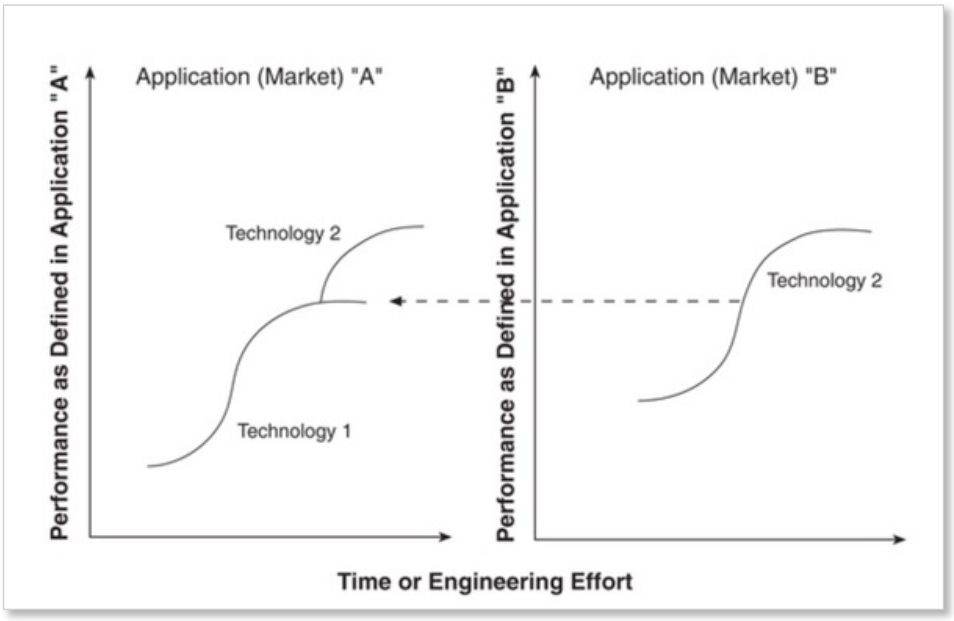

Figure 11: Disruptive Technology S-Curve (Christensen, 2016, p. 41)

As shown in Figure 11, the introduction of the same follow-up technology (Technology 2 in this example) in Market 'A' works as in the conventional technology S-curve, replacing Technology 1 at its inflection point. In a new Market 'B', on the other hand, it is likely to be able to 'disrupt' from the outset, even if the performance of the technology at the same time is lower than that of Technology 1. Creating a new market is always risky, but it also brings with it the opportunity to operate in that market independently and without competitors. In their book "The innovator's solution", Christensen and Raynor (2003) explain how disruptive innovations are likely to enter at the lower end of an existing market or even create a new market. At the bottom end of a market, disruptive innovations seek to capture the least profitable and most underserved customers, while in new markets they do not face an incumbent but must overcome non-consumption (Christensen and Raynor, 2003).

According to Foster (1986), the S-curve theory can be adopted by both researchers and managers. For both, the challenge is to determine the exact point at which old and new technologies intersect. Identifying this exact point helps to identify and switch to new technologies that threaten long-established markets. Foster (1986) states that whenever this point is missed, it is the cause of failure for incumbent firms and, on the contrary, gives a significant advantage to new market entrants or attacking firms that exploit their disruptive technology.

Both Meckl (2014) and Backhaus (2003) looked at the right time to enter a particular market and put forward theories (e.g. the waterfall strategy when launching a particular product in a country, including an appropriate learning curve during this process).

2.3.5 The Value Network Framework for innovation

According to Christensen (2016), "value networks strongly define and delimit what companies within them can and cannot do" (Christensen, 2016, p. 53). Christensen (2016) has put forward five theses in relation to technological change and the corresponding problems faced by successful incumbents from a value network perspective.

Christensen's first thesis is that the value network in which a company operates influences its ability to focus on the resources and capabilities needed to remove technological and organisational barriers that impede innovation (Christensen, 2016, p. 54). The boundaries of a value network "are determined by a unique definition of product performance - a ranked ordering of the importance of various attributes differing markedly from that employed in other systems-of-use in a broadly defined industry" (Christensen, 2016, p. 54). Value networks are also defined by individual cost structures that correspond to the needs of customers within the network (Christensen, 2016, p. 54). However, the needs of the current customer may be at odds with those of the new or end customer. Allocating the wrong resources to the wrong customer needs can hinder innovation. To defend

certain cost structures and revenue generation, organisational values may also readily allocate resources to sustain innovation. Bower (1970) defined this strategy of allocating resources to existing customer-driven innovations as “pressure from the market that reduces both the probability and costs of being wrong” (Bower, 1970, p. 274). This strategy fails to identify or provide the impetus to invest in technologies, markets and end-user needs that could disrupt and create new industries or markets.

In his second thesis, Christensen (2016) describes that the extent to which a company responds to the well-understood needs of current stakeholders within the value network. Incumbents tend to pursue simple innovations of all kinds (e.g. architectural, components) while maintaining their leadership position in the industry because their value and application are clear (Christensen, 2016, p. 54). Conversely, because disruptive innovations are complex (their value and application are uncertain), incumbents will avoid “development of technologies - even those in which the technology involved is intrinsically simple – that only address customers’ needs in emerging value networks” (Christensen, 2016, p. 54).

Christensen’s third thesis concerns the fatal decision of incumbents to ignore technologies that do not meet their customers’ needs. The two slopes define “the performance demanded over time within a given value network, […] [the other] the performance that technologists are able to provide within a given technological paradigm” (Christensen, 2016, p. 54). If the two slopes are similar, the technology should remain relatively strong in its initial value network. However, if the slopes are different, the new technology may migrate to other networks, allowing other innovators in the new network to attack the incumbent network (Christensen, 2016, p. 54). These attacks occur when the ranking of performance attributes in different value networks changes.

The fourth thesis is about firms entering an established market and thus gaining the ‘attacker’s advantage’ over incumbents, namely “in those innovations […] that

disrupt or redefine the level, rate, and direction of progress in an established technological trajectory" (Christensen, 2016, p. 55). As these technologies do not create value in the established network, incumbents need to enter the value network where they create value in order to lead the commercialisation of such technologies (Christensen, 2016, p. 55). According to Tedlow (1994, p. 68), who studied the development of the retail market in America, "the most formidable barriers for established firms and their value networks is that they [the retailers] did not want to do this, i.e., be in the discount market, they considered it inappropriate to their traditions and values".

Christensen's fifth and final thesis relates to the 'attacker's advantage' associated with disruptive technological change. The 'attacker's advantage' is that the firm entering the market is more easily able than incumbents to "identify and make strategic commitment to attack and develop emerging market applications, or value networks" (Christensen, 2016). Finally, the relative flexibility of firms - whether incumbents or new entrants - in changing strategies and cost structures, rather than technologies, is the key to success or failure.

It summarises Christensen's 'Value Network Framework for Innovation' and offers new dimensions for analysing technological innovation in the context of value networks. The theses show clear impacts of the innovative technology on existing value networks. The innovator must analyse whether the performance characteristics of the innovation are valued in the already existing networks, whether other networks need to be addressed or new ones created (Christensen, 1992, p. 55). It is also imperative to "address customers' needs today to squarely address their needs in the future" (Christensen, 2016, p. 55).

2.3.6 The Resources, Processes and Values theory

Based on Prahalad and Hamel's (1990) theory of 'core competencies', Christensen (2016) developed his theory of 'Resources, Processes and Values' (RPV) (see Table 2 for details). The RPV theory identifies what a firm needs to be successful in the

face of disruptive innovation and what core competencies the firm needs (including the appropriate environment, people skills, mindset and resources). According to Christensen (2016), a company's ability to act is closely related to three factors: "its resources, its processes, and its values" (Christensen, 2016, p. 162). RPV theory is based on the understanding that these three factors "collectively define an organization's strengths as well as its weaknesses and blind spots" (Christensen, Anthony and Roth, 2004, p. xvii), thus providing a framework for organisational capabilities.

Resources	Processes	Values
Things or assets that organizations can buy or sell, build or destroy. Examples: - People - Technology - Products - Equipment - Information - Cash - Brand - Distribution channels	Established ways companies turn resources into products or services. Examples: - Hiring and training - Product development - Manufacturing - Planning and budgeting - Market research - Resource allocation	The criteria by which prioritization decisions are made. Examples: - Cost structure - Income statement - Customer demands - Size of opportunity - Ethics

Table 2: The Resources, Processes and Values theory framework (Christensen, Anthony and Roth, 2004, p. xviii)

Resources are the most visible of the three factors and in most cases are things or assets such as "people, equipment, technology, product design, brands, information, cash, and relationships with suppliers, distributors, and customers" (Christensen, 2016, p. 162). The higher the quality of a particular resource, the greater the chance that a company's organisation can be transformed (Christensen, 2016, p. 162). Resources are in the hands of organisational leaders, who evaluate them whenever the organisation faces changes. However, looking only at available resources would dilute the overall picture, "because the capabilities to transform inputs into goods and services of greater value reside in the organization's processes and values" (Christensen, 2016, p. 163). In summary, resources are 'what a firm has'.

Processes are the organisational procedures that direct employees to accomplish the transformation of the above resource inputs into products and services of greater value (e.g. “manufacturing processes, […] product development, procurement, market research, budgeting, planning, employee development and compensation, and resource allocation” (Christensen, 2016, p. 163)). Processes can be divided into ‘formal’ and ‘informal’ processes. While formal processes are subject to explicitly defined instructions, informal processes emerge through habitual routines and develop over time (Christensen, 2016, p. 163). For consistency, processes should not be changed. If change occur, they should be within controlled procedures (Christensen, 2016, p. 164). This leads to the conclusion that “the very mechanisms through which organizations create value are intrinsically inimical to change” (Christensen, 2016, p. 164). According to Christensen (2016), it is the organisation’s typically inflexible processes that are most likely to be barriers to change. This, in turn, means that processes retain some flexibility in that they can be changed if management determines that they are having a negative impact on the business. In summary, processes are the way ‘how a firm does its work’.

Clear, consistent and widely positioned and understood values of a company are the third compelling factor that influences whether an organisation is able to solve its self-imposed tasks and goals (Christensen, 2016, p. 164). A company’s values should necessarily include its business model, or at least its cost structure, as these are the crucial points where a company can make money. According to Christensen (2016)

> an organization’s values are the standards by which employees make prioritization decisions – by which they judge whether an order is attractive or unattractive; whether a customer is more important or less important; whether an idea for a new product is attractive or marginal (Christensen, 2016, p. 164).

The relevant decisions are made by employees at all levels, with senior management more involved in decisions about investments in products, services and processes. For example, sales staff are more involved in the 'day-to-day decisions' about which products to push through to customers and which not to push (Christensen, 2016, p. 164). Employees' decisions about priorities should be "consistent with the strategic direction and the business model of the company" (Christensen, 2016, p. 164). According to Peters and Waterman (1982), it is essential that the given values permeate an organisation consistently. The company's values change predictably along two dimensions, gross margin and growth rate, as both financial indicators vary throughout the natural financial year and form a coherent unit with the size of a company (Christensen, 2016, p. 165). Smaller firms intend to enter smaller markets, while larger firms fail to enter smaller markets even though their resources are huge, but the change in value prevents them from doing so (Christensen, 2016, p. 166). Christensen (2016) points to the fact of 'mega-mergers' and emphasises that two large companies together will have enormous resources to solve innovation problems, but the "huge size constitutes a very real disability in managing innovation" (Christensen, 2016, p. 166). In summary, values are 'what a firm wants to do'.

Christensen's RPV framework of organisational capabilities has already shown in early case studies that incumbent firms tend to fail in pursuing disruptive technologies because the size of the firm prevents them from pursuing them successfully. Although he identified companies that had the necessary resources to profitably pursue both sustainable and disruptive technologies, "their processes and values constituted disabilities in their efforts to succeed at disruptive technologies" (Christensen, 2016, p. 167). According to Christensen (2016), large companies avoid operating in emerging growth markets because, in most cases, they are not able to adapt to disruptive technologies, so these markets consist mostly of SMEs. The values of incumbent firms "will not prioritise disruptive innovations and the firm's processes will not help them to achieve what they need to do to react to disruptive technology" (Christensen, Anthony and Roth, 2004, p. xix). This leaves incumbent

manufacturers, distributors and retailers vulnerable. Although SMEs lack resources compared to larger companies, their values and cost structures are better suited to smaller markets and lower profit margins (Christensen, 2016, p. 167).

Managers faced with a disruptive innovation must therefore not only review the existing resources in their organisation, but also “scrutinize whether the organization’s processes and values fit the problem” (Christensen, 2016, p. 168).

2.3.7 The innovator’s dilemma

The definition of disruptive innovation in section 2.3.3 ff. has already addressed the ‘innovator’s dilemma’. The ‘innovator’s dilemma’ is a phenomenon first described by Christensen (1997) and explains the two choices offered by innovation. A firm must decide whether to hold on to an existing market by doing the same thing a little better, or to capture new markets by adopting new technologies and introducing new business models (see also Thomond, Herzberg and Lettice (2003)). Christensen concludes that companies often fail because their management practices make them industry leaders, but they then fail to develop “the disruptive technologies that ultimately steal away their markets” (Christensen, 1997, p. 231). On the one hand, disruptive technologies need to be clearly distinguished from sustainable technologies. On the other hand, according to Putz and Raynor (2005), growing firms such as start-ups need to pursue both sustainable and disruptive innovations if they are to grow profitably. This dilemma is also evident from a strategic perspective, see section 2.4.4.2 on entrepreneurial ambidexterity.

Christensen (2016) has therefore developed the five principles of disruptive technology to illustrate that existing best management practices are counterproductive when it comes to developing disruptive innovation in an organisation. He predicts that “managers can be extraordinarily effective in managing even the most difficult innovations if they work to understand and harness the principles” (Christensen, 2016, p. xvii). The principles of disruptive innovation are directly related to corporate strategy.

(1) Companies depend on customers and investors for resources

The 1st principle shows that while managers may think they are in control of the organisation of their companies, “in the end it is really customers and investors who dictate how money will be spent” (Christensen, 2016, p. xxiii). Companies that plan to introduce a disruptive technology and do not adapt their organisational behaviour with regard to the allocation of critical financial and human resources and “set up an autonomous organization charged with building a new and independent business around the disruptive technology” are likely to fail in the long run (Christensen, 2016, p. xxiv). Ultimately, the only successful path for managers is to create an independent organisation that follows a separate cost structure that aimes to “achieve profitability at the low margins characteristics of most disruptive technologies” (Christensen, 2016, p. xxiv).

(2) Small markets don’t solve the growth needs of large companies

Typically, companies pursuing disruptive technological innovation enter new emerging markets and benefit from first mover advantages there (Christensen, 2016, p. xxiv). As the business growths, they face the difficulty of entering further emerging markets and still maintaining their share prices. In order to overcome the problems faced by large organisations, Christensen (2016, p. xxiv) suggests that “responsibility to commercialize the disruptive technology to an organisation whose size matches the size of the targeted market”. The commercialisation aspect should open up a range of business opportunities for large organisations facing this dilemma.

(3) Markets that do not exist cannot be analysed

Whenever a company pursues an innovation strategy, gathering sound market data is a key issue for proactive strategic planning. Managers of companies that are pursuing - in most cases - a sustainable innovation

strategy should be able to draw an accurate picture of the size and growth rates of the markets in which they operate (Christensen, 2016, p. xxv). Instead, managers of firms pursuing a disruptive innovation strategy will face difficulties because the markets in which disruptive technologies are developing provide the least data. Nevertheless, they imply strong first mover advantages. Christensen therefore suggests taking a different path by adopting what he calls 'discovery-based planning', "it suggest that managers assume that forecasts are wrong, rather than right, and that the strategy they have chosen to pursue may likewise be wrong" (Christensen, 2016, p. xxvi). In order to deal with disruptive technologies more efficiently, managers should "develop plans for learning what needs to be known" (Christensen, 2016, p. xxvi).

(4) An organization's capabilities define its disabilities

Christensen (2016) states that:

> an organization's capabilities reside in two places. The first is in its processes – the methods by which people have learned to transform inputs in labor, energy, materials, information, cash, and technology into outputs of higher value. The second is in the organization's values, which are the criteria that managers and employees in the organization use when making prioritization decisions. […] The very processes and values that constitute an organization's capabilities in one context, define its *dis*abilities in another context (Christensen, 2016, pp. xxvi-xxvii).

Therefore, according to Christensen, managers need the right tools to create new capabilities, whenever the current processes and values in an organisation are "incapable of successfully addressing a new problem" (Christensen, 2016, p. xxvii).

(5) Technology supply may not equal market demand

According to disruptive innovation theory, "products that seriously underperform today, relative to customer expectations in mainstream markets, may become directly performance-competitive tomorrow" (Christensen, 2016, p. xxvii). Thus, when two products exceed the market needs in terms of performance, "the basis of product choice often evolves from functionality to reliability, then to convenience, and, ultimately, to price" (Christensen, 2016, p. xxvii). Therefore, managers should carefully observe the markets in which they operate and "carefully measure trends in how their mainstream customers *use* their products […] [to] catch the points at which the basis of competition will change in the markets they serve" (Christensen, 2016, p. xxviii).

In conclusion, of the five principles presented, only the last three are relevant for start-ups. On the road to disruptive product innovation, they need to assess the future of an uncertain market, develop the right tools to acquire new skills within the start-up, and finally monitor market trends to be able to react quickly to market changes.

2.3.8 Characteristics of innovation in the MedTech industry

The use of medical devices in the EU is limited by two factors: Regulations and national laws on the one hand, and doctors' medical guidelines and treatment plans on the other. These limiting factors must be taken into account when inventing new or modified medical devices, and careful consideration must be given to whether a company's business is still profitable. There are a significant number of innovations that are not ultimately profitable because the financial and time implications of meeting regulatory requirements would preclude any profitability.

The European market for medical devices is regulated by the European MDR and national regulations, directives and laws. This restricts the market entry for medical device companies, as analysed in section 2.2.5.

Consoli and Mina (2009) analysed health innovation systems and made significant contribution to understanding the complex networks of actors involved in medical device innovation processes (see Figure 12).

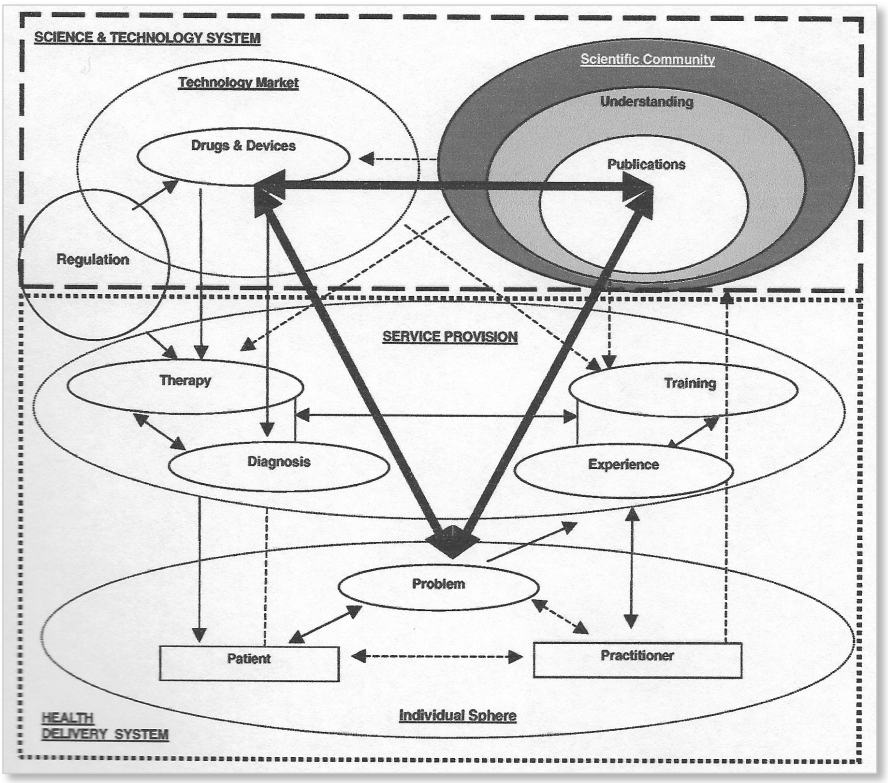

Figure 12: Outline of a health innovation system (Consoli and Mina, 2009, p. 308)

The ultimate end-user and beneficiary of a medical device is the patient, while the physician assumes the role of 'facilitator', selecting and using the required product to best treat the patient's condition by applying the appropriate therapeutic guidelines. However, when choosing the appropriate treatment for a patient, the doctor does not primarily consider the economic aspect of the product, but rather the pure product performance of the device to be chosen. There is also a strong moral aspect to the doctor's consideration of whether the cost of a (perhaps expensive) innovative medical device justifies the impact on the patient's health. Of course, there is also the possibility that a doctor will choose a more expensive medical device because it will improve patient outcomes. This is a significant departure from traditionally studied industries, where product acceptance is based

on the customer's perception of value, which includes the economic cost of the product of choice.

To give an example of disruptive innovations in our daily lives, Christensen and Raynor (2003) in their study of disruptive technologies and innovations in healthcare/medical products identified endoscopic minimally invasive surgery as a disruptive technology. Its scope was initially very limited as it was only suitable for simple procedures. Improvements have been made continuously, so that today "even certain relatively complicated heart procedures are done through a small port" (Christensen and Raynor, 2003, p. 59). The disruptive effect affects both medical device manufacturers and doctors. Ultrasound technology has also been described as a new market disruptor because it has replaced the long-established X-ray technology (Christensen and Raynor, 2003, p. 64) and its importance in medical examinations continues to grow today. Christensen and Raynor (2003, p. 63) identified Sonosite's handheld ultrasound devices as a disruptive innovation in the medical device sector because they do not require the highly trained technicians or expensive medical equipment to treat patients, but rather "provide more accurate and timely diagnosis" (Christensen and Raynor, 2003, p. 63). These examples illustrate the alleged successful implementation of disruptive technologies and innovations in the healthcare/medical device sector.

In their book "The Innovator's Prescription", Christensen, Grossmann and Hwang (2009, p. 324) note that the incumbents Johnson & Johnson and GE Health Care have studied and partially mastered "the methods of targeting products at jobs to be done, of shaping their business plans to be disruptive relative to competitors, and of managing them, as appropriate, in separate business units".

Even though sustainable innovations seem to be in the majority in this particular industry, disruptive innovations are - under certain conditions - a possible way forward. Several examples demonstrate the profitability of disruptive medical

devices. The current business plans of companies pursuing a disruptive path are not disclosed.

2.3.9 Disruptive potential in the MedTech industry

While the potential for disruption is high in the MedTech industry, the success of disruptive innovations is not predictable. Yu and Hang (2010, p. 444) refer to the empirical research of Chesbrough (1999) and point out that "the success of disruptive innovation also depends on the variation in some contextual factors such as regulation, entrepreneurship culture and economic conditions of different countries". In their study on innovative milieus in Germany, Pohl and Kempermann (2019, p. 30) discuss the point that future technologies cannot be advanced without radical innovation approaches and that there are far too few start-ups in Germany that exploit the obvious disruptive potential and put Germany in a leading role in this field. Schmidt (2004) has developed a theoretical model that can provide firms with some "tools to use in assessing whether a market is ripe for disruption" (Yu and Hang, 2010, p. 440).

Berlin, Davidson and Schoen (2015, p. 1709), in their study on transcatheter aortic valve implantation, highlight the importance of disruptive technological innovations in the healthcare sector and how the "convergence of technological progress and medical care has yielded impressive advances in health outcomes and standard of care, and, often yielded economic benefit". One of the much-discussed disruptive innovations in the MedTech sector is the 3D printing of customised implants. Here, the German start-ups Kumovis and Mecuris have developed a brought to market disruptive 3D printing technologies. Magnosco, for example, is a MedTech start-up offering a disruptive medical device for cancer diagnosis. These few examples already show the disruptive potential that exists in the MedTech industry and that disruptive innovation is useful and necessary and therefore an important part of the industry.

2.3.10 Criticism to the theory of disruptive innovation

Every theory has its critics. This is also true of disruptive innovation theory. Although Christensen has done seminal work in the field of disruptive innovation theory, there are criticisms of his theories (e.g. Danneels, 2004; Markides, 2006; Yu and Hang, 2010) that should be carefully considered in further research. Markides (2006) in his paper on disruptive innovation states that he disagrees with Christensen and Raynor (2003) when they treat different disruptive innovations as one. For Markides (2006, p. 19), a "disruptive *technological* innovation is a fundamentally different phenomenon from a disruptive *business-model* innovation: These innovations arise in different ways, have different competitive effects, and require different responses from incumbents".

Chesbrough (2001), reviewing several of Christensen's empirical studies on disruptive technologies, criticises the inconsistency and the lack of identical criteria for defining the different types of technologies. Several other researchers also point to the problem of when a particular technology should be considered disruptive. According to Charitou and Markides (2003), there is a framework for defining disruption because the disruptive effect of the technology depends only on the capabilities, resources and markets of the incumbents and innovators that promote the technology. Tushman and Anderson (1986) defined disruption only as a conceptual or subjective description, while technology appears only as either "competence-enhancing or competence-destroying technological shifts" (Tushman and Anderson, 1986, p. 464). According to this view, the change is the disruptive element, not the technology itself. Chesbrough (2001) criticises Christensen for focusing only on the internal factors affected by disruptive technology, while failing to focus on the external factors affecting disruptive technology.

According to Cohan (2000), Christensen's research topics and case studies are selective and disruptive technologies do not change markets. Finkelstein and Sanford (2000) criticise the analytical problem that Christensen's case studies do not include research on disruptive technologies that do not replace incumbent

technologies. Danneels (2004) notes that incumbents reject the label ‘disruptive technology’ because the impact of disruptive technologies is volatile and they may never evolve to disrupt the current market sector and incumbents. Doering and Parayre (2000) discussed the issue of the uneven impact of new products and processes in terms of disruptive innovation theory. According to them, it is difficult to say whether a technology is truly disruptive, as this can only be determined once the market has seen the impact of the technology and consumers are using it. If consumers have no interest in a new product, the technology is redundant and not disruptive.

Sood and Tellis (2005) criticise Christensen’s use of the S-curve theory developed by Rogers (1963), Foster (1986) and Utterback (1994). They worry that the empirical evidence for the S-curve theory is ‘scattered’ and that “using the S-curve to predict the performance of a technology is quite risky and may be misleading” (Sood and Tellis, 2005, p. 164). Most technologies do not follow the perfect S-curve but have multiple S-curves. Ignoring this fact can lead to the premature abandonment of a promising technology. Accordingly, they suggest that incumbents “need to explore R&D options on multiple dimensions to react appropriately to threats posed by entrants” (Sood and Tellis, 2005, p. 164).

Christensen’s thesis that incumbents faced with a disruptive technology must exit the market or are likely to fail is criticised by King and Tucci (2002). In contrast to Christensen, they argue that firms operating in multiple markets with multiple products can create new markets with the new technology. They see the affected incumbents as being strengthened rather than disrupted by the new technology. Most importantly, they have multiple product lines and efficient resource allocation protocols to adapt their organisation to market and consumer trends.

Christensen (2016) argues that incumbents have a sluggish or short-sighted attitude towards new technologies. Christensen’s “incumbent curse of disruptive technology” was considered exaggerated by Chandy and Tellis (2000). In their study

of the television market, Klepper and Simons (2000) question whether the increase in television sales in favour of simple radios was a disruptive or rather a sustainable innovation using new technologies. In contrast to Christensen, they argue that the knowledge of incumbents prior to the introduction of a new product can be an advantage and should not hinder the introduction of new technologies.

Charitou and Markides (2003) see Christensen's RPV theory not only as a 'failure framework' but also as very useful for established firms to successfully structure their resources for the introduction of innovative products and processes. Christensen's assertion that companies can only succeed with new technologies by creating a new company was challenged by McDermott and Colarelli-O'Connor (2002, p. 431), who claimed that "isolation may protect the project from the counterproductive forces within the mainstream, but it also cuts the project off from its most important sources of learning, competences and resources". According to Chesbrough (2003), the less the main company is involved in management decisions, the more profitable the spin-offs.

Christensen has always offered constructive criticism of his theories, and revised or reconsidered them in further research. In relation to the discussion of the need for spin-offs, he reiterated his 1997 assertions, stating that "when a threatening disruptive technology requires a different cost structure in order to be profitable and competitive, or when the current size of the opportunity is insignificant relative to the growth needs of the mainstream organisation, then – and only then – is a spin out organisation required as part of the solution" (Christensen, 2016, p. 176).

Further research should include the exploration of innovation standards as well as innovation practices in the European MedTech industry. Drucker (2002), Gilbert and Bower (2002), Rigby and Corbett (2002), Schmidt and Druehl (2008) and Yu and Hang (2011) have already made valuable contributions in this area.

2.3.11 Key results

In this section, the origins and theoretical underpinnings of disruptive innovation have been described in detail. Disruptive innovation, according to Christensen's teachings, is a very risky but, with careful planning and successful implementation, also beneficial form of business development and growth. While it disrupts existing markets and products, it also opens up new business opportunities. Even though patient safety ethics severely limit disruptive medical products, this does not mean that disruption in this area cannot occur.

According to Foster (1986), companies may fail to develop and adopt new technologies in a timely manner, which can be the reason why companies fail in the market and can lead to an advantage for attacking companies. He therefore introduced the S-curve theory to help managers plan new innovative technologies that successfully replace established products. Christensen's prescriptive S-curve strategy describes the ideal transition from one technology to the next in a company, where a new technology is ideally up and running when the previous one is still at its peak. The S-curve underlines the importance of continuous innovation for a growing business.

In parallel, Christensen developed the 'Value Network Framework', which views the collaboration of different firms and institutions that face incumbents in a market as a larger entity. According to Christensen, value networks influence the ability of participating firms to focus on the resources and capabilities necessary to remove technological and organisational barriers to innovation and not to ignore technologies that do not meet their customer's needs, as incumbents often do. By entering an established market, a value network can gain an 'attacker's advantage' over incumbents by disrupting an established technological path. The relative flexibility of start-ups in changing strategies and cost structures should be a key to their success.

According to Christensen's five principles of the innovator's dilemma, a start-up in particular should engage in discovery-based planning to assess the future of an uncertain market, develop the right tools to acquire new capabilities within the start-up, and finally monitor market trends to be able to react quickly to market changes. The theory of the innovator's dilemma is in line with the assumptions of entrepreneurial ambidexterity (see section 2.4.4.2).

The specific market characteristics and market barriers presented in sections 2.2.5 ff. and 2.3.8 show the specific disruptive potential in the MedTech sector studied.

As with any theory, the theory of disruptive innovation has been subject to criticism. None of the work presented has been able to overturn Christensen's proven cases, so the theory will continue to be applied unchanged in future research.

This section concludes with a brief overview of the advantages and disadvantages of disruptive product innovation, specifically from the perspective of a start-up (see Figure 13).

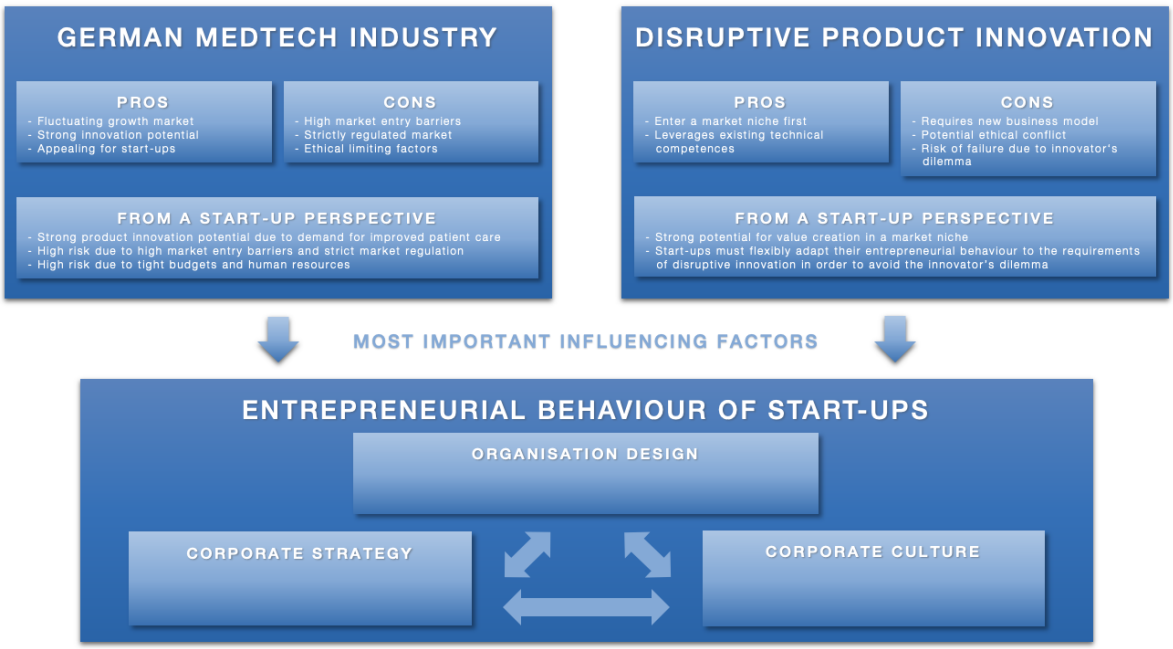

Figure 13: Key findings on disruptive product innovation

2.4 Entrepreneurial behaviour

2.4.1 Introduction

In this section, the key components of corporate behaviour, as an umbrella term encompassing, among others, the characteristics of organisational design, corporate strategy and organisational culture, are defined and presented in more detail as far as they are relevant in the context of this research project.

Focusing on start-ups, researchers have developed the originally very formal concept of corporate behaviour into entrepreneurial behaviour in order to better illustrate the specific management behaviour of these contemporary micro-enterprises - mostly pioneers in their field. The term ‘entrepreneur’ is derived from the French words ‘entre’ (in between) and ‘prendre’ (to take) and refers to someone who acts as an intermediary to achieve something. Entrepreneurs have two main roles in business: introducing new ideas and driving business processes. As mentioned in the introductory sections on innovation management (see section 1.1) and disruptive innovation (see section 2.3.3), Schumpeter (1934) developed fundamental theories on entrepreneurship, in particular on the upstream influences and drivers of entrepreneurial behaviour, placing the entrepreneur at the centre of his magnum opus ‘The Theory of Economic Development’. He thus had a seminal influence on entrepreneurship and innovation. Schumpeter (1934, p. 66) developed the concept of ‘new combinations’, which encompasses the following five cases: “(1) The introduction of a new good […] or a new quality of a good. (2) The introduction of a new method of production […] (3) The opening of a new market […] whether or not this market has existed before. (4) The conquest of a new source of supply of raw materials or half-manufactured goods, again irrespective of whether this source already exists […] (5) The carrying out of the new organization of any industry […]”. Schumpeter reserved the special economic role of entrepreneurs in realising these new combinations. For him, the existence of opportunities for innovation is a necessary but not a sufficient condition for the development of firms, and entrepreneurs are needed to implement innovations.

Based on these theoretical foundations of entrepreneurship, there are myriad contemporary definitions of 'entrepreneurial behaviour'. McAdam and Cunningham (2019, pp. 1-2) describe that "entrepreneurial behaviour is a subset of entrepreneurial activities concerned with understanding, predicting and influencing individual behaviour in entrepreneurial settings. […] Studies of entrepreneurial behaviour thus focus on the observable actions of individuals […] usually in the start-up or early stages of an organisation". The latter definition fits perfectly with the intention of this research project. Luthans (2011, p. 20) similarly defines organisational behaviour as "the understanding, prediction, and management of human behaviour in organizations".

Entrepreneurial behaviour can thus be seen as the study of human behaviour in start-up companies, the quasi-interface between employees and the formal organisation itself. Related disciplines include sociology, psychology, economics and engineering. In line with the 2nd research objective, this research project focuses on organisational design as the fundamental framework for a business, and on corporate strategy and organisational culture as two key leverage disciplines that influence entrepreneurial behaviour in a start-up. The impact of organisational design, corporate strategy and organisational culture on (disruptive) innovation performance will be addressed and theoretically explored in the following.

This section concludes with the development of a conceptual framework that builds on the theoretical findings of this section and allows for a deeper exploration of entrepreneurial behaviour as formulated in the 3rd research objective.

2.4.2 Start-up organisation design

In this section, the organisational design is introduced and its influence on entrepreneurial behaviour is examined. According to Ahmady, Mehrpour and Nikooravesh (2016, p. 456), every company consists of an organisational structure, which is the "manifestation of systematic thought". Mintzberg (1972a) viewed the organisational structure from a strategic persepective as a "framework of relations

on jobs, systems, operating process, people and groups making efforts to achieve the goals" (Ahmady, Mehrpour and Nikooravesh, 2016, p. 456), a set of methods that divide the work into specific tasks and then coordinate them. According to Duncan (1979, p. 59), "organisation structure is more than boxes on a chart; it is a pattern of interactions and coordination that links the technology, tasks, and human components of the organization to ensure that the organization accomplishes its purposes". Hamel (2002, p. 25) observes the impact of innovation on organisational design and concludes that "innovation is fine so long as it doesn't disrupt a company's finely honed operational model".

In their paper, Visscher and Fisscher (2012) show the path from the classical design approach to the more modern developmental approach. Organisational design theories have evolved significantly since their emergence in antiquity, especially in the last century when modern industrial work changed the economic landscape. Taylor (1911) set one of the first milestones by developing "a blueprint for efficient organizations and a 'scientific' way for designing them" (Visscher and Fisscher, 2012, p. 2). Since then, organisational design has evolved considerably. Following the classical approach that favours formal structures of organisations, Mintzberg (1979b) compares "designing an organization with turning the knobs of a control panel, adjusting and fine-tuning the division and coordination of labor to achieve stable and productive behavioral patterns" (Visscher and Fisscher, 2012, pp. 2-3).

	Classical design approach	Developmental approach
Design focus	Formal structure	Collective structure
Design process	Rational problem-solving	Collective learning process
Designers	Managers	Whole organizations
Designee's role	Passive	Active
Design knowledge	General, science-based knowledge	Local, experience-based knowledge
Design/implementation	Separated	Integrated

Table 3: Key differences in organisational design approaches (Visscher and Fisscher, 2012, p. 7)

The main differences between the classical design approach and the developmental approach are shown in Table 3. Although one might think that the developmental approach has been used most used recently, there is a tendency in the new generation of design approaches to combine, mix or balance elements of both approaches and to synthesise the dichotomies described in Table 3 (Visscher and Fisscher, 2012). The three main insights of the new generation of design approaches are the emphasis on the "integral process of bringing a new organization into being", the "room for the uncertain and the unexpected" and that "designing is more complicated than classic designing" (Visscher and Fisscher, 2012, pp. 11-12).

According to Katz and Kahn's (1978) theory, strategic thinking obviously plays an important role in entrepreneurial behaviour as it is the key to successful strategy implementation. It is important to closely align company policies and practices with strategic goals in order to meet the expectations of the role of employees. 'Human capital', first identified by the Nobel Laureate economist Gary Becker (1964), is therefore central as it is the only changeable factor within an organisation. In his theory, the knowledge, skills and abilities of employees are regarded as economic assets. Eisenhardt's (1989a) 'agency theory' proposes a strategic alignment of the interests of agents (employees) and principles (managers), which would lead to a rationalisation of the relationships and systems between employees and managers. The term 'human capital' later evolved into 'human resources' (HR).

Before presenting the different models of organisational design, it is important to highlight the specific framework conditions for start-ups. First, "a startup is not a smaller version of a large company. A startup is a temporary organization in search of a scalable, repeatable, profitable business model" (Blank and Dorf, 2020, p. xvii). In theory, all start-ups are SMEs, but not vice versa, as they have different structures and visions (Steigerthal, Maurer and Say, 2018, p. 6). The definition of SMEs in the EU was set out in Commission Recommendation 2003/361/EC (European Commission, 2003), which recognised that "SMEs are confronted with a unique set

of issues" such as 'market failures' and 'structural barriers' (European Commission, 2020, p. 5). As SMEs account for 99% of all enterprises in the EU (European Commission, 2021b), the European Commission plans to support these small but dynamic players in financial and administrative aspects (Rossignol, 2006, p. 187) in order to "free them from burdensome regulation" (European Commission, 2020, p. 3). According to Article 2 of the Annex to Commission Recommendation 2004/361/EC, SMEs are defined on the basis of two criteria: Number of employees and financial size. Accordingly, all enterprises with fewer than 250 employees, an annual turnover of less than EUR 50 million and/or an annual balance sheet of less than EUR 43 million are classified as SMEs (European Commission, 2003). There is no single definition for start-ups, but they tend to meet three criteria: They are younger than ten or five years old (depending on the industry), they pursue innovative products, services or business models, and their goal is to scale (Kollmann et al., 2022, p. 6; Steigerthal, Maurer and Say, 2018, p. 7). Ries (2017, p. 27) defines a start-up as a "human institution designed to create a new product or service under conditions of extreme uncertainty".

Due to their limited human and financial resources, SMEs and start-ups in particular must strive to bring new and innovative products to the market in order to "respond to competitive pressures and to find attractive market segments in order to remain vital and sustain competitive advantage in the face of market concentration and rivalry" (Hyvönen, Tuominen and Erälinna, 2004, p. 167). In the management and marketing literature, favourable market positions (Porter, 1985) and the possession of relevant 'resource differentials' (Barney, 2001; Day, 1994; Grant, 1998; Sanchez, Heene and Thomas, 1996; Wernefelt, 1984) are believed to lead to sustainable competitive advantage and superior performance (Hyvönen, Tuominen and Erälinna, 2004, p. 167). Even when SMEs face capacity constraints, the development of 'resource differentials' is inherent, so they should consider innovation and renewal of their processes as a fundamental option (Coates and McDermott, 2002). According to Christensen (2016, p. 167), SMEs may lack

resources compared to larger firms, but their values and cost structures are better adapted to smaller markets and lower profit margins (see section 2.3.6).

As mentioned in the previous section, innovation is a central element of entrepreneurship (Schumpeter, 1934). According to Hyvönen, Tuominen and Erälinna (2004, pp. 167-168), "innovation has been conceptualized both as an antecedent for performance and as an outcome of key resources and capabilities, ie a dimension of performance" (e.g. Baker and Sinkula, 1999; Gatignon et al., 2002; Hurley and Hult, 1998). SMEs also benefit from the assumption that firm size is negatively correlated with the success of disruptive innovation (Christensen and Raynor, 2003; DeTienne and Koberg, 2002; Tushman and O'Reilly, 2002). This suggests that larger firms should maintain their flexibility by forming smaller business units in order to keep their decision-makers excited and to take emerging opportunities seriously.

With the multitude of different organisational structures (e.g. bureaucratic, functional multi-divisional, matrix and hybrid structures), one must first distinguish between hierarchical/vertical and flat/horizontal organisational designs. The first era of so-called 'self-contained' vertical organisational designs (e.g. functional, division and matrix designs) developed from the mid-1800s to the late 1970s. Anand and Daft (2007, p. 330) describe the structure of 'self-contained' organisations as: "(1) the grouping of people into functions or departments; (2) the reporting relationships among people and departments; and (3) the systems to ensure coordination and integration of activities both horizontally and vertically".

For the purposes of this study, it is also important to distinguish between managers/leaders and the employees of a start-up. Heskett, Sasser and Wheeler (2008) summarise that "leadership is critical in codifying and maintaining an organizational purpose, values, and vision", see also section 2.4.4. for further statements. Managers, including entrepreneurs, lead organisations and determine the organisational design in which their employees are to work. Mintzberg (1972b)

defines managers as the ‘nerve centre’ of any organisation. A manager must process all external and internal information and assemble it into specific information to be communicated to members of the organisation (internally) and to outsiders (Mintzberg, 1972b, p. 93). Importantly, Mintzberg (1972b, p. 93) also sees the manager’s role as that of a ‘strategist’ who uses the compiled “information for models, plans, entrepreneurship and crises”. Thus, the manager’s role is not only to process the information gathered internally and externally in day-to-day operations, but also to predict and plan for future business objectives. Accordingly, the manager is the key decision-maker when it comes to the strategic choices a company has to make; he is the only one who can orchestrate such a complex system over the long term.

Ahmed (1998, p. 39) states that managers have the opportunity to empower their employees to take responsibility for innovation through the support and commitment of their superiors. Empowerment will mobilise their energies and enthusiasm to be creative (Ahmed, 1998, p. 39). Therefore, an organisation needs a “strong value system capable of driving activities in a unified and aligned manner to the super-ordinate goals of the organisation” (Ahmed, 1998, p. 39).

Hogan (2005) describes the organisational structure of a small firm focused on disruptive innovation as often flat, but the morale is the opposite. According to her, start-ups in this field gain a lot of confidence in their intellectual property by raising a lot of money through an early Initial Public Offering (IPO) or by being acquired by established companies that were once competitors.

According to Luthans (2011, p. 57), “organization design and culture are dominant factors that interact with the personal cognitions and the behavior”, so he draws on the aforementioned ‘human capital’ theory as the core of organisational design. In addition to the ‘open-systems concept’, the ‘contingency approach’ and the ‘organisational ecology theory’, Luthans (2011) focuses on the ‘learning organisation’ based on systems theory and has identified its three main dimensions:

first, the presence of tension ('creative tension'), which acts as a catalyst for learning; second, a shared vision of the whole organisation which promotes openness to new ideas; third, an organisational culture that promotes learning. He goes on to show that successful companies tend to create inter-functional teams that work on projects and remove the "artificial barriers between functional areas and between line and staff" (Luthans, 2011, p. 61). As the term 'creative tension' implies, developing employees' creativity plays a critical role in making organisations successful because "creativity is the ability to formulate unique approaches to problem solving and decision making" (Luthans, 2011, p. 61). The following three dimensions are essential to unleash the creativity of employees to think 'outside the box': personal flexibility and the willingness to take risks and accept failure (Luthans, 2011, p. 61). Among several other possible variants of learning organisations, Luthans (2011) points to the advantages of a horizontal organisational design as opposed to the traditional vertical, hierarchical design. Characteristics of horizontal designs include a significantly flattened hierarchy, an organisation focused on process rather than task, self-managed team structures, customers driving performance, employees in close contact with suppliers and customers, fully informed and trained, and regularly rewarded (Luthans, 2011, p. 64). Anand and Daft (2007, p. 331) put it succinctly: "The horizontal organization advocates the dispensing of internal boundaries that are an impediment to effective business performance. If the traditional structure can be likened to a pyramid, the metaphor that best applies to the horizontal organization is a pizza - flat, but packed with all the necessary ingredients". Steigerthal, Maurer and Say (2018, p. 61) found in their study that "flat hierarchies are dominating the startup landscape: 34.0% have one hierarchy level, 41.6% two hierarchy levels and 20.5% three hierarchy levels". Due to their low hierarchy and bureaucracy, start-ups are often considered to be more flexible and agile (Kollmann, 2016).

Gulati (2019, p. 86), who has studied the organisational design of start-ups, goes a step further and is the first to describe the 'soul' of start-ups as "an essential, intangible something in start-ups […] it inspires people to contribute their talent,

money, and enthusiasm and fosters a sense of deep connection and mutual purpose. As long as this spirit persists, engagement is high and start-ups remain agile and innovative, spurring growth". But even if there is evidence for the existence of a start-up soul, like everything else, it also has a downside: "When it vanishes, ventures can falter, and everyone perceives the loss – something special is gone" (Gulati, 2019, p. 86). However, this rather theatrical portrayal of the downside should not stop us from taking the soul of start-ups seriously and believing in this one core.

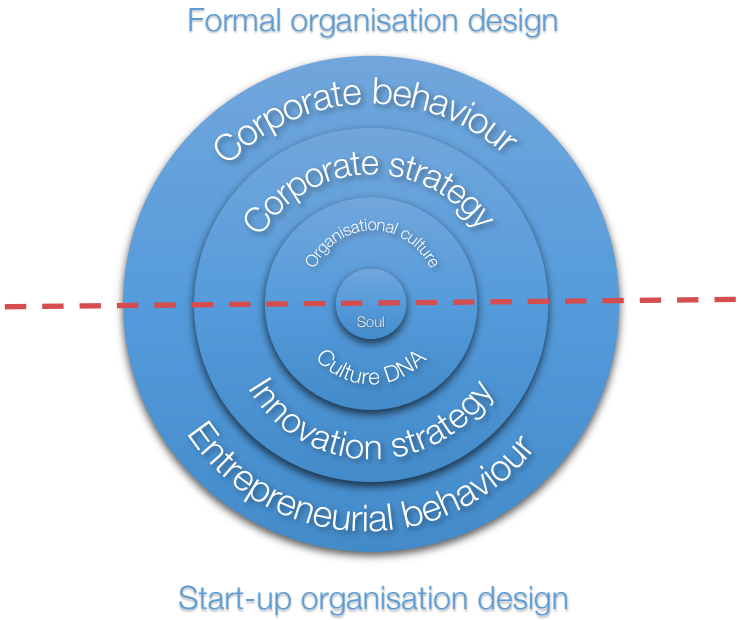

Figure 14: Formal vs. start-up organisational design (Illustration by the author)

Figure 14 shows the different names for of a formal organisational design and the resulting start-up organisation.

Ahmed (1998) found correlations between certain firm structures and innovation and summarised his findings as follows:

Organic structures promote innovation
- freedom from rules;
- participative and informal;
- many views aired and considered;
- face to face communication; little red tape;
- inter-disciplinary teams; breaking down departmental barriers;

- emphasis on creative interaction and aims;
- outward looking; willing to take on external ideas;
- flexibility with respect to changing needs;
- non-hierarchical;
- information flow downwards as well as upwards.

Mechanistic structures hinder innovation
- rigid departmental separation and function specialisation;
- hierarchical;
- bureaucratic;
- many rules and set procedures;
- formal reporting;
- long decision chains and slow decision making;
- little individual freedom of action;
- communication via the written word;
- much information flow upwards; directives flow downwards (Ahmed, 1998, p. 36).

The latter is a remarkable summary of all the previously mentioned literature sources and could serve as a perfect description of the organisational design of start-ups as the most innovative form of enterprise. It is equally important to point out that the organisational design of start-ups is complex and requires a great deal of effort to implement in the strategic and cultural design of the company. The following sections presents theories of business strategy and organisational culture, both of which are based on the specific organisational design of start-ups.

2.4.3 Effects of organisation design on innovation performance

An important finding from section 2.4.2 was that the more employees a company has, the less flexible its organisational structure becomes. In their book “Musterbrecher” (‘Pattern Breakers’; translation by the author), Kaduk et al. (2016, p. 54) examined that organisation is anything but an instrument for promoting ‘creative destruction’ and subsequent comprehensive renewal. Rather, organisation leads to reliability and replicability (Ortmann and Sydow, 2001). Innovation, on the other hand, necessarily requires uncertainty; the ‘maximum security’ approach offered by an organisation is an obstacle (Kaduk et al., 2016, p. 55).

Christensen (2016, p. 29) noted that organisational barriers may be the reason why "leading firms frequently stumble when confronting technology change". Simple reasons include "bureaucracy, complacency, or 'risk-averse' cultures" (Christensen, 2016, pp. 29-30). If a firm developing a product is organised into subgroups corresponding to the components of the product, the organisational structure should facilitate innovation at the component level (Henderson and Clark, 1990). An exception where this type of organisational structure hinders innovation is architectural technological change, which requires employees and teams to adopt new ways of communicating and working (Henderson and Clark, 1990). Christensen (2016) concludes that certain established corporate structures may facilitate the development of dominant products, but may have a negative impact on the development of new products. The research findings of Clark (1985), Tushman and Anderson (1986) and Anderson and Tushman (1990) collectively support the hypothesis that "firms failed when a technological change destroyed the value of competencies previously cultivated and succeeded when technologies enhanced them" (Christensen, 2016, p. 31).

An important insight of Christensen (2016, p. 32), which deals with the above incident, is the 'concept of the value network' (see section 2.3.5) - based on the ideas of Christensen and Rosenbloom (1995) and Rosenbloom and Christensen (1994) - which he defines as "the context within which a firm identifies and responds to customers' needs, solves problems, procures input, reacts to competitors, and strives for profit". Accordingly, the competitive strategies of firms within the same value network contain their specific perceptions of the economic value of a new technology (Christensen, 2016). In contrast to incumbents, which steer "the allocation of resources towards sustaining innovations and away from disruptive ones", firms within a value network pursue both sustainable and disruptive innovations (Christensen, 2016, p. 32).

Pillkahn published his dissertation in 2011 on "Innovation zwischen Planung und Zufall – Bausteine einer Theorie der bewussten Irritation / Innovation between

planning and chance – building blocks of a theory of conscious irritation" (Pillkahn, 2011; translation by the author). His research focuses on understanding how organisational structures inhibit innovation within a company, and developing strategies to generate and drive radical innovation in larger organisations. Pillkahn (2013) compares the innovation process to the game of roulette, claiming that innovation is not predictable, but rather follows a random principle. According to Pillkahn (2014), companies usually recognise the need to innovate in order to drive organic growth and to differentiate themselves from competing products. Because managers of established companies understand the effort required to create an innovative growth business, most of them rely on the strength of their R&D department. Unfortunately, the allocation key of most R&D departments is not uniform. Most efforts are spent on development, leaving almost nothing for research. Established companies with their entrenched organisational structures, customers and prejudices, prevent managers from turning to new business areas when a decision on a new investment is pending. By staying in the core business, the risks ahead are more predictable and manageable, and easier for management to defend. Instead, investment in radical or even disruptive innovation is harder to justify, so managers fear experimentation and stick to their core business. In his conference paper, Pillkahn (2014) suggests how companies can break out of their 'comfort zone' and avoid the looming 'innovation coma' (see Figure 15).

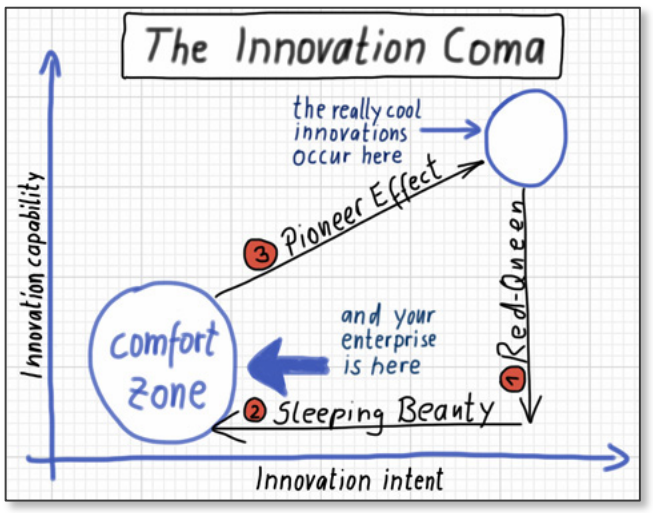

Figure 15: The Innovation Coma (Pillkahn, 2014)

By analysing the innovation behaviour of hundreds of firms, Pillkahn (2014) found the following three effects:

(1) Red-Queen Effect: focusing on pure improvements and neglecting genuine innovations – more of the same instead of the 'new'.
(2) Sleeping Beauty Effect: missing out on developments in the environment, clinging to the successful businesses of the past.
(3) Pioneer Effect: exploring, experimenting and discovering new technologies and creating new markets (Pillkahn, 2014).

Pillkahn (2014) describes the apparent paradox as follows: "Ground-breaking innovation requires discontinuous thinking. Organizations however are just prepared for conventional thinking" (Pillkahn, 2014). The only way out of the 'innovation coma' is to avoid the 'Red-Queen Effect' and the 'Sleeping Beauty Effect' and to pursue the 'Pioneer Effect' by trying to research, test and discover new - possibly disruptive - technologies and use them to create new markets to compete against incumbents (see Figure 15).

As innovation itself is a continuous process, the challenge for managers is to prioritise radical or disruptive innovation over sustainable opportunities. Even if the creation of a new market attracts competitors who attack the core business, managers should be pioneers, not be afraid of disruptive threats and always seize new growth opportunities (Pillkahn, 2014). Severin Schwan, Chief Executive Officer (CEO) of the Roche Group (an established pharmaceutical medical device company), explains that staying innovative means "exploring new, unknown paths, taking risks, trying out new ideas and constantly reinventing ourselves" (Schwan, 2013, p. 92). Accordingly, Roche creates the conditions for innovative thinking and gives its employees the freedom to make their own decisions, because "innovative people need their room to breathe" (Schwan, 2013, p. 98). Accordingly, it is essential that companies understand disruptive mechanisms and build capabilities to turn them into advantages. Schwan (2013, p. 99) echoes the latter finding that

large companies tend to stifle their own innovation potential, stating that “probably 99% of all discoveries happen outside of Roche, so we need to stay open and bring in external expertise to the company”.

2.4.4 Corporate strategy

One of the most important researchers in the field of strategic management, Mintzberg (1987, p. 14), stated that corporate strategy is “potentially about anything. About products and processes, customers and citizens, social responsibilities and self interests, control and color”. Glueck (1980, p. 9) vividly defines corporate strategy as “a unified, comprehensive, and integrated plan […] designed to ensure that the basic objectives of the enterprise are achieved”. A strategic plan for the future is called ‘intended strategy’ and strategic actions are called ‘realised strategy’. Strategic means plans and policies, while strategic objectives can be broad (visions and missions) or focused (goals and objectives). A well-defined ‘mission statement’ serves as a blueprint for a start-up company and consists of three indices: strategic direction and intent, goals and objectives and a ‘vision’ (Sackmann, 2010, p. 56).

Mintzberg (1987) developed a framework of five elements of strategic planning in his ‘Five Ps For Strategy’: ‘Plan’, ‘Ploy’, ‘Pattern’, ‘Position’ and ‘Perspective’. Although the five ‘Ps’ are used more to describe the characteristics of strategic planning from different perspectives, they are also relevant to organisational behaviour. The general ‘Plan’ is consciously and purposefully developed to serve as a general guide from the current state to the desired strategic goals. The latter is an intended strategic action, as is the specific ‘Ploy’, a deliberate manoeuvre to mislead the competition. Strategic ‘Patterns’, which do not contradict ‘Plan’ and ‘Ploy’, but stand alongside them, describe a ‘stream of actions’, regardless of whether these actions were intended or resulted from a specific behaviour. Observed successful behaviours that contribute to strategic success should be repeated to develop an advantage. ‘Position’, a very important data-driven part of strategic planning, is about examining your existing and future market position,

which affects, for example, your brand, pricing and relationships with buyers and suppliers. Since every aspect of the analysis has a direct impact on your strategic planning, it could be considered a core element of planning. The final element described by Mintzberg (1987), 'Perspective', is used to align managers with the views of their employees, customers, suppliers and competitors to gain an overview of how the company is perceived, including its strengths and weaknesses.

Pisano (2015, p. 46) slightly devalues business strategy in his definition as "nothing more than a commitment to a set of coherent, mutually reinforcing policies or behaviours aimed at achieving a specific competitive goal". To remain competitive, companies need to refine their business strategy in terms of scope and positioning and specify how functional parts such as marketing, operations, finance and R&D will support it (Pisano, 2015, p. 46). Interestingly, according to Pisano (2015), the precise formulation of a business strategy is rather uncommon.

Hogan (2005, pp. 21-23) points to the danger that disruptive innovation start-ups, with "their flexibility, no-constraints attitude and drive to succeed", may find it difficult to "recreate their own success when the company grows and has to simultaneously manage a larger range of products". In her view, it is then inevitable to "adopt some of the processes used by their more unwieldy competitors, but with a 'lighter touch' that suits the size of the business and does not stifle the teams that made the first products successful" (Hogan, 2005, p. 23).

In addition, it is important to consider how strategic thinking can be captured and strategic objectives refined. Doerr (2018), in his work 'Measure What Matters', has presented a contemporary method called the 'Objectives and Key Results' (OKR) management framework as a strategic controlling tool, which has evolved from the 'Management by Objectives' (MBO) framework. The OKR method is an agile management tool, i.e. it enables quick reactions and radical transparency in the company, while strategic objectives are aligned in quarterly workshops (Doerr, 2018, p. 6 ff.). While classical strategic goal setting followed the waterfall principle,

i.e. it was dictated by top management to all employees and had a duration of one year, modern systems prevent the inevitable goal amnesia that results from this. This touch of socialism in a thoroughly capitalist company should result in employees identifying more closely with the strategic goals through their active participation in them. Niven and Lamorte (2016, p. 6) define OKRs as a "framework for critical thinking and a continuous discipline that seeks to ensure that employees work together to make measurable contributions with focused efforts that drive the business forward". According to Teipel and Alberti (2019), strategic goals are translated into 'Objectives' and should define a clear outcome and be formulated in a precise, concrete, qualitative, action-oriented and inspiring way. The first key question is: 'Where do I want to go?', while the second question relates to how to achieve the defined goal and how to measure whether it has been achieved. To this end, an actionable plan is developed, a 'Key Result' is defined that describes how the company will achieve the desired result, and the answer is: 'How do I get there?' The Key Result is always linked to an Objective. Key Results should also be precise, concrete and ambitious - yet achievable. Above all, they must be measurable (Teipel and Alberti, 2019). OKRs are the building blocks of the 'OKR framework'. The OKR management method seems to be perfectly suited to the organisational design of start-ups as extremely agile and scalable micro-enterprises.

2.4.4.1 Innovation Strategy

In parallel to a company's corporate strategy, which sets out the goals for its global operations, there should be an innovation strategy, which focuses on the strategic parameters for innovation design that a company will pursue in the long term. Skarzynski and Rufat-Latre (2011) call for a well-articulated innovation strategy to develop, plan and execute disruptive innovations. Pisano (2015, p. 46) refines his definition of a business strategy when it comes to the more specific innovation strategy, defining it as an "innovation system: a coherent set of interdependent processes and structures that dictates how the company searches for novel problems and solutions, synthesizes ideas into a business concept and product designs, and selects which projects get funded". An innovation strategy is most

important when a company needs to change its prevailing patterns. According to Pisano (2015), trade-offs are inherent in defining a company's innovation strategy. Imitating another company's innovation strategy does not make sense as each company needs to develop its own dedicated innovation strategy (Pisano, 2015, p. 53). Even if there is a clear business strategy, companies without a clear innovation strategy may face serious problems as "different business units can wind up while pursuing conflicting priorities" (Pisano, 2015, p. 46). Therefore, an innovation strategy is needed to integrate and align the different perspectives (Pisano, 2015, p. 47).

In more detail, an innovation strategy must include both sustainable and disruptive innovations, as most of the benefits comes from 'the stream of routine', the sustainable innovations (Pisano, 2014, p. 2). Therefore, managers should "achieve the optimal balance between disruptive and sustaining efforts" (Pisano, 2014, p. 4). Disruptive strategies are the only way to find alternative value propositions (Pisano, 2014, p. 4). In pursuing their innovation strategy, companies need to "understand how to leverage distinctive existing strengths to generate value and capture value […] [and] how your repertoire of R&D skills, intellectual property, operating capabilities, relationships, distribution channels, and brand can protect and extend the value from innovation" (Pisano, 2014, p. 4). Value creation is a given in the MedTech industry, as the primary purpose of medical devices is to improve the health of their customers (patients) as end users.

Pisano (2015) argues that there are four tasks involved in creating and implementing an innovation strategy:

(1) To answer the question "How are we expecting innovation to create value for customers and for our company?" and then explain that to the organization
(2) Create a high-level plan for allocating resources to the different kinds of innovation

(3) Manage trade-offs
(4) Recognize that innovation strategies must evolve as any strategy represents a hypothesis that is tested against the unfolding realities of markets, technologies, regulations, and competitors (Pisano, 2015).

Manufacturing should always be involved in the innovation processes carried out by R&D in order to be able to consistently produce the required parts in a certain high quantity once the innovation has reached its final state (Pisano, 2015). According to Pisano (2015), an innovation strategy - like the innovation process itself - involves constant experimentation, learning and adaptation. Even if a company has a clear corporate strategy, without an innovation strategy, "different parts of an organisation can easily wind up pursuing conflicting priorities" (Pisano, 2015).

Siguaw, Simpson and Enz (2006), Stock and Zacharias (2011) and Stock, Six and Zacharias (2013) in their studies on innovation orientation as a cultural and strategic orientation support the assumption that innovation orientation is a "multidimensional knowledge structure […] to promote innovative thinking and facilitate successful development, evolution, and execution of innovations" (Siguaw, Simpson and Enz, 2006, p. 560). According to Siguaw, Simpson and Enz (2006, p. 557), a broad innovation orientation at the firm level that "produces capabilities that spawn innovations" is far more important than a focus on specific innovations.

The corporate strategy is based on business-specific tasks and parameters, while the innovation strategy focuses on the innovation-specific tasks and parameters within the corporate strategy. Both are essential for start-ups in the field of disruptive innovation, as the results show that a clearly formulated strategic positioning of a company increases the innovation potential, especially when it comes to disruptive innovations. The characteristics of start-ups and SMEs showed that small companies are less constrained by their formal organisational structure, as they are significantly more flexible when it comes to changes in resource allocation, process generation or value description.

In their recent study on innovation milieus in Germany, Pohl and Kempermann (2019, p. 32) found that most disruptive innovators have a clearly defined innovation strategy focusing on selected innovation areas, and that around 90% stated that they regularly review innovation projects for effort and progress and adjust them if necessary. Chen et al. (2018, p. 1) note that the fit between innovation strategy and organisational culture is "critical for effective and efficient implementation of innovation strategy […] [and] a key source of competitive advantage for organizations, rather than the pure strategy". One of the key findings of the study was that innovation strategy alone is not enough to drive a company's innovation performance. Rather, it is important that a particular innovation strategy is implemented based on the respective organisational culture (Chen et al., 2018, p. 14). The latter, in turn, supports Drucker's hypothesis that 'culture eats strategy for breakfast'.

2.4.4.2 Entrepreneurial ambidexterity

In addition to the results of corporate and innovation strategy, the phenomenon of entrepreneurial ambidexterity needs to be examined in more detail. Ambidexterity describes the existence of two points of view and the ability to hold both. As O'Reilly and Tushman (2004) note, "this mental balancing act can be one of the toughest of all managerial challenges". On the one hand, managers strive to continuously improve an existing product, which is called exploitation (March, 1991); on the other hand, they may fail to create breakthrough innovations in parallel, which is called exploration (March, 1991; Markides, 2013). O'Reilly and Tushman (2004) cite the examples of Kodak and Boeing as two dominant firms that failed to adapt to market changes. Kodak did not recognise the market shift to digital photography in time and stuck to the old familiar analogue photography. Boeing has always relied on its success in selling commercial aircraft and is struggling in the defence business as it is attacked by better positioned competitors such as Airbus.

Ambidexterity has two sides: exploitation and exploration. Managers should therefore build on successful products and develop them in incremental/sustainable

innovation steps, but also switch to exploration mode to look for future radical/disruptive innovations. He and Wong (2004, p. 481) in their study on exploration versus exploitation suggested that "exploration implies behaviours characterized by search, discovery, experimentation, risk taking and innovation, while exploitation implies firm behaviours characterized by refinement, implementation, efficiency, production and selection". In their study, O'Reilly and Tushman (2004) discovered the model of 'ambidextrous organisations', which separates the new exploratory firms from the traditional exploitative ones, thus also allowing them to have different processes, structures and cultures. Conversely, it also strengthens the links between managers. They believe that this is a "practical and proven model for forward-looking executives seeking to pioneer radical or disruptive innovations while pursuing incremental gains" and note that "more than 90% of the ambidextrous organizations achieved their goals" (O'Reilly and Tushman, 2004). Tushman, Smith and Binns (2011) developed the method further in their in-depth study, outlining three principles that an 'ambidextrous CEO' should keep in mind. First, it is important to develop an overarching identity that integrates all lines of business, whether they are exploitative or exploratory. Second, it is important to keep the tension at the top, saying that managers are responsible for keeping conflict out of the lower levels and that decisions are made at the executive level. The third principle is to allow inconsistency while working with a dual agenda, because "supporting core businesses and innovation units requires leaders to be consistently inconsistent" (Tushman, Smith and Binns, 2011, p. 80).

Entrepreneurial ambidexterity and entrepreneurial agility should be inextricably linked. Ultimately, it expresses a firm's ability to respond flexibly and appropriately to external and internal developments. According to Volery, Mueller and von Siemens (2015, p. 110), "growth-oriented entrepreneurs show an ability to pursue both exploration and exploration [sic], although the vast majority of activities are related to exploitation".

In addition to their findings on the relationship between innovation strategy and innovation-oriented culture, Chen et al. (2018) found in their study that “the fit between organizational culture and innovation strategy is not significant for achieving superior innovation speed and innovation quality for ambidextrous organisations”, as the emphasis on innovation strategy is the top priority for ambidextrous companies that focus on organisation-environment co-evolution.

Haines (2016) describes the tension between revolutionary and evolutionary activities of start-ups as a dichotomy they experience when choosing between radical and incremental innovation.

The literature presented shows the different elements of corporate strategy, including the aspects of innovation orientation and ambidexterity, and their specific influence on start-ups. Naranjo-Valencia, Jiménez-Jiménez and Sanz-Valle (2011, p. 55) have analysed and tested the relationship between innovation orientation and organisational culture in a research project. They conclude that organisational culture is a clear determinant of innovation strategy. In the following sections, therefore, the results of the literature on organisational culture, corporate climate and innovation-oriented culture will be presented in particular.

2.4.5 Organisational culture

The term ‘organisational culture’, which originated in cultural anthropology, has a firm place in the organisational behaviour literature (Homburg and Pflesser, 2000; Schein and Schein, 2017). Various definitions of culture as a human phenomenon were collected and systematised in the 1950s by Kroeber and Kluckhohn (1952):

> Culture consists of patterns, explicit and implicit, of and for behaviour acquired and transmitted by symbols, constituting the distinctive achievements of human groups, including their embodiments in artefacts; the essential core of culture consists of traditional (i.e. historical derived and selected) ideas and especially their attached values, culture systems may,

> on the one hand, be considered as products of action, on the other as conditioning elements of further action (Kroeber and Kluckhohn, 1952, p. 181).

In simple terms, culture can be summarised as "the way of life, especially the general customs and beliefs, of a particular group of people at a particular time" (Cambridge Dictionary, 2022b). Cultural groups can be peoples, nations, tribes, but also companies. There are probably as many definitions of organisational culture as there are facets of cultures around the world. For the purposes of this dissertation, business organisations should be seen as organisms: a living entity that 'lives' through the actions of each employee, rather than a theoretical construct that can be captured, for example, in a series of numbers. Culture is the phenomenon of interpersonal behaviour and the tacit social order of an organisation that has existed since the dawn of humanity and is present in every company from the beginning. Sackmann (2010) recommends the size of the discrepancy between the normatively postulated or proclaimed organisational culture and the organisational culture actually lived out in behaviour as a measure of the quality of the respective organisational culture. However, organisational culture can also be consciously influenced, e.g. to better achieve organisational goals. Tripathi et al. (2019) describe the unique organisational culture and ecosystem of start-ups as 'start-up culture' and 'start-up ecosystem'. In the following section, the theoretical foundations of organisational culture will be highlighted, focusing in particular on innovation-oriented culture as a quasi 'ideal cultural environment' for innovative companies/start-ups.

Among the many definitions of organisational culture, Hofstede (2001, p. 9), a pioneer in business culture research, aptly treats culture as "the collective programming of the mind that distinguishes the members of one group or category of people from another". According to Fichter, Basel and Keller (2018, p. 164), organisational culture describes "a system of rules, norms, values and typical behaviour that has become established over time among the members of an

organisation. The latter are usually not aware of it, but it does have a great influence on their behaviour. Operationalisation and thus measurement and change of an organisational culture are difficult" (translation by the author). Schein and Schein (2017, p. 2) emphasise that "cultures are learned patterns of beliefs, values, assumptions, and behavioral norms that manifest themselves at different levels of observability". Jassawalla and Sashittal (2002, p. 52) take up Schein and Schein's statement and refine organisational culture as "beliefs, value systems, assumptions dominant in the social and cognitive environment reflected in a consistent pattern of behaviors", with the aspect of consistent patterns of behaviour being particularly important here.

Tian et al. (2018) conducted a systematic analysis of academic papers dealing with either national or organisational culture, as these are the most relevant areas of analysis for culture studies (Hofstede, 1984). Their examination of the relationship between culture and innovation found it to be "complex and idiosyncratic" (Tian et al., 2018, p. 1088).

Although organisational culture has an external impact, it is particularly effective internally and is an important factor in achieving organisational goals (Baetge et al., 2007). Hogan and Coote (2014, p. 1609) summarise that organisational culture is a "powerful means to elicit desired organizational outcomes". According to Martins and Terblanche (2003), organisational culture is a critical success factor for an organisation and is at the heart of organisational innovation (Tushman and O'Reilly, 2002). Schein and Schein (2017) see organisational culture as a social force that is largely invisible but very powerful. Many organisations therefore tend to capture their culture in their knowledge management tools, for example in the form of mission statements, process maps or leadership principles. The interweaving of cultural and strategic elements should help to make the organisational culture more tangible for (new) employees and to create a basic mechanism for change (e.g. in the context of organisational development). A computer-based method for recording and tracking mission

statements or process maps would be the OKR management framework presented in section 2.4.4.

Schein and Schein (2017, p. 6), arguably the most widely cited researchers in the field of organisational culture, further define a group's culture as "the accumulated shared learning of that group as it solves its problems of external adaptation and internal integration; which has worked well enough to be considered valid and, therefore, to be taught to new members as the correct way to perceive, think, and behave in relation to those problems". This rather formal definition should be understood as a generalisation for any culture and needs to be adapted for each individual organisational situation. As pioneers of organisational culture research, Schein and Schein (2017) observed cultural phenomena and classified them into three levels, from very tangible, obvious phenomena to unconscious basic assumptions embedded in the cultural essence, the 'Cultural DNA' of a company (see section 2.4.5.2).

According to Luthans (2011), the phenomenon of organisational culture is quite complex. Following literary definitions of organisational culture, he identifies the following six main cultural characteristics: observed behavioural regularities, norms, prevailing values, philosophy, rules and organisational climate. He emphasises that the list is not exhaustive and that organisational culture and corporate climate are often confused (see section 2.4.5.1).

Ostroff (1999, p. 11) sees a competitive advantage in a horizontal organisational structure and stresses the importance of building an "organisational culture of openness, cooperation, and collaboration, a culture that focuses on continuous performance improvement and values employee empowerment, responsibility, and well-being".

According to Heskett, Sasser and Wheeler (2008), there are good reasons to actively shape organisational culture because "strong, adaptive cultures can foster innovation, productivity, and a sense of ownership among employees":

(1) Leaders must codify and uphold the organisation's purpose, values and vision. They must live the elements of the culture: Values, behaviours, measures and actions.
(2) Invest in the culture. Norms and values are created through team action and learning. Strong cultures have teeth. Managers should recognise those employees whose actions exemplify the values, behaviours and standards of the organisation (e.g. by creating awards such as 'Employee of the Month', 'Champions' or 'Legends').
(3) Employees at all levels of the organisation perceive and endorse the elements of the culture.
(4) Organisations with a clearly codified culture have labour cost advantages.
(5) Organisations with clearly codified and lived cultures have high levels of employee and customer loyalty.
(6) A business strategy based on a strong, effective culture is selective towards potential customers.
(7) Beware of creating of dogmatic cults that are difficult to change. High performing organisations regularly review and reaffirm their core values and associated behaviours.
(8) Organisations with strong and adaptive cultures promote effective successions at the leadership succession.
(9) Always remember: Cultures can fail for a many reasons.

Perhaps the most important finding of Heskett, Sasser and Wheeler (2008) is that there is a "pattern in the actions and activities involved in developing strong and adaptive ownership cultures", similar to the findings of Jassawalla and Sashittal

(2002). Companies that consistently build and strengthen such a culture have a distinct competitive advantage.

Denison, Haaland and Goelzer (2004) developed a cultural framework for organisations. They identified and validated four key dimensions: adaptability, consistency, involvement, and mission. Adaptability is the ability of an organisation to change its behaviour, structures and systems on response to environmental change. Consistency is the ability of employees to adhere to beliefs, values and expectations. Involvement refers to the extent to which an employee is involved in decision making and mission refers to the organisation's strategy (Denison, Haaland and Goelzer, 2004).

Ahmed (1998, p. 36) argues that it is the right cultural norms in an organisation that are important for activating the creativity that drives innovation. Gulati (2019, p. 89) puts it well: "What set apart successful firms was not a 'fun' or 'crazy' culture but the unusual creativity and autonomy employees showed". The aspect of creativity in a start-up will be explored in the following sections.

According to Zheng, Yang and McLean (2010), organisational culture contributes more to knowledge management and organisational effectiveness than corporate strategy. Klein (2011, p. 25) states that companies need to "manage their cultures as strategic resource by establishing flexible, adaptive, constructive cultural norms". Both researchers confirm Drucker's opening quote in this dissertation that 'culture eats strategy for breakfast', which remains to be confirmed.

The following sections will help to clarify the characterisation of organisational culture, particularly with regard to its tangibility and the specific characterisation of an innovation-oriented culture.

2.4.5.1 Corporate climate

In everyday language, the terms organisational culture and corporate climate are often confused or used synonymously. However, from a business psychology perspective, they have different meanings, as corporate climate is a part of the overarching organisational culture. Schein and Schein (2017, pp. 3-4) define corporate climate as "the feeling that is conveyed in a group by the physical layout and the way in which members of the organization interact with each other, with customers, or with other outsiders. Climate is sometimes included as an artifact of culture and is sometimes kept as a separate phenomenon to be analyzed" (Ashkanasy, Wilderom and Peterson, 2000; Ehrhart, Schneider and Macey, 2014; Schneider, 1990; Tagiuri and Litwin, 1968). Dabic et al. (2018, p. 526) see corporate climate as the "manifestation of culture […] a conglomerate of attitudes, feelings, and behaviours that characterise life in an organisation". The different definitions of corporate climate show that, unlike organisational culture with all its facets, corporate climate consists of attitudes, feelings and behaviours that characterise life in the organisation (Dabic et al., 2018). It is a phenomenon that can either be observed or easily narrated by group members (Dabic et al., 2018). According to Fichter, Basel and Keller (2018, p. 168), corporate climate describes "the manners, the jointly experienced atmosphere and the degree of activation of the members of an organisation. It lasts for a relatively long time and influences the experience, the behaviour and the satisfaction of the members of an organisation. It can be consciously perceived and is therefore relatively easy to measure and shape" (translation by the author). McLean (2005) also supports the notion that organisational climate is more directly observable and measurable.

For further research, it is important to distinguish between the two phenomena in their manifestations and to see corporate climate as an artifact of culture in the sense of Schein and Schein (2017). This will be important for the case study design envisaged in this research project (see section 3.6).

2.4.5.2 Culture design

This section presents different methods that are commonly used to decipher complex organisational cultures. As mentioned in section 2.4.5, Schein and Schein (2017), in their basic research on organisational culture, observed cultural phenomena and classified them into three levels, the so-called 'Cultural DNA' of a company. The latter is probably the most basic classification of organisational culture phenomena:

(1) Artifacts
   - Visible and feelable structures and processes
   - Observed behavior (Difficult to decipher)

(2) Espoused Beliefs and Values
   - Ideals, goals, values, aspirations
   - Ideologies
   - Rationalizations (May or may not be congruent with behavior and other artifacts)

(3) Basic Underlying Assumptions
   - Unconscious, taken-for-granted beliefs and values (Determine behavior, perception, thought, and feeling) (Schein and Schein, 2017, p. 17).

The three levels of culture range from tangible, visible and palpable structures and processes to intangible, unconscious beliefs and values. The order of the levels is a result of the strength of the employee's awareness of these levels. All cultural levels are strongly interconnected (Hofstede, 1984; Schein and Schein, 2017). Artifacts are the most visible level of organisational culture and include stories, arrangements, rituals and language and have strong symbolic meaning (Schein and Schein, 2017; Trice and Beyer, 1984). Observed behaviours are associated with patterns of organisational behaviour that have an instrumental function (Homburg and Pflesser, 2000).

According to Herbig and Dunphy (1998, p. 13), culture consists of both “explicit and implicit rules through which experience is interpreted”. Schein (2010) suggests that corporate culture cannot be validly measured because each company has a unique mix of artifacts, values and assumptions that cannot be quantified by standardised questionnaires (Schein, 2010, p. 69). However, it is possible to decode the culture of a company, i.e. to identify the meaning of the artifacts and to find and evaluate the assumptions and values (Schein, 2010, p. 74). This is important to Schein because it allows two things to happen: first, current problems and issues can be checked for compatibility with the existing culture; second, this is the basis for further development, expansion and, if necessary, change of the organisational culture (Schein, 2010, p. 92). The essence of Schein’s concept of culture is that, in his view, culture can be both beneficial and obstructive. Therefore, it is important not only to address the issue, but to continually develop the culture. For Schein, this is a transformation in which the old must be unlearned before the new can be learned. However, unlearning is a painful process that is usually met with strong resistance. According to Schein (2010), this resistance is only overcome when the fear of survival - the goals cannot be achieved as they are now - becomes greater than the fear of temporary incompetence and loss of group membership. Schein (2010) refers to this as ‘learning anxiety’.

Following the theoretical assumptions around the Cultural DNA, this part of the literature review provides an overview of other theoretical models for clustering and representing organisational culture: Business Culture Design (BCD) and the widely used Competing Values Model (CVM). Admittedly, this overview is rather limited, but it is sufficient to pave the way for further research.

Figure 16: The Culture Map following the Business Culture Design approach (Sagmeister, 2018, p. 58)

Sagmeister (2018) developed the 'Culture Map', which explores cultural patterns in organisations (see Figure 16) and visualises the theoretical BCD concept. The hexagons on the left represent individualistic, dynamic values, while the hexagons on the right represent group-oriented, stabilising values. The Culture Map essentially follows the iceberg model of visibility and tangibility of cultural factors proposed by Schein and Schein; most of it lies below the waterline and is therefore neither visible nor tangible (Sagmeister, 2018, p. 17). The advantage of this theoretical model lies in its evaluability, as the different patterns can be easily elicited in quantitative studies using questionnaires and scaled response options. The weighted results are then reflected in the size of the hexagons. The result is an individual Culture Map that provides a quick overview of the dominant cultural patterns. The latter can then be compared with previously created Culture Maps, supporting incremental innovation or even 'life-changing' radical innovation (Sagmeister, 2018, p. 183).

The CVM developed by Cameron and Quinn (2006, p. 375) "reveals the complexity of value orientations and allows the comparison of value orientations within organizations. It thus is regarded as an appropriate model for organizational culture studies conducted in the context of developing economics with great evolutionary dynamics".

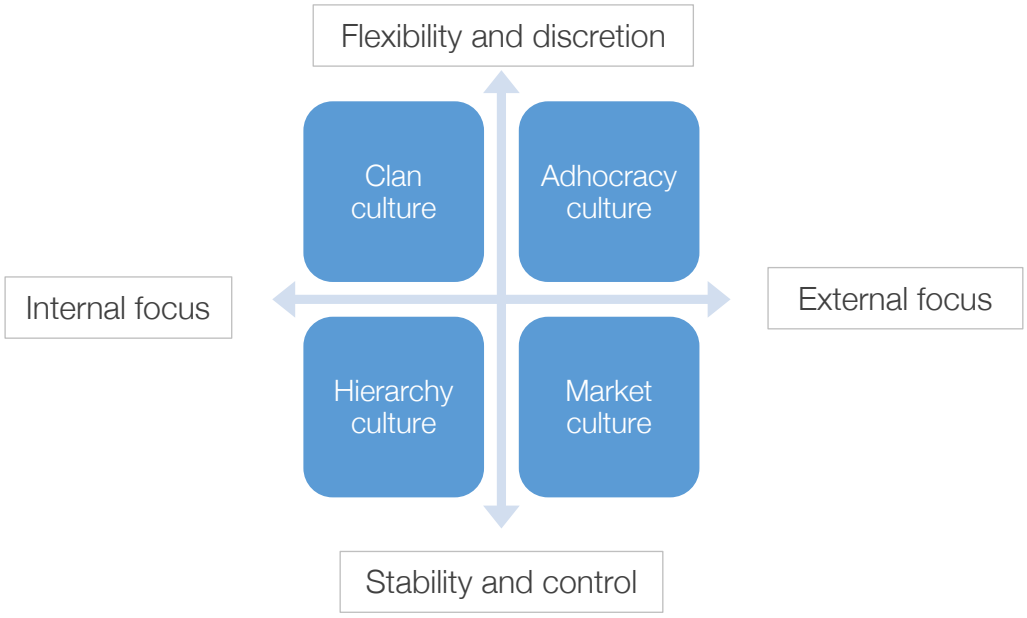

Figure 17: The Competing Values Model (Cameron and Quinn, 2006, p. 35)

Essentially, the CVM is divided into four quadrants of cultural values and norms, ranging from flexibility (valuing empowerment, flexibility and spontaneity) to stability (valuing order, efficiency and achievement) on the vertical axis (Chen et al., 2018). The CVM also represents an internal focus (emphasising the development of people and systems within the organisation) versus an external focus (emphasising external positioning and interactions with the environment) on the horizontal axis (Chen et al., 2018). The four quadrants represent the four different types of culture: Clan culture, Adhocracy culture, Hierarchy culture and Market culture (see Figure 17), each with its own characteristics.

Type of culture	Flexibility vs. control	Focus	Corporate behaviour
Adhocracy culture	Flexibility	External focus	Creativity, entrepreneurship, and risk taking
Clan culture	Flexibility	Internal focus	Teamwork, employee involvement, and corporate commitment to employees

Market culture	Control	External focus	Productivity and competitiveness; has low levels of trust, morale, and resistance to change
Hierarchy culture	Control	Internal focus	Uniformity, efficiency, and close adherence to rules and regulations

Table 4: Behavioural expression of different corporate cultural dimensions (Chen et al., 2018, p. 4)

Chen et al. (2018, p. 4) examined the entrepreneurial behaviours for each of the four culture types, see Table 4. Interestingly, the behaviours of an adhocracy culture, namely 'creativity', 'entrepreneurship' and 'risk-taking', seem to be the closest to an innovation-oriented culture, which, according to the results of the literature review (see section 2.4.5.3), is the most suitable for innovative start-ups.

In their study, Naranjo-Valencia, Jiménez-Jiménez and Sanz-Valle (2011) found that organisational cultures with an external focus on flexibility tend to be innovation-oriented, while internally-oriented cultures are associated with an imitation orientation. They conclude that a company with an adhocracy culture is a "dynamic and entrepreneurial place where people are willing to take risks", which matches the results for start-up behaviour (Naranjo-Valencia, Jiménez-Jiménez and Sanz-Valle, 2011, p. 64). According to their findings, the CVM does not reflect a perfect innovation-oriented culture, as an "adhocracy culture does not foster team working and this variable is considered to be a key element for enhancing innovation" (Jamrog, Vickers and Bear, 2006; Martins and Terblanche, 2003; McLean, 2005).

To summarise the results on organisational culture, climate and Cultural DNA, culture is a system with complex characteristics. As a pervasive phenomenon, only explicit cultural expressions such as norms and artifacts, are visible or tangible and can be observed. In contrast, implicit culture, with its tacit beliefs, values and assumptions, is very difficult to observe and capture. Theoretical models such as Cultural DNA, BCD and CVM attempt to capture at least the observable explicit culture of an organisation. None of these models has a specific view of the innovative factors within an organisational culture. It is therefore imperative to find a

more precise characterisation of innovation-oriented cultural patterns, which is the focus of the next section.

2.4.5.3 Innovation-oriented Culture

Building on the findings of the previous sections, this section serves to identify the specific characteristics of an innovation-oriented culture. According to Büschgens, Bausch and Balkin (2013), there has been extensive research on the relationship between organisational culture and innovation-oriented culture, which has led to a more fragmented concept of innovation-oriented culture that has not yet been incorporated into management theory. Stock, Six and Zacharias (2013) define "innovation-oriented organisational culture as the degree to which cultural values, norms, and artifacts support the company's innovativeness" (Stock, Six and Zacharias, 2013, p. 285). Following the CVM, Büschgens, Bausch and Balkin (2013) advise managers who aim for radical - and thus probably almost disruptive - innovations to strive for an adhocracy culture. Accordingly, the most antithetical and thus innovation-inhibiting culture would therefore be a hierarchy culture, as found in large, established companies. Although Chen et al. (2018) attribute entrepreneurship, creativity and risk-taking to the entrepreneurial behaviour of adhocracy cultures (see Table 4), the question remains whether there is not a broader characterisation of an innovation-oriented culture. In contrast to the above results, Tellis, Prabhu and Chandy (2009, p. 15) have examined the importance of organisational culture as a driver of innovation and conclude that „internal organisational culture is an important driver of radical innovation". However, it is difficult to sustain a "culture of relentless innovation" (Tellis, Prabhu and Chandy, 2009, p. 16). The following overview summarises the most important, but still fragmentary, results in order to paint a more complete picture of an innovation-oriented culture.

According to researchers in the field of organisational culture, there is a proven link between organisational culture and business success. Furthermore, an innovation-oriented organisational culture has a positive effect on innovation capacity and

performance (Han, Kim and Srivastava, 1998; Homburg and Pflesser, 2000). The dimensions identified include learning orientation and adaptation orientation, which can be subsumed under innovation orientation (Sackmann, 2006). Innovation capability also includes novel processes and systems that increase efficiency and/or effectiveness and thus strengthen a firm's competitive position. Ogbonna and Harris (2000) as well as Den Hartog and Verburg (2004) show that more outward-looking organisational cultures, in terms of stronger competitive and innovation orientation, are directly correlate with business success. According to Sackmann (2006, p. 11), objective indicators of innovation capacity can be:

- the number of patents registered
- new products, services
- investments in research and development
- number of suggestions for improvement by employees, and
- implemented suggestions for improvement. (Translation by the author)

Firestone (2017, p. 377) outlines the ten most important characteristics Nietzsche envisioned for the 'Übermensch': "self-determination, creativity, becoming, overcoming, discontent, flexibility, self-mastery, self-confidence, cheerfulness, and courage". Based on this philosophical antecedent, contemporary literature largely supports the assumption that creativity is one of the main characteristics of an innovative culture and therefore serves as a determinant of the pioneering nature of an enterprise (Claver et al., 1998; Jamrog, Vickers and Bear, 2006; Martins and Terblanche, 2003; McLean, 2005; Mostafa, 2005; Schneider, Gunnarson and Niles-Joly, 1994; Shrivastava and Souder, 1987; Wallach, 1983). It can be understood as a means of generating new and valuable ideas (Amabile, 1998). Kaufmann (1974, p. 414) derives from Nietzsche's assumptions that the human capacity for creativity leads to the "creation of new values and norms". Gulati (2019) links a company's success to the presence of unusual creativity and autonomy among its employees.

In their study, Stock, Six and Zacharias (2013) - based on the theory of Schein and Schein (2017) - developed typical values, norms and artifacts that should be found in innovation-oriented cultures (see Table 5).

Construct	Items	Factor Loadings
Innovation-oriented Cultural Values	In our company… … we particularly emphasize innovativeness and creativity. … we rate the flexibility of the employees very high. … we are open to innovation.	 0.75 0.75 0.31
Innovation-oriented Cultural Norms	In our company… … we expect that unbureaucratic solutions are found quickly in difficult situations. … we expect that new value-adding products and services are detected and developed permanently. … we appreciate unconventional ideas.	 0.39 0.80 0.97
Innovation-oriented Cultural Artifacts	In our company… .. stories of exemplary innovation-oriented behaviour of executives (e.g. founders, chief executives, managers) are circulating. … attractive meeting and discussion areas (e.g., cafeterias or intranet) exist where information regarding innovations can be exchanged informally. … we regularly organize events for customers or cooperation partners in the context of new product innovations.	0.91 0.80 0.69

Table 5: Scale items for construct measures (self-developed by Stock, Six and Zacharias (2013, p. 295), based on Homburg and Pflesser (2000))

According to Stock, Six and Zacharias (2013), flexibility, creativity and openness to innovation are the most important cultural values for an innovation-oriented company. The most important norms are the willingness to find quick, unbureaucratic solutions, the expectation to constantly develop new products and the appreciation of unconventional ideas (Stock, Six and Zacharias, 2013). The main artifacts are widely shared innovation stories, informal discussion spaces and ritualised innovation events with customers and partners (Stock, Six and Zacharias, 2013).

In their study on “Innovative milieus in Germany”, Pohl and Kempermann (2019) define different ‘milieus’ (groups of companies that are as homogeneous as possible) based on the innovation success and innovation profile of the companies (see Figure 18). Based on company data from the IW Future Panel of the German

Economic Institute, they conducted an empirical multi-level cluster analysis, from which they derived statements for the entire German innovation landscape in the industrial services network.

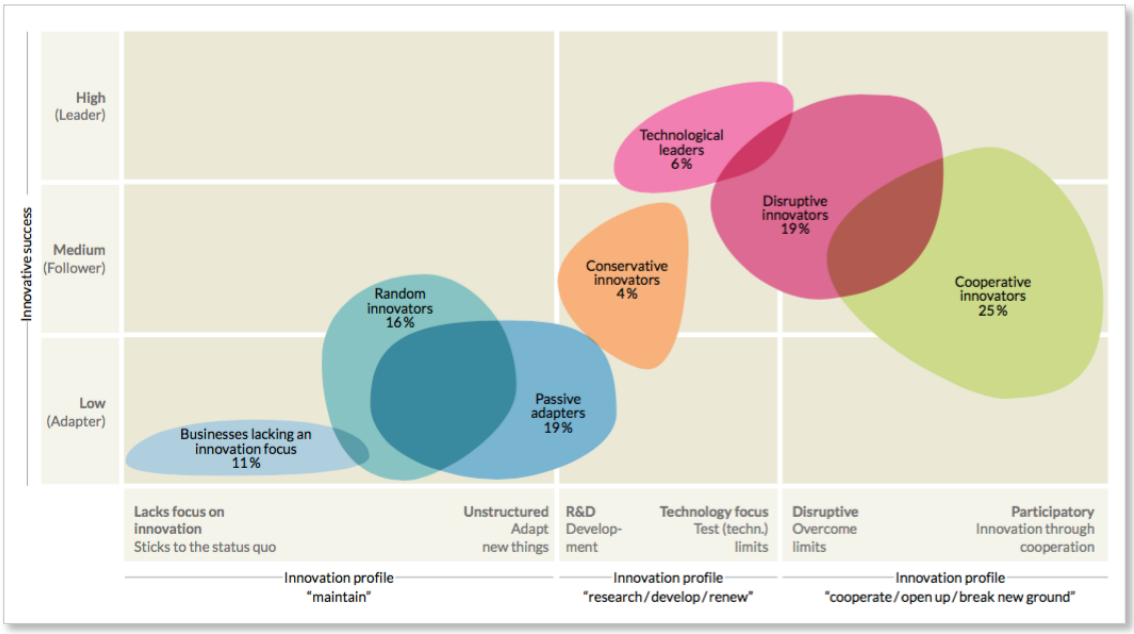

Figure 18: Innovative milieus in Germany, 2019 - Share as a percentage of all enterprises (Pohl and Kempermann, 2019, p. 8; N=1,002)

The empirical study proves that innovation success is highest in the milieus grouped as 'Innovation leaders', consisting of the milieus 'Technological leaders' and 'Disruptive innovators' (Pohl and Kempermann, 2019, p. 8; see Figure 18). On a scale describing innovation performance from zero (non-innovative) to 100 (highly innovative), the 'Technological leaders' and 'Disruptive innovators' achieve an average of 69 and 62 respectively, followed by the 'Conservative innovators' with an average of 46 and the other milieus with decreasing values and thus lower innovation performance (Pohl and Kempermann, 2019, p. 21). The result of the study clearly shows the innovation advantage of the 'Disruptive innovators' compared to the 'Conservative innovators'. Drucker (1985, p. 170 ff.) instead saw the 'Conservative innovator' as one of his five key principles for innovation. However, the comparison is somewhat misleading as the theory of disruptive innovation was only developed by Christensen seven years later. The results of Pohl and Kempermann's (2019) study on 'Disruptive innovators' are essential to the

underlying work, and are intended to extend the theory of the conceptual framework. The specific characteristics of ‘Disruptive innovators’ described in the study are:

(1) the openness to the new, which manifests itself in a high willingness to take risks and the courage to undertake radical innovation projects with disruptive potential;
(2) the organisational culture - especially the involvement and motivation of the employees - is central;
(3) innovations are not created in a top-down process in narrowly defined areas, but the entire company is oriented towards innovation and employees are actively involved in the process (Pohl and Kempermann, 2019, p. 5; translation by the author).
(4) Innovation activities are well structured, organised and integrated into the business model;
(5) participative innovation culture;
(6) partly high risk-taking and high disruption potential (Kempermann and Pohl, 2019, p. 96; translation by the author).

To underline the above characteristics, the study presents some of the questions and the corresponding results of the survey. There were only four possible answers to these questions: yes, rather yes, rather no, and no. As expected, all the responses from the ‘Disruptive innovators’ were much more positive than the average of all the milieus. Picking up on the obvious core theme of ‘risk appetite’ in a start-up pursuing disruptive innovation, 96% of employees and 98% of managers responded that they are encouraged to try out unconventional ideas - even if their success is uncertain - and implement them as part of innovation projects (see Figure 19). As mentioned above, Drucker (1985, p. 171 f.) favours the ‘Conservative innovator’ and believes that successful innovators and entrepreneurs are not ‘risk takers’ and are not ‘risk focused’ but ‘opportunity oriented’.

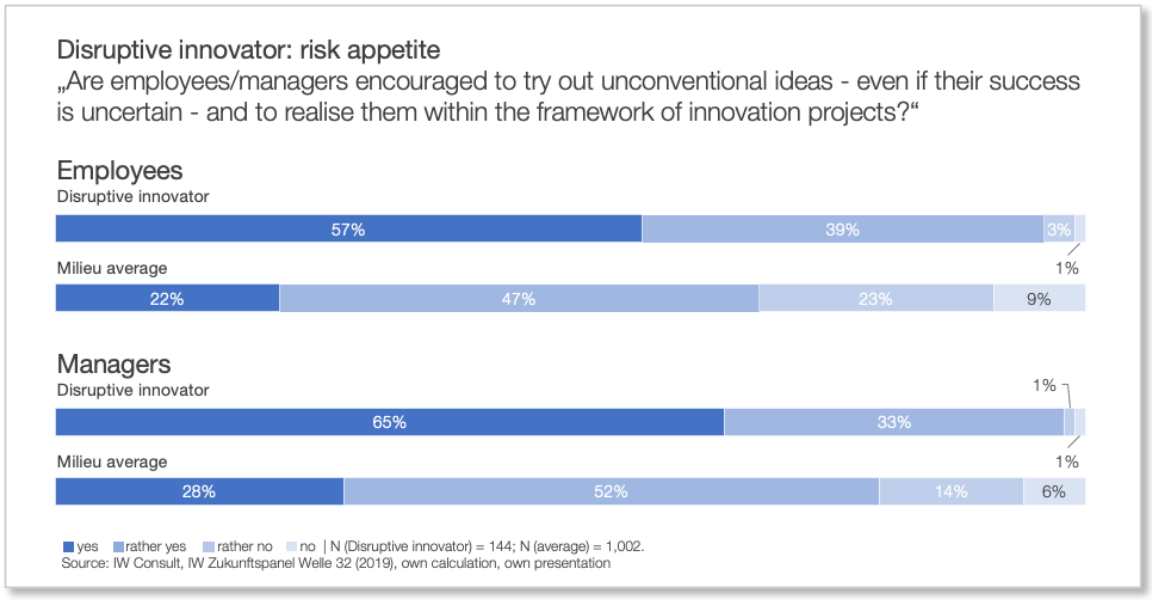

Figure 19: Disruptive innovators: risk appetite
(Pohl and Kempermann, 2019, p. 28; adaptation and translation by the author)

Furthermore, ‘Disruptive innovators’ state that they place a high value on teamwork, participation and employee development (Pohl and Kempermann, 2019, p. 30). Their long-term goals are entrepreneurship, dynamism and creativity (see Figure 20).

Figure 20: Disruptive innovators: organisational culture
(Pohl and Kempermann, 2019, p. 30; adaptation and translation by the author)

Although this question is more in the realm of strategic planning, it is important to note that most 'Disruptive innovators' systematically monitor market and technology trends, have a clearly defined innovation strategy with a focus on selected areas of innovation, and regularly review innovation projects in terms of effort and progress and modify them if necessary (e.g. by cancelling projects) (see Figure 21).

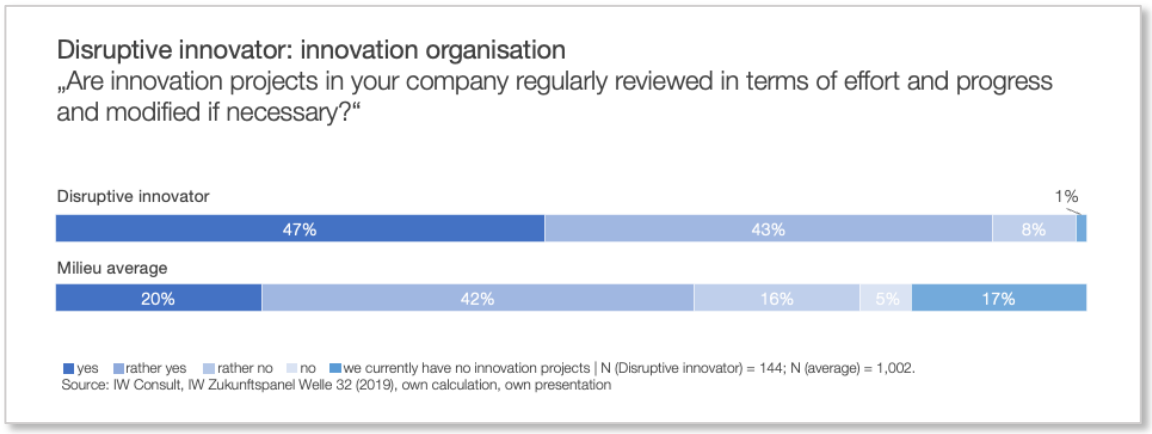

Figure 21: Disruptive innovators: innovation organisation
(Pohl and Kempermann, 2019, p. 32; adaptation and translation by the author)

The study by Pohl and Kempermann (2019) provides important insights into German innovation milieus and the specific characteristics of innovation-oriented organisational cultures. The results are included in the concluding overview.

Following the results on the OKR management framework presented in section 2.4.4, Lihl, Mahlendorf and Schmoltzi (2019, p. 49) suggest that "OKR can motivate employees and promote an agile and adaptive organisational culture". Although implementing an OKR management framework requires some significant changes in terms of an open, people-oriented and ambitious organisational culture, the advantages of this framework outweigh the disadvantages (Lihl, Mahlendorf and Schmoltzi, 2019, p. 49). Together with the findings from section 2.4.4 on the use of an OKR, an innovation-oriented start-up should definitely consider the use of such a management framework.

The multitude of different findings on innovation-oriented culture needed to be bundled and streamlined for the planned case study. For this reason, a detailed table was developed (see Table 8), which is presented in the next section on the key findings of the overall literature review.

2.4.6 Key results

The section on entrepreneurial behaviour has shown the importance of organisational design, corporate strategy and organisational culture and their interrelationships as the ultimate levers for maintaining the viability and effectiveness of start-ups. Corporate design establishes the formal structure of what is usually a lean start-up entity. Corporate strategy provides a more formal logic for the organisation's goals and aligns employees with those goals. Organisational culture is the more elusive lever, as it expresses strategic goals through values and beliefs and guides activities through shared assumptions and group norms (Schein and Schein, 2017).

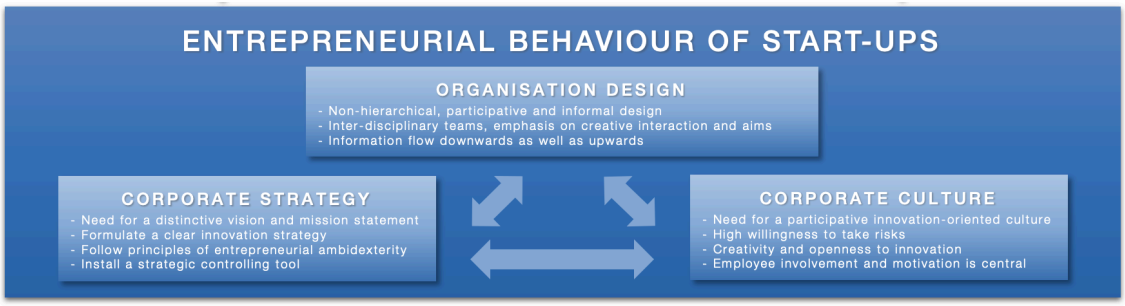

Figure 22: Key findings on start-ups' entrepreneurial behaviour

The main findings on the entrepreneurial behaviour of start-ups are summarised in Figure 22, which shows the most important and salient factors within organisational design, corporate strategy and organisational culture interacting with each other. The list is therefore neither complete nor exhaustive. Following the introductory statement of this dissertation that 'culture eats strategy for breakfast', the literature review on entrepreneurial behaviour tends to confirm the underlying message, at least as far as it relates to the specific form of start-up culture is concerned.

2.4.6.1 Start-up organisational design

There are many current relevant sources of information on organisational design for start-ups. Table 6 summarises the main findings on the advantageous and disadvantageous factors that management should consider.

Start-up organisational design		
Reference	Advantageous factors	Disadvantageous factors
Ahmed (1998)	Freedom from rules; participative and informal; many views expressed and considered; face-to-face communication; organic structures, interdisciplinary teams; emphasis on creative interaction and goals; outward-looking; flexible to changing needs; non-hierarchical; information flows downwards as well as up	Rigid departmental separation and functional specialisation; hierarchical; bureaucratic; many rules and fixed procedures; formal reporting; long decision chains and slow decision making; little individual freedom of action; communication via the written word; much information flows upwards; directives flow downwards
Becker (1964)	'Human capital' as an economic value and the only changeable factor within an organisation	
Christensen (2016)	Company size is negatively correlated with the success of disruptive innovation; creating a value network; pursuing sustainable and disruptive innovation	
Coates and McDermott (2002)	Process innovation and renewal as a fundamental option	
Hamel (2002)		Innovation is fine as long as it doesn't disrupt a company's finely honed operating model
Hogan (2005)	The organisational structure of a small company focused on disruptive innovation is often flat, but the morale that is just the opposite	
Hyvönen, Tuominen and Erälinna (2004)	Possessions of relevant 'resource differentials' lead to sustainable competitive advantage and superior performance	
Kaduk et al. (2016)	Uncertainty is a necessity	Organisation leads to reliability and replicability; 'maximum security' approach is an obstacle
Luthans (2011)	Successful companies tend to create inter-functional teams; horizontal organisational design;	

	creative tension that acts as a catalyst for learning	
Pillkahn (2014)	Favouring disruptive innovation over sustainable opportunities	
Visscher and Fisscher (2012)	'Design mix': Combining, blending or balancing elements of the classical and developmental design approaches	

Table 6: Key literature findings on start-up organisation design in alphabetical order

Summarising the main aspects of organisational design in start-ups, strategy plays a common important role in predecessor researchers such as Mintzberg (1972a, 1972b), Katz and Kahn (1978) and Eisenhardt (1989a). In contrast, contemporary researchers such as Ahmed (1998) and Luthans (2011) describe the capacity of organisational culture as a powerful lever within an organisation.

Important differences can be identified between the complex organisational design of start-ups and the more formal corporate behaviour of established or incumbent firms. Starting with what many researchers such as Hogan (2005), Luthans (2011), Anand and Daft (2007), Steigerthal, Maurer and Say (2018) and Kollmann (2016) consider to be the most important must-have, the flat hierarchies in start-ups compared to the hierarchical organisational design of established companies, there are certainly many more differences when it comes to, for example, creative work versus routine work and variable working hours versus a nine-to-five work schedule. Ahmed (1998) found that the organic structures of start-ups, with their non-hierarchical, participatory, informal, flexible, creative and communicative environments, foster innovation and thus developed an important model for characterising contemporary start-up designs.

Kaduk et al. (2016) and Ortmann and Sydow (2001) critically argue that the 'maximum security' approach offered by organisations hinders 'creative destruction' and the comprehensive renewal that follows, leading to reliability and replicability. Instead, innovation necessarily requires uncertainty. Christensen (2016)

adds that 'risk-averse' organisational cultures can foster organisational barriers that cause firms to stumble in managing technological change.

Corporate design should therefore be a carefully planned management task that needs to be constantly questioned, revised and adapted as environmental factors and management theory evolve. There are tendencies that Drucker's 'culture eats strategy for breakfast' hypothesis has gained validity, while management theory has evolved over the decades from a formal, strategy-oriented organisational design to a flexible, agile, creativity-oriented design, especially when it comes to innovation-intensive start-ups.

2.4.6.2 Corporate Strategy / Innovation Strategy

Table 7 summarises he main results of the literature on corporate strategy and, in particular, innovation strategy. Apparently, the sources examined do not explicitly describe any disadvantageous factors for strategic decisions, so that it is rather disadvantageous to ignore the advantageous factors mentioned or to do the opposite.

Corporate strategy / Innovation strategy	
Reference	Advantageous factors
Chen et al. (2018)	Fit between innovation strategy and organisational culture as a key source of competitive advantage; innovation strategy needs to be implemented based on organisational culture (culture first)
Mintzberg (1987)	'Plan', 'Ploy', 'Pattern', 'Position' and 'Perspective'
Niven and Lamorte (2016)	'Critical thinking' using the OKR management framework
Pisano (2014, 2015)	Formulate an innovation strategy to integrate and align different perspectives; incorporate sustainable and disruptive innovation (ambidextrous); develop disruptive strategies to find alternative value propositions
Sackmann (2010)	'Mission statement' including strategic direction and intent, goals and objectives, and a 'vision'
Siguaw, Simpson and Enz (2006)	Encourage innovative thinking; create a broad innovation orientation
Tushman, Smith and Binns (2011)	Embracing inconsistency while working with a dual agenda (ambidextrous CEO)

Table 7: Key literature findings on corporate strategy / innovation strategy in alphabetical order

Strategic objectives are the blueprint of an organisation. They are written down in the form of a corporate vision and mission statement and are used to ensure the achievement of the management's short-term goals and objectives. Mintzberg's five Ps break down the concept of strategy into its five key elements, with 'Position' - the data-based examination of the current and future market position - being a core element of strategic planning. The overarching vision and mission statement, as well as the strategic goals and objectives, can be captured and monitored in a strategic controlling tool. A popular method for effectively monitoring strategic planning is the OKR management framework, which is supported by Doerr (2018), Niven and Lamorte (2016) and Teipel and Alberti (2019). The OKR method is perfectly suited to the organisational design of start-ups as highly agile and scalable micro-enterprises.

According to Pisano (2014, 2015), a company should also define a specific innovation strategy that builds on the overall corporate strategy and focuses on innovation-specific tasks and parameters within a company. Siguaw, Simpson and Enz (2006), Stock and Zacharias (2011) and Stock, Six and Zacharias (2013) promote the importance of a firm's innovation orientation as supportive cultural and strategic alignment. Chen et al. (2018) point out the importance of implementing a specific innovation strategy based on the respective organisational culture.

Christensen (2016), Pillkahn (2011), O'Reilly and Tushman (2004) and Volery, Mueller and von Siemens (2015) emphasise the great importance of a balanced ambidextrous management in a start-up. Both sides, exploitation and exploration, should lead to incremental/sustainable innovation steps as well as future radical/disruptive innovations. According to O'Reilly and Tushman (2004), the success rate of ambidextrous organisations in achieving their goals is over 90%. Tushman, Smith and Binns (2011) define the 'ambidextrous CEO' as someone who develops an overarching identity that integrates exploitative and exploratory business units, maintains tension at the management level and embraces inconsistency while working with a dual agenda. Entrepreneurial ambidexterity

should include entrepreneurial agility to ultimately express a firm's ability to respond flexibly and appropriately to external and internal developments.

2.4.6.3 Innovation-oriented culture

The main results on innovation-oriented culture are summarised in Table 8, following Schein and Schein's (2017) 'Cultural DNA' distinction between explicit and implicit cultural factors.

Innovation-oriented culture		
Reference	Explicit cultural factors (Corporate climate): Norms/Artifacts	Implicit cultural factors: Espoused Beliefs and Values
Ahmed (1998)	Organisational design and layout to create a physical environment that encourages interaction, visible leadership decisions, balanced autonomy (operational autonomy that promotes individual empowerment, but strategic autonomy for top management), meaningful action boundaries	Awards, personalised recognition, creative thinking, action orientation, define risk tolerance, creativity, customer focus, tolerate ambiguity, risk taking, emphasise innovation, intrinsic rewards for individuals and groups, sensitive leadership
Bates and Khasawneh (2005)		Create organisational knowledge
Brettel and Cleven (2011)		Technological innovation orientation, learning orientation, risk-taking, future market orientation
Gulati (2019)	Customer connection, employee experience	Energy, creativity, autonomy, business purpose, a reason for being, soul
Heskett, Sasser and Wheeler (2008)	Live the elements of the culture: values, behaviours, policies and actions, team actions, learning, employee awards, strong, adaptive culture	Codified culture, high levels of employee and customer loyalty, corporate strategy, regularly review and reaffirmation of core values and associated behaviours
Hogan and Coote (2014)		Success, openness & flexibility, internal communication, competence & professionalism, inter-functional collaboration, responsibility, appreciation, risk-taking
Jassawalla and Sashittal (2002)	Employee involvement in the new-product development process, employees exhibit high levels of co-creative, collaborative behaviour, willingness to be vulnerable to feedback from others	Taking initiative, creativity, risk-taking, trusting employees in a co-creative endeavour, employees are equal stakeholders, organisational change should be embraced

Kempermann and Pohl (2019); Pohl and Kempermann (2019)	The whole organisation is focused on innovation, employees are actively involved in the (innovation) process, teamwork, employee involvement and motivation	Openness to new ideas, high risk taking, radical innovation projects with disruptive potential, entrepreneurship, dynamism, creativity, willingness to try unconventional ideas, clearly defined innovation strategy, people development, risk appetite
Ostroff (1999)	Value employee empowerment, responsibility and well-being, focus on continuous performance improvement	Openness, cooperation and collaboration
Stock, Six and Zacharias (2013)	Informal discussion spaces, ritualised innovation events, circulated innovation stories	Flexibility, creativity, openness to innovation, willingness to find unbureaucratic solutions quickly, expectation to create new products continuously, appreciation of unconventional ideas

Table 8: Key findings from the literature on innovation-oriented culture

According to Schein and Schein's (2017) theories on organisational culture, consistent patterns of corporate behaviour are manifested in their codified 'Cultural DNA', which is based on the following cultural phenomena: Artifacts, held beliefs and values, and basic assumptions. Instead, the corporate climate consists only of attitudes, feelings and behaviours that can either be observed or easily narrated. This fact will be important when it comes to the practical part of this dissertation, the case study. There are many different types of organisational cultures, but the CVM is a method for distinguishing four fundamentally different characteristics. Büschgens, Bausch and Balkin (2013) and Chen et al. (2018) describe an innovation-promoting tendency of the 'Adhocracy culture', but it is not perfect when it comes to a strong innovation orientation of a company (Jamrog, Vickers and Bear, 2006; Martins and Terblanche, 2003; McLean, 2005). In a start-up, the culture should be innovation-oriented because its sole raison d'être is, for example, to commercialise a new product. The literature review revealed that many scholars have contributed to the theory of innovation-oriented organisational culture, adding to the list of characteristics of an innovation-oriented organisational culture (Sackmann (2006), Ogbonna and Harris (2000), Den Hartog and Verburg (2004), Gulati (2019), Stock, Six and Zacharias (2013), Pohl and Kempermann (2019)).

2.4.7 Conceptual framework

Based on the key findings of the previous literature review, the purpose of this section is to address research objective (2) and develop a conceptual framework that encompasses the most advantageous and therefore favourable organisational design requirements, as well as the critical strategic and cultural factors in firms that foster entrepreneurial behaviour in start-ups focused on disruptive innovation. The conceptual framework can be seen as a condensed version of the key results presented in the previous section. Since the framework conditions for the German MedTech market and for disruptive product innovations can be regarded as given and rigid (see Figures 5 and 13), the variable components of entrepreneurial behaviour such as organisational design, corporate strategy and organisational culture with their leverage function within a start-up play an important role and are therefore examined in the further context of this dissertation.

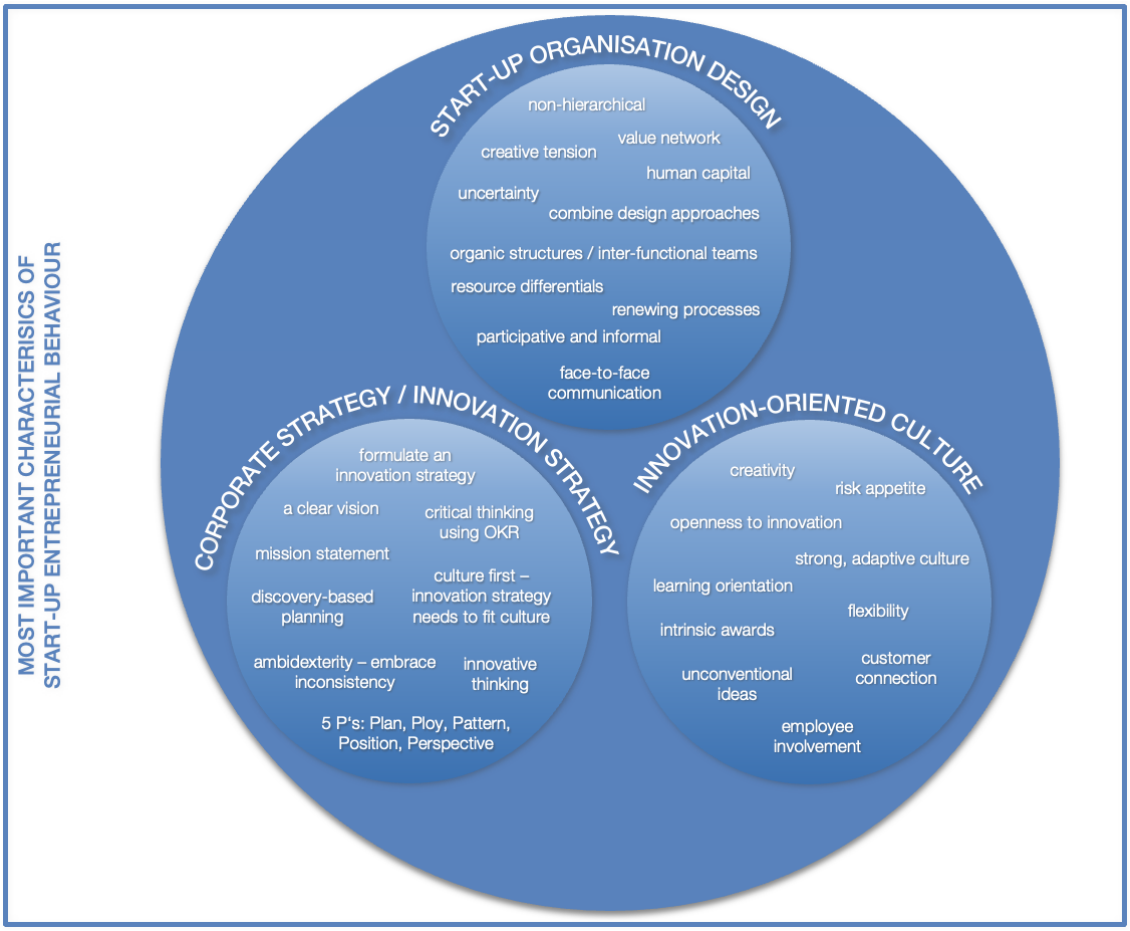

Figure 23: Conceptual framework based on key findings from the literature review (see Tables 5-7, developed for research)

The conceptual framework summarises the key findings from the literature review that precedes this section. As mentioned in the introductory section, no study or research has previously summarised these particular findings in this context. The observations are therefore not new in detail, but they are new in the context of the conceptual framework developed.

According to the conceptual framework (see Figure 23), the 'ideal' start-up organisational design is based on a flat hierarchical system that values employees as 'human capital' and combines different design approaches. Organic structures should avoid bureaucratic, rigid work processes and encourage personal communication within an inter-functional team structure. Employees should be open to a continuous process of renewal to maintain resource differentials. Uncertainty (e.g. in innovation success) should be seen as an opportunity to evolve, while maintaining a creative tension that fosters innovative thinking. In building a value network inside and outside the start-up, employees should be involved in the activities of the company in a participative and informal way.

When it comes to the strategic and innovative direction of a start-up, in addition to the formulated mission statement (following Mintzberg's 5 Ps), there should also be a clear vision as well as a formulated innovation strategy to define the future goals of the start-up. To address the core hypothesis of this dissertation, culture should be considered first, as the innovation strategy should be adapted to the prevailing start-up culture. Managers should rely on discovery-based planning, as we have learned that uncertainty should be part of the business in order to foster innovative thinking. Continuous software-based review of strategic objectives using OKR software should encourage critical thinking by all employees. Managers should follow the rules of ambidexterity and accept inconsistencies in achieving strategic goals.

An innovation-oriented culture, which is probably best suited to start-ups, should be strong and adaptable. It should allow and encourage employee creativity, which

in turn should lead to unconventional ideas. In addition, flexibility, risk-taking, learning, teamwork, customer loyalty and a general openness to innovation should be firmly embedded in the culture. Start-up managers should involve their employees in all processes and introduce intrinsic rewards to keep motivation high.

2.5 Conclusion

The previous extensive literature review presented the various theoretical underpinnings of this research project. The key points of the German MedTech industry outline an attractive, developed but still growing market as an important prerequisite for start-up ventures. Although the various market barriers identified are likely to hinder market entry and thus socially important innovations in the health sector, there are ample opportunities for newcomers to innovate and enrich the extensive research-intensive market. The market barriers force start-ups to expose their business to high risk and thus potentially fail from day one. The most important favourable factors found were integrated into the conceptual framework as they influence the innovative capacity of German MedTech start-ups. The second part of the literature review, which introduces innovation management and the characteristics of disruptive innovations, was able to show the disruptive potential in the MedTech sector and give examples of successful companies that pursue disruptive innovations. Thus, the first part of research objective (1) has already been assessed and can be answered with a ‘yes’, disruptive innovations in medical devices are possible for German MedTech start-ups.

Disruptive innovation, according to Christensen’s teachings, is a very risky but, with careful planning and successful implementation, also beneficial form of business development and growth. While it disrupts existing markets and products, it also opens up new business opportunities. Even though ethical aspects of patient safety severely limit disruptive medical products, this does not rule out disruption in this area. According to Christensen’s principles (see section 2.3.7), a start-up should

use discovery-based planning to assess the future of an uncertain market, develop the right tools to acquire new capabilities within the start-up, and monitor market trends to be able to respond quickly to market changes.

Another result of the literature review is that start-ups, in their particular form as micro-enterprises, require an entrepreneurial behaviour from their managers and employees. This requires a start-up organisational design, a strategy including an innovation strategy and an innovation-oriented culture (see Figure 24). While strategic measures can be written down and thus internalised by employees, the development, maintenance and possibly also the adaptation of a start-up culture is a sensitive area.

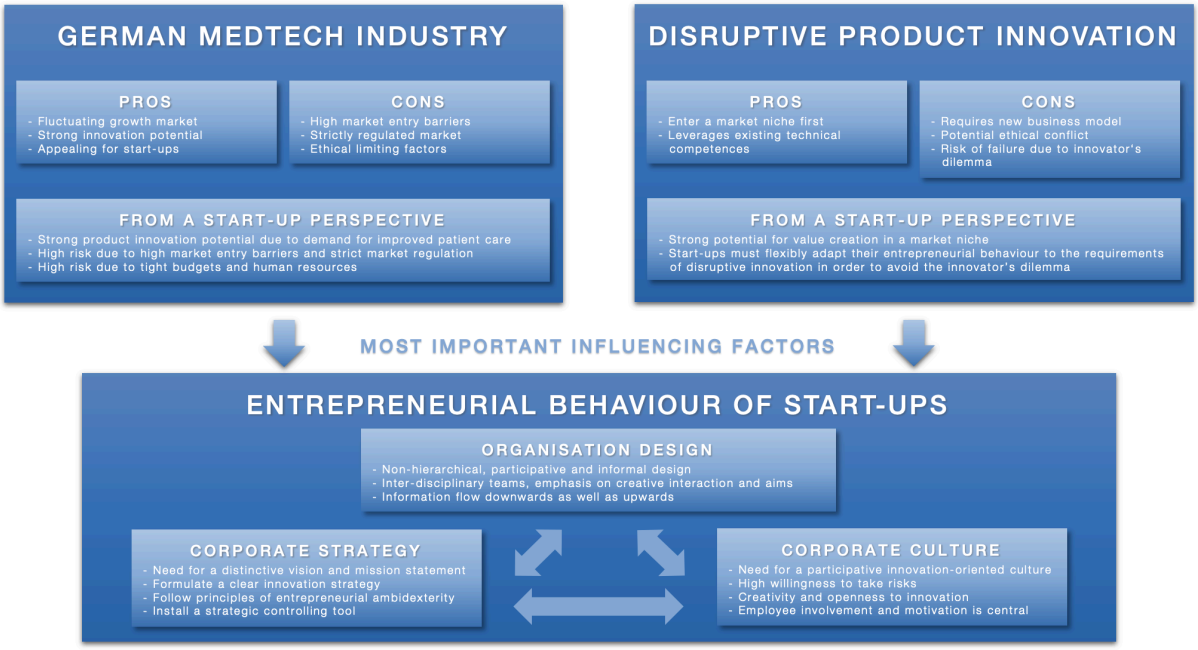

Figure 24: Key literature review findings (based on Figures 5, 13 and 22)

Finally, the extensive literature review and the insights gained from it led to the development of a conceptual framework, which is presented in section 2.4.7. This serves as the basis for the following case study and contributes to the achievement of research objective (2), which is to combine crucial corporate strategic and cultural

factors that influence the entrepreneurial behaviour of German MedTech start-ups in a comprehensive conceptual framework.

3 Research Methodology

3.1 Introduction

Section 1.1 outlines the specific research framework on which this dissertation is based. In particular, it highlights the existing knowledge gap in economic research, especially when it comes to entrepreneurial behaviour. Blaikie (2009) defines economic research as the science of being, concerned with the nature of reality. Before delving into the details of research methodology and design to justify and validate the 3rd research objective, it is important to develop a solid awareness of the underlying philosophical assumptions that form the basis for social researchers (Easterby-Smith, Thorpe and Jackson, 2015). Bajpai (2011) explains that research philosophy is concerned with the source, nature and development of knowledge and provides guidance to social researchers on how data about a phenomenon should be collected, analysed and used. Unlike other areas of research, such as the natural sciences, where researchers obtain truth trough observation and statistical analysis of observed facts, ultimate truth in the social sciences can only be achieved through written contributions and communication with people. Therefore, if research in the social sciences is to be considered scientific, there are a number of criteria that must be met (Blaikie, 2009). The German philosopher Max Scheler (1926) observed the particularities of the social system and therefore introduced the term ‘sociology of knowledge’ (‘Wissenssoziologie’) in his book ‘Die Wissensformen und die Gesellschaft’ (‘The forms of knowledge and society’ (translation by the author)). Although there are various definitions of the nature and scope of the sociology of knowledge, “there has been general agreement to the effect that the sociology of knowledge is concerned with the relationship between human thought and the social context within which it arises” and “that the sociology of knowledge constitutes the sociological focus of a much more general problem, that of the existential determination (‘Seinsgebundenheit‘) of thought as such” (Berger and Luckmann, 1966, p. 16). Society itself has a dual character “in terms of objective facticity and subjective meaning that makes its ‘reality sui generis’” (Berger and Luckmann, 1966, p. 30), the latter being a term introduced by the French sociologist

and ethnologist Émile Durkheim (1982). According to Berger and Luckmann (1966, p. 13), “reality is socially constructed and […] the sociology of knowledge must analyse the process in which this occurs”. They define ‘reality’ “as a quality appertaining to phenomena that we recognize as having a being independent of our own volition (we cannot ‘wish them away’)”, and ‘knowledge’ “as the certainty that phenomena are real and that they possess scientific characteristics” (Berger and Luckmann, 1966, p. 13).

Social research is based on the oral and written contributions (including papers, books and studies) of people, and therefore all knowledge is based on the fact that the human mind operates from either an objective or a subjective point of view. By definition, an objective judgement is defined as “expressing or dealing with facts or conditions as perceived without distortion by personal feelings, prejudices, or interpretations”, and objectivity is “limited to choices of fixed alternatives and reducing subjective factors to a minimum” (Merriam-Webster, 2022b). In contrast, a subjective judgement is “modified or affected by personal views, experience, or background”, and a subjective sensation “arises from conditions within the brain or sense organs and not directly caused by external stimuli” (Merriam-Webster, 2022c). In order to conduct social research, a (dialectical) discussion needs to identify the most favourable philosophical approach and a final decision needs to be made as to which view best fits the underlying research aim and objectives.

To provide a comprehensive understanding of social research, Saunders, Lewis and Thornhill (2019) introduced the ‘research onion’ (see Figure 25). The research onion visually separates the different stages of social research, from research philosophies, research approaches, methodological choices, strategies, time horizons to the final techniques and procedures used to conduct the social research.

At the beginning of any social research pursuing this research project, a decision has to be made about the appropriate research philosophy and method.

Philosophy in general is a ‘broad field’ (‘ein weites Feld’), as there are a variety of different research philosophies that are constantly evolving. To distinguish the four main research philosophies, Saunders, Lewis and Thornhill (2019) have visually represented them in the outer layer of the research onion (see Figure 25).

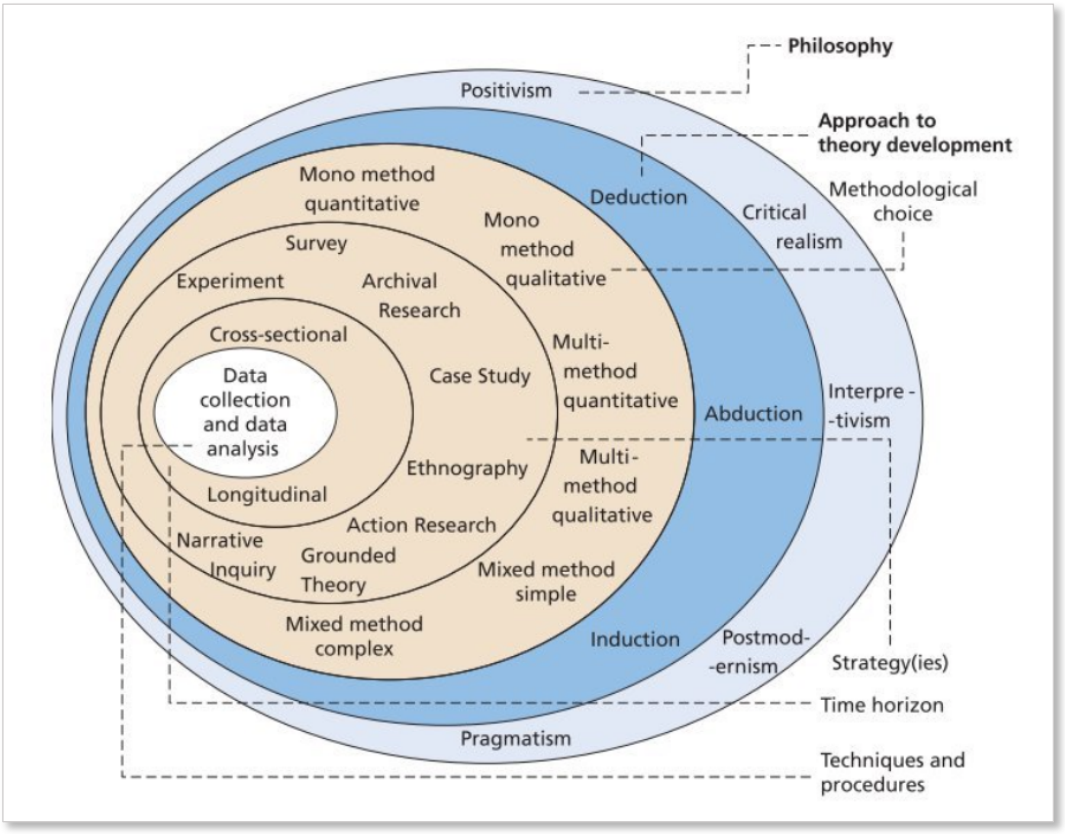

Figure 25: The ‘research onion’ (Saunders, Lewis and Thornhill, 2019, p. 130)

According to Saunders, Lewis and Thornhill (2019), positivism, realism, interpretivism and pragmatism are four different philosophical positions that need to be carefully distinguished and compared when conducting a social research. These four different philosophical orientations are important when it comes to choosing the means of conducting research in the social sciences. At the beginning of the discussion that will lead to a methodological choice in this research project, the four different philosophical positions need to be considered from an ontological and an epistemological perspective and their implications for research discussed in order

to finally choose an appropriate research philosophy for this specific research project.

3.2 Ontological assumptions

Ontology is a philosophical view of research and is concerned with the question: "What is the nature of the 'knowable'? Or, what is the nature of 'reality'?" (Guba, 1990, p. 18). Easterby-Smith, Thorpe and Jackson (2015, p. 47) define ontology as the fundamental "philosophical assumptions about the nature of reality. Ontology is a belief system that reflects a person's interpretation of what a fact is. According to Bryman (2015), the key aspect of ontology is whether social entities need to be perceived as 'objective entities' that "have a reality external to social actors" or as 'subjective entities' that "can and should be considered social constructions built up from the perceptions and actions of social actors" (Bryman, 2015, p. 28). It is therefore important to define possible objective and subjective ontological and epistemological research approaches, discuss them in the light of the underlying research project, and choose the most appropriate approach.

Interestingly, Bryman (2015) illustrates objectivism and subjectivism by relating them to 'organisation' and 'culture', two very common and central concepts in the social sciences. These connections will be explored further in the following sections.

3.2.1 Objective ontological viewpoint

Objectivism is an ontological position "that asserts that social phenomena and their meanings have an existence that is independent of social actors. It implies that social phenomena and the categories that we use in everyday discourse have an existence that is independent or separate from actors" (Bryman, 2015, p. 29). Objectivism can be compared to an 'organisation' with its rules and regulations, standardised procedures, hierarchies and mission statements (Bryman, 2015). An organisation has a reality that is "external to the individuals who inhabit it" (Bryman, 2015, p. 29). Objectivity thus presupposes that individuals/social actors act in a

fixed process that is not questioned or changed. Processes and ways of thinking are almost standardised. Individual thinking and creativity are forbidden. When Bryman (2015) linked objectivism to ‘organisation’, he was referring to the inflexibility of organisational structures and processes, and thus the impossibility of changing deeply ingrained behaviours. Although the definition and interpretation of objectivism sounds harsh, the basic idea of objectivism is not negative.

3.2.2 Subjective ontological viewpoint

The opposing position to objectivism is subjectivism - also called constructivism. This is an ontological position “that asserts the social phenomena and their meanings are continually being accomplished by social actors. It implies that social phenomena are not only produced through social interaction but are in a constant state of revision” (Bryman, 2015, p. 29). Subjectivism thus implies, in contrast to an objectivist position, that social actors have the capacity to think creatively and to apply their thinking to existing processes in order to change and thus improve them. Subjectivism, which is linked to (organisational) ‘culture’, wants social actors to participate in redefining internal processes. Although the idea of free thinking and process development sounds very positive, the possibility of change always implies the possibility of deterioration.

3.2.3 Discussion

Determining the appropriate ontological position is crucial as it influences the choice of research design and the course of the underlying research project. The theoretical prescriptions surrounding the philosophy of pragmatism have not been considered in this discussion as it is an approach that involves a mixture of both philosophical positions. Therefore, this approach is only suitable for research projects that consist of a specific research question that requires a multiple perspective as an indispensable basis. As this research project has clear research objectives, the philosophy of pragmatism would not be useful and will not be considered further.

Bryman (2015) relates objectivism to the ‘organisation’, attempting to describe how an organisation’s rules, regulations and standard procedures form a static framework that cannot be changed by management or employees. This formalised framework does not allow for external influence and establishes clear procedures to be followed from the outset. In contrast, Bryman (2015) refers to the subjectivism of (organisational) ‘culture’, which consists of social actors who continuously influence processes.

In analysing the arguments for and against the above key research philosophies from an ontological standpoint, this research adopts a subjective ontological standpoint as the latter should be the appropriate choice to best achieve the research objective. Although the initial literature review was conducted from an objective standpoint, the research objective of validating the conceptual framework needs to be approached from a subjective standpoint, as corporate strategy plays in the realm of organisational culture and therefore implies the possibility of change. The underlying research should focus on social actors, as they have the ability to think creatively and apply their thinking to existing processes in order to change and improve them. Further research clearly needs to be subjective, open to change and engaged with social actors and their individual thinking. An objective view would hinder the necessary ‘cultural freedom’ and is therefore not considered as another option.

3.3 Epistemological assumptions

Epistemology - the theory of knowledge - is another way of looking at the philosophy of research, alongside ontology. It is defined as “a general set of assumptions about ways of inquiring into the nature of the world” (Easterby-Smith, Thorpe and Jackson, 2015, p. 47). Epistemology pursues the question of truth behind research: “What is the nature of the relationship between the knower (the inquirer) and the known (or knowable)?” (Guba, 1990, p. 18). The Greek philosopher Plato distinguished

between epistemology (knowledge that is known to be true) and doxology (knowledge that is believed to be true). The aim of science is thus the process of transforming the believed into the known: ‘doxa to episteme’.

According to Hirschheim (1985), since their debut in classical Greece, epistemological standpoints have been divided into two worlds, with Plato and Aristotle as positivists on one side and the Sophists as antipositivists on the other. Since the philosophical renaissance of the 16th and 17th centuries, Bacon, Descartes, Mill, Durkheim, Russell and Popper are well-known positivists. The other side was represented by Kant, Hegel, Marx, Freud, Polanyi and Kuhn. The study of their arguments does not lead to a universal philosophy, but to many philosophical approaches that are useful for the variety of different research objectives.

As introduced in section 3.1, the research onion refers to the four main research philosophies in social research: positivism, realism, interpretivism and pragmatism. According to Saunders, Lewis and Thornhill (2019, p. 144 f.), these four main philosophies have the following distinct characteristics:

(1) Pragmatism: External, multiple, viewpoint chosen to best enable answering the research question
(2) Positivism: External, objective and independent of social actors
(3) Critical realism: Is objective. Exists independently of human thoughts and beliefs or knowledge of their existence (realist), but is interpreted through social conditioning (critical realist)
(4) Interpretivism: Socially constructed, subjective, subject to change, multiple

If positivism and realism are seen as objective ontological standpoints, interpretivism is obviously a contrasting subjective standpoint. Pragmatism does not have a clear position between these opposing viewpoints, but can be chosen in cases where the research question justifies several epistemological viewpoints.

In the following two sections, the objective and subjective epistemological standpoints are distinguished, their theoretical underpinnings described, and classified as advantageous or disadvantageous.

3.3.1 Objective epistemological viewpoint

According to Easterby-Smith, Thorpe and Jackson (2015), positivism means that "the social world exists externally, and that its properties can be measured through objective methods rather than being inferred subjectively through sensation, reflection or intuition" (Easterby-Smith, Thorpe and Jackson, 2015, p. 51). This statement was echoed by the 19th century French philosopher August Comte, who noted that "all good intellects have repeated, since Bacon's time, that there can be no real knowledge but that which is based on observed facts" (Comte, 1853, p. 3). Like natural scientists, positivist researchers prefer "working with an observable social reality and that the end product of such research can be law-like generalisations similar to those produced by the physical and natural scientists" (Remenyi et al., 1998, p. 32). This means that only observable phenomena will lead to the production of credible data. Positivist research is based on the development of hypotheses that are tested and confirmed or refuted - in whole or in part. The latter leads to the development of theories that are tested by further research.

Easterby-Smith, Thorpe and Jackson (2015) developed the following theoretical requirements of positivism:

- Independence: the observer must be independent from what is being observed.
- Value-freedom: the choice of what to study, and how to study it, can be determined by objective criteria rather than by human beliefs and interests.
- Causality: the aim of the social sciences should be to identify causal explanations and fundamental laws that explain regularities in human social behaviour.

- Hypothesis and deduction: science proceeds through a process of hypothesizing fundamental laws and then deducing what kinds of observations will demonstrate the truth or falsity of these hypotheses.
- Operationalization: concepts need to be defined in ways that enable facts to be measured quantitatively.
- Reductionism: problems as a whole are better understood if they are reduced into the simplest possible elements.
- Generalization: in order to move from the specific to the general it is necessary to select random samples of sufficient size, from which inferences may be drawn about the wider population.
- Cross-sectional analysis: such regularities can most easily be identified by making comparisons of variations across samples (Easterby-Smith, Thorpe and Jackson, 2015, p. 52).

According to Hirschheim (1985, p. 33), “positivism has a long and rich historical tradition. It is so embedded in our society that knowledge claims not grounded in positivist thought are simply dismissed as ascientific and therefore invalid”. Positivism is very often associated with research in the physical and natural sciences, where there is no room for subjective opinion. The positivist approach - from a scientific point of view – is concerned with verifiable observations and measurable relationships between these observations. Speculation and conjecture are strictly forbidden.

Realism is an alternative objective epistemological view alongside positivism that relates to scientific inquiry (Saunders, Lewis and Thornhill, 2019). There are different types of realism, such as transcendental realism, which assumes that “the ultimate objects of scientific inquiry exist and act (for the most part) quite independently of scientists and their activity” (Bhaskar, 1989, p. 12), and internal realism, which assumes that there is a single reality that is not directly accessible to researchers (Putnam, 1987). Internal realism assumes that scientific laws are absolute and independent of further observation (Easterby-Smith, Thorpe and Jackson, 2015).

3.3.2 Subjective epistemological viewpoint

The subjective epistemological view contrasts with the views of positivism, and is often referred to in the literature as ‘social constructionism’. Easterby-Smith, Thorpe and Jackson (2015), state that social constructionism belongs to constructivism and interpretivism. The latter term is used by Saunders, Lewis and Thornhill (2019).

Interpretivism presupposes subjective meanings and social phenomena. It rejects absolute facts as these are based on perceptions rather than objective truth. Conclusions are drawn from participants’ interpretations rather than researchers’ abstract theories. Since the world is constantly evolving through social actors, there are no universal laws or experiences. On the other hand, the researcher must have the expertise to understand the meanings, values and contexts of his or her subjects.

The key to the interpretivist philosophy is the assumption that reality can only be fully understood by studying phenomena in their natural setting, and the recognition that scientists cannot avoid being influenced by the phenomena they study. There may be many interpretations of reality, but these are themselves part of the scientific knowledge they seek.

Ernst (1996) distinguishes between ‘normal’ constructivism, which refers to those who construct their own knowledge and accept the existence of independent, objective knowledge, and ‘strong’ constructivism, which assumes that there is no difference between individual and social knowledge.

Variants of interpretivism include phenomenology, hermeneutics and symbolic interactionism. Phenomenology is also called non-positivism and “describes the philosophical approach that what is directly perceived and felt is considered more reliable than explanations or interpretations in communication” (Remenyi et al., 1998, p. 97). Ideas are gained through induction and human interest from a large amount of data. Phenomenology is often viewed from the perspective of the

participant exploring human experience in management studies, for example, using the in-depth interview research strategy. According to Easterby-Smith, Thorpe and Jackson (2015), the benefits of phenomenology include a better understanding of people's meanings, the ability to adapt to new themes and ideas as they emerge, contributing to the development of new theories, and collecting data that is seen as natural rather than artificial. In contrast, data collection can be time and resource consuming, data analysis and interpretation can be difficult, and ultimately policy makers may give little credibility to a phenomenological study.

3.3.3 Discussion

As mentioned in the previous sections, positivism and social constructionism are two diametrically opposed epistemological views. Whereas positivism assumes that scientific evidence is generated through independent observation, the generation of hypotheses and conclusions, and a large number of randomly selected samples, social constructionism advocates the generation of evidence by a participant observer who collects rich data from which ideas are derived from a small number of specifically selected cases.

According to Easterby-Smith, Thorpe and Jackson (2015), the main differences between positivism and social constructionism are as follows:

	Positivism	Social Constructionism
The observer	must be independent	is part of what is being observed
Human interests	should be relevant	are the main drivers of science
Explanations	must demonstrate causality	aim to increase general understanding of the situation
Research progress through	hypotheses and deductions	gather rich data from which ideas are induced
Concepts	need to be operationalised so that they can be measured	should incorporate stakeholder perspectives
Units of analysis	should be reduced to simplest terms	may include the complexity of 'whole' situations
Generalisation through	statistical probability	theoretical abstraction
Sampling requires	large numbers selected randomly	small numbers of cases chosen for specific reasons

Table 9: Contrasting implications of positivism and social constructionism
(Easterby-Smith, Thorpe and Jackson, 2015, p. 53)

In light of the above, this research will follow the epistemological standpoint of social constructionism, as the underlying philosophical assumptions are most consistent with the research aim and objectives. Although the initial literature review was conducted from an objective standpoint - with inevitable subjective influences - the practical part of the research, with its defined research objectives, is best conducted using the inductive - theory-building - social constructionist approach. The 3rd research objective, the empirical testing of the conceptual framework, can only be achieved if the researcher/observer and the existing ideas of the conceptual framework are included in the subsequent inductive research.

3.4 Major paradigm and research approach

To avoid any confusion, as the term ‘paradigm’ obviously has several meanings, the following assumptions are based on Saunders, Lewis and Thornhill’s (2019, p. 140 f.) definition “that a paradigm is a way of examining social phenomena from which particular understandings of these phenomena can be gained and explanations attempted”.

Burrell and Morgan (2005) have developed a simplified representation of the four main paradigms and presented them in a matrix notation (see Figure 26). The distinction is intended to help researchers to clarify their view of the nature of science and society and to plan their research agendas (Burrell and Morgan, 2005). The horizontal dimension represents the two opposing ontological views of subjectivism and objectivism. The vertical dimension separates the sociology of radical change from the sociology of regulation. According to Saunders, Lewis and Thornhill (2019, p. 141), “the radical change dimension approaches organisational problems from the viewpoint of overturning the existing state of affairs; the regulatory dimension seeks to work within the existing state of affairs”.

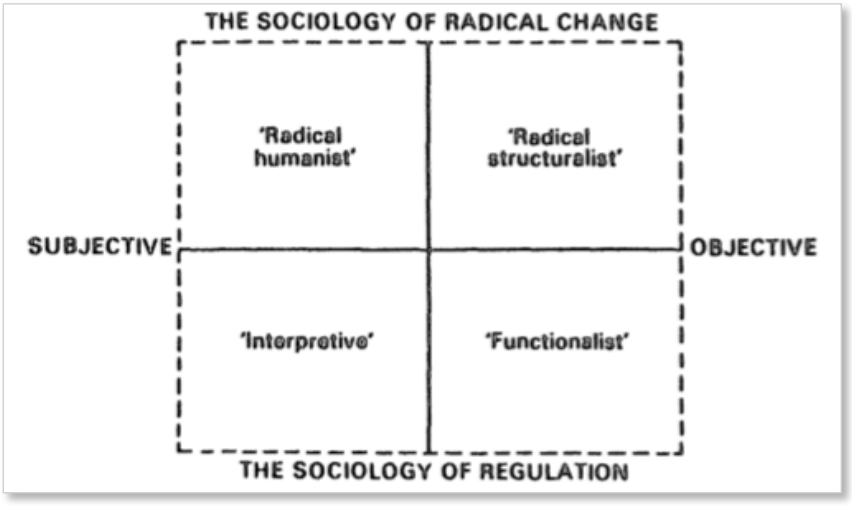

Figure 26: Four paradigms for the analysis of social theory (Burrell and Morgan, 2005, p. 22)

Following the discussions in sections 3.2.3 and 3.3.3, a social constructionist and therefore highly subjective philosophical perspective was identified for this research. As the 3rd research objective is about reviewing existing knowledge, the sociology of radical change, with its approach of overturning the existing state of affairs, does not seem to fit the underlying research. Instead, the sociology of regulation, with its approach of working within the existing state, seems to fit. Consequently, the latter assumptions lead to the conclusion that this research is subject to the 'interpretative paradigm'. Burrell and Morgan (2005) suggest that

> the interpretative paradigm is informed by a concern to understand the world as it is, to understand the fundamental nature of the social world at the level of subjective experience. It seeks explanation within the realm of individual consciousness and subjectivity, within the frame of reference of the participant as opposed to the observer of action (Burrell and Morgan, 2005, p. 28).

The interpretive paradigm, which derives from the German idealist tradition of social thought and in particular from the work of the German philosopher Immanuel Kant, emphasises the essentially spiritual nature of the social world, which is created subjectively in the sense of an ongoing process of 'as it is' (Burrell and Morgan,

2005). Burrell and Morgan (2005) place the phenomenological paradigm and the hermeneutic paradigm very close to the interpretive paradigm. The following differences between positivist/objectivist and phenomenological/subjectivist paradigms have been elaborated by Easterby-Smith, Thorpe and Jackson (2015) (see Table 10).

	Positivist paradigm	Phenomenological paradigm
Basic notions	- The world is perceived as external and objective - Independency of the observer - Value-free approach of science	- The world is perceived to be socially constructed and subjective - Observer is considered a part of the object of observation - Human interests drive science
Responsibilities of researcher	- Focusing on facts - Causalities and fundamental laws are searched - Phenomenon are reduced to the simplest elements - Hypotheses formulation and testing them	- To be focusing on meanings - Aiming to understand the meaning of events - Exploring the totality of each individual case - Ideas developed by induction from data
Most suitable research methods	Concepts have to be operationalised	Using several methods in order to different aspects of phenomena
Sampling	Samples have to be large	Small samples are analysed in a greater depth or over longer period of time

Table 10: Difference between the positivist paradigm and the phenomenological paradigm (Adapted from Easterby-Smith, Thorpe and Jackson, 2015)

According to Kelemen and Rumens (2008), the interpretive paradigm leads the researcher to understand the underlying meanings associated with organisational life while engaging in the daily activities of the organisation in order to understand and explain what is going on, rather to change things.

Research approaches can be either deductive, inductive or abductive depending on their specific design (see Table 11). Saunders, Lewis and Thornhill (2019) identify the following key differences between the deductive and inductive approaches:

	Deduction	Induction
Logic	In a deductive inference, when the premises are true, the conclusion must also be true	In an inductive inference, known premises are used to generate untested conclusions
Generalisability	Generalising from the general to the specific	Generalising from the specific to the general
Use of data	Data collection is used to evaluate propositions or hypotheses related to an existing theory	Data collection is used to explore a phenomenon, identify themes and patterns and create a conceptual framework
Theory	Theory falsification or verification	Theory generation and building

Table 11: Deduction and Induction: from reason to research (Saunders, Lewis and Thornhill, 2019, p. 145)

Following Saunders, Lewis and Thornhill's (2019) assumptions about contrasting research approaches, the inductive approach is appropriate for this research project. The data collection serves to investigate the phenomenon of entrepreneurial behaviour in German MedTech start-ups, to identify themes and patterns, and to validate or further develop the conceptual framework (see section 2.4.7).

While deduction clearly leads from theory to data and induction from data to theory, the abductive approach combines both approaches by moving back and forth (Suddaby, 2006). Van Maanen, Sørensen and Mitchell (2007) explain that the abductive approach starts with the observation of a 'surprising fact' and then uses the combination of deduction and induction to potentially uncover more 'surprising facts'. For the remainder of this research project, the inductive approach will be used to generate data.

To summarise the philosophical arguments, this research will continue to follow a qualitative research strategy, pursued from a subjective ontological and epistemological standpoint, combined with an inductive interpretivist approach that meets the requirements of the interpretive paradigm. The following section outlines the methodological choices that will ultimately determine the choice of the appropriate research method(s).

3.5 Methodological choice

Methodology follows the question: "How should the inquirer go about finding out knowledge?" (Guba, 1990, p. 18) and therefore requires strategic decisions about the method(s) to be used in order to create a detailed plan for the research project going forward. According to Saunders, Lewis and Thornhill (2019), research method addresses the general issue of how research is conducted. It is defined as "the techniques and procedures used to obtain and analyse research data, including for example questionnaires, observations, interviews, and statistical and non-statistical techniques" (Saunders, Lewis and Thornhill, 2019, p. 808). The method chosen for a research project has a strong influence on how the research is conducted, and highlights the implications of these choices. McGrath (1981, p. 179) defines the research process itself as "a series of interlocking choices, in which we try simultaneously to maximize several conflicting desiderata" and argues that there is no one true method that can be considered the methodological answer and there is no guarantee of success. Saunders, Lewis and Thornhill (2019) have listed the methodological implications of different ontologies/epistemologies (see Table 12).

Ontology	Realism	Internal realism	Relativism	Nominalism
Epistemology / Methodology	Strong positivism	Positivism	Constructionism	Strong constructionism
Aims	Discovery	Exposure	Convergence	Invention
Starting points	Hypotheses	Proposition	Questions	Critiques
Designs	Experiments	Large surveys; multi-cases	Cases and surveys	Engagement and reflexivity
Data types	Numbers and facts	Mainly numbers with some words	Mainly words with some numbers	Discourse and experiences
Analysis/Interpretation	Verification/ falsification	Correlation and regression	Triangulation and comparison	Sense-making; understanding
Outcomes	Confirmation of theories	Theory testing and generation	Theory generation	New insights and actions

Table 12: Methodological implications of different epistemologies
(Easterby-Smith, Thorpe and Jackson, 2015, p. 54)

Based on a subjectivist/relativist ontology and a constructivist epistemology, the research design should be cases and survey based, using mainly words as data types. The analysis or interpretation should be based on triangulation and comparison with the results in order to develop a theory. This is in line with the assumptions made in the previous sections.

The research onion (see Figure 24) lists the following methodological options: either quantitative or qualitative mono- or multi-method research, or complex or simple mixed methods. According to Saunders, Lewis and Thornhill (2019), the choice of interpretivism as a research philosophy implies the popular method of data collection with small samples, in-depth investigations and qualitative methods. The qualitative approach and inductive data collection as a research technique are consistent with the qualitative method described by Saunders, Lewis and Thornhill (2019).

Wrona (2005) claims that qualitative methods, unlike quantitative methods, are subject to the interpretive paradigm. Their strategy is to construct a theory from empirical material/data (Erzberger, 1998; Glaserfeld, 1990; Mayring, 1993). The strength of qualitative research lies in its empirical basis. For this reason, it is easiest to measure the theoretical categories obtained through case study analysis, because they have been obtained through empiricism (and are not theoretical concepts). The world is perceived, perceptions are interpreted and meanings are attached. According to Wrona (2005), the interpretive paradigm claims to provide differentiated and non-trivial solutions. It goes without saying that qualitative research will never claim to be representative. Otherwise, its results would not be random and, through certain mechanisms, might even be valid beyond the cases studied. In other words, a sophisticated qualitative analysis of a few cases may be indicative of other similar cases. This is very close to the quality criterion of generalisability. The statements of Wrona (2005) support the findings of section 3.4.

Wrona (2005) further states that qualitative research should be ‘open’ and allow for surprising observations. Therefore, it be inductive rather than deductive and theory-oriented. All prior knowledge should unfold and be used as a heuristic frame of reference. This framework should underlie the literature review, the selection of companies to be interviewed, the development and structuring of the guide and the analysis of the interview transcripts.

Qualitative social research is particularly strong in developing new concepts and hypotheses. For example, by confronting different individual cases, it supports the uncovering of characteristics or determinants that have previously received little attention (cf. ‘unfreeze’ thinking by Eisenhardt (1989c, p. 546)). Eisenhardt (1989b, p. 532). explains that “this research approach is especially appropriate in new topic areas. The resultant theory is often novel, testable, and empirically valid”.

Following the findings on qualitative social research, this research will continue to follow a social constructivist point of view, combined with an inductive interpretivist approach that meets the requirements of the interpretive paradigm. The chosen methodology is based on a case study conducted through interviews. The results will be analysed and validated by comparing primary and secondary data. A detailed plan of the research design and the methods to be chosen will follow in the next section.

3.6 Research design

Fusch and Ness (2015) define the three most important aspects for researchers seeking an appropriate research design: The design should allow the researcher to best answer the research question posed, it should help the researcher achieve data saturation, and it should allow the researcher to conduct the study in a reasonable time frame at minimal cost. According to Saunders, Lewis and Thornhill (2019), the research design determines the methodological choice between

quantitative, qualitative or multi-method design. Therefore, in this section, one or more research strategies will be selected (e.g. case study, survey, grounded theory, etc.). Following the selection in the previous section, this research project will focus on qualitative research methods. According to Saunders, Lewis and Thornhill (2019, p. 130), the different appropriate research strategies that can be used are as follows:

- Experiment
- Survey
- Archival research
- Case study
- Ethnography
- Action research
- Grounded theory
- Narrative inquiry

Experiment and survey are strategies that follow the positivist/quantitative research philosophy, but they are therefore inappropriate and will not be considered further for this research project. Instead, archival research, case study, ethnography, action research, grounded theory and narrative inquiry are interpretivist/qualitative research philosophies from which it is important to find the most appropriate research strategy.

On the way of qualitative research, the methods of archival research, action research, narrative inquiry and grounded theory can be shelved as they do not meet the requirements of the underlying research objective.

Archival research would mean searching for data in archives and documents. Instead, validating the conceptual framework means questioning the concrete circumstances, which cannot be solved by examining archives or documents, but requires oral communication with the managers and employees involved.

An action research strategy promotes “organisational learning to produce practical outcomes through identifying issues, planning action, taking action and evaluating action” (Saunders, Lewis and Thornhill, 2019, p. 202). Accordingly, action research focuses on “addressing worthwhile practical purposes” (Reason, 2006, p. 188) and solving real organisational problems (Shani and Pasmore, 1985), which are also not identical to the underlying research objective.

Narrative inquiry is also conducted through verbal communication, with its main strength being the collection and analysis of complete stories, as opposed to the collection of “bits of data that flow from specific interview questions and which are then fragmented during data analysis” (Saunders, Lewis and Thornhill, 2019, p. 209). The purpose of the research is to investigate of phenomena, possibly identify themes and patterns, and the revisit/modify a conceptual framework that has emerged from intensive data analysis. The latter is not compatible with the timeframe of this dissertation, and therefore narrative inquiry is not an appropriate method.

Grounded theory was developed by Glaser and Strauss (1967) in response to the prevailing ‘extreme positivist’ social research, more akin to research in the natural sciences. Glaser and Strauss (1967) describe in their book ‘The Discovery of Grounded Theory’ that their aim is to discover or develop theory based on the data produced by social actors. The term itself can be used to refer to a methodological approach, a research method or the outcome of a research process. According to Saunders, Lewis and Thornhill (2019, p. 205), grounded theory as a research strategy can “be used loosely to incorporate methodology and method but more specifically it refers to a theory that is grounded in or developed inductively from a set of data”. Bryant and Charmaz (2007) noted that the “process of data collection and analysis becomes increasingly focused, leading to the generation of a contextually based theoretical explanation” (Saunders, Lewis and Thornhill, 2019, p. 207). Based on ‘theoretical sensitivity’, the researcher should “focus on interpreting meanings by using in vivo and researcher-generated rather than *a priori*

codes […] to analyse […] data and construct grounded theory" (Saunders, Lewis and Thornhill, 2019, p. 208). Although theory construction seems to be in line with the underlying research objectives, the term 'theory' has a much broader meaning than research design. Therefore, grounded theory would lead to a far too complex theoretical approach that would go beyond the focus of this dissertation.

Ethnography, which has its origins in anthropology and aims to analyse human culture in a holistic, relativistic and comparative way (Fetterman, 2020; Fusch et al., 2016; Zaharlick, 1992), generally helps to study the culture or social world of people or ethnic groups and therefore plays a growing role in business innovation research (Haines, 2016). Although anthropology is an imprecise science with no formal rules, it contributes to organisational behaviour theory with its "ability to facilitate understanding between peoples in other countries or organizations […], by noting differences in values, attitudes, and behaviour" (Fusch, Fusch and Ness, 2017, p. 924), focusing not on the individual but on the macro level (group processes and organisation). Hasbrouck (2018, p. 12) attests to a genuine curiosity in ethnographic thinking, which requires the ethnographer to "see the world with a wider lens". According to Patton (1990, p. 74), an ethnomethodologist must "elucidate what a complete stranger would have to learn to become a routinely functioning member of a group, a program, or a culture". To achieve this goal, he should not be content with in-depth interviews and observations, but should conduct "ethnomethodological experiments" that "violate the scene" or deliberately "shake up" the taken-for-granted behaviours in that culture in order to shed light on the roles that underlie behaviour. Sackmann (2010, p. 128) sees ethnography as the "method of choice for gaining a detailed and in-depth understanding of cultural processes in organizations" and describes the method as a time-consuming process conducted 'in situ' by insiders with a long-term perspective. Suryani (2008) describes the ethnographer's data collection directly at the research site as participant observation in the field. Flick (2019) points out that ethnographic research only examines a few cases or even one case, and researchers should be aware that the findings may not be generalisable to other social contexts.

Sackmann (2010, pp. 23-24) advocates the method of ‘ethnographic fieldwork’ combined with in-depth interviews and storytelling when culture is considered as a metaphor from an interpretivist perspective to understand corporate life. Accordingly, ethnography seems to be an appropriate method when it comes to the understanding of organisational cultures. However, since the resources of the underlying research project are limited, a long-term method such as ethnographic fieldwork is out of the question, provided that an adequate and possibly more resource-efficient method would also enable the research objectives to be achieved. This dilemma is probably the reason why start-ups seem to be “generally unaware of the potential of ethnographic approaches” (Haines, 2016, p. 175). According to Monahan and Fisher (2015), researchers should change the focus of their study if they do not receive permission from a company to conduct organisational ethnography.

The case study method is an in-depth investigation of an issue or phenomenon in its real-world setting, where the ‘case’ may refer to an organisation (Yin, 2018). Ridder, Hoon and McCandless (2009, p. 137) highlight the importance of case studies in the field of strategy and management, as they are “detailed empirical investigations into a complex entity that emphasize the uniqueness of the case and are valuable for making a theoretical contribution”. Case studies play a prominent role in extending and refining theory while providing detailed, fine-grained and process-related data (Ridder, Hoon and McCandless, 2009). They have been used in a variety of disciplines such as architecture, political science, health research, operations research and business management and have proven to be viable (Taylor, Dossick and Garvin, 2011). Yin (2018, p. 15) defines the case study method as an “empirical method that investigates a contemporary phenomenon (the ‘case’) in depth and within its real-world context, especially when the boundaries between phenomenon and context may not be clearly evident”. Case studies can be exploratory, explanatory or descriptive and can involve one or more organisations (Yin, 2018).

According to Eisenhardt and Graebner (2007), cases are used to provide the basis for inductive theory development. They go on to say that “theory is emergent in the sense that it is situated in and developed by recognizing patterns of relationships among constructs within and across cases and their underlying logical arguments” (Eisenhardt and Graebner, 2007, p. 25). Van Maanen (1979) also recommends an inductive methodology as it provides valuable insights into the nature of complex phenomena.

In his research, Yin (2018) noted that case studies can be conducted on single or multiple cases and at numerous levels of analysis. Although the case study approach tends to support the deductive approach, it can also generate data that contributes to the development of theories, thus moving in an inductive direction. Ridder, Hoon and Baluch (2014) highlight the strengths of interpretivist researchers who work inductively, analysing their data, identifying themes and patterns in this data and locating it at a particular point in the existing literature in order to refine, extend or develop theory. Within a case study design, there are various methods of data collection: for example, interviews, direct observation, document review, focus group sessions, diary keeping and participant observation (Amerson, 2011).

Looking at their unique characteristics, there are significant differences between ethnography and case study that lie in their intention and focus (see Table 13). While ethnography is inward looking and aims to uncover the tacit knowledge of cultural participants, case study is outward looking and aims to describe the nature of phenomena through the detailed examination of individual cases and their contexts (Cohen and Court, 2003).

	Ethnography	Case study
Differences	The detailed and systematic study of people and culture	Detailed investigation of a single event, situation or an individual in order to explore and unearth complex issues
Focus	Observes cultural phenomena	Focus on a single event, incident or individual
Intend	Aims to describe the nature of phenomena through detailed investigations of individual cases	Intends to uncover the tacit knowledge of culture participants
Data collection methods	Use participant observations and interviews	May use interviews, observations, questionnaires, checklists, analysis of recorded data and opinionnaires
Special requirements	The researcher has to spend a considerable time inside that particular community	The researcher does not have to live in a particular community

Table 13: Differences between ethnography and case study (Cohen and Court, 2003)

To summarise the above facts about ethnography and case studies, there are limiting factors in both. However, there are useful and important factors in both that should be considered in order to combine them into a strong and validated method that best answers the underlying research question. Experienced ethnographers Fusch, Fusch and Ness (2017, p. 927) describe in their study how to construct a mini-ethnographic case study design with the “benefit of an ethnographic approach that is bounded within a case study protocol that is more feasible for a student researcher with limited time and finances”. White (2009) also emphasises that the mini-ethnographic case study is particularly suited to specific and limited research where time is short. In contrast to mixed methods (combining qualitative and quantitative methods), which is often referred to as ‘methodological pluralism’, Fusch, Fusch and Ness (2017) mention that blended study designs can use the best of both designs and thus also mitigate their limitations. Using the data collection methods from both designs limits the study in time and space, allows researchers to explore causal relationships (which is usually not possible for a ethnographers), and allows researchers to both generate theory and explore it in real-world applications (Fusch, Fusch and Ness, 2017). Morgan (2012) advocates the use of ethnographic work in the context of a case study.

In both mini-ethnography and case study design, the researcher's subjectivity and cultural and experiential background contain biases, values and ideologies that need to be taken into account as the research progresses. To overcome bias, Holloway, Brown and Shipway (2010) advise researchers that the interpretation of the cultural phenomena is that of the participant, not the researcher.

The blended method of mini-ethnographic case study has been used in several studies (Fusch and Ness, 2015; Fusch, Fusch and Ness, 2017; Moore, 2011; Storesund and McMurray, 2009; Thompson, 2016) and can therefore be said to be accepted and validated.

The previous considerations show that the mini-ethnographic case study method is perfectly suited to the underlying research aim and objectives and should therefore be chosen as a valid research method. In contrast to the expected bias, the mini-ethnographic case study provides the opportunity to observe meaning as an objective subject who has a neutral view of the organisation from the outside, is not an employee and does not know the channels of communication.

3.6.1 Building Theory

The process of theory building using the case study method has been described by Eisenhardt (1989b; Eisenhardt and Graebner, 2007) in various reference works. She highlights three strengths of case theory building (Eisenhardt, 1989b). First, "its likelihood of generating novel theory" because the "constant juxtaposition of conflicting realities tends to 'unfreeze' thinking, and so the process has the potential to generate theory with less researcher bias than theory built from incremental studies or armchair, axiomatic deduction" (Eisenhardt, 1989b, pp. 546-547). Second, "that the emergent theory is likely to be testable with constructs that can be readily measured and hypotheses that can be proven false" (Eisenhardt, 1989b, p. 547). Third, "the resultant theory is likely to be empirically valid […] because the theory-building process is so intimately tied with evidence that it is very likely that the resultant theory will be consistent with empirical observation" (Eisenhardt,

1989b, p. 547). According to Wrona (2005), ‘unfreeze thinking’ is intended to help identify features or influencing variables that have received little attention. Eisenhardt (1989b, p. 548) concludes that “building theory from case study research is most appropriate in the early stages of research on a topic”, which fits perfectly with the planned research project.

Eisenhardt (1989b) divides the process of theory development in case study research into eight steps. In the first step, ‘entry’, the researcher defines the research question (see section 1.2.1) and possibly a priori constructs such as the further research design (see section 1.2.2 ff.). This step is followed by the ‘selection of cases’ based on a theoretical, non-random sample (see section 3.6.2). In this step it is important to “focus efforts on theoretically useful cases – i.e., those that replicate or extend theory by filling conceptual categories” (Eisenhardt, 1989b, p. 533). In the third step, ‘crafting instruments and protocols’, the different data collection methods were analysed and the appropriate method for the underlying research objectives was determined. This step and the subsequent data collection will be discussed in more detail in section 3.6.4. The fourth step, ‘entering the field’, involves practical data collection, e.g. conducting the planned semi-structured interviews. In this step it is important to keep an accurate record of the data collection, analysis and field notes in order to meet the inherent requirements of research reliability. This step should be used by the researcher to ‘push the thinking forward’, asking questions such as “What am I learning?” and “How does this case differ from the last?” (Eisenhardt, 1989b, p. 539). Another important theme is that a key feature of theory building case research is “the freedom to make adjustments during data collection phase”, it is “legitimate to alter and even add data collection methods during a study” (Eisenhardt, 1989b, p. 539). According to Eisenhardt (1989b), the fifth step, ‘analysing data’, is “the heart of building theory from case studies” and involves an in-depth within-case analysis to “gain familiarity with data and preliminary theory generation” (Eisenhardt, 1989b, p. 533). Step six is concerned with ‘shaping hypotheses’, including the “iterative tabulation of evidence for each construct” to sharpen their definition, validity and measurability. Here it will

be important to replicate cases rather than samples in order to confirm, extend and sharpen the theory. In the seventh step, 'enfolding literature', the researcher compares his findings with competing literature to build internal validity, raise the theoretical level and sharpen the definitions of the constructs. Comparison with similar literature will "sharpen generalizability, improve construct definition, and also raise theoretical level" (Eisenhardt, 1989b, p. 544). Eisenhardt sees the key to this process in the consideration of "a broad range of literature" (Eisenhardt, 1989b, p. 544). The result should be deep insights into both "the emergent theory and the conflicting literature, as well as sharpening of the limits to generalizability of the focal research" (Eisenhardt, 1989b, p. 544). 'Reaching closure' is the eighth and final part of the process of theory building through case study research with "theoretical saturation (when possible)" (Eisenhardt, 1989b, p. 533). The researcher should stop adding new cases when he feels that theoretical saturation has been reached (Eisenhardt, 1989b, p. 545).

3.6.2 Sampling method and data saturation

Sample selection is about selecting cases that are relevant to the research questions, as it is unlikely that all employees, even in a small business such as a start-up, can be included in the mini-ethnographic case study. In both qualitative and quantitative research, it is essential to define and justify the selection of the sample in order to adequately answer the research questions (Flick, 2019; Saunders, Lewis and Thornhill, 2019). There are two contrasting sampling techniques: Probability Sampling and Non-Probability Sampling. At its core, probability sampling is random selection or chance, as each member of the population has a known, non-zero chance of participating in the study. Non-probability sampling, on the other hand, does not randomly select the members of the sample group, so only certain members of the population have the chance to participate in the study (Saunders, Lewis and Thornhill, 2019).

As the underlying research questions lead to the method of a mini-ethnographic case study methodology focused on gaining detailed insights into the

entrepreneurial behaviour of a German MedTech start-up with a focus on disruptive innovation, there is no tendency to favour certain employees based on their position, experience or knowledge of the company's organisational design, strategy or culture. There is no need for expertise. It is therefore obvious that any employee of the start-up can express his or her personal experiences and opinions on the various individual issues identified in the conceptual framework. There should be no weighting according to specific criteria, but a random selection of participants should lead to a field of participants that is as heterogeneous as possible, thus covering as many different perspectives within the start-up as possible. It is worth considering whether participants should have a certain minimum period of employment in the start-up, otherwise personal experiences and opinions may be too limited.

Consequently, the sampling method of choice for the underlying research project should be a non-probability sample, namely 'convenience sampling'. In the latter, cases are selected for inclusion in the sample through, for example, personal recruitment, crowdsourcing websites or pre-existing groups because they are the easiest for the researcher to access. As the underlying research is an investigation of the entrepreneurial behaviour of a start-up where the managing director has given permission to conduct the study but cannot provide a list of all employees due to data protection regulations, he assumes the role of gatekeeper in the sampling process (see also section 3.9.3).

On the one hand, it is important to choose an appropriate sampling method to justify the selection of respondents for this research project. Once this has been decided, the number of interviews needed to address the research questions becomes important. Saturation is an important component of scientific rigour and is a crucial element in qualitative research. It is therefore all the more surprising that Fusch and Ness (2015) claim that "the field of data saturation is a neglected one". There are many ways to think about and consider the issue of saturation.

Following the work of Guest, Bunce and Johnson (2006); Hennink, Kaiser and Marconi (2016) argue that saturation is determined by the research question, the study population, the type of codes and the complexity and robustness of the codebook. According to Hennink, Kaiser and Marconi (2016), a larger sample size is required to understand or explain complex phenomena or to develop theories. Kerr, Nixon and Wild (2010) define the point of data saturation using three objective markers: the point in data collection at which no more additional insights are discovered, the data begin to repeat, and further data collection becomes unnecessary to answer the research questions. Similar to this theoretical saturation approach, Eisenhardt (1989b) and Hennink, Kaiser and Marconi (2016) suggest that saturation is reached when data collection only gradually yields new insights and begins to repeat. The researcher should stop adding new cases when he or she feels that theoretical saturation has been reached (Eisenhardt, 1989b, p. 545).

In contrast to the theoretical saturation approaches mentioned above, many researchers tend to provide a priori recommendations for a sufficient number of interviews per case study. For example, Creswell (2012) recommends a sample size of at least three to ten interviewees along with other data for case study research, Eisenhardt (1989b) recommends a sample size of four to ten interviewees (see section 3.6.4.2), Lincoln and Guba (1985) instead recommend about 12 to 20 interviewees. Comparable to this research project, Pöllänen (2021) conducted an organisational ethnography on start-up culture consisting of field notes, a research diary and thematic interviews with five employees. However, these should be taken with a pinch of salt, as the numbers may well vary in individual cases and the study designs are not universal. In any case, critical reflection in advance is advisable. Bernard (2012) mentions that the number of interviews in qualitative research cannot be quantified until data saturation is reached, but that the researcher should “take what he can get”. According to Lamnek and Daxböck (1995), it is more important for the researcher to focus on the qualitative input of the respondents than on the total number of interviews conducted.

In order to meet the quality criteria for this research project, particularly in terms of neutrality and validity, no fixed sample size was set in terms of interviews and the theoretical saturation approach was chosen. The final number of interviews required for the mini-ethnographic case study depends on saturation in terms of knowledge gained about the research topic (Eisenhardt, 1989b; Hennink, Kaiser and Marconi, 2016; Peck and Mummery, 2017; Sim et al., 2018; Wernet, 2000). In practice, this means documenting progress during thematic analysis to identify emerging themes, the frequency with which themes emerge, or when existing themes evolve (Guest, Bunce and Johnson, 2006). The latter helps to avoid unnecessary use of HR in the form of interviewees. An efficient research process helps to minimise resources on both sides and avoid unnecessary effort and data.

3.6.3 Participant profile

Based on the findings of the previous sections, a single case design with multiple units of analysis is planned for this research project (Yin, 2018). The single case design is the appropriate methodology to generate in-depth qualitative data from the perspectives of multiple organisational members.

A potential German MedTech start-up that could participate in this single case study was identified through an intensive internet search, as the start-up is focused on the commercialisation of disruptive medical devices. The willingness to participate in this research project was expressed by one of the managing directors of the MedTech start-up in a telephone conversation on 27 July 2021. The name of the start-up company, as well as the names of all employees and the exact description and name of the medical devices marketed, have been anonymised in this dissertation for ethical reasons (see section 3.8). In order to meet the anonymisation criteria, the actual name of the start-up company was changed to 'Start-up X', the participants in the interviews are named according to the order in which they were interviewed, e.g. 'Interviewee no. 1'.

In order to achieve the highest level of data quality, the profile of participants should be representative of all employees at all levels of the organisation using the chosen sampling method (see section 3.6.2); it is essential that as many employees as possible participate in order to eliminate any possible bias. Whenever interviews are conducted in this study, the 1:1 interview situation (one researcher facing one interviewee) is preferred in order to maximise the focus on the selected interviewee and to give the interviewee maximum freedom in answering. An interview situation with several interviewees at the same time could distort the answers due to, among other things, supervision ratios, etc.

Possible participants, and thus units of the single mini-ethnographic case study, are all employees of the selected start-up. In accordance with the chosen sampling method, the interviewees were selected randomly, with the exception that one of the managing directors of the start-up is included in the cohort to ensure that at least one manager with her or his extensive knowledge participates in the interview series.

3.6.4 Data collection methods

Data collection involves collecting data from the selected sample (see section 3.6.2) in order to achieve the research aim and objectives (Bryman, 2015, p. 12). Draper and Swift (2011) in their study highlighted two important aspects: “a) there is no universal accepted design for data collection and b) the researcher plays a central, key role in the data collection phase of the study” (Fusch, Fusch and Ness, 2017, p. 927).

Typically, mini-ethnographic case studies may combine data collection methods from a variety of sources, including surveys, interviews, archives, visual methods and participant observation (Dooley, 2002). Van Maanen, Sørensen and Mitchell (2007) claim that the methods generate discoveries, not just validations. According to Fusch (2013), data saturation can be achieved much earlier with mini-ethnography because the research is bounded in time and space by a case study

design. Storesund and McMurray (2009) have also addressed the time requirements of a mini-ethnographic case study, claiming that “mini-ethnographies can be conducted within a week, a month, or up to a year” (Fusch, Fusch and Ness, 2017, p. 926).

In order to validate the research objectives stated in section 1.2.3, data collection is an inevitable process of gathering all information from relevant sources. There are two methods of data collection: secondary methods of data collection and primary methods of data collection. Eisenhardt (1989b) refers to the step in which the methods of data collection are selected as ‘crafting instruments and protocols” (Eisenhardt, 1989b, p. 533). According to Eisenhardt (1989b, p. 534), case studies “combine data collection methods such as archives, interviews, questionnaires, and observations”. According to Yin (2018), it is possible for case study research to include only qualitative data, only quantitative data, or even both. He notes that even a combination of the two can be very synergistic. Mintzberg (1979a) described this synergy as follows:

> For while systematic data create the foundation for our theories, it is the anecdotal data that enable us to do the building. Theory building seems to require rich description, the richness that comes from anecdote. We uncover all kinds of relationships in our hard data, but it is only through the use of this soft data that we are able to explain them (Mintzberg, 1979a, p. 587).

3.6.4.1 Secondary data collection methods

The conceptual framework presented in section 2.4.7 was created using secondary data during the literature review phase of this research project. Secondary data includes all types of data, including academic journals, books, magazines, newspapers and online portals that contain extensive information about the specific research area of this dissertation. In order to increase the validity and reliability of this research, it is important to apply a number of criteria to the secondary data used in the research. These criteria should include the date of publication, the

qualifications of the author, the reliability of the source (ideally peer-reviewed), the quality of the discussion and the depth of the analysis.

3.6.4.2 Primary data collection methods

Primary data collection methods can be either quantitative or qualitative. The choice between them depends on the particular research area and the nature of the research objectives. Since the chosen research strategy focuses on a qualitative research method, the primary data collection should also be based on a qualitative method. Qualitative methods are unlikely to involve numbers or mathematical calculations, as this type of research is closely related to non-quantifiable elements such as words, sounds, feelings, emotions, colours and other elements.

The study plans to work with semi-structured interviews to keep interview responses and findings as open and informal as possible and to ensure a consistent focus on specific themes (Saunders, Lewis and Thornhill, 2019). Eisenhardt (1989b) suggests a sample size of four to ten cases (see section 3.6.2). It is important that the interview questions remain open-ended, to allow for the possibility that the empirical findings may contradict the literature findings summarised in the conceptual framework. In addition, an interview guide will be developed as a preparatory tool for the semi-structured interviews to ensure that the key issues are addressed, but that interviewees' responses remain flexible and allow them to express their own committed thoughts (Cooper and Schindler, 2014).

According to Eisenhardt (1989b), the actual data collection consists of carrying out the planned interviews. In this step it is important to keep an accurate record of the data collection, analysis and field notes in order to meet the intrinsic requirements of research for reliability. Van Maanen (1988) describes field notes as an "ongoing stream-of-consciousness commentary about what is happening in the research, involving both observation and analysis – preferably separated from one another" (Eisenhardt, 1989b, p. 539). Eisenhardt (1989b, p. 533) describes data collection as "flexible and opportunistic", allowing the researcher to "take advantage of

emergent themes and unique case features". Another important theme is that a key feature of theory building case research is "the freedom to make adjustments during data collection phase", it is "legitimate to alter and even add data collection methods during a study" (Eisenhardt, 1989b, p. 539). According to Eisenhardt, it is advantageous to use non-systematic flexibility to change data collection when a new opportunity for data collection arises, or when a new line of thought emerges that better justifies the theory or provides new theoretical insights. The researcher is thus free to "take advantage of the uniqueness of a specific case and the emergence of new themes to improve resultant theory" (Eisenhardt, 1989b, p. 539).

Carlson (2010) sees 'member checking' as an important way for qualitative researchers to check meaning rather than word choice by asking clarifying questions such as "Is that what you meant?" to avoid gaps in understanding of the phenomenon. Houghton et al. (2013) mention that interviewees sometimes stick to their original statement, but there is a good chance that they will expand on it. Member checking is therefore an important tool for increasing the validity of research findings and confirming the relevance of the data (Carlson, 2010; Holloway, Brown and Shipway, 2010; Marshall and Rossman, 2016; Wolcott, 2009). Ultimately, one does not necessarily need to triangulate data, but it is important to 'crystallise' by recognising that one needs to approach a concept from many angles (Richardson and Adams St. Pierre, 2008). According to Andrade (2009) and Yin (2018), "good data collection and analysis procedures and sharing interpretations with participants throughout the study are important" (Fusch, Fusch and Ness, 2017, p. 931).

3.6.5 Analysis process design

The process of analysis involves managing, analysing and interpreting data through thematic analysis of the interview transcripts (Bryman, 2015, p. 12). As mentioned in section 4.2, Eisenhardt (1989b, p. 533) states that 'analysing data' is at "the heart of building theory from case studies" and involves in-depth analysis within the case to achieve "familiarity with data and preliminary theory generation".

3.6.5.1 Thematic analysis and coding of the data

According to Saunders, Lewis and Thornhill (2019), coding is a key element of case studies. It is the point in the research where pure data is transformed into information and then into knowledge (and the further step would be wisdom).

Charmaz (2006) defined initial coding and focused coding as the two main stages of coding in a case study research strategy. Initial coding is a first-cycle method used in the "beginning stages of data analysis that fracture or split the data into individually coded segments" (Saldaña, 2016, p. 55). Focused coding is a second-cycle method used "for the latter stages of data analysis that both literally and metaphorically constantly compare, recognize, or 'focus' the codes into categories, prioritize them to develop 'axis' categories around which others revolve, and synthesize them to formulate a central or core category" (Saldaña, 2016, p. 55).

Braun and Clarke (2006) reviewed the various possible techniques of thematic analysis. In summary, they stated that "thematic analysis involves the searching across a data set […] to find repeated patterns of meaning" (Braun and Clarke, 2006, p. 15). According to them, thematic analysis is a constant shift between the whole data set, the coded data extracts and the analysis of the data produced (Braun and Clarke, 2006). Following their principles, thematic analysis in qualitative research is divided into six phases:

(1) Becoming familiar with the data by transcribing and repeatedly reading the oral data.
(2) The manual or software-based creation of initial codes to identify features of the data that appear to be of interest for analysis.
(3) Searching for themes within the identified codes, sorting the codes into potential themes and compiling the relevant coded data extracts within the identified themes.
(4) Test the themes by rereading all the collected extracts on each theme and checking whether they seem to form a coherent pattern.

(5) Define and name the themes and write a detailed analysis for each theme in relation to your research question.
(6) Write the thematic analysis in the form of a report.

Braun and Clarke (2006) place particular emphasis on the final report of the thematic analysis, advising in particular to "tell the complicated story of your data in a way which convinces the reader of the merit and validity of your analysis […] a concise, coherent, logical, non-repetitive, and interesting account of the story the data tell – within and across themes" (Braun and Clarke, 2006, p. 23).

3.6.5.2 Qualitative data analysis

The analysis part of the research project is carried out by manually coding and marking sections of the translated interview transcripts. As the transcripts are reread and coded, thoughts can be stored in parallel, extending the analysis.

The manual coding technique is preferred over Qualitative Data Analysis Software (QDAS) such as QSR's (2022) 'NVivo' because the manual coding supports the validity of the research itself and emphasises its purely inductive approach, allowing theory to emerge. A small number of interviews, and therefore a manageable amount of data, clearly argues for a manual coding technique, as the use of QDAS with its automation function does not seem to save time or allow for a more efficient analysis of the data obtained. On the contrary, the highly subjective aspect of manual coding is further encouraged, thus promoted and thus providing the opportunity for new theories to be developed. Maxwell (1996, p. 87) defined the concept of validity as the "correctness or credibility of a description, conclusion, explanation, interpretation, or other sort of account" and emphasised that the strength of qualitative research lies in describing the process that led to the results (Siccama and Penna, 2008). According to Richards (2004), there are four methods to ensure that the right data are used, that the research is deep and that the best possible outcome is achieved (Siccama and Penna, 2008):

(1) Challenge interpretations for sound research
(2) Scope data for sound analysis
(3) Establish saturation for robust explanation
(4) Maintain audit and log trails

Accordingly, the manual analysis should be in line with the current scientific knowledge and study findings and prove helpful for the thematic analysis of primary data.

3.7 Quality criteria

Qualitative research focuses on the world of subjectivity and aims to gain a deeper understanding of social, emotional and observational phenomena (Flick, 2007; Flick, 2019; Lamnek and Daxböck, 1995; Wrona, 2005). In contrast to quantitative research, there are no standardised quality criteria for qualitative research. This is mainly due to the fact that qualitative research is used to establish new scientific hypotheses, rather than to verify existing ones as in quantitative research. Qualitative research is therefore considered to be more subjective, which is why the classical quality criteria of quantitative research are often considered to be inapplicable. In qualitative research methods, such as expert interviews or group discussions, the researcher is present. The results of qualitative research can therefore be influenced more by the researcher than, for example, by the quantitative method of a survey.

Brühl and Buch (2006) and Hoepfl (1997) examined common quality criteria in empirical research. According to them, the core statements of qualitative research are objectivity (confirmation of the collected data (confirmability)), reliability (do factors of instability and change influence reliability? (dependability)) and internal/external validity (as a process aiming at trustworthiness (credibility/transferability)). According to Johnston, Leach and Liu (2000) and

Kikooma (2010), rigour and relevance add to the internal validity and generalisability of the case study.

Objectivity

Objectivity plays an important role in research, especially in subjective qualitative research. According to Mayring (2002) and Flick (2007), potential biases due to the subjectivity of the researcher and the methods used should be mitigated by applying the principles of objectivity. For example, qualitative researchers should avoid closed questions in interview situations, as these can lead the interviewee in a particular direction (Patton, 1990). Therefore, the mini-ethnographic case study relies only on open-ended questions that allow for a wide range of answers.

The personal encounter and the interpretation of the results are influenced by an always value-bound, subjective researcher who brings his or her own dedicated thought structures and interpretations to the research. Unlike in quantitative research, objectivity here is not promoted by generalisability but by intersubjective understanding (Bhaskar, 2008; Horsburgh, 2003; Robson, 2002; Wrona, 2005).

It is quite common among researchers that existing knowledge can be used as comparative data. It is even considered necessary to identify patterns in the data and to assess the meaning of concepts. To ensure neutrality, the methods chosen for data collection and analysis must therefore be described and discussed in detail (Strauss and Corbin, 2008; Wrona, 2005).

According to Yin (2018), a prominent scholar in the field of social research who focuses on case study research design and methods, objectivity in case studies can be achieved by controlling and following the general and verified approaches to confirm the collected data.

Reliability

According to Wrona (2005), reliability refers to the veracity and accuracy of the research approach chosen to answer the research question. The researcher should consciously act objectively when collecting and interpreting data and then critically reflect on and discuss their decisions (Horsburgh, 2003; Pillow, 2003). Finally, according to Yin (2018), reliability can be achieved through a case study protocol, which should ensure that a study is replicable and can be replicated by any other researcher and would result in the same findings. Therefore, according to Yin (2018), the research design was developed to be as accurate and understandable as possible, considering that anyone would conduct the research using the documented information and instructions.

Researchers who use qualitative methods for data collection and analysis interact with an interviewee, thus creating a bond. In order to avoid bias due to this particular closeness, the interview process should be critically reflected upon before and during the study. In order to avoid bias, the transcripts were manually coded after all interviews had been conducted.

Another way to avoid misunderstandings and increase reliability is to ask clarifying questions when the meaning of an answer is not clear to the researcher (Mero-Jaffe, 2011).

Validity

Validity refers to the validity of a research method, i.e. whether it actually measures what it claims to measure. According to Mayring (2002) and Wrona (2005), the quality criterion of internal validity focuses on the feasibility and applicability of the results. In the present research project, an explicit research design was created, which includes the way the data were collected and thematically analysed, as well as the transcribed and translated verbal primary data presented, to support the consistency, completeness and replicability of the collected data. This approach should support the scientific evidence and allow a researcher familiar with the

research area or research design to reach similar conclusions using the chosen research method and handling of the raw material (Flick, 2007; Robson, 2002).

Yin (1994) states that data collection is an important part of the research design to improve the construct and internal validity of case studies as well as external validity and reliability. Validity can be achieved through multiple sources of data, triangulation, pattern matching, explanation building and/or replication (Stake, 1995; Yin, 2018). This research project focuses on the first point, which deals with the source of data. According to Robson (2002), greater objectivity and reliability can be achieved by using more than one source of data. This means, for example, that more respondents could be approached to increase the number of data sources. If the same evidence can be obtained from several different sources, the conclusion will be more meaningful than if only one source is used.

To increase the validity and reliability of the research, it is important to apply a set of criteria to the secondary data used in the research. These criteria should include the date of publication, the qualifications of the author, the reliability of the source (ideally peer-reviewed), the quality of the discussion and the depth of the analysis.

Rigour and relevance

According to Johnston, Leach and Liu (2000) and Kikooma (2010), case studies require a rigorous research design that includes definition of the unit of analysis, case selection, data collection/saturation and data analysis. A rigorous research design enhances the internal validity and generalisability of the case study (Guest, Bunce and Johnson, 2006; Kerr, Nixon and Wild, 2010; Wrona, 2005). Following the guidelines of a rigorous research design, this research project describes in detail in section 3.6 (‘Research design’) how the unit of analysis was defined, how the case was searched and selected, how data collection was conducted and how data saturation was achieved, and how the thematic analysis was conducted. Sargeant (2012) found that a detailed explanation by the researcher of the chosen sample size and sampling procedure increases internal validity (Flick, 2007; Lamnek and

Daxböck, 1995; Wrona, 2005). A detailed explanation of the sample size and sampling method is described in section 3.6.2.

In order to draw a conclusions from the above, it is important to question the quality criteria of qualitative research and to build the research project on them, as outlined above.

3.8 Ethical considerations

Social research must be conducted in accordance with fundamental ethical principles. Emerging ethical concerns must be identified and addressed as soon as they arise. In order to avoid emerging ethical issues, ethical approval of the research project was obtained at the time of enrolment and registration of the research degree.

The research project is designed as qualitative social research using the empirical instrument of a mini-ethnographic case study. Case studies are a very common and ethically accepted research method for research projects in the social sciences. The research will be designed to contribute to the body of knowledge and to make the best use of available resources. The research project is neither funded nor tied to a business opportunity and is therefore free of agendas.

The mini-ethnographic case study is planned as an empirical, qualitative, inductive, semi-structured, interview-based approach adapted to the chosen methodology. In particular, the semi-structured interviews, which form the core of the research project, will be conducted according to general ethical standards in accordance with the General Data Protection Regulation (GDPR). To avoid any compromise in ethical standards, the research project will be guided by the four key concerns of the ‘FAIR’ framework: treating people fairly, respecting individual autonomy, acting

with integrity and seeking the best outcomes by avoiding or minimising harm through the most beneficial use of resources.

This research project will adhere to the following ethical rules at every stage of the research:

(1) The mini-ethnographic case study will include interviews that do NOT involve members of vulnerable groups. Vulnerable groups include: Children and young people (under 18), people with a learning disability or cognitive impairment, parents, people in custody, people involved in illegal activities (e.g. drug use), or people in a dependent or unequal relationship.
(2) Interviews will NOT cover sensitive topics. Sensitive topics include, but are not limited to: participants' sexual behaviour; their illegal or political behaviour; their experience of violence, abuse or exploitation; their mental health; their gender or ethnic status. The research must not involve groups where permission from a gatekeeper is normally required for initial access to members, e.g. ethnic or cultural groups, aboriginal or indigenous communities.
(3) Participants will NOT be deliberately misled during interviews.
(4) The research will NOT involve access to records containing personal or confidential information, including genetic or other biological information, about identifiable individuals.
(5) The research will NOT cause psychological distress, fear or humiliation, cause more than minimal pain, or involve intrusive procedures. This includes, but is not limited to, the administration of drugs or other substances, vigorous physical activity, or techniques such as hypnotherapy that might cause participants to disclose information that could be relevant to their daily lives.
(6) The research will avoid causing commercial harm to people involved in business or entrepreneurship.

(7) Interviews will be conducted with the full and informed consent of participants at the time of the study:
   a. The main procedure will be explained to participants in advance so that they know what to expect.
   b. Participants will be informed that their participation in the study is voluntary.
   c. Written informed consent is obtained from the participants.
   d. Participants will be informed of how to withdraw from the study at any time and for any reason.
   e. Participants will be given the opportunity to skip any questions they do not wish to answer.
   f. Participants will be informed that their data will be kept strictly confidential and that, in the event of publication, every effort will be made to ensure that the data cannot be identified as theirs (anonymity). The data obtained will not be used for any other purpose (or by any other person) than that for which the research participant has given informed consent.
   g. Participants will be given the opportunity to be debriefed, i.e. to learn more about the study and its results.

The case study part of the research project will explore the conceptual framework based on the entrepreneurial behaviour of start-ups, which was described in the literature review as the 1st milestone. In doing so, the well-founded results from the theory-based literature and the practical considerations/insights from an operational MedTech start-up will be merged into a refined, valuable conceptual framework that will be useful for start-ups in the German MedTech industry for further application.

This section will serve as the basis for the subsequent data collection, which will take the form of an empirical, qualitative, inductive, semi-structured interview-based mini-ethnographic case study.

3.9 Mini-ethnographic case study

Based on the previously defined method of a mini-ethnographic case study, interviews will be conducted with a suitable German MedTech start-up commercialising disruptive medical devices.

Suryani (2008, p. 126), as an expert in the field of ethnography and a proponent of participant observation, concludes that nowadays “it has become possible to conduct a valid and high-class case study by using Internet and telephone interviews”. According to Bryman (2015), a telephone conversation is suitable for conducting an interview when the interviewees are located in different geographical areas. This was the case for this research project. Other factors, such as pandemic-related regulatory requirements and time and budget constraints were taken into account when selecting a telephone call as an appropriate tool for this research project. However, the use of telephone calls for interviewing means that certain non-verbal cues are lost, which can lead to misinterpretation.

As mentioned in section 3.6.2, data saturation can be achieved much earlier in the context of a mini-ethnography, as the research is bound in time and space by a case study design (Fusch, 2013).

Each interviewee was informed in advance of the purpose of the interview, in particular about the main research question, the right to withdraw and the anonymity of their data. All interviewees signed a consent form to participate in this research project and were informed that the interviews would be recorded. To avoid issues of reflexivity and bias, none of the questions asked in the interviews were leading or biased (Bell, Bryman and Harley, 2018). The researcher is not an employee, nor does he work closely with, or own shares in, the selected start-up. Therefore, the importance of objectivity was acknowledged throughout the research process. The researcher explicitly took the published data at face value, and did not allow personal relationships to influence the explicit research findings.

3.9.1 Value of a pilot study

Conducting a pilot study before the final case study is a common research tool, especially when quantitative and mixed methods are chosen. It aims to provide additional information about the research area in order to ensure and increase the validity and reliability of the research. However, the literature shows discrepancies in the value of pilot studies in qualitative research. Therefore, the relevance of a pilot study in the specific situation of this very narrow research topic should be carefully considered and discussed in advance.

The usefulness of pilot or so-called feasibility studies is well documented in the scientific literature. These small studies, or applications of methods that precede larger studies, serve to refine plans for data collection both in terms of the “content of the data and the procedures to be followed” (Yin, 2018, p. 106). Pilot studies are often used to assess the practicality of the chosen method and supporting technical tools, and their suitability for answering the research questions.

In contrast, Holloway (1997), Ismail, Kinchin and Edwards (2017) and Wrona (2005), among others, further discuss and question the purpose and necessity of pilot studies, as qualitative methods and their implementation are iterated and improved during the research process itself, for example through the use of the hermeneutic spiral. As the data collected in a pilot study may not be relevant in any way to the final case study, it may even distract the researcher and lead him/her astray by making false assumptions. There is also the possibility of data contamination due to inaccuracies in data processing and analysis, which could lead to invalid data and biased conclusions. Creswell (2012) emphasises the importance of a flexible method when researching human experience. Flexibility should allow the researcher to adapt the research question to the specific area of research. It also provides the space to continuously adapt the data collection and its analysis - as envisaged in hermeneutics - based on the findings (Creswell, 2012). If the researcher finds that an interview question does not meet his or her objectives, the flexibility allows the researcher to refine it even spontaneously during the interview. Based on these

assumptions, Ismail, Kinchin and Edwards (2017, p. 3) summarise that “a qualitative final study can therefore often be pursued without the need for piloting".

The conduct of a pilot study should therefore be undertaken with caution in terms of the time frame available, the specific methodological approach and the overall added value of the research project. The underlying qualitative research project focuses on a very narrow research field, so the number of suitable start-ups for a mini-ethnographic case study is small and the hurdles to find an agile German MedTech start-up that markets disruptive innovations and agrees to participate in an empirical research project are very high. Experience has shown: If you get a response at all from a senior manager of such a start-up, it usually fails at the next hurdle, which is to make time available for the research project in the form of interviews with various employees. Although issues such as corporate strategy and culture my not appear to be subject to strict secrecy - the company’s vision and mission are often available for all on the company’s website - these small companies have a legitimate fear of industrial espionage when it comes to innovation planning. This latter legitimate fear makes it extremely difficult to carry out such a research project without having a real possibility to prove the seriousness of the research project.

As mentioned earlier, qualitative methods and their implementation are iterated and improved during the research process itself, for example through the use of the hermeneutic spiral. The latter is a learning model from the field of integrative therapy according to the German psychologist Hilario Gottfried Petzold. For him, learning is a dynamic and multidimensional process. The spiral consists of several recurring stages: 1. Perception: We perceive through our senses. We can only perceive what is revealed to us. Anything that deviates from the expected or the usual is what we perceive as a phenomenon and what gives us cause for reflection. So we focus our attention on it. 2. grasping: In grasping, we take in the atmosphere, the feelings and the mood. Grasping and perceiving creates an unconscious exchange between the person and his or her environment. This process occurs frequently in everyday life.

When one person listens to another, he or she simultaneously grasps the situation. 3. understanding: In this step it is particularly important to consciously try to separate phenomena from interpretation, so that understanding is not influenced by prejudices or subjective experiences. 4. explain: In the final step, knowledge, values and actions are consciously linked and interrelated. It is important that all participants agree with the resulting connections.

Although these four steps are repeated, the spiral, unlike the hermeneutic circle, is not a circular process. Although one may return to the same themes, one is never at the same level. By the time one returns to the same issue, one has already evolved within the process and thus has a new perspective on the whole. This also gives rise to the shape of the spiral, which is always seen as an upward spiral.

With regard to the overarching research question and in order to adequately answer the research questions developed, the relevance of a compulsory pilot study for this research project was considered low, as emerged from the previous discussion. Due to the tightly scheduled mini-ethnographic case study with the only suitable start-up company willing to participate, the cancellation of an already committed pilot interview could not be adequately replaced. Ultimately, the benefit of a pilot study to the underlying research design is considered negligible, provided that the main study is conducted using the hermeneutic spiral.

3.9.2 Interview framework

Case studies are ideal when a ‘how’ or ‘why’ question is asked about a current event over which the researcher has no control (Yin, 2018). In addition, the researcher must be able to formulate precise research questions and interpret the answers in depth (Yin, 2018).

The interviews are conducted in German, the mother tongue of the researcher and the interviewees, in order to avoid losses in the expression of the interviewees’ answers. The research questions are therefore first formulated in German. The

audio recordings of the interviews are transcribed using software and anonymised. The transcripts are then checked by the researcher against the audio recordings and corrected if necessary. The latter work helps the researcher to reflect on the interviews again, thus further increasing the validity of the research. The final transcripts are then submitted to the German supervisor for review. They will also be translated into British English using software and made available to the Welsh supervisor of this dissertation. The dissemination of the interview transcripts will serve as a peer review of the data obtained, thus increasing the reliability of this study.

To achieve the goal of a semi-structured interview, the interview framework should consist of 15-20 questions with 2-4 semantic banks (main themes). Due to their particularly comprehensive insights into the entrepreneurial behaviour of the start-up, the interview guide will contain additional questions specifically for the managing director of the MedTech start-up with which the case study will be conducted. The interview guide for the mini-ethnographic case study can be found in Appendix 1. The semantic banks of the semi-structured interviews are defined as follows:

(1) Organisational design
    a. Hierarchies / Team structure
    b. Processes / Value network
    c. Internal communication
(2) Business / Innovation Strategy / Disruptive Innovation
    a. Vision / Mission statement
    b. Innovation process / Innovation strategy
    c. Ambidexterity
(3) Innovation-oriented culture / climate
    a. Employee involvement
    b. Learning orientation

Although organisational culture is a complex phenomenon to describe, Schein (1995, pp. 113-114) notes that “many of the methods advocated by organisational culture analysts […] seem to assume that if one just asks the ‘right’ questions initially, one can decipher the culture”. All questions should be answered by the interviewee from a subjective, self-referential perspective. No restrictions should be placed on the interviewee, as all answers/data will be treated with the utmost care and anonymised after transcription.

3.9.3 Collection of primary data

The German 'Start-up X' participating in the research project developed surgically invasive devices intended for temporary use, which are fully absorbable and are therefore classified as a Class III medical devices according to the MDR (European Parliament and Council of the European Union, 2017, p. 142), see also section 2.2.2. The technology used meets the requirements for a disruptive product innovation according to Christensen's theory (see Table 14), as the product has inferior product characteristics compared to conventional non-absorbable devices and enters the lower end of the market. However, it has the major advantage of not requiring a revision surgery to remove the conventional non-absorbable device, thus sparing the patient the associated anaesthesia and additional surgical risk.

Criteria for defining disruptive product innovation applied to ‘Start-up X’			
Year	Author	Criteria	‘Start-up X’
1942	Schumpeter	“Economic development is driven by innovation through a dynamic process in which new technologies replace the old”; introduced the concept of ‘**creative destruction**’, showing the way for entrepreneurs to sustain long-term economic growth; **new entrants must be radically different** by ensuring a **fundamental improvement over the incumbent’s product**	The fully absorbable surgical screws developed by 'Start-up X' as a new market entrant are fundamentally different from the established titanium or stainless steel surgical screws. From a medical point of view, there is a fundamental improvement compared to conventional procedures, as patients perceive the absorbable screw differently and revision surgery is not required.

1996	Dru	"Discontinuity is at the heart of disruption"; "disruption is about finding the **strategic idea that breaks and overturns a convention** in the marketplace, and then makes it possible to **reach a new vision or to give new substance to an existing vision**"; "disruption is about **displacing limits**"	The new material used for the surgical screws breaks with the conventional view, which has not been changed for decades, and turns it on its head. The product innovation thus gives new substance to an existing vision and pushes the existing boundaries.
1997/2016	Christensen	Christensen developed the theory of disruptive innovation in 1992; "a form of innovation that creates new markets (market disruption) by discovering new categories of customers. It does this partly by **harnessing new technologies** but also by developing new business models and **exploiting old technologies in new ways**. The innovative products are **low cost/easier to use and they enter the lower end of the market**"; "disruptive technologies are **typically simpler, cheaper, and more reliable and convenient than established technologies**", disruptive technologies are characterised by **poorer product performance**, they perform significantly worse than established products in mainstream markets, to generate a customer benefit, they are likely to **have other features that the established products do not have**, thus **creating new product categories**	The new technology/product mix has turned a very long-established process on its head, using old technologies in new ways. The new products are cheaper than the established products and are at the lower end of the market. Product performance in terms of material stiffness is lower and therefore the product is not yet used in particularly demanding patients such as children and athletes. Because they are absorbable, they have the added benefit of not requiring revision surgery, creating a new product category of absorbable surgical products.
2014	Pisano	"Innovation that **fundamentally transforms the way value gets created and distributed** in an industry"	The innovative new product changes the perception of patients and surgeons, creating new value that actually exceeds the value of the established product. Only market awareness prevents it from replacing the incumbent product on a large scale or even almost completely.

Table 14: Criteria for defining disruptive product innovation applied to 'Start-up X' (based on Table 1)

A comparison of the product characteristics of the magnesium surgical screws developed by 'Start-up X' with the criteria of a disruptive product innovation clearly shows that most of them are fulfilled. In particular, the detailed characteristics of Christensen, who has shaped and developed the theory of disruptive innovation like

no other, show many similarities. Furthermore, 'Start-up X' fulfils the definitional criteria of a start-up mentioned by Kollmann et al. (2022) and Steigerthal, Maurer and Say (2018): less than 10 years old, growth-oriented in terms of employees/sales and highly innovative in terms of its products and/or technologies. 'Start-up X' was founded in April 2018, so had already been on the market for 4 years at the time of the interviews, is highly innovative in terms of disruptive innovations in the field of medical devices and will continue to grow in the near future (see Table 15).

Key figures of 'Start-up X'	
Date of foundation (University spin-off)	April 2018
Initial employees	3 founding partners + 2 employees
Initial number of products	1 product approved
Timeframe of interviews	August – September 2022
Employees at the time of interviews	12 (and 2 new employees to start soon)
Number of products at the time of interviews	3 products approved, 2 in the pipeline

Table 15: Key figures of 'Start-up X'

As described in section 3.6.2, convenience sampling was used to select the participating interviewees. Due to data protection regulations, the Managing Director of 'Start-up X', as gatekeeper, identified 5 possible interview partners from the existing group of all 12 employees. Finally, one possible interviewee dropped out due to illness, but the required data saturation was already achieved after the 4th interview.

List of interviewees (anonymised):

- Interviewee no. 1: Managing Director, 4 years with 'Start-up X'
- Interviewee no. 2: Regulatory Affairs Manager/Quality Manager, 2,5 years with 'Start-up X'
- Interviewee no. 3: Clinical Affairs Manager, 1,5 years with 'Start-up X'
- Interviewee no. 4: Development Engineer, 1,5 years with 'Start-up X'

The primary data will be collected through semi-structured interviews as these are “the ethnographer’s most important data-gathering technique” (Fetterman, 2020, p. 51) and this method was selected in section 3.6.4.2 as the most appropriate method for data collection in this research project.

Interviews were conducted by telephone between 25 August and 9 September 2022. All interview recordings were transcribed and anonymised immediately after completion using ‘Trint’ (Trint Limited, 2022) and translated into British English using ‘DeepL’ (DeepL SE, 2022). After each step, the results obtained were carefully re-checked manually and amended where necessary to ensure the highest possible accuracy of the data. In order to anonymise the participants, but still keep a clear record of them, they were named from interviewee no. 1 (I#1) to interviewee no. 4 (I#4) and each interview transcript was given line numbers so that the quotes used in the sections for analysis and discussion could be quickly found in their original context.

Data saturation, an important point in the mini-ethnographic case study (see section 3.6.1 f.), was reached with the completion of the 4th interview. After reviewing the last interview and comparing it intensively with the previous interviews, the point of data saturation seemed to have been reached, as the answers to the questionnaire, which had been slightly refined and changed in the course of the process, seemed to be repetitive and thus no additional insights could be gained from further interviews. Overall, the data collected seemed sufficient to answer the research question.

3.9.4 Collection of secondary data

As explained in section 3.6.4.2, the secondary data was mainly obtained through an intensive theoretical literature review, that led to the conceptual framework (see section 2.4.7). The literature review was based on information from professional journals as a solid, peer-reviewed academic source, legal texts and standards, as well as studies, books by scholars and conference papers, which can be

considered as the most reliable academic sources. In addition, as mentioned in section 3.6.3, potential German MedTech start-ups were identified through intensive internet research using public databases, e.g. on start-up initiatives and start-up competitions in the MedTech sector, as well as publicly available summaries/information on the companies. The latter meant that detailed information about German MedTech start-ups and their disruptive medical innovations/products was already known before contact was made with these potential participants in this research.

3.10 Conclusion

The purpose of this section is to determine the empirical means of a mini-ethnographic case study as the most appropriate method to adequately answer the still open 3rd research question.

To summarise the arguments about philosophical standpoints, the underlying research of this dissertation is based on constructivism, a subjective ontological standpoint that is best suited to achieve the research objective. The research focuses on social actors because they have the capacity to think creatively and to bring their thinking into existing processes. From a subjective epistemological standpoint, social constructionism advocates the creation of evidence by a participant observer who collects rich data from which ideas are derived from a small number of specially selected cases.

Social constructionist philosophy, which adopts an interpretivist approach to theory development with an inductive strategy, fits perfectly with the research objectives outlined and will provide sufficient data that can be analysed and interpreted to extend the knowledge gathered in the literature and potentially provide new insights.

Consequently, the latter assumptions lead to the conclusion that the underlying research is subject to the interpretive paradigm, which is characterised by the attempt to understand the world as it is, in order to understand the fundamental nature of the social world at the level of subjective experience.

From a social constructivist philosophical perspective, this research uses the qualitative method of a mini-ethnographic case study to best achieve the set research objectives, incorporating individual aspects from both worlds. The validated blended method combines an ethnographic approach for the detailed and systematic study of cultures with a case study protocol for, inter alia, the detailed investigation of a situation to explore and uncover complex issues.

The next chapter contains the thematic analysis of the data from the mini-ethnographic case study and the discussion of these data with the results from the literature review.

4 Analysis and discussion of findings

4.1 Introduction

This chapter is a core chapter of the underlying research project to answer the overarching research question: How is disruptive innovation in medical devices possible for German MedTech start-ups, and what entrepreneurial behaviour is appropriate to overcome the high market barriers? As Eisenhardt (1989b, p. 533) noted, data analysis is the "heart of building theory from case studies" and involves an in-depth within-case analysis to "gain familiarity with data and preliminary theory generation".

The primary data obtained from the semi-structured interviews will be systematically analysed using thematic analysis (see section 3.6.5). The results of the thematic analysis, supported by interview quotes as empirical evidence to ensure intersubjective understanding and plausibility (Flick, 2007; Mayring, 2002; Peck and Mummery, 2017), are presented in descriptive form in the following section. The findings of the analysis are then summarised and finally compared with the results of the literature review and critically discussed. The findings of the discussion, in turn, form the basis of the concluding chapter, in which the contributions to knowledge and practice of this research project are derived.

4.2 Thematic data analysis

The strength of the manual analysis lies in the repeated, in-depth and comprehensive evaluation of the interview transcripts, which contain the statements of almost a third of all employees of the selected start-up. This comprehensive insight gives the analysis and the final conclusions considerable scientific value (see section 3.7).

The thematic analysis of the mini-ethnographic case study focuses on the key findings gained from the semi-structured interviews conducted with the selected

German MedTech ‘Start-up X’, which focuses on disruptive product innovation. The analysis of the data identified a total of five overarching themes: organisational structure, strategic approach, innovative thinking, market barriers and start-up culture. Each theme is in turn linked to 17 different codes, which correspond to sub-themes and subdivide the respective main themes in order to further differentiate and group the various statements in a meaningful way:

(1) Theme: Organisational structure
    a. Hierarchy
    b. Team structure
    c. Cross-company work
    d. Communication tools
    e. New Work
(2) Theme: Strategic approach
    a. Vision
    b. Mission statement
    c. Strategy
    d. Management tools
    e. Market/trend monitoring
(3) Theme: Innovative thinking
    a. Innovation planning
    b. Innovation capacity
(4) Theme: Market barriers
    a. Regulatory/MDR
(5) Theme: Start-up culture
    a. Creativity
    b. Cultural assumptions
    c. Values
    d. Awards/benefits
    e. Knowledge/learning management
    f. Emphasis on culture or strategy?

In the following sections, the main responses from the interviews on each theme are presented according to the principles of Braun and Clark's (2006) thematic analysis.

4.2.1 Organisational structure

In compiling all the interview responses on the theme of organisational structure, five different codes were identified: hierarchy, team structure, cross-company work, communication tools and New Work. The subdivision of the codes is important so that the data can be further structured and analysed thematically.

It can be observed that the characteristics of organisational structure sometimes overlap or are even confused with the characteristics of organisational culture (see e.g. I#1, 7-8).

Hierarchy

Most interviewees saw the formal hierarchical organisation, i.e. the positioning of employees in the company, as the most obvious factor to describe the construct of a start-up organisation. 'Start-up X' is seen as a very young and dynamic company with a very low hierarchical structure, "hierarchies are almost non-existent" (I#3, 9-10).

Although it seems that there is only one level of hierarchy (e.g. I#2, 11, 16: "It's more like a community, no different levels […] we don't really have hierarchies at all"), 'Start-up X' has grown over the years to three levels, so that the company is run by two Managing Directors, followed by middle managers who supervise the rest of the employees.

Because of its small size, with a total of about twelve employees, 'Start-up X' has a very flat hierarchy. Everyone is an expert in his or her field, and because of the apparently clear structure, "you know relatively quickly who is the contact person here and to whom information must or should be forwarded" (I#4, 11-12).

Team structure

Although 'Start-up X' has a fixed organisational structure that divides the staff into two teams with different tasks and duties, the team structure can vary from project to project (e.g. I#2, 24-27: "You are not rigid in your position, but you also take over the tasks of other people or sometimes slip into development, even though you don't actually work in it […] it's actually project dependent or situation-dependent, depending on what's going on at the moment"). One team is involved in all project processes, from the initial launch to the 'design freeze' of a potential new product innovation, after which the other team takes over and deals with issues such as regulatory and clinical issues. Once these phases have been completed, the projects return to the original team to take care of marketing and sales (I#1, 25-31).

Development projects in particular have a team structure that is "very different and very dynamic […] more of a matrix structure" (I#1, 39-40). It is also mentioned that "everyone is really involved and helps organise everything in the company, helps structure everything, helps set up processes, and at every meeting or every round everyone is asked for their opinion" (I#2, 13-15).

On the one hand, a flexible structure is an advantage if it can adapt to certain situations, but on the other hand there is also the disadvantage that whenever new tasks arise that have not been assigned before, there is a certain gap until the task is assigned and someone takes care of it (I#2, 32-38). Obviously, there is room for improvement - "I think this is part of our work" (I#2, 69).

It is typical for a start-up that "not everything is developed yet, in terms of strategies and processes" (I#2, 65-66). Employees see it as their job to solve things and think about how they can change the structure for the better.

According to interviewee no. 2, teams such as 'Regulatory' and 'Product Development' work very closely together in day-to-day project work, as the areas

of work overlap and are very closely linked, so that a close cooperation has developed with clearly separated areas of work and responsibilities.

With its young and dynamic team, ‘Start-up X’ can achieve a lot in a short time because the communication channels are short and there are no rigid procedures where they are not absolutely necessary. The team structure is very flexible because ‘Start-up X’ “consist of one, at most two-man departments” (I#3, 50).

Due to the different types of projects, the team structure is correspondingly flexible. Especially in smaller projects, the extent of the required expertise and responsibilities does not always seem to be known. Due to legal constraints, there has to be an intermediate level, which includes the Quality Management Officer (QMO) when it comes to hierarchy, but this “only has to do with the legal framework and has less to do with decision-making process and procedures” (I#4, 45-46).

Cross-company work

‘Start-up X’ works on up to six research projects in parallel (I#1, 55). These projects lead to long-term partnerships as well as of collaborations with similar MedTech start-ups and spin-offs because they have the same ‘speed’ compared to working with established companies (I#1, 54-69). There is no explicit collaboration with customers/surgeons, but there is collaboration and active exchange with ‘related’ start-ups in the same office building (I#2, 45-47).

According to interviewee no. 3, there is not necessarily cooperation with other companies, but the training centre of the university hospital is used, for example, for services such as clinical studies and others.

Interviewee no. 4 reports joint research projects with clinics, biomechanics laboratories and material suppliers.

Obviously, the statements about the collaboration with external experts vary due to the different levels of knowledge and understanding of collaboration processes.

Communication tools

‘Start-up X’ bundles project-related communication with the collaboration software Microsoft Teams, as the exclusive email conversation is perceived as too static. Interviewee no. 1 emphasises the importance of communication within the company and that different communication channels should be considered and used depending on individual preferences. Furthermore, (informal) communication, e.g. at the coffee machine, is explicitly encouraged.

Communication in ‘Start-up X’ is definitely not in written form - with the exception of meeting minutes (I#2, 73). There is a certain tendency towards casual oral communication in breakout rooms such as the kitchen/coffee zone or other office spaces (I#2, 76-77).

Start-ups have the advantage of short communication channels that allow them to be move quickly. Nevertheless, you have to be careful “that you don’t overtake yourself […] and become a very bureaucratic mill” (I#3, 29-30, 44). This is the difficulty for any small business that grows. In the office, the opportunity for direct interaction is widely used. When written communication is essential, Microsoft Teams, with its ability to chat and also store files and data, is the method of choice. Different meeting formats help to achieve different project goals. For example, the 'RACA (Regulatory Affairs, Clinical Affairs) hike' was created to re-synchronise and bring the two departments involved up to speed in an environment untypical of office meetings. Of course, all communication channels are used and there is always room for improvement when it comes to finding the right dose, when it comes to informing "the right people, at the right time and no more than necessary" (I#3, 124-125), especially as tasks are growing very fast and “staff can’t keep up with the pace at which the tasks grow” (I#3, 129).

According to interviewee no. 4, there is definitely a lot of verbal communication in 'Start-up X' within an ‘open door policy’, which makes communication easy and efficient. Important meetings and decisions are of course recorded in minutes.

New Work

Even before the Corona pandemic began in early 2020, 'Start-up X' was prepared for its employees to work remotely. This meant that the company was perfectly prepared for the pandemic’s lockdown phases. Today, as the pandemic restrictions have eased, employees are working in a hybrid model that provides certain office days within the week, but ultimately gives the employees the flexibility to choose where they work (I#1, 124-133; I#2, 98-99).

According to interviewee no. 3, working from home can be done “without any losses” (I#3, 143), but he likes to be in the office because he does not want to “miss the interpersonal, social component” (I#3, 147-148).

There is a natural flexibility to switch between office time and home office. Nevertheless, the interpersonal exchange through direct communication and the direct visual feedback from the other person is much better in the office. “That simplifies communication considerably and makes it more efficient than digital” (I#4, 117-118). Whenever 'Start-up X' has to deal with external partners, videoconferencing can be productive and save unnecessary travel time. Interviewee no. 4 likes to keep work and home separate and therefore prefers to work in the office and spend his free time at home.

4.2.2 Strategic approach

Five codes were identified within the ‘Strategic approach’ theme: Vision, mission statement, strategy, management tool and market/trend monitoring. The exact reasons as well as their importance for the further strategic orientation of 'Start-up X' will be discussed in more detail in the following discussion (see section 4.4).

Vision

When asked about the current vision of 'Start-up X', the individual interviewees answered as follows:

- “To significantly improve surgical therapy for patients through the use of absorbable implants” (I#1, 137-138, I#3 165-166).
- “Offering patients better implants, of being able to significantly improve the surgical therapy of patients” (I#2, 109-111).
- “To offer an improved therapy or surgical therapy for the patient through the new material technology and through the product that we offer, which will make the healing process and also the realisation in normal everyday life easier, perhaps also faster, and thus enable an optimal therapy for the patient” (I#4, 136-140).

Mission statement

The mission statement of ‘Start-up X’ was described as follows:

- “To provide physicians with absorbable solutions for improved treatment and to focus clearly on the ‘clinical need’” (I#1, 138-139).
- “We can provide surgeons with an absorbable solution and improved treatment” (I#2, 111-112).
- “To offer the user high-quality resorbable implants for relevant problems in therapy” (I#3, 166-167).

Strategy

The statements on the company's strategy were all quite similar: “To develop a market-established, continuously improved technology platform with distribution of the product derivates through partnerships.” (I#1, 157-159). “To continue to establish ourselves on the market and to constantly improve our technology” (I#4, 141-142). The vision, mission statement and strategy are clearly visible on the collection of OKR results printouts. The strategy is reviewed quarterly by the two managing directors and discussed and changed during the regular OKR cycles.

According to interviewee no. 2, the strategy is reviewed once a year in a strategy workshop. The current strategy is to “establish ourselves on the market with a constantly improved technology platform and a sales department that really gets the different product variants to the partners” (I#2, 114-116). The start-up’s strategy is tangible, for example in the New Year’s cards, where the focus on the future is very clear. Interviewee no. 4 mentioned that the HR strategy is an essential part of the strategy.

Management tools

To keep track of the strategy, ‘Start-up X’ has been using an OKR management tool for three years. The OKR system is led by a Managing Director and progress is reviewed in a workshop every tertial. A monthly progress meeting is held for development projects that years to complete. In parallel with the strategic OKR tool, ‘Start-up X’ uses an Enterprise Resource Planning (ERP) tool to track the financial accounting and material flows of its traceable products.

OKR meetings “are there for us to determine: well, what do we want to achieve, how do we achieve it and what status are we at?” (I#2, 125-126). At these meetings, at the very beginning of the year, the achievability of the objectives is reassessed and new objectives are set on the basis of the values and vision. Nevertheless, it has happened that strategic objectives have been changed during the year because they no longer seemed realistically achievable. The development of strategic objectives is initially the responsibility of the two Managing Directors, who develop a certain basic structure. It is then up to all employees to refine these with their input, resulting in achievable strategic objectives that employees can work towards. OKR meetings take place every fortnight, but the strategy itself is not part of the discussion at each meeting (I#3, 176).

The OKR process is divided into three cycles that take place throughout the year. Although management sets the direction, employees are involved in fine-tuning future goals. Meetings are held every fortnight to track progress and check that the

projects are still working on track to meet the objectives. The vision and mission, once defined, have not changed since the last workshops. More work is now being done at the objectives level to achieve the mission objectives.

OKR meetings take place every fortnight and the key points are distributed to employees on postcards so that they can "always critically question it: Is this now purposeful or in the sense of the company and the corporate strategy or not?" (I#4, 154-155). Fundamental strategic objectives can be adjusted on the basis of employee feedback. Short-term strategic objectives are quite flexible and can respond to market and environmental situations, while the long-term objectives (five-year or ten-year plans) are more fixed.

Market/trend monitoring

'Start-up X' does not have a specific market or trend monitoring system in place, so these are not systematically monitored. Insights into future demand come from feedback from the cooperating surgeons or companies.

4.2.3 Innovative thinking

Two different codes were identified for the theme ‘Innovative thinking’: innovation planning and innovation capacity.

Innovation planning

Interviewee no. 1 reported that product innovations are bundled in a ‘product roadmap’. The whole innovation process has been democratised so that new ideas are discussed together. The final decision on whether an idea becomes an innovation project lies with the development team. The extent of possible further innovation is described as incremental (e.g. a design variation), driven by a clinical need where the use case is very obvious (I#1, 87-97).

There are other products in the development team's innovation pipeline, but these are still more in the literature phase or based on dissertations. New innovations usually come from surgeons, which 'Start-up X' generates through demand.

'Start-up X' is driven by innovation, because the idea of combining the advantages of different types of implants in one leads to innovative new medical devices. It all started with material technology, which evolved into more specific solutions for customer needs. Whenever prototypes are made, they are developed based on a specific clinical/customer need communicated by surgeons. It is then "developed in a targeted way with input from clinical partners" (I#3, 225).

Of course, the depth of innovation is very limited by the requirement that the collaborating surgeons identify the current clinical need and then assess whether the innovation can be implemented with the specific mechanical properties of the material technology of the resorbable implants. These mechanical properties appear to be a limiting factor for further innovation.

'Start-up X' is innovative because of the innovative material technology and not because of the products themselves. The innovative material technology is combined with classic surgical products that are tied to a highly regulated market.

Innovation capacity

'Start-up X' still feels innovative and is far from being established. The full performance of the products only becomes apparent after twelve to 36 months, when the implant dissolves in the bone. It will therefore take time for surgeons to respond positively to these new products.

According to interviewee no. 2, 'Start-up X's working methods and environment are very innovative, e.g. with a dedicated laboratory where clinical operations can be carried out. There is also integrated animal research where the implants can be

tested in vivo, as well as the possibility to test prototypes, which in turn brings in feedback from product development and doctors.

In the last two and a half years, “nothing has come from the team in terms of innovative, new ideas, or at least I haven’t heard anything about them” (I#3, 266-268). It seems that ‘Start-up X’ is fixated on the material (technology) and on the specialisation, medical implants. The generation of ideas is a complete pull mechanism, they only come from external doctors or clinical partners. There are no internal inventions of technologies that could be successful on the market in two years. Everything depends on what external doctors and clinical partners say to pick up ideas. “We want it to come from the end user, whose daily bread is to deal with these things […] and these are the things we really try to find out and implement proactively” (I#3, 283-284, 287-288). Sure, “you can come up with great ideas yourself and put a lot of power, manpower and money into it and come up with a prototype. And then the doctor says: […] I wouldn’t use anything absorbable. Besides, it’s far too expensive. I just take the titanium thing” (I#3, 292-295).

There are currently, three medical devices are traded on the German medical device market. ‘Start-up X’ does not have the capacity to develop medical technology on its own, this is only possible in cooperation with other companies. Within ‘Start-up X’, there is a Business Development team that reviews new business opportunities and examines each new opportunity to see if it is feasible from a technical or product perspective. The source of opportunities is fairly balanced between strategic motivation and market and user demand.

4.2.4 Market barriers

Although market barriers are not part of the conceptual framework, the specific opinion of employees on regulation, which has been identified in the literature as a high barrier to overcome, should be of additional value for the later part of the discussion. The theme on market barriers only includes the code regulatory/MDR.

Regulatory/MDR

'Start-up X's resorbable implants belong to the highest class (III) of medical devices according to the MDR. As a result, the effort required to certify class (III) medical devices is much greater than that required to certify lower class medical devices. A huge amount of money is already spent on the pre-clinical and clinical phases of the product. There is a need to “dovetail this time-to-market and this development process and the regulations so closely that we don’t need to take an unnecessarily long time and then have to drag along a rather large cost apparatus at the same time” (I#1, 192-194). There are plans to hire more staff to deal with regulatory issues and to set up a regulatory affairs department, as regulatory tasks alone “eat up 30% of our capacity” (I#1, 204). Nevertheless, ‘Start-up X’ sees its regulatory affairs capabilities as one of its core competencies, which it has built up with great effort and care. The latter is “one of the key reasons why we can develop quickly and make a lot of metres in order to open up new markets […] it’s actually an opportunity to clearly differentiate ourselves from other market participants” (I#1, 207-208; 226-227). It is likely that many other company founders, who also have a technical academic background, have no idea about regulatory and clinical issues because it was not part of their curriculum. Outsourcing regulatory affairs is an expensive business.

Although regulation, with its many guidelines and standards, seems to restrict creativity, it is also “about setting up new processes. And there you are actually completely unrestricted in your creativity” (I#2, 61-62). The new MDR has led to a much higher workload, especially in product approval. The transition to the MDR also brought new tasks, such as the EudaMed database, which requires a lot of preparatory work, including the safety reports that have to be uploaded annually. This maintenance work already takes up a large part of the workload. There are also other tasks, such as animal studies, that need to be carried out.

Although the MDR imposes a strict framework and thus a “huge amount of documentation that slows down the work” (I#3, 231), there is the advantage that

the pre-MDR classification has not changed. Nevertheless, the MDR change brought with it some additional tasks and efforts. ‘Start-up X’ was “more or less prepared” (I#3, 241-242).

4.2.5 Organisational culture

The theme of ‘Organisational culture’ generated six codes: creativity, cultural assumptions, values, awards/benefits, knowledge/learning management and emphasis on culture or strategy?

Creativity

The ‘Start-up X’ interviewees see creativity, inter alia, as a means of finding solutions to problems: “We try to get people to deal with the solution of a problem or to challenge themselves. And we also explicitly encourage that” (I#1, 74-76). Interviewee no. 2 associates creativity with innovation: “Creativity is very important to us, because that’s what it’s all about, to develop new things […] you are almost not restricted at all” (I#2, 55-56, 58).

For interviewee no. 4, creativity and creative freedom are an important part of daily work, especially in the area of product development. Even if the premise ‘form follows function’ is omnipresent, creativity and openness are means to break down new ground.

Cultural assumptions

The interviewees agreement that, despite the flat hierarchy and the division of staff among departments, 'Start-up X' “coordinate[s] responsibilities for projects and sub-projects at an early stage, which people can then fulfil with the maximum possible scope for action” (I#1, 77-79).

Interviewee no. 1 reports a “super relaxed, collegial atmosphere” (I#1, 260-261) that has just changed from a more ‘family’ to a ‘sports team’ attitude. The latter is apparently typical of the start-up scene. There are regular outdoor activities with all

employees, which are fun. According to interviewee no. 1, there is a very strong identification with the company among the team members.

Interviewee no. 2 highlights the strong organisational culture of 'Start-up X', which creates a family atmosphere where every voice is heard. The family aspect is lived through regular team activities and retreats for all employees to network and talk about internal processes. Interviewee no. 2 notes that this is not necessarily typical of comparable start-ups or small companies.

For interviewee no. 3, it is important that “there is a working atmosphere in which everyone can freely express their opinion, where it is clearly lived that every opinion counts and is important, regardless of” (I#3, 5-7) one’s professional experience. The team concept enables everyone to work together towards the same goals. Creativity is present in the sense that a start-up needs to introduce processes and tools as it grows and therefore gives its employees all the freedom to define them and make them as efficient as possible. In the early days of ‘Start-up X’, everyone had to be creative in establishing processes, but this will become less and less the case over time, not least because of QM regulations and the development of Standard Operating Procedures (SOPs) to ensure quality standards.

Team building works particularly well with regular events such as leisure activities and meals, as well as annual retreats where leisure activities are mixed with strategic work and brainstorming on future issues, such as which congresses 'Start-up X' will attend next.

“There is definitely a very harmonious and collegial organisational culture” (I#4, 224-225). Although each person is unique, there are almost no conflicts. Discussions are only held on a professional level. Being a team is the most important thing for ‘Start-up X’. Teamwork is supported by offering free leisure activities every month, “this is a very broad and very well diversified framework” (I#4, 238).

Values

‘Start-up X’s values, which are reviewed and changed once a year during a strategy workshop, are based on Technology, Science, Innovation and Transparency (I#1, 156-157, I#2, 104-106).

There is a strong interrelationship between employees as they should value each other. Outwardly, people or companies that do not seem to match the values of ‘Start-up X’ are ignored in order to build valuable connections with corresponding companies in a long-term relationship.

The values of ‘Start-up X’ are re-evaluated once a year during the strategy workshop to identify “four values that we want to carry to the outside world or that we can identify with at the moment” (I#2, 105-106). The main corporate values are Technology, Science, Innovation and Transparency.

Interviewee no. 2 emphasises that ‘Start-up X’ does not just “set up values, we really live them” (I#2, 257). It is important to all of them that the values are externalised within the company and reflected in the way they work. She feels valued by the other employees because her work is appreciated and her opinion and contribution are valued.

“The four values are what we really try to implement and live” (I#3, 372). Interviewee no. 3 attaches great importance to Transparency, as 'Start-up X' always tries to be as transparent as possible with its customers and clinical partners, and receives positive feedback from them as a result. Open and transparent conversations take place because it is believed that this is the key to “create a very clear basis of trust with our customers and partners […] a solid network of customers” (I#3, 384-385, 387-388). It is important to be valued by the others and at the same time to know that everyone is a cog in the wheel and contributes to the big picture.

For interviewee no. 4, the four defined values: Technology, Science, Innovation and Transparency are lived by the company, especially Transparency, so that the market gains confidence in 'Start-up X' and its products.

Awards/rewards/benefits

There are no special awards for employees, such as ‘Employee of the Month’, but an effort is made to link company objectives with personal development, so there is a system of employee bonuses closely linked to individual target agreements. The company has a pension scheme and many small amenities in the office. Interviewee no. 1 would like to introduce a VSOP (Virtual Stock Option) pool in the future to retain people for the long term, but apparently the shareholders do not agree.

Interviewee no. 2 emphasises that there are generally no obvious rewards for good work, but when projects are successfully completed, the whole team shares in the success. However, it is possible to receive individual bonuses/salary increases if certain set targets are achieved in a given time.

'Start-up X' has a basic bonus system and every employee is entitled to a bonus. The bonus is paid according to targets to be achieved, which are jointly set and assessed by the managers and the employee for one year. The bonus system is well received by the employees, who are motivated to work towards their individual goals.

Knowledge/learning management

In ‘Start-up X’ there is a clear focus on learning, as employees are expected to develop over time into the leaders of tomorrow (I#1, 52). In parallel, there is a certain attitude of 'learning from mistakes', so that managers always proactively report when they have done something wrong, and there are 'mistake sessions' during retreats, where everyone is expected to learn from the most reported ‘embarrassing mistakes’.

There is regular QM training and a digital library with a wiki. Every new employee receives intensive induction. Annual training sessions are held by the managers on topics such as ‘work safety’, ‘ergonomics’, etc. If employees wish to attend training, it is booked and supported by the managers, who place great emphasis on personal development.

'Start-up X' has a comprehensive literature database. Various event formats are used to inform employees about specific topics, e.g. in the area of clinical activities. A wide range of product brochures and implant demo boxes have also been developed. The latter move from theory to hands-on demo products. Knowledge is also passed on through in regular training/safety instructions, for example on QM.

There are regular training courses, which are also required by law. Training also depends on individual requests to management, “a skill that is learned but not used is unlearned” (I#4, 265-266).

Emphasis on culture or strategy?

When asked whether culture or strategy was more important to them, interviewees answered as follows:

- “I’d say it’s clearly the strategy when I look at it personally. But culture is an essential tool to get there” (I#1, 324-325).
- “I would say culture first, but only because I think that strategy plays into culture” (I#2, 252-253).
- “We try to focus the strategic orientation somewhere very clearly in what we do and to maintain lively control […] it is important that both things work” (I#3, 360-362).
- “As in every company, the strategic orientation is of course the most important thing, or should be the most important thing. But you have to say that the cultural orientation and also the working climate is a clear component of the strategy” (I#4, 269-272).

There seems to be a slight tendency to emphasise strategy over culture, although this response should not be overstated in the overall context due to the nature of the earlier questions and the spontaneity that did not allow for a long period of reflection.

4.3 Summary of thematic data analysis

Overall, the interviews conducted as part of the mini-ethnographic case study produced very homogeneous responses that provided a very consistent view of various themes and codes to be analysed. Looking at the previous interviews, it was obvious that the point of data saturation had been reached by the fourth interview, as it could be assumed that further interviews would not have provided any further insights or views on the issues raised. This is consistent with Eisenhardt's (1989b, p. 533) 'reaching closure' as the final part of the process of theory building through case study research with "theoretical saturation (when possible)". The researcher should stop adding new cases when he feels that theoretical saturation has been reached (Eisenhardt, 1989b, p. 545). According to Hennink, Kaiser and Marconi (2016), data saturation is reached when data collection only gradually yields new insights and begins to repeat itself. Kerr, Nixon and Wild (2010) come to the same conclusion and pinpoint data saturation to three objective markers: the point in data collection at which no additional insights are discovered, the data begin to repeat, and further data collection becomes unnecessary to answer the research questions. The following summary of the thematic data analysis is divided into the five main themes identified.

Organisational structure

As this is obviously very much related to the organisational design, all interviewees almost unanimously answered that there is a very flat to non-existent hierarchy in 'Start-up X', although on paper there are three levels of hierarchy. The flat structure, which gives everyone the chance to be equal, seems to be very popular. The very

small number of employees (twelve) means that everyone knows each other's skills and expertise very well.

Although there is a certain formal hierarchy and departmental structure, project-based teams are formed individually for each project. Again, the small number of employees and the fact that most departments consist of only one or two people contribute to the structural flexibility and dynamism of 'Start-up X'. The composition of the teams is also partly determined by a legal framework (e.g. by the installed QM system).

The statements on the cross-company work of 'Start-up X' differ greatly when it comes to the perception of existing cooperation. Obviously, the statements on cooperation with external experts vary due to the different levels of knowledge and understanding of cooperation processes.

Communication through all possible channels plays an important role in 'Start-up X'. Whenever possible, however, casual verbal communication in the office is preferred. Whenever written communication is required, Microsoft Teams collaboration software helps 'Start-up X' organise project work and ensure that all different types of information and data can be managed and easily found. In addition, alternative forms of team communication have become established, such as the 'RACA hike', which is a very different form of communication to formal meetings in conference rooms.

New Work, the phenomenon of remote/hybrid working, which became the only possible way of working in certain industries worldwide in 2020 as a result of the Covid pandemic restrictions, was already an issue for 'Start-up X' before the pandemic began, so that they were well prepared for the lockdown situation and were able to productively survive this difficult business phase.

Strategy

The vision of ‘Start-up X’ was fairly unanimously reflected as "to significantly improve surgical therapy for patients through the use of absorbable implants".

The mission statement can be summarised from the responses as “to provide physicians with absorbable solutions form improved treatment and to focus clearly on the ‘clinical need’”.

The responses to the company’s strategy were also quite similar and can be summarised as follows: “Develop a market-established, continuously improved technology platform with distribution of product derivates through partnerships”. In order to keep track of the strategic direction, ‘Start-up X’ has implemented an OKR management process to track progress against the objectives set for each tertial.

'Start-up X' does not monitor trends, competition or the market, but only uses insights from practice, e.g. from discussions at congresses or with cooperating surgeons and companies.

Innovation

The innovation process involves the expertise and opinions of all employees. The final decision to pursue an innovation rests with the development team. The level of possible further innovation is described as incremental (e.g. a design variation or additional functionality), driven by a clinical need (demand requirement) where the use case is very obvious. The mechanical properties of the resorbable implants are something of a limiting factor for further innovation.

‘Start-up X’ sees its strong capacity for innovation in its working methods and environment, e.g. its own laboratory where clinical operations can be performed, animal research and prototype testing can be carried out. However, the team has not come up with any innovative ideas in the last two and a half years. Everything is focused on what the surgeons have to say. There are currently three medical

devices traded on the German MedTech market. Obviously, ‘Start-up X’ is not in a position to develop medical technology on its own; this can only be done in cooperation with other companies.

Market barriers

Due to the highest classification as a medical device by the MDR, 'Start-up X' is faced with a high effort to certify its medical devices in order to be allowed to market them on the German MedTech market. In addition to the enormous cost of certification, regulatory tasks consume up to 30% of the company’s human resources. In order to make the approval process as resource-efficient as possible, 'Start-up X' has made it a core competence, which has been built up with a great deal of effort and care.

Culture

Creativity is used, for example, to find solutions for specific processes, to drive product development and to break new ground.

The general climate within the company, described as a ‘sports team’, is perceived as very positive. There is a very strong identification with the company among the team members. The family aspect is lived through regular team activities and retreats for all employees, where they can network and talk about internal processes. The open working atmosphere allows everyone to express their opinions freely.

The values are defined together, refined from time to time and should be lived in everything the team members do. The four main defined values are Technology, Science, Innovation and Transparency. This is in line with Christensen (2016) who states that clear, consistent and broadly well-positioned and understood values of an organisation are the third compelling factor that affects whether an organisation is able to solve its self-imposed tasks and objectives.

Instead of awards, there is an appropriate reward programme in the form of an individual bonus system. The bonus, which can take the form of a salary increase or a one-off payment, is linked to the achievement of targets. There are plans to introduce a virtual stock option pool in the future to retain employees in the long term, but apparently the shareholders are not yet in favour of this.

‘Start-up X' offers various training courses and has set up a wiki and literature database. There is also an emphasis on personal development, so that employees can take part in training programmes as and when required.

According to the responses of the interviewees, there is a certain focus on strategic orientation, so that strategy is usually at the forefront and culture is influenced accordingly.

Finally, the thematic data analysis leads to an extension of the originally developed conceptual framework (see Figure 23) by including the external influencing factors, such as the conditions of the German MedTech market and the impact of the theories on disruptive product innovations, as well as the external collaborations of the analysed ‘Start-up X’, shown in Figure 27.

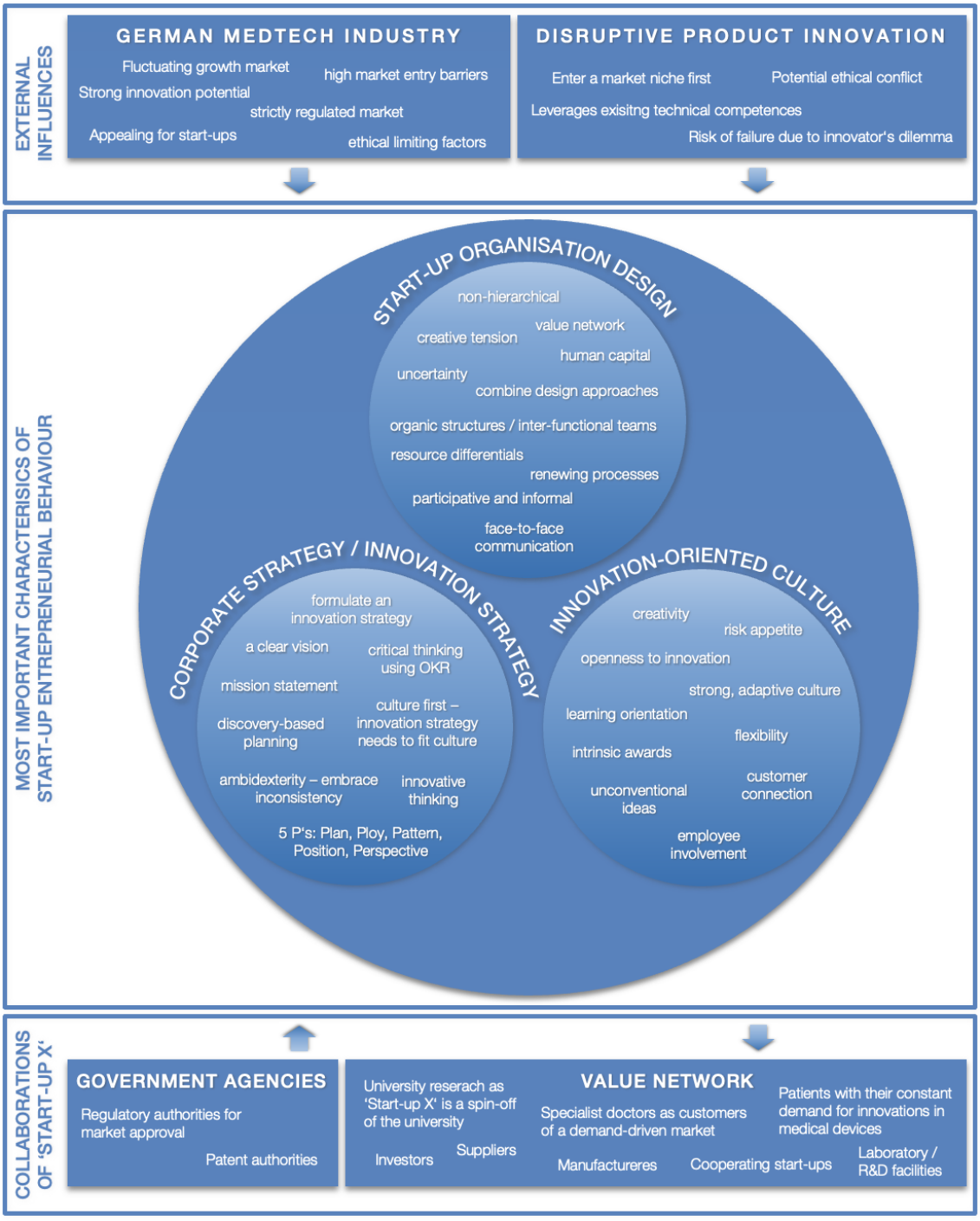

Figure 27: Conceptual framework extended with external influences (developed for research)

4.4 Discussion of findings

The discussion of the findings follows the thematic analysis of the data set and critically compares the results of the theoretical literature review that led to the

conceptual framework with the findings from the data collected during the mini-ethnographic case study.

Following the in-depth analysis of both the primary and secondary data collected during this research project, the findings are presented in a visually comprehensive overview table (see Table 16). The green boxes represent the congruences of the literature results with the findings from the interviews. Yellow boxes represent constructs that were partially applied or partially observed. The red boxes represent components that could not be observed and are therefore considered not to be applied. The latter are core issues for discussion, where the relevance and possible future implications need to be analysed in detail, based on the available literature results.

Coding table and interview evaluation					
Conceptual framework	Interview evaluation				'Start-up X'
Start-up organisational design	#1	#2	#3	#4	Organisational design
non-hierarchical					non-hierarchical, flat structures
value network					cooperation with doctors
creative tension					creativity for processes and product development
human capital					valued employees, bonus system
uncertainty					n/a
combine design approaches					uses different design approaches
participative and informal					informal communication, participation encouraged
renewing processes					processes are rethought
resource differentials					specific regulatory resources
organic structures / inter-functional teams					teams are put together flexibly
face-to-face communication					oral communication preferred

Corporate strategy / innovation strategy	#1	#2	#3	#4	Corporate strategy / Innovation behaviour
formulate an innovation strategy					n/a
a clear vision					vision
critical thinking using OKR					use of OKR tool
mission statement					mission statement
discovery-based planning					n/a - planning is based on insights from doctors
culture first - innovation strategy needs to fit culture					strategic orientation is more obvious
ambidexterity - embrace inconsistency					n/a
innovative thinking					Only sustainable innovative thinking
5 Ps: Plan, Ploy, Pattern, Position, Perspective					Plan, Pattern, Perspective

Innovation-oriented culture	#1	#2	#3	#4	Cultural assumptions
creativity					creativity in certain processes
openness to innovation					sustainable innovations
risk appetite					n/a
strong, adaptive culture					lived 'sports team' mentality
learning orientation					learning appreciated
teamwork					lived teamwork
flexibility					flexibility
intrinsic awards					personalised rewards
customer connection					cooperation with doctors
unconventional ideas					n/a
employee involvement					employee involvement

Legend of above table:
is lived / is respected
partially applied / partially observed
is not applied / does not find any attention

Table 16: Coding table and interview evaluation (developed for research by the author)

Market barriers

Although this theme is not presented in Table 16 because it is not part of the initial conceptual framework, it should be included in the following discussion section of the dissertation as one of the main factors influencing the entrepreneurial behaviour of MedTech start-ups. As already summarised in the key points of the German MedTech industry, an attractive, developed but still growing market is an important basic prerequisite for start-ups. Although the various high market entry barriers identified (see section 2.2.5 ff.) are likely to hinder market entry and thus socially important innovations in the health sector, there are ample opportunities for

newcomers to innovate and enrich the extensive research-intensive market. The market barriers force start-ups to expose their companies to high risks and thus possibly fail from day one.

A high-risk class III classification under the MDR puts enormous pressure on 'Start-up X' due to scarce human and capital resources. In addition to the enormous cost of certification, regulatory tasks consume up to 30% of staff capacity. In order to make the regulatory process as resource-efficient as possible, 'Start-up X' has made it a core competence and, with a great deal of effort and care, has built up a regulatory affairs department. This department deals with all regulatory issues and is in close contact with the relevant authorities to ensure that existing and future medical devices comply with regulatory requirements. The decision to keep regulatory affairs in-house and integrate it into the relevant processes can be seen as very wise. Of course, not all MedTech start-ups are willing or able to do this, and therefore have to hire external consultants who slow down the process - due to long communication channels - and are certainly more expensive in the end than a dedicated team. ‘Start-up X’ thus lays the foundation for a complex, but also almost smooth process with strict regulations before a medical device is launched on the market. By accepting and symbolically embracing the regulations surrounding its medical devices, 'Start-up X' shows that it recognises and proactively addresses the market conditions and tries to keep the hurdles as low as possible.

Start-up organisational design

Looking at the gap analysis between the theoretical approaches and the surveyed reality (see Table 16), it is quite clearly that the results of the literature review and the answers given in the interview phase match best in the area of the start-up organisational design. As described by Luthans (2011), organisational design and culture are dominant factors that are strongly perceived by employees. Therefore, the responses should provide a reliable picture of the perceived organisational design and culture, but the themes are sometimes mixed or assigned to other themes by the interviewees.

Summarising the statements on perceived organisational design, it seems that ‘Start-up X’ follows the tendency of the new generation of design approaches to mix elements of both approaches (classical design approach and developmental approach) and to synthesise the dichotomies described in Table 3 (Visscher and Fisscher, 2012). The ‘design focus’ in ‘Start-up X’ clearly focuses on a collective structure with a strong emphasis on building a ‘sports team’ mentality, where one hand reaches into the other and no player can win a game alone, but team cohesion leads to success. The ‘design process’ is based on a collective learning process, with internal training and the offer of individual training whenever appropriate. Instead of a social market economy approach, where all employees are equally involved in the direction of the company, the 'designers' in ‘Start-up X’ are the managing directors, who set the initial strategic course and determine the main directions of the company. However, all other employees are involved and consulted in the detailed design of the next action points. The managing directors demand an active role for the ‘designer’, while the ‘design knowledge’ is a mixture of general, science-based knowledge and local, experience-based knowledge, and implementation is integrated. In summary, it is a combination of both worlds, with some emphasis on the more modern approach of the development organisation, which is in line with the findings of Visscher and Fisscher (2012).

From a hierarchical perspective, ‘Start-up X’ is consistently described by interviewees as an organisation with a very flat to non-existent hierarchy, which is consistent with Hogan (2005) in the literature, who describes the organisational structure of a start-up focused on disruptive innovation as often flat, but with the opposite morale. Steigerthal, Maurer and Say (2018) found in their study that flat hierarchies dominate the start-up landscape. Anand and Daft (2007, p. 331) further summarise it by claiming that “the horizontal organization advocates the dispensing of internal boundaries that are an impediment to effective business performance. If the traditional structure can be likened to a pyramid, the metaphor that best applies to the horizontal organization is a pizza – flat, but packed with all the necessary ingredients”. Ostroff (1999, p. 11) sees a competitive advantage in a horizontal

organisational structure and stresses the importance of building a “corporate culture of openness, cooperation, and collaboration, a culture that focuses on continuous performance improvement and values employee empowerment, responsibility, and well-being”.

Luthans (2011) points out the advantages of a horizontal organisational design over the traditional vertical, hierarchical design: focus on the process rather than the task, self-managed team structures, customers driving performance, employees in close contact with suppliers and customers, fully informed, trained and regularly rewarded. Even though the team structures in ‘Start-up X’ are not self-managed, all the other characteristics and therefore advantages can be found which lead to the conclusion that their methods are the best possible way to represent the organisational design of a start-up.

Even though there are three levels separating the twelve employees, starting with two managing directors, a middle level and the rest of the employees, it should be emphasised that in 'Start-up X' these seem to exist only on paper, but have no direct influence on the above mentioned beneficial characteristics lived by the employees in their daily work. In contrast to ‘self-contained’ companies that rely on a vertical hierarchy, as described by Anand and Daft (2007), ‘Start-up X’ seems to benefit from its flat hierarchy, which enables efficient processes by eliminating unnecessary and almost artificially created boundaries from the outset.

With regard to collaboration with other start-ups, surgeons, manufacturers and research institutions, the interviewees gave different accounts. On the one hand, interviewees reported close links with universities and research institutions, as well as collaboration with other start-ups and surgeons in order to gain valuable insights into further possible innovations. On the other hand, it was also reported that there were no cooperations with other companies at all. In summary, however, it can be assumed that 'Start-up X' maintains a vibrant 'value network' and derives very favourable benefits from it. Christensen (2016, p. 32) describes the ‘concept of the

value network' - based on the ideas of Christensen and Rosenbloom (1995) and Rosenbloom and Christensen (1994) - which he defines as "the context within which a firm identifies and responds to customers' needs, solves problems, procures input, reacts to competitors, and strives for profit". With the help of the customers, 'Start-up X' identifies the specific 'clinical needs' on a professional basis, considering surgeons as customers and patients as beneficiaries of the medical devices, in order to develop further innovative medical devices with a clear clinical need. This contrasts with the findings of Mina et al. (2007) who concluded that biological technology has a greater influence on medical innovation than social needs. Nevertheless, a 'value network' is a win-win situation for all parties involved, be it healthy growth for the participating start-up, expanded treatment options for the surgeon or more orders for the manufacturer. Moreover, the collaboration of different key stakeholders such as physicians, scientific researchers and hospitals is necessary to balance the unevenly produced knowledge through the mutual interaction of scientific knowledge and applied techniques (Consoli et al., 2005; Consoli and Mina, 2009).

A general observation that runs through all the interviews is that 'human capital', a term first described by Becker (1964), is highly valued in all areas at 'Start-up X'. The cultural conditions include, for example, the working atmosphere in the office, the various communication possibilities, an individual bonus system, the home office possibilities, the favourable work-life balance and the internal leisure activities. Ultimately, these all contribute to the fact that all interviewees rate the prevailing corporate climate as consistently positive. This underlines the importance of employees as 'human capital', the only changeable factor within an organisation, and the knowledge, skills and abilities of employees as economic assets (Becker, 1964). Eisenhardt's (1989a) 'agency theory', which suggests that the interests of agents (employees) and principles (managers) should be strategically aligned, leading to a rationalisation of relationships and systems between employees and managers, also fits well. Valuing 'human capital' within 'Start-up X' should be seen as a very beneficial asset.

Internal communication is an important issue to ensure efficient project progress and good cooperation between employees. Face-to-face communication is generally the preferred method of communication, although during the Covid pandemic employees were forced to adapt to the concept of ‘New Work’ and work from their home offices. However, after the pandemic regulations were relaxed, employees quickly found themselves in a hybrid system where they worked partly in the office and partly at home. Within 'Start-up X' there is a certain tendency to prefer working in the office, as the possibility of direct communication, be it in the office, in the meeting room or in the kitchen, is highly valued. In the literature, this is equated with the criterion of participatory and informal communication, which Ahmed (1998) sees as beneficial.

It was clear from the various interviews that the team structures were set up on the basis of the different operational approaches. However, all interviewees mentioned that the team structures could vary according to needs, so that certain needed insights or skills could be integrated into a team. This is in line with the ‘renewing processes’ described in the literature. The processes described are agile and flexible, can be rethought and adapted according to the task at hand (organic structures/inter-functional teams). This is in line with Mintzberg (1979b), who compares “designing an organization with turning the knobs of a control panel, adjusting and fine-tuning the division and coordination of labor to achieve stable and productive behavioral patterns” (Visscher and Fisscher, 2012, pp. 2-3). He goes on to show that successful companies tend to form inter-functional teams to work on projects, removing the “artificial barriers between functional areas and between line and staff” (Luthans, 2011, p. 61).

As mentioned in the literature review, a favourable market position (Porter, 1985), and the possession of relevant ‘resource differentials’ (Barney, 2001; Day, 1994; Grant, 1998; Sanchez, Heene and Thomas, 1996; Wernefelt, 1984) are believed to lead to sustainable competitive advantage and superior performance (Hyvönen, Tuominen and Erälinna, 2004, p. 167). Even if start-ups face capacity constraints,

the development of ‘resource differentials’ is inherent, so they should consider innovation and renewal of their processes as a fundamental option (Coates and McDermott, 2002). A salient point in 'Start-up X's organisational structure is the establishment of a dedicated regulatory affairs department to deal with all regulatory issues internally, sending a strong signal to overcome this disruptive market barrier. The establishment of the internal regulatory affairs team demonstrates the managers full understanding of the resource-intensive regulations that apply to highly classified medical devices and their strong desire to manage the knowledge and processes around regulatory issues internally.

After summarising and discussing the codes of 'Start-up X' that correspond to the characteristics mentioned in the conceptual framework, there are still two characteristics described in the literature that could not be assigned to them and therefore have to be considered as non-existent.

Firstly, there is no reference to ‘creative tension’ in any of the interview responses. However, creativity in 'Start-up X' is used for process renewal (as described above) and probably for sustainable product development, but not in the sense of exploring completely new, radical or even disruptive medical devices. Creativity is deliberately limited by the managing directors to a sustainable and predictable outcome. This contrasts with Luthans’ (2011) focus on the ‘learning organisation’ based on systems theory, which identifies the presence of tension (‘creative tension’) as a catalyst for learning. As the term ‘creative tension’ suggests, the development of employee creativity plays a crucial role in organisational success, as “creativity is the ability to formulate unique approaches to problem solving and decision making” (Luthans, 2011, p. 61). However, although creativity seems to be desired by the managing directors, the responses from the interviews are consistent in suggesting that it should only be used in the context of process optimisation and the development of sustainable innovation. Christensen (2016) also states that a certain established company structure can facilitate the development of the dominant product, but negatively influence the development of new products.

Secondly, there is no evidence of conscious uncertainty, as described by Visscher and Fisscher (2012, p. 11) as one of the key insights of the new generation of design approaches, to create “room for the uncertain and the unexpected”. In the responses of the interviewees, everything seems to be planned from scratch, nothing tends to be left uncertain in the organisational design and the installed processes. This may be due either to a lack of familiarity with modern forms of organisational design or to a fundamental reluctance to take entrepreneurial risks. The literature explicitly states that innovation necessarily requires uncertainty and that the ‘maximum security’ approach offered by organisations is an obstacle (Kaduk et al., 2016, p. 55).

Even if the last two elements - creative tension and uncertainty - are only partially present or absent, the characteristics found in ‘Start-up X’ are consistent with Ahmed’s (1998) findings on organic structures that foster innovation: participatory, informal and face-to-face communication, low bureaucracy; interdisciplinary teams that cross departmental boundaries; emphasis on creative interaction and goals; outward-looking; willing to adopt external ideas; flexible to changing needs; non-hierarchical, information flows both downwards and upwards. The implications of the missing characteristics of creative tension and uncertainty need to be discussed with the findings from the other parts of the conceptual framework in question.

Corporate strategy / innovation strategy

Heskett, Sasser and Wheeler (2008) summarise that “leadership is critical in codifying and maintaining an organizational purpose, values, and vision”. ‘Start-up X’s corporate strategy is manifested in a clear vision, mission and strategic approach. According to Mintzberg (1972b), a manager has to deal with all external and internal information and assemble it into specific information to be communicated both to members of the organisation (internally) and to outsiders. Mintzberg (1972b, p. 93) emphasises the role of the managinger as a ‘strategist’ who uses the compiled “information for models, plans, entrepreneurship and crises”. According to this, the manager’s role is not only to process the collected

information internally and externally in day-to-day operations, but also to predict and plan for future business objectives. He is the only one who can orchestrate such a complex system over the long term. Therefore, an organisation needs a “strong value system capable of driving activities in a unified and aligned manner to the super-ordinate goals of the organisation” (Ahmed, 1998, p. 39).

The vision of ‘Start-up X’ was fairly unanimously reflected as "to significantly improve surgical therapy for patients through the use of absorbable implants". The mission statement can be summarised from the responses as follows: “To provide physicians with resorbable solutions for improved treatment, with a clear focus on the ‘clinical need’”. The company’s strategy can be summarised as follows: “Develop a market-established, continuously improved technology platform with distribution of the product derivatives through partnerships”.

Luthans (2011) has identified as a central theme a shared vision across the organisation that promotes openness to new ideas. The vision of ‘Start-up X’ to "significantly improve surgical therapy for patients through the use of resorbable implants" is very broad and does not include any openness to new ideas, but is actually limited to the well-being of the patient through the provision of resorbable implants. The vision in its current form obviously lacks the necessary openness to new ideas.

According to the literature, a well-defined ‘mission statement’ serves as a blueprint for a start-up and consists of three indices: strategic direction and intent, goals and objectives, and a ‘vision’ (Sackmann, 2010, p. 56). Many companies therefore tend to capture their culture in their knowledge management tools, for example in the form of mission statements. In ‘Start-up X’, the vision, mission statement and strategic approach are critically reviewed in the installed OKR cycles, which serve to keep the specific strategic goals in mind and to challenge the status quo. According to Teipel and Alberti (2019), strategic goals are transformed into ‘Objectives’ and should define a clear outcome and be formulated in a precise,

concrete, qualitative, action-oriented and inspiring way. Key Results should be precise, concrete and ambitious - but still be achievable. In particular, they need to be measurable (Teipel and Alberti, 2019). Doerr (2018) mentions that OKR systems prevent the goal amnesia that inevitably results from classical strategic goal setting, which is dictated to all employees by top management and has a duration of one year. This touch of socialism in a thoroughly capitalist organisation is intended to encourage employees to identify more closely with the strategic goals through their active participation in refining them. This is in line with Niven and Lamorte's (2016, p. 6) definition of OKRs as a "framework for critical thinking and a continuous discipline that seeks to ensure that employees work together to make measurable contributions with focused efforts that drive the business forward".

Innovative thinking is explicitly encouraged in 'Start-up X', but seems to be limited to process optimisation and to sustainable product innovation with a predictable outcome in the field already explored. As mentioned in the previous section, innovation is a central element of entrepreneurship (Schumpeter, 1934). According to Hyvönen, Tuominen and Erälinna (2004, pp. 167-168), "innovation has been conceptualized both as an antecedent for performance and as an outcome of key resources and capabilities, ie a dimension of performance" (e.g. Baker and Sinkula, 1999; Gatignon et al., 2002; Hurley and Hult, 1998). The latter suggests that 'Start-up X' is missing an opportunity if it installs an OKR tool but does not give full freedom to innovative thinking.

Mintzberg (1987) developed the key elements of strategic planning with his 'Five Ps For Strategy': 'Plan', 'Ploy', 'Pattern', 'Position' and 'Perspective'. The overall 'Plan' is consciously and deliberately developed to serve as a general guideline from the current state to the desired strategic goals. This can be seen as achieved by 'Start-up X' by defining a clear value, mission and strategic approach. A specific 'Ploy', a deliberate manoeuvre to mislead competitors, does not appear to exist in 'Start-up X'. Strategic 'Patterns' describe a 'stream of actions', regardless of whether these actions were intended or the result of a specific behaviour. Observed successful

behaviours that contribute to strategic success should be repeated to develop an advantage. The latter is a very broad description, but could, for example, be attributed to ‘Start-up X’, given that its refined strategic positioning using the OKR management tool and the development of a regulatory affairs department, gave it a competitive advantage. Another element described by Mintzberg (1987), ‘Perspective’, is used to align managers with the views of their employees, customers, suppliers and competitors to gain an overview of how the company is perceived, including its strengths and weaknesses. Competitive analysis is also an important part of the fifth P: ‘Position’, as a very important data-driven part of strategic planning that involves examining your existing and future market position as it affects, for example, your brand, your pricing and your relationship with buyers and suppliers. As each aspect of the analysis has a direct impact on your strategic planning, it could be considered as a core element of planning. From the interview responses it appears that there is a deep understanding of ‘Perspective’, particularly at managing director level. However, it appears that no specific market research is carried-out at ‘Start-up X’ and that feedback from surgeons and manufacturers is the only source of information that influences the strategic thinking. The latter seems to be a missed opportunity when it comes to developing a comprehensive strategic concept for ‘Start-up X’. Even though managers tend to always keep an eye on their employees, customers and manufacturers, a reasonable observation of competing start-ups and established companies, current market movements and developments as well as future market trends in the German medical device market should serve as a solid basis to better understand the market in which ‘Start-up X’ is operating, scaling and optimising its position.

In terms of corporate strategy, ‘Start-up X’ has a clearly understandable vision, mission statement and short strategic positioning that is known to all employees and thus fulfils its role as a guide. However, during the development of the conceptual framework, other important characteristics were identified that ‘Start-up X’ has only partially or not at all. These are the clear formulation of an innovation strategy, discovery-based planning, ambidexterity and the ability to accept

inconsistency. Finally - and here there is already an overlap with the next theme, innovation-oriented culture - the core hypothesis that ‘culture eats strategy for breakfast’ needs to be further investigated on the basis of the perceptions of the employees of ‘Start-up X’.

A very obvious deficiency in the strategic thinking of ‘Start-up X’ is the lack of an explicit innovation strategy. Although the vision and mission statement of ‘Start-up X’ contain strategic - albeit future-oriented - goals, there is no reference to new innovations in the form of, for example, new medical devices that are not in the field of resorbable implants. As mentioned by Pisano (2015), an innovation strategy is something that is not often found in companies, but is nevertheless a means to make future innovative steps more tangible. On the other hand, ‘Start-up X’ clearly states to focus on incremental innovation of already marketed products, so it does not seem to see the need to make the strategy even broader. Pisano (2015, p. 46) argues that an explicit innovation strategy is a “coherent set of interdependent processes and structures that dictates how the company searches for novel problems and solutions, synthesizes ideas into a business concept and product designs, and selects which projects get funded”. The latter helps to focus on the strategic parameters that a company will pursue in the long term. Even with a clear business strategy, companies can face serious problems without a clear innovation strategy, as “different business units can wind up while pursuing conflicting priorities” (Pisano, 2015, p. 46). Therefore, an innovation strategy is needed to integrate and align the different perspectives (Pisano, 2015). In pursuing their innovation strategy, companies need to “understand how to leverage distinctive existing strengths to generate value and capture value […] [and] how your repertoire of R&D skills, intellectual property, operating capabilities, relationships, distribution channels, and brand can protect and extend the value from innovation” (Pisano, 2014, p. 4). According to Pisano (2015), an innovation strategy - like the innovation process itself - involves continuous experimentation, learning, and adaptation. In their recent study on innovative milieus in Germany, Pohl and Kempermann (2019, p. 32) found that most disruptive innovators have a clearly defined innovation

strategy with a focus on selected fields of innovation. Chen et al. (2018, p. 1) found that the fit between innovation strategy and organisational culture is "critical for effective and efficient implementation of innovation strategy […] [and] a key source of competitive advantage for organizations, rather than the pure strategy".

As mentioned earlier, 'Start-up X' does not carry out any further market or competitor analysis, on the basis that the knowledge gained from discussions with surgeons, manufacturers, etc. should be sufficient to identify the market or clinical need and to establish an appropriate development plan. This is completely at odds with the theory of discovery-based planning, a method that embraces uncertainty at the outset and does not guarantee that a successful medical device will emerge at the end. However, the advantages of discovery-based planning lie in the possibility of further disruptive medical devices that could be developed in parallel with those already on the market. Christensen's (1992) prescriptive S-curve strategy, as well as the disruptive technology S-curve, could help to address further sustainable and disruptive MedTech innovations and plan for their market introduction.

The findings on innovative thinking, innovation strategy and discovery-based planning show how start-ups and SMEs in particular can expand their product range and still maintain a certain product diversity with completely different products in the MedTech sector. In the literature, the phenomenon of ambidexterity is described as the existence of two points of view and the ability to hold both. As O'Reilly and Tushman (2004) note, "this mental balancing act can be one of the toughest of all managerial challenges". Managers strive to constantly improve an existing product, referred to as exploitation (March, 1991); on the other hand, they may fail to create breakthrough innovations in parallel, referred to as exploration (March, 1991; Markides, 2013). This eloquent description was closely observed in 'Start-up X'.

There are two sides to ambidexterity: exploitation and exploration. Managers should therefore build on successful products and develop them in incremental/sustainable innovation steps, but also switch to exploration mode to look for future radical/disruptive innovations. Putz and Raynor (2005) emphasise the importance of growing firms, such as start-ups, pursuing sustainable and disruptive innovations if they want to grow profitably. According to Christensen (2016, p. 192), "disruptive technologies are typically simpler, cheaper, and more reliable and convenient than established technologies". He and Wong (2004, p. 481), in their study of exploration versus exploitation, suggested that "exploration implies behaviours characterized by search, discovery, experimentation, risk taking and innovation, while exploitation implies firm behaviours characterized by refinement, implementation, efficiency, production and selection". O'Reilly and Tushman (2004) discovered the model of 'ambidextrous organisations', which separates the new exploratory entities from the traditional exploitative ones, allowing them to have different processes, structures and cultures. Conversely, it also strengthens the links between managers. They believe that this is a "practical and proven model for forward-looking executives seeking to pioneer radical or disruptive innovations while pursuing incremental gains" and note that "more than 90% of the ambidextrous organizations achieved their goals" (O'Reilly and Tushman, 2004). Christensen (2016, p. 231) recognises that companies often fail because their management practices make them industry leaders, but then fail to develop "the disruptive technologies that ultimately steal away their markets". This statement supports the call for ambidextrous thinking in business.

Tushman, Smith and Binns (2011) developed the method further in their in-depth study and outlined three principles that an 'ambidextrous CEO' should have in mind. First, it is important to develop an overarching identity that integrates all lines of business, whether exploitative or exploratory. Second, it is important to maintain tension at the top by saying that managers are responsible for keeping conflict out of lower levels and that decisions are made at the executive level. The third principle is to allow inconsistency while working with a dual agenda because "supporting

core businesses and innovation units requires leaders to be consistently inconsistent" (Tushman, Smith and Binns, 2011, p. 80).

In parallel with the call for ambidexterity in start-ups, Pisano emphasises that innovation strategies must include both sustainable and disruptive innovation, as most profits comes from sustainable innovation, the 'stream of routine' (Pisano, 2014, p. 2). Therefore, managers should "achieve the optimal balance between disruptive and sustaining efforts" (Pisano, 2014, p. 4).

There is no evidence of ambidextrous thinking or action in 'Start-up X'. As described above, the strategic approach involves innovative thinking that is limited to sustainable innovation in the same research area of resorbable implants with a conservative, predictable outcome. There is a complete lack of ambidexterity. Disruptive innovation has taken hold in the MedTech sector, and all future innovation - for what is planned now - will only be sustainable and in the realm of exploitation. No discovery-based planning, no acceptance of inconsistency, no risk-taking, no entrepreneurial courage. A major omission compared to the literature identified on this important topic of entrepreneurial behaviour. At the same time, there is a risk, as has been described several times (Foster (1986), Christensen (1997), Pillkahn (2014)), that start-ups do not to build up sufficient competitive advantages and ultimately fail because the theoretical insights were not recognised and implemented accordingly.

The core hypothesis of this research project, based on Drucker's statement and the question of whether culture or strategy comes first, is that most interviewees spontaneously tend to see strategy as the more important (and at the same time more adaptable) tool, and culture as more in line with it - but this is a rather negligible fact that relates more to the opening statement and was asked out of interest. One of the main findings of Chen et al. (2018) was that innovation strategy alone is not able to increase a firm's innovation performance. Rather, it is important that a particular innovation strategy is implemented based on the basis of the respective

corporate culture. This in turn supports Drucker's hypothesis that 'culture eats strategy for breakfast'. Naranjo-Valencia, Jiménez-Jiménez and Sanz-Valle (2011, p. 55) have analysed and tested the relationship between innovation orientation and organisational culture in a research project. They conclude that organisational culture is a clear determinant of innovation strategy. Just as the opinions on this topic vary within 'Start-up X', so do the opinions in the prevailing literature when it comes to the topic of culture and strategy, especially for start-ups and SMEs.

Innovation-oriented culture

Observing and interpreting cultural assumptions is usually a difficult task due to their high complexity. It is almost impossible to capture, decipher and interpret the full scope of a particular organisational culture, even that of a start-up, through interviews. What should be possible, however, is to capture the prevailing corporate climate at a particular point in time. This is a limited and condensed version of the complex phenomenon of organisational culture, but should be sufficient for a targeted investigation of corporate climate as part of organisational culture. Schein and Schein (2017) state that it is important to distinguish between the two phenomena in their manifestations and to see corporate climate as an artifact of culture. The interweaving of cultural and strategic elements should help to make organisational culture more tangible for (new) employees and provide a basic mechanism for change (e.g. in the context of organisational development). According to Stock, Six and Zacharias (2013), flexibility, creativity and openness to innovation are the most important cultural values for an innovation-orientated company. As Baetge et al. (2007) state, organisational culture has an external impact, it is particularly effective internally and is an important factor in achieving organisational goals.

Schein and Schein (2017) have observed cultural phenomena and categorised them into three levels, from very tangible, obvious phenomena to unconscious basic assumptions embedded in the cultural essence, the 'Cultural DNA' of a company. The innovation orientation is a "multidimensional knowledge structure […] to

promote innovative thinking and facilitate successful development, evolution, and execution of innovations" (Siguaw, Simpson and Enz, 2006, p. 560). According to Fichter, Basel and Keller (2018, p. 168), the corporate climate describes "the manners, the jointly experienced atmosphere and the degree of activation of the members of an organisation. It lasts for a relatively long time and influences the experience, the behaviour and the satisfaction of the members of an organisation. It can be consciously perceived and can therefore be relatively easily measured and shaped". As a pervasive phenomenon, only explicit cultural expressions, such as norms and artifacts, are visible or tangible and can be observed. In contrast, implicit culture, with its tacit beliefs, values and basic assumptions, is very difficult to observe and capture. Although it is difficult to sustain a "culture of relentless innovation" (Tellis, Prabhu and Chandy, 2009, p. 16), an innovation-oriented organisational culture has a positive impact on innovation capacity and performance (Han, Kim and Srivastava, 1998; Homburg and Pflesser, 2000).

Ahmed (1998, p. 36) argues that what matters is having the right cultural norms in an organisation to activate the creativity that drives innovation. Gulati (2019, p. 89) puts it well: "What set apart successful firms was not a 'fun' or 'crazy' culture but the unusual creativity and autonomy employees showed". Contemporary literature largely supports the notion that creativity is one of the main characteristics of an innovative culture and therefore serves as a determinant of a firm's pioneering character (Claver et al., 1998; Jamrog, Vickers and Bear, 2006; Martins and Terblanche, 2003; McLean, 2005; Mostafa, 2005; Schneider, Gunnarson and Niles-Joly, 1994; Shrivastava and Souder, 1987; Wallach, 1983). Creativity can be understood as a means of generating new and valuable ideas (Amabile, 1998). Gulati (2019) links the success of a company to the presence of unusual creativity and autonomy among its employees. It seems that creativity is understood and handled differently in 'Start-up X' than in the literature. It seems that there are fixed limits to creative processes and creative thinking. This is also due to a limited openness to innovation, as all innovation efforts are limited to sustainable product innovations with a predictable outcome.

Even if the first two characteristics that an innovation-driven start-up should have are not fully present in 'Start-up X', it benefits from a strong, adaptive culture with a strong emphasis on building a 'sports team' mentality that is desired and encouraged by the company's leaders. Start-ups are often considered to be more flexible and agile due to their low levels of hierarchy and bureaucracy (Kollmann, 2016). Ahmed (1998) noted that managers have the opportunity to empower their employees to take responsibility for innovation through leadership support and commitment. Empowerment will mobilise their energies and enthusiasm to be creative. All employees in 'Start-up X' report a strong cohesion in the project teams and a teamwork mentality in action. Nevertheless, the project teams are structured with some flexibility according to the needs of each type of project.

'Start-up X' also benefits from a strong learning orientation, which keeps knowledge levels high and facilitates the induction and development of employees. This is in line with literature, e.g. Luthans (2011), who focused on the 'learning organisation' based on systems theory and found that building an organisational culture that promotes learning is intrinsic. Sackmann (2006) identified dimensions such as 'learning orientation' and 'adaptation orientation', which can be summarised as innovation orientation.

As the interviewees reported close 'customer links' with universities and research institutions, as well as collaboration with other start-ups and surgeons to gain valuable insights into further possible innovations, it can be assumed that 'Start-up X' maintains a vibrant 'value network'. The benefits of maintaining such a value network have already been mentioned in the section on organisational design.

Employees are recognised and rewarded through an individual bonus system based on personal objectives to be achieved each year. This type of system certainly increases individual motivation – on the other hand, it could be argued that the individual bonus system hinders teamwork, as the team does not win if individuals

receive different bonuses. This type of bonus system also differs from an open bonus system such as ‘employee of the month’ that some companies offer.

The above characteristics of an innovation-oriented culture, which seem to match the behaviour of 'Start-up X', underline its ambitions to approach the future in an innovative way. However, there were two features in the conceptual framework that were not found in 'Start-up X'.

The first characteristic is that unconventional ideas are neither wanted nor supported in ‘Start-up X’. In their study, Pohl and Kempermann (2019) take up the topic of ‘risk appetite’ in a start-up aiming for disruptive innovation. 96% of employees and 98% of managers said that they are encouraged to try out unconventional ideas - even if their success is uncertain - and to implement them as part of innovation projects. Unconventional ideas overlap with very similar characteristics such as creative tension, uncertainty, discovery-based planning and inconsistency, which have already been analysed and discussed and which were found to be only partially or not at all present in ‘Start-up X’. The lack of unconventional ideas, uncertainty and inconsistency is an important insight in identifying what is probably not best practice for a growing start-up.

The second characteristic, and probably the most important one, which brings together all the previously mentioned missing characteristics, is the overarching theme of the unwillingness of entrepreneurs to take risk. Luthans (2011) defined three dimensions that are essential for unleashing the creativity of employees to think ‘outside the box’: personal flexibility and the willingness to take risks and accept failure, thus introducing the issue of entrepreneurial risk-taking. Christensen (2016) noted that organisational barriers may be the reason why “leading firms frequently stumble when confronting technology change” (Christensen, 2016, p. 29). Simple reasons for this include “bureaucracy, complacency, or ‘risk-averse’ company cultures” (Christensen, 2016, pp. 29-30). Investing in radical or even disruptive innovation is harder to justify, so managers fear experimentation and stick

to their core business. Pillkahn (2014) suggests how companies can break out of their ‘comfort zone’ and avoid the looming ‘innovation coma’ (see Figure 15). Companies that focus on mere improvements and neglect real innovation (more of the same instead of the ‘new’) inevitably encounter the ‘Red-Queen effect’ and then miss out on developments in the environment by clinging to the successful businesses of the past (‘Sleeping Beauty effect’). Instead of limiting themselves to minor improvements of already known products, companies should use the ‘Pioneering effect’ and explore, experiment and discover new technologies and create new markets (Pillkahn, 2014), which is in line with the exploratory approach proclaimed by the theory of ambidexterity. As innovation itself is a continuous process, the challenge for managers is to prioritise radical or disruptive innovations over sustainable opportunities. Kaduk et al. (2016) and Ortmann and Sydow (2001) critically argue that the ‘maximum security’ approach offered by organisations hinders ‘creative destruction’ and subsequent comprehensive renewal, leading to reliability and replicability. Instead, innovation necessarily requires uncertainty. Christensen (2016) adds that ‘risk-averse’ organisational cultures can foster organisational barriers that cause firms to stumble in managing technological change. Foster (1986) goes further, stating that when firms fail to develop and adopt new technologies in a timely manner, this can be the reason for the failure of firms in the market and can lead to an advantage for attacking firms.

It is also interesting to note that the word ‘disruption’ was not mentioned once in any of the interviews, although it was mentioned several times in the description of the research project prior to the interviews. This could be an indication that neither the theory of disruptive (product) innovation nor the influence of disruptive (product) innovation on the entrepreneurial behaviour of a start-up is known in ‘Start-up X’.

The lack of risk-appetite as well as the apparent ignorance of the theory of disruptive product innovation in ‘Start- up X’ could be explained by the fact that both managing directors studied engineering and are therefore experts in the natural

sciences, with less expertise in business administration or specific entrepreneurship topics.

4.5 Summary and conclusion of findings

This chapter contains the thematic analysis of the primary data and the final discussion of the primary data in comparison with the results from the academic literature. The discussion shows that the characteristics of the conceptual framework are largely reflected in the start-up studied. Some characteristics are obviously missing, but could be important for future business success as the start-up grows and thus becomes more established.

This research focuses on the German MedTech industry, which has high market barriers (see section 2.2.5 ff.), but is overall an attractive, developed and growing market. Although the various market barriers identified are likely to hinder market entry and thus socially important innovations in the health sector, there are ample opportunities for newcomers to innovate and enrich the extensive research-intensive market. The market barriers force start-ups to expose their business to high risk and thus potentially fail from day one. ‘Start-up X’ faced the competition and has built a regulatory affairs department as a core competency, dealing with all regulatory issues and working closely with the relevant authorities to ensure that existing and future medical devices comply with regulatory requirements. By accepting and symbolically embracing of the regulations surrounding its medical devices, 'Start-up X' shows that it recognises and proactively addresses market conditions and tries to keep the hurdles as low as possible. This can be seen as a smart and innovative move to outperform the competition.

In terms of organisational design, ‘Start-up X’ seems to live and breathe the theoretical results from the literature review: the combination of design approaches, no obvious hierarchies, flat structures, the creation of a value network with doctors

and cooperating companies, laboratories, etc., lived values for all employees and a motivating bonus system, participative, informal and mostly oral communication, flexible teams working on installed processes that are regularly rethought, resource differentials, e.g. in the form of the specially formed regulatory department. Everything seems to correspond to the 'optimal characteristics' of the conceptual framework. Nevertheless, two characteristics are listed that were not found in 'Start-up X'. First, there was no creative tension in 'Start-up X' to explore completely new, radical or even disruptive medical devices. Although creativity seems to be desired by the managing directors, the responses from the interviews are consistent in suggesting that it should only be used in the context of process optimisation and the development of sustainable innovations. The lack of creative exploration of new pathways, technologies or products is also evident in the assessment of the strategic behaviour of 'Start-up X' and the lack of ambidexterity. Second, in 'Start-up X' everything seems to be planned, there is no evidence of conscious uncertainty. This could be due either to a lack of familiarity with modern forms of organisational design or to a fundamental reluctance to take entrepreneurial risks.

In terms of 'Start-up X's strategic approach, the formulation and existence of a clear vision, mission and strategy show that these are taken seriously and regularly reviewed to ensure that they are up to date. An OKR management tool is used to monitor and adjust project progress. Innovative thinking in the strategic area tends to be reduced to small innovation steps that sustainably expand current disruptive products. This is also reflected in the only partial implementation of Mintzberg's 5 Ps, where pattern and perspective are well implemented and obvious discovery-based planning does not take place in this form, as 'Start-up X' focuses purely on incremental progress. This behaviour clearly shows that ambidexterity, i.e. the balance between disruptive and sustainable innovation, is neither actively addressed nor implemented at 'Start-up X'. Even though culture is written in capital letters and people and teamwork are at the forefront of the company's thinking, the majority of the respondents say that the company's strategy comes first and that the culture has to adapt.

As already mentioned, organisational culture plays a very important role in 'Start-up X'. Again, many of the behaviours identified are consistent with the literature on innovation-oriented culture. ‘Start-up X' has a strong adaptive culture, teamwork, flexibility and learning orientation, and employees are involved in the company's processes. Intrinsic rewards are compensated by personal rewards, which is certainly due to the small number of employees. However, when it comes to creativity and openness to innovation, it is noticeable here (as already described in the areas of corporate strategy and organisational design) that creativity is only wanted and used in the sense of internal processes, but not to develop completely new, radical or even disruptive products and bring them to market. The openness to new innovations ends with sustainable innovations. There is no room for unconventional ideas, and a certain degree of entrepreneurial risk-taking is not even apparent.

It is obvious that the essential characteristics of entrepreneurial behaviour reflected in the conceptual framework cannot be expressed in numbers, so that no conclusive (statistical) assessment can be made as to whether one or all of these characteristics, which are not present in 'Start-up X', will lead to an economic disadvantage or even ultimate failure. Nevertheless, the large number of publications and studies considered in this dissertation provide a scientifically sound basis of behavioural ‘disruptive patterns’, so that appropriately positioned start-ups should also follow these in order to ultimately be able to operate successfully in the market. Due to high market barriers, start-ups that want to become active in the German MedTech market in particular have to show a high degree of risk-taking, unconventional thinking, discovery-based planning and ambidextrous behaviour. The latter seems to be difficult to achieve, as it is certainly a sensible way of trading to prefer conservative actions in the further course. On the basis of the theoretical findings, however, it must be stated that ultimately market success and thus long-term profitability in this particular market can only be guaranteed by constant entrepreneurial courage in the form of risky entrepreneurial action. The original willingness to take risks in order to enter this difficult market with a complex

disruptive innovation in the first place should then be maintained in order to develop further disruptive innovations in line with sustainable innovations on already existing products/product groups to market maturity. If, however, these entrepreneurial requirements are nipped in the bud and only conservative measures and thus only incremental progress are relied upon, the risky approach to disruptive action described in theory with steady success is unfortunately taken ad absurdum. For start-ups, and not only in the medical technology industry, disruptive innovation ultimately means acting according to a ‘disruptive pattern’, which the conceptual framework describes from a certain selected perspective, following Schumpeter’s (1942) pioneering theory of ‘creative destruction’ and Christensen’s (1992) development of the theory of disruptive innovation. Dru (1996, p. 55) sums it up rather succinctly: “disruption is about displacing limits”.

Finally, Drucker's introductory hypothesis that "culture eats strategy for breakfast" cannot be answered conclusively. In the course of this dissertation, the picture that has emerged in the literature is that organisational culture is a factor (albeit a difficult one to change) in a start-up and that the rather static strategic orientation must be adapted to the prevailing organisational culture. In the end, it is certainly not a matter of forming a preference, but of constantly rebalancing the two fundamental pillars of the start-up.

5 Conclusion

5.1 Introduction

This chapter concludes the underlying research project and reflects on both the underlying assumptions and the final findings, which were obtained through an in-depth literature review combined with a validated empirical investigation. The latter is not only a recognised method for social science studies to generate new theoretical insights. Businesses and market research organisations also benefit from this efficient form of data collection and analysis. When the right research method is used, empirical studies can have a lasting impact on a company's success.

In short, empirical social research is a scientific methodology that relies primarily on surveys, observations and measurements to make statements about reality. In an empirical study, researchers try to test their hypotheses (theoretically derived statements) with facts and information. Depending on the outcome of the empirical investigation, the hypotheses are either confirmed or falsified. The aim of empirical research is to examine facts scientifically and thus arrive at reliable findings. This is particularly useful in market research. However, like any type of research, empirical research has its advantages and disadvantages. The advantages of empirical research are that it provides new insights into a particular topic, it is practical and it is based on applied fieldwork, not just on literature. Disadvantages of empirical research can be its dependence on the cooperation of participants, the amount of work and planning involved, and the fact that empirical research often creates an artificial environment so that the results have limited applicability to reality.

Qualitative research methods are used to collect and interpret a selected set of non-numerical data. This method is well suited to eliciting meanings, opinions or underlying causes in the context of an empirical study. The study is conducted in an unstructured or semi-structured format. In this case, researchers use a conversational method with the samples to obtain in-depth information about a research question. Qualitative research findings are descriptive rather than

predictive. This type of empirical research is therefore particularly suited to more complex studies.

Using the qualitative case study method, researchers carefully examine existing cases to gain new information about them. It is particularly suitable for business research or for gaining empirical insights for specific research purposes. The results of the case study allow conclusions to be drawn about the topic of the study.

This concluding chapter is divided into four parts: the reflection on the aim and originality of this research project, the final contributions to theoretical knowledge and to practice resulting from the research findings, the limitations of the research and finally the conclusion and outlook for further research.

5.2 Reflecting on the aim and originality

In order to discuss the academic value of the underlying research, the aim of the research is first briefly outlined and then the originality of the research is demonstrated.

Based on the research question on “How is disruptive innovation in medical devices possible for German MedTech start-ups, and what entrepreneurial behaviour is appropriate to overcome the high market barriers?”, which arose from the daily handling of regulatory issues around medical devices, the research aim “To investigate whether disruptive innovations in medical devices also lead to specifically disruptive entrepreneurial behaviour among German MedTech start-ups” led to the empirical endeavour of this dissertation. The further derived research objectives point the way to a well-founded literature review on the core characteristics of entrepreneurial behaviour, which are viewed from a completely new perspective, namely the triad of organisational design, corporate strategy and organisational culture. The theoretical insights thus gained are incorporated into a newly developed

conceptual framework, which practically contains the cornerstones of ‘optimal’ entrepreneurial behaviour of start-ups.

The three research objectives derived from the research aim were answered in the course of the dissertation. Research objective (1) “To assess whether disruptive innovations in medical devices are at all possible for German MedTech start-ups, and if so, to identify favourable and unfavourable factors influencing the entrepreneurial behaviour of German MedTech start-ups with a focus on disruptive innovations” was answered with a clear “yes” in section 2.5 at the end of the literature review.

The research objective (2) “To combine the most favourable components of organisation design as well as crucial corporate, strategic and culturally modifiable ‘human factors’ that influence the entrepreneurial behaviour of innovative German MedTech start-ups into a comprehensive conceptual framework” was achieved with the development of the conceptual framework (see section 2.4.7), which summarises the most important characteristics of entrepreneurial behaviour from a unique new perspective, namely the triad of organisational design, corporate strategy and organisational culture, which points to a new ‘disruptive pattern’.

The conceptual framework suggested that the ‘ideal’ start-up organisational design is based on a flat hierarchical system that values employees as ‘human capital’ and combines different design approaches. Organic structures should avoid bureaucratic, rigid work processes and encourage personal communication within a cross-functional team structure. Employees should be open to a constant process of renewal to maintain resource differentials. Uncertainty (e.g. in innovation success) should be seen as an opportunity to evolve, while maintaining a creative tension that fosters innovative thinking. While building a value network inside and outside the start-up, employees should work on the activities of the company in a participatory and informal way.

When it comes to the strategic and innovative direction of a start-up, in addition to the formulated mission statement and following Mintzberg's 5 Ps, there should be a clear vision as well as a formulated innovation strategy to define the future goals of the start-up. To address the core hypothesis of this dissertation, culture should be considered first, as the innovation strategy should be adapted to the prevailing start-up culture. Managers should rely on discovery-based planning, as we have learned that uncertainty should be part of the business in order to foster innovative thinking. Continuous software-based review of strategic objectives using OKR software should encourage critical thinking by all employees. Managers should follow the rules of ambidexterity, supporting both sustainable and disruptive innovation and accepting inconsistencies in achieving strategic goals.

An innovation-oriented culture, which is probably best suited to start-ups, should be strong and adaptable. It should allow and encourage employee creativity, which in turn should lead to unconventional ideas. In addition, flexibility, risk-taking, learning, teamwork, customer loyalty and a general openness to innovation should be firmly embedded in the culture. Start-up managers should involve their employees in all processes and introduce intrinsic rewards to keep motivation high.

The thematic analysis, which added important insights to the conclusions of the empirical social research, and the discussion of the results of the literature and the findings of the mini-ethnographic case study revealed a majority of matching characteristics, but also some important missing characteristics of the start-up under study. The comparison of the data obtained with the conceptual framework revealed that 'Start-up X' lacks the important points of ambidexterity, uncertainty, creative tension and an innovation strategy, as well as entrepreneurial risk-taking in the form of an emphasis on unconventional ideas and, even if the outcome is initially uncertain, discovery-based planning. The latter behaviour requires entrepreneurial courage and probably knowledge of current theoretical assumptions in the field of start-up entrepreneurial behaviour. According to several scholars, not knowing the missing characteristics can lead to the ultimate failure of a venture. According to

O'Reilly and Tushman (2004), ambidexterity is a "practical and proven model for forward-looking executives seeking to pioneer radical or disruptive innovations while pursuing incremental gains". They note that "more than 90% of the ambidextrous organizations achieved their goals", despite this being arguably one of the most difficult challenges managers face. Christensen (2016, p. 231) describes the 'innovation dilemma' as companies often fail because their management practices make them industry leaders, but then they fail to develop "the disruptive technologies that ultimately steal away their markets".

For this reason, the underlying research addresses this specific research question by developing a conceptual framework and, in conjunction with the empirical data from the mini-ethnographic case study, providing a simple practical guide as to why a start-up focused on disruptive innovation must also implement a 'disruptive pattern' of entrepreneurial behaviour. The characteristics of the 'disruptive pattern' are summarised in the conceptual framework and were investigated in the empirical research conducted to answer the research objective (3): "To investigate this conceptual framework using empirical methods and to derive recommendations for the organisation design and corporate strategic and cultural orientation of German MedTech start-ups with a focus on disruptive innovations". Following the analysis and discussion of the findings, it is clear that many of the characteristics mentioned in the conceptual framework are intertwined in some way, but they all seem to be an essential part of the most important characteristics of entrepreneurial behaviour. 'Start-up X' showed during the mini-ethnographic case study that it lacks mainly ambidexterity, uncertainty and creative tension as well as entrepreneurial risk-taking and thus entrepreneurial courage and probably also knowledge of the current theoretical assumptions about the 'disruptive pattern'.

In addition to the theoretical insights, a dissertation must meet certain requirements, and one of these criteria is originality. Gill and Dolan (2015) and Phillips and Pugh (2010) have explored this point, examining the main criteria for originality of a dissertation. Delamont, Atkinson and Parry's (2004) experience, cited in Gill and

Dolan (2015, p. 14), was that a good dissertation should be “theoretically exciting and original, without necessarily being earth-shattering”. According to Phillips and Pugh (2010), a dissertation must meet at least one of the following criteria, although this list is only an excerpt from the wealth of possibilities:

- Put important new information in writing for the first time
- Test someone else's theory
- Doing empirical work that has not been done before
- Making a synthesis of things that have not been put together before
- Extend knowledge in a way that has not been done before

The criteria presented were chosen because they can be observed in the underlying research project, which does not redefine the specific research area, but adds ‘disruptive insights’ by introducing a new perspective on entrepreneurial behaviour. The fulfilment of the originality of this research project through the above criteria will be clarified in the next sections, which will elaborate on the contributions of this dissertation.

5.3 Contributions

This research project contributes to both theoretical knowledge and management practice in several ways. The uniqueness of the contribution lies, on the one hand, in the identification and, on the other hand, in the operationalisation of a conceptual procedure that sheds light on the darkness. In this context, it is important to note that the findings of the underlying research relate very specifically to the German MedTech market in direct connection with the innovation and/or distribution of disruptive medical devices. Therefore, the specific findings can only be applied to other markets or industries with great caution.

5.3.1 Contribution to theoretical knowledge

This study has made an important contribution to theoretical knowledge in three ways: it has introduced a new perspective on entrepreneurial behaviour, provided a unique conceptual framework and validated the findings empirically. The empirical investigation of the theoretical antecedents of disruptive product innovation to finally gain insight into the possibility of a 'disruptive pattern' in entrepreneurial behaviour adds another piece to the knowledge puzzle.

There is a lack of knowledge and theoretical insights in general and in particular when it comes to the intersection of different areas of business administration (e.g. strategy, culture, organisation, etc.).

A new perspective on entrepreneurial behaviour

First, the research introduced an unprecedented focused view of entrepreneurial behaviour from a triangular perspective encompassing organisational design, corporate strategy and organisational culture. The new perspective emerged from the identification of the research gap and the subsequent initial literature review, which narrowed the research topic in a logical way.

The research aim and objectives identified a framework of relevant literature on the emerging core themes, from their historical origins to recent findings and developments. The specific research area was chosen because the research gap identified a lack of academic research on entrepreneurial behaviour (McAdam and Cunningham, 2019) and, in particular, on understanding the mechanisms of entrepreneurial culture (Hogan and Coote, 2014; Jassawalla and Sashittal, 2002; Pöllänen, 2021). By synthesising the key literature and recognising that the literature always treats the individual areas in an overarching but never coherent way, the novel perspective on entrepreneurial behaviour emerged in terms of all three core areas: organisational design, corporate strategy and organisational culture. The latter perspective allowed for a comprehensive overview of the behavioural

characteristics and thus a synthesis of things that had not been put together before, a criterion for the originality of a dissertation mentioned above.

Creation of a unique conceptual framework

Second, the study makes a novel contribution to the academic literature by introducing a unique conceptual framework that incorporates the key features of the three behavioural domains studied, derived from the main findings and insights of the literature review. The development of the unique conceptual framework derived from the comprehensive literature review can be seen as an important new piece of theory that has been developed for the first time, another criterion mentioned above for demonstrating the originality of a dissertation.

The final conceptual framework, as shown in Figure 28, includes the most important characteristics of the entrepreneurial behaviour of start-up's as well as the external influences of German MedTech start-ups dealing with disruptive product innovation.

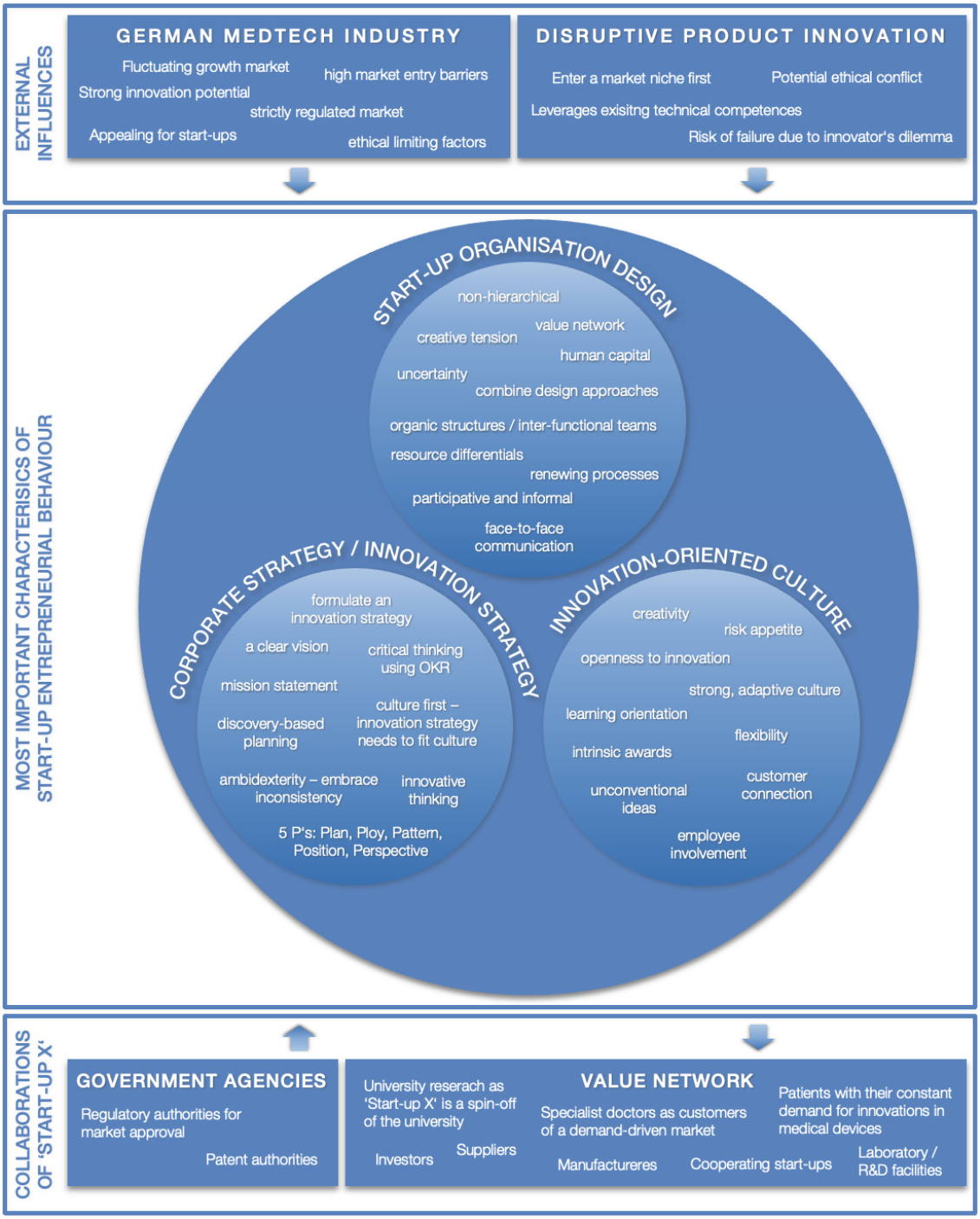

Figure 28: Unique conceptual framework as contribution to theory (developed for research)

Validation through empirical means

Third, an inductive empirical research setting was chosen as the research methodology, so that a mini-ethnographic case study and the use of semi-structured interviews with employees of a German MedTech start-up could be used

to explore their understanding and experience of the underlying phenomena. Finally, the results of the mini-ethnographic case study showed that most of the characteristics found in the conceptual framework could be found in a suitable start-up, but also revealed gaps in the results of the literature that could not be validated in this way. The thematic analysis of the responses from the interviews and the subsequent discussion, combined with the results from the literature, then leads to new, unique insights that can enable validated generalisation in further research. Although the mini-ethnographic case study is a recognised method, the empirical work carried out in the underlying context has not been done before and therefore extends knowledge in a way that has not been done before, which are two further criteria when it comes to the originality of a dissertation, while at the same time contributing to the body of theoretical knowledge.

Finally, the participation of 'Start-up X' in a mini-ethnographic case study confirmed most of the characteristics included in the conceptual framework. However, it also became clear that not all of the characteristics that emerged from the literature review and that were identified as essential components of contemporary entrepreneurial behaviour are implemented in practice. The latter will be analysed in more detail in the next section when it comes to the contribution of this research to practice.

5.3.2 Contribution to practice

As mentioned earlier, the focus of this research project was on independent research with clear value, relevance and application to a specific area of professional practice. Therefore, from the outset, the overall research design was to contribute to theoretical knowledge but also to make a clear contribution to practice.

By meeting certain criteria of originality in terms of contribution to knowledge, this dissertation is intended to serve as a kind of blueprint for the entrepreneurial behaviour of start-ups in the German MedTech industry that focus on disruptive innovation. The German MedTech industry was chosen in particular because of its

stringent regulatory environment, which forces start-ups to take on a high level of risk to get to market when developing and marketing disruptive medical products. This study makes a practical contribution by providing an up-to-date and uniquely comprehensive list of characteristics, summarised in a conceptual framework, that serve as a ’disruptive pattern’ of entrepreneurial behaviour.

The majority of MedTech start-up managing directors are usually engineers, as was subjectively observed in the search for suitable start-ups for the empirical case study part of this research project. They inadvertently lack an academic background in entrepreneurial behaviour, disruptive product innovation theory and its impact on business objectives. This study fills the gap by fulfilling the research aim and objectives.

Comparing the approaches of the contemporary literature with the responses of 'Start-up X's interviewees, there is a clear lack of risk-taking and, ultimately, entrepreneurial courage. Even if one might think that the conceptual framework was too broad and therefore contains information that can be neglected, the discussion of the results has shown that the results of the literature review on start-ups need to be taken into account, especially when it comes to disruptive innovation.

To paraphrase Skarzynski and Rufat-Latre (2011), start-ups need to combine disruptive and incremental innovation in a disciplined and systematic way, adopting their best practices and learning how to outperform their competitors by developing new products and finding white markets.

Summarising the previous sections and reviewing the contribution to the theoretical corpus, there is a clear practical contribution of this dissertation for start-ups belonging to the underlying research area, providing targeted insights and recommendations on how best to protect themselves from the innovation coma and position themselves for a successful future.

5.4 Limitations of research

This quality criterion requires the determination of the scope and limits of the generalisability of a developed theory. It should be analysed to which specific research conditions the results are applicable and to which further areas they can be generalised. The limitations of this research project, particularly in relation to the chosen methodological approach of a mini-ethnographic case study, which affect the reliability and validity of this specific research, are discussed in more detail in this section.

First, the underlying research is already fundamentally limited by the chosen qualitative approach, which involves a comparatively small number of participants, e.g. through interviews, compared to a larger number of participants if a quantitative approach is chosen, e.g. through a survey. As a result, the findings of a qualitative research method, in this case a single mini-ethnographic case study with only one start-up being studied, limit the possibility of generalising the findings to other start-ups / companies (Yin, 2018). Consequently, the lack of generalisability must also be taken into account when drawing conclusions from the data collected. In contrast, as generalisability is an important aspect in quantitative research, qualitative case study research, as evidenced by the research findings of the underlying dissertation, aims at transferability and leads to a large amount of 'rich data', even with a rather small number of interviews conducted. The latter would not have been possible through the use of surveys, as these, unlike open-ended interviews, do not lead to 'rich data'. According to Porte (2013) and Marshall and Rossman (2016), transferability is at the discretion of the reader due to the uniqueness of qualitative studies.

Second, the small number of German MedTech start-ups engaged in disruptive innovation further limits the research. Since start-ups by nature have a very limited number of employees and are in a constant state of flux, the number of start-ups willing to invest their working time and participate in a research project is very small. Finding a suitable start-up for the mini-ethnographic case study proved difficult, but

not impossible. The data obtained and the uniqueness of the resulting research findings confirm that the search for the proverbial 'needle in a haystack' was ultimately worthwhile, despite the time constraints.

Third, while every effort was made to ensure that interviewees were able to respond fully and feel comfortable, for example by organising a distraction-free interview and asking open-ended questions, it is important to accept the limitation that participants may have been bound by legal contracts not to disclose proprietary information, as strategic decisions to gain competitive advantage are often subject to confidentiality.

Fourth, the mini-ethnographic case study was conducted with only the researcher as the interviewer. Consequently, there is a bias in the performance of the inexperienced researcher' who is subject to human impermanence. In addition, the researcher, as a human being, cannot guarantee that he can rely on a completely objective view, as his subjectivity also enters into his judgement.

5.5 Conclusion and outlook for further research

In conclusion, based on the empirical research conducted in this dissertation, a unique conceptual framework has been developed that enables start-up companies operating in the German MedTech sector with disruptive product innovations to adjust their entrepreneurial behaviour in such a way that their company is best positioned in the market according to the theoretical and practical findings. Although this study is based on a single case and cannot a generalised, the conclusions may be applicable to other similar start-ups. As a compact study with concentrated theoretical and practical knowledge, it should be used to shed light on a small but important part of the knowledge gaps in the deep theoretical jungle of entrepreneurial behaviour.

The specific research gap underlying this research project has been identified, operationalised in the conceptual framework (see Figure 28) and now serves as a blueprint that should facilitate a larger scale empirical study in the future. Although small-scale empirical research is not yet as powerful, it is still internally construct valid. In addition to the present single-case study, a more comprehensive multi-case study could be conducted to improve and substantiate the findings, for example, by focusing on multiple start-ups in the MedTech industry (Yin, 2018). The latter would meet the requirements to introduce quantitative methods and thus provide statistical evidence. Future research could pursue a combination of qualitative and quantitative data collection and use a mixed methods research design to compensate for the weaknesses of specific qualitative or quantitative methods (Robson, 2002; Stake, 1995).

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7 Appendices

Appendix 1: Mini-ethnographic case study – protocol and field notes

The search for a suitable start-up for the mini-ethnographic case study proved to be an extremely difficult and therefore lengthy undertaking. Since the underlying assumptions only allow for a very restrictive circle of possible companies, the circle of suitable start-ups was ultimately very small. In addition, the limited resources (employees' working time is a very valuable asset and every minute spent on non-business-related activities is not welcome) and the rather restrictive attitude of such start-ups towards the publication of internal company information made it difficult for them to be willing to participate in a case study. Nevertheless, in a telephone conversation on 8 April 2022, a suitable German MedTech start-up with a focus on disruptive innovation was contacted and one of the company's managing directors agreed to participate in this research project. He assured an interview with him personally as well as four more with randomly selected employees. The real name of the start-up was changed to 'Start-up X' for anonymity reasons. ‘Start-up X’ was founded in early 2018, has about 11 employees and is an innovative, growth oriented MedTech company that focuses on disruptive technologies to develop and commercialise disruptive product innovations.

The main source of primary data was five telephone interviews conducted from 25 August to 9 September 2022. The interviews ranged through all levels of the company up to the top management level (see section 3.6.3). The primary method of data collection is semi-structured interviews.

STUDY PROTOCOL

(1) General procedure:
    a. Execution type: Initial contact with each agreed interviewee via email, introduction and interview via recorded telephone conversation
    b. Participants to telephone conversation: Interviewee and researcher

c. Consent: The interviewee was informed before the interview and has given his/her oral consent before the start of each interview
d. Duration of the interview part: approx. one hour
e. Recording: Two digital sound recording devices (Smartphone and Laptop as backup)
f. Interview language: German as both participants are German native speakers

(2) Interview part I: Introduction
a. Short introduction and overview of research project, purpose and reiteration of ethical principles; in case of ambiguity, clarification questions may be asked
b. consent of interviewee to conduct the interview

(3) Interview part II: Guide for semi-structured questionnaires
a. Semantic bank #1: Organisation design
- Question 1: Imagine the following situation: you are sitting in a pitch meeting with a potential investor. How would you describe the current organisational structure of ‘Start-up X’?
- Question 2: Would you describe the organisational structure of ‘Start-up X’ as more rigid or flexible? Are there moments when changes are made spontaneously, e.g. by creating new teams and/or processes?
- Question 3: Would you say that this is the ideal structure, or would you spontaneously have ideas in your head that it should be organised differently, more rigidly?
- Question 4: How does communication work below the staff at 'Start-up X' is it more verbal or more strictly written down?
- Question 5: The topic of 'New Work', i.e. flexible workplace design in the office and at home in the home office. How does this work from your point of view or at 'Start-up X' and what are your experiences?

b. Semantic bank #2: Corporate / Innovation strategy / Disruptive Innovation

- Question 6: Do you have professional contact with other colleagues from other start-ups in the MedTech field or research institutions with which you cooperate to develop new innovations or bring them to market?
- Question 7: What role does creativity play at 'Start-up X'? Is there a creative freedom for employees? Do you have any freedom in particular or is that not part of your job description?
- Question 8: If I understand correctly, the creative scope is only around the existing products. It's more about perfecting what's already there than developing a completely new product, isn't it?
- Question 9: What is the current corporate strategy or vision of 'Start-up X'?
- Question 10: How present is the vision or the corporate strategy?
- Question 11: Would you describe the corporate strategy as rather rigid or is it constantly reconsidered in the strategy meetings and then also adapted?
- Question 12: How innovative would you describe 'Start-up X'?
- Question 13: To what extent do you see your work influenced by the MDR, i.e. the Medical Device Regulation on medical devices?
- Question 14: Are product innovations or ideas systematically promoted, stimulated and implemented? Or are there regular meetings where people brainstorm and ideas are collected in order to start new innovation projects?

c. Semantic bank #3: Innovation-oriented culture / climate

- Question 15: From your personal perspective, is there a strong organisational culture within 'Start-up X'? And are there, for example, special activities in the company that are not directly related to the project-related work?
- Question 16: Is there a kind of knowledge database at 'Start-up X' or are employees regularly trained or able to further their education? And to what extent do you use this offer yourself or have you already benefited from it?

- Question 17: What would you say is the culture or the strategic direction of 'Start-up X' first?
- Question 18: How important are values in your company and which values would you emphasise in particular?
- Question 19: Final question Do you feel valued professionally?

The interview transcript was created with the browser-based software 'Trint' (Trint Limited, 2022). The transcript was thoroughly proofread by the researcher and - where necessary - corrected or supplemented. The final transcripts were then translated using the software 'DeepL' (DeepL SE, 2022), proofread again by the researcher and - where necessary - corrected or supplemented.

FIELD NOTES

The following protocol shows all notes taken by the researcher before, during and after the interview phase of this research project in chronological order.

June 2021 – March 2022

- Email requests to a dozen possible German start-ups pursuing disruptive innovation for participation in the mini-ethnographic case study
- Sobering response, mostly no answers even to repeated enquiries

Monday, 10 January 2022

- Telephone call with a managing director of a possible German MedTech start-up about the research project
- Refusal to conduct the study due to lack of capacity in the start-up
- Nevertheless, the managing director offered to be available for an interview
- The contact was pencilled in for a possible interview as part of a possible pilot study

Friday, 8 April 2022

- Telephone call with a managing director the German MedTech start-up ‘Start-up X’ about the possible implementation of the mini-ethnographic case study in his start-up
- The managing director agreed in principle to the possibility of conducting the study and asks for another phone call to introduce the research topic in more depth

Tuesday, 12 April 2022

- Telephone call with the named managing director and presentation of the research topic, aim and objectives
- Consent of the managing director to participate in the study as well as consent to conduct interviews with further employees

12 July 2022

- Telephone call with the managing director of a possible German MedTech start-up, who agreed to participate in a possible pilot study
- Cancellation due to time constraints

25 August – 9 September 2022

- Conducting four interviews with employees of ‘Start-up X’