Innovating Innovation Management in the Medical Device SME Sector through Coopetition

Dirk Dembski

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Candidate Declaration

I hereby declare that:

1. I have not been enrolled for another award of the University, or other academic or professional organisation, whilst undertaking my research degree.

2. None of the material contained in the thesis has been used in any other submission for an academic award.

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Name	Dirk Dembski
Date	August 2022
Award	Doctor of Business Administration
Faculty	Sheffield Business School
Director of Studies	Dr Roy Woodhead, Sheffield Business School

Abstract

About 95% of all companies in the European medical device industry are SMEs, which are also the source of most innovation in the sector. New EU directives are threatening the innovation capacity and potentially even the survival of these smaller firms, since SMEs may not have the resources needed to comply with the new regulations.

This thesis explores coopetition, a partnership between companies that usually compete, as an alternative business model to keep delivering innovation. To provide practical value to leaders of medical device SMEs, the focus is on identifying the critical success factors for coopetition in this specific industry and under the influence of the new regulations.

The chosen research methodology uses qualitative methods to gather data from 15 senior executives working in diverse medical device product categories by means of semi-structured interviews. Grounded theory was adopted as the methodological approach, with data analysed using different coding techniques, which provides deep insights into a complex topic.

As a result of the study, recertification and business continuity under the new medical device directives takes full attention of senior management. Nevertheless, SMEs need to keep innovating to secure their future. Whilst balancing both aspects, the study shows that collaborating with a competitor can help to overcome resource issues, but for coopetition to be a successful business model between SME in the medical device industry, they must minimise barriers.

The barrier that stood out throughout the interviews was ‘trust’ between the partnering companies. Studies so far have not examined the concept of ‘trust’ in detail, let alone specify the requisite type of trust necessary. This research identified the trust involved as ‘conditional trust’ that starts with agreeing rules and boundaries before the coopetitive relationship deepens.

Aligned to this is positioning organisational culture, structure and leadership that will lead to successful outcomes. SMEs must determine and agree appropriate representations of values, beliefs, and aspirations, as well as the behaviours, for instance communication, empowerment, and ability to compromise.

Keywords: medical devices, SME, regulations, innovation, coopetition, conditional trust

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List of Abbreviations

Full Phrase	Acronym
Artificial Intelligence	AI
Active Implantable Medical Devices	AIMD
Biobanking and Biomolecular Resources Research Infrastructure	BBMRI
European Conformity/Conformitè Europëenne	CE
Critical Failure Factor	CFF
Critical Success Factor	CSF
Chief Technology Officer	CTO
European Advanced Translational Research Infrastructure in Medicine	EATRIS
European Clinical Research Infrastructures Network	ECRIN
European Patent Office	EPO
Essential Requirements	ERs
European Strategy Forum for Research Infrastructures	ESFRI
European Union	EU
European Database of Medical Devices	EUDAMED
Federal Drug Agency	FDA
Foreign Direct Investment	FDI
Gross Domestic Product	GDP
Human Resource Management	HRM
Internet of Things	IoT

Intellectual Property	IP
Intellectual Property Rights	IPR
International Standards Organisation	ISO
In Vitro Diagnostic Medical Device Directive	IVDD
Merger and Acquisition	M&A
Medical Device Directive	MDD
Medical Device Regulation	MDR
New Product Development	NPD
Poly Implant Prothèse	PIP
Post Market Clinical Follow ups	PMCFs
Research and Development	R&D
Responsible Research Innovation	RRI
Small and Medium Size Enterprise	SME
Unique Device Identification	UDI
United Kingdom	UK
United States	US
World Health Organisation	WHO

CHAPTER 1: INTRODUCTION

Increasing regulatory requirements, decreasing sector investment and rising global competition make it necessary, if not vital, for European small and medium size medical device companies to look into new ways of delivering innovation (Doran & Ryan, 2012; Hansen, Sondergaard & Meredith, 2002; Jiménez, 2005; Mills & McCarthy, 2016). In this thesis, the possibility of coopetition will be explored as an appropriate business model to accomplish such successful product innovation without high financial investment. Coopetition has been found to support companies struggling with resource difficulties in several studies (Teixeira, Robles & González-Barahona, 2015; McCarthy, Ford Carleton, Krumpholz & Chow, 2018). However, its applicability to medical device SME in the context of major regulation changes is uncertain and needs to be addressed through research (WHO, 2010; Racchi, Govoni, Lucchelli, Capone & Giovagnoni, 2016; Marketline, 2017).

As this research is in response to new legislation and attempts to study the critical success factors for coopetition of small and medium sized companies in the European medical devices industry, the introductory chapter will highlight the relevant recent changes in this sector, refine the research problem with regards to coopetition and outline the overall structure of this study.

1.1 The European Medical Device Industry

The World Health Organization defines medical devices as objects for the specific purpose of diagnosis, prevention, monitoring, treatment or alleviation of a disease or an injury. Also, items for investigation, replacement, modification, or support of the anatomy or of a physiological process, supporting or sustaining life and a few other purposes fall under this definition (WHO, 2021). What medical devices cannot have, is a pharmacological, immunological, or metabolic impact on the human body, which separates the devices from pharmaceuticals and medical biotechnology (Altenstetter, 2003). Industry data like MedTech Europe (2021) shows that the medical device sector is a significant socio-economic pillar and, in the EU, very much driven by small and medium sized enterprises (SMEs). In

2019, 95% of medical device companies in Europe were SMEs (MedTech Europe, 2020), in other words companies with annual turnover of less than €50 million and employing less than 250 people. Most were even small or micro companies (Miglierini, 2018; Maresova, Hajek, Krejcar, Storek, & Kuca, 2020a) with less than 50 or 9 employees respectively (EC, 2014).

In Europe more than 500,000 different devices are in use in hospitals, home settings and community care locations (MedTech Europe, 2021). They vary from the smallest items such as syringes and latex gloves to wheelchairs, total body scanners, replacement joints and heart valves. Medical devices contribute not only to the health but also to the wealth of a nation. In the EU, the GDP contribution relating to medical devices in the member states averages around 10%, with an average expenditure on medical technology per capita of about €225 (MedTech Europe, 2021). Currently Europe exports more medical technology devices than it imports, the balance of trade varying by EU member state, but overall, the gap is €11.7 billion surplus.

The high contribution that the medical devices sector makes to economic growth in the EU is also indicated by the proliferation of patent applications and patents granted. In 2020 medical technology made 14,295 patent applications the highest of any sector including digital communication and computer technology; pharmaceutical companies made 8,589 applications by comparison (EPO, 2021). Despite the EU medical device sector making the most patent applications locally, the US generates more than half the medical device patents issued globally, underlining the strong global competition in the medical device market.

The data infers that medical technologies is a highly competitive, attractive industry, but it relies on constant innovation because patients looking for the best treatment will be drawn to those offerings that are superior (Porter & Teisberg, 2004; WHO, 2021). Small medical device businesses are the source of most innovation, because established larger organisations generally lack the capability to generate disruptive innovation (Gad, 2011). This difference is attributed to the high levels of organisational bureaucracy and conflicting internal interests within large companies (Chang, Chang, Chi, Chen & Deng, 2012). Therefore, they acquire small companies that give them access to innovative capacity and

potential to be faster to market than competitors (Fernández, Triguero & Alfaro-Cortés, 2019; Whittington, Regner, Angwin, Johnson & Scholes, 2019).

Hence, it can be stated that without innovation, companies cannot survive (De Bes & Kotler, 2011). This is especially true in healthcare as patients strive for the best possible treatment accessible to them, and that makes innovation a key success factor (Davey, Brennan, Meenan & McAdam, 2011). Moreover, it is mainly SMEs driving disruptive innovation (Gad, 2011). They count for most of the European medical device industry; in Germany more than 93% of all companies in the industry are SMEs (BMBF, 2019). Subsequently less innovation capacity at SMEs may lead to less health care improvement.

1.2 Major Trends in the Medical Device Industry

From the above innovativeness plays a major role in the survival, growth, and prosperity of medical device SMEs. Several important and recent developments and trends, however, have the potential to negatively affect innovativeness, or at least result in challenges that need to be overcome. The most relevant ones are briefly summarized below.

1.2.1 Novel European Directives and Legislation

As a result of numerous product specific quality issues in the medical device industry, more stringent clinical data requirements, extended data management, more complex conformity assessment procedures, and product liability and penalties have been introduced (Loh & Boumans, 2017; Neeser, Mueller & Ehreth, 2017). Mainly, the two new EU regulations for medical device manufacturers are (EU) 2017/745 and (EU) 2017/746, the latter referring directly to in-vitro diagnostic medical devices. These directives were scheduled to become operational in 2020. However, the COVID-19 pandemic resulted in delaying the regulation until 2021, and respectively in 2022 (EC, 2020b).

New regulation is often linked with surges in innovation (Maresova et al., 2020a), and the EU suggests that the new regulations will increase innovation and

competitiveness in the industry and enhance the performance and safety of medical devices (Ben-Menahem, Nistor-Gallo, Macia, von Krogh, & Goldhahn, 2020). The regulations also aim to harmonise the diverse national medical devices regulations existing in EU member states (Al Nassir, 2020; Maresova, Klimova, Honegr, Kuca, Ibrahim & Selamat, 2020b). However, the processes associated with gaining authorisation to market new innovations are lengthy, more rigid and higher cost than previously (Ben-Menahem et al., 2020).

As a result, smaller companies are affected by novel legislation differently than larger corporations. The later are usually capable, due to their resources, to cope with the challenges of such change in the legal environment (Wagner & Hansen, 2005). SMEs, on the other hand, might face a potential loss of competitive advantage (Clemens, 2018; Groennvold, 2017; Wagner & Schanze, 2018; Yeo, 2018) and lack the resources to handle the new regulations, which threatens their survival (Deloitte, 2017; van den Heuvel, Kapadia, Stirling & Zhou, 2018).

1.2.2 Exacerbating Financial Climate

A valuable indicator of the future investment climate are mergers and acquisitions (M&A), one of the major strategies employed by large medical technology manufacturing companies to rapidly leverage innovation rate, speed to market, and profitability (Fernández et al., 2019; Whittington et al., 2019). From 2013 to 2017, an average of 2,700 M&A transactions occurred in this sector, but activity has declined more recently as private investors and large medical technology companies remain cautious about the return to be gained (Medical Device Network, 2017a). The underlying challenges are that public and private sector purchasing and investment has declined owing to political pressure globally to reduce national healthcare costs. A report by Deloitte (2017) revealed a decline in medical technology research and related start-up companies due to venture capital becoming more difficult to access, and existing start-ups were experiencing challenges in transforming ideas into commercially viable products that would be adopted by larger companies.

1.2.3 Rising Global Competition through Emerging Markets

While the financial climate is exacerbating, emerging nations such as China and India are changing the global competitive landscape (Lane & Milesi-Ferretti, 2018). These emerging nations are described by van den Heuvel et al. (2018) as rapidly becoming innovation hubs, with local companies that threaten European manufacturers future market share. The EU expects the new legislation to impact competitiveness positively (Maresova et al., 2020a) by reducing the potential for market failure that would be more likely in the increasingly competitive global market (Fraser et al., 2018; Melvin & Torre, 2019).

However, European manufacturers have already begun to offshore innovation and development activities to emerging nations such as China for cost reasons, but also due to less stricter regulations. As Woodhead (2012) points out, off shoring substantial corporate functions may not only hollow out a company, but also have a negative macro-economic effect due to rising unemployment, pressure on welfare cost and taxation policy as well as reduced consumer spending in home markets.

1.2.4 Medical Technology Trends demanding Speed of Innovation

The new EU regulations for medical devices are not the only challenge to the industry. As outlined in the previous paragraphs the sector is facing lower investment (Medical Device Network, 2017a) and increasing global competition (van den Heuvel et al., 2018). These additional aspects intensify the need for exploring new business models.

On the other hand, there are immense opportunities since the market is moving into new methods and technology of healthcare delivery characterised by connected devices and highly integrated collaborative working (Deloitte, 2018). New devices also include bio stamps and smart inhalers for drug delivery and patient monitoring and increasing use of advancing Artificial Intelligence (AI), which makes diagnosis occur faster. Surgical robots are forecast to improve the outcomes from complex surgery (van den Heuvel et al., 2018).

Figure 1 provides an overview of what innovation can be expected during the coming years. The four quadrants outline the new methods and technology of healthcare delivery foreseen over the next years in the areas of surgical interventions, diagnosis and imaging, drug delivery and patient monitoring, and assistive care and therapy devices. These offer tremendous business opportunities for companies involved in development, manufacturing, and sales of medical devices.

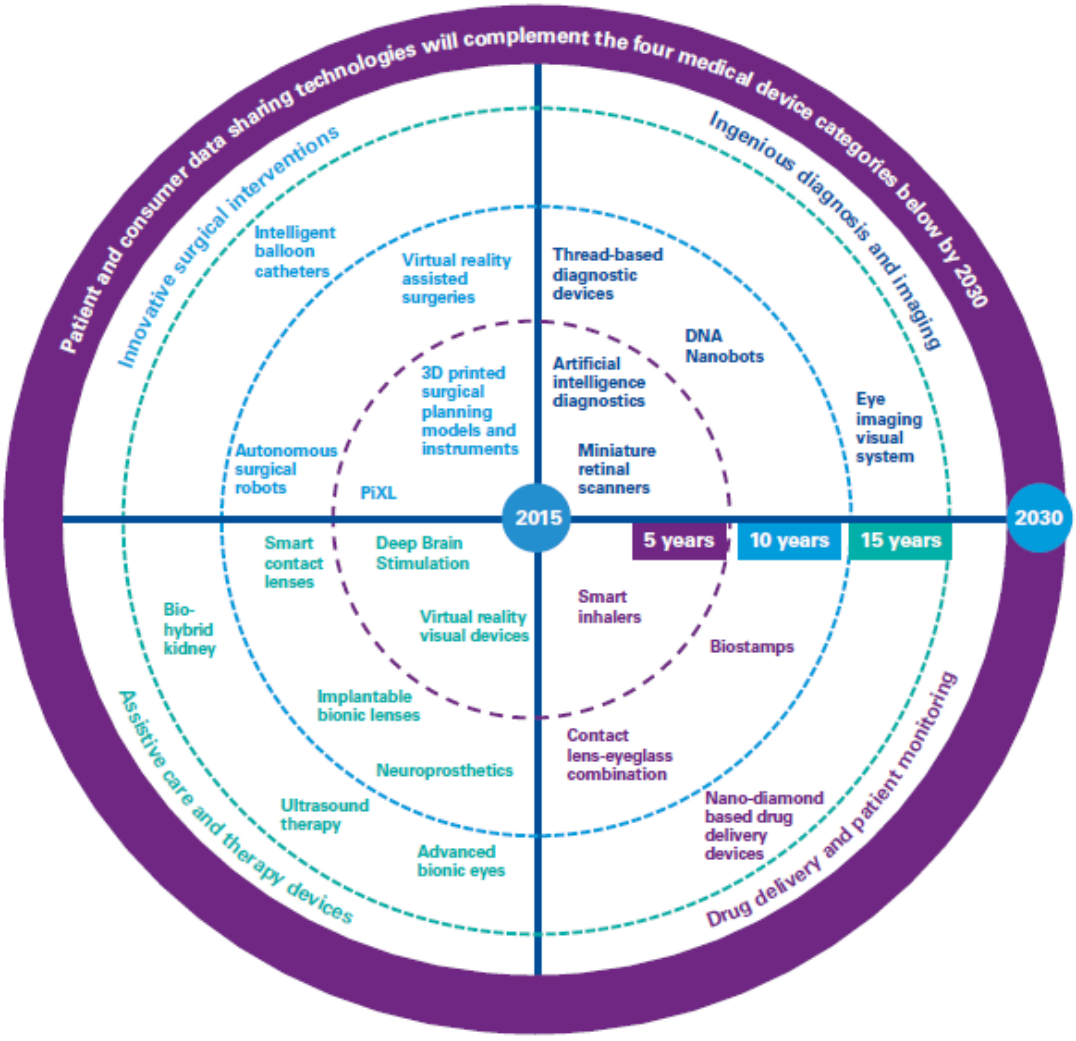

Figure 1: Fast Paced Medical Devices Innovation

Source: van den Heuvel et al. (2018, p. 13)

1.3 Research Problem

As stated above, and to make the most pressing issues more concrete, on May 25, 2017, new regulations on medical devices entered into force in the European Union. They have replaced the existing directives after a transitional period in spring 2021, respectively 2022. There are a series of changes to the old system and manufacturers can expect a major impact on time and cost-to-market and regulatory knowledge requirements and risks of non-approval of products (Neeser et al., 2017). This is especially relevant, as more than 90% of all companies in the medical devices industry are SMEs and it must be assumed that resource limitations compared to larger companies do exist (Colombo, Laursen, Magnusson & Rossi-Lamastra, 2012).

This research is not attempting to answer whether the changes in legislation will enhance or diminish innovation and competitiveness in the European medical device sector overall. Maresova et al. (2020a) suggest that from a macroeconomic perspective the stimulus for innovation will prevail, some companies however may not be able to survive the environmental changes. Consequently, this research is focussed on answering how individual SMEs can overcome the challenges.

Literature reveals that across industries coopetition, a relationship between firms that simultaneously cooperate and compete (Brandenburger & Nalebuff, 1996), is a recognized methodology when common issues come into play, including the influence of the regulatory environment (Tether, 2002). Hence, the exploration of coopetition in the medical devices sector may lead to a business model helping SMEs to continue delivering new medical solutions under the new regulations.

Beyond new regulations, the expected development of the medical device industry over the next decades needs to be considered, as innovativeness will be key, not only to survive but to outperform the competition. The challenge is how to fully exploit these opportunities, especially for smaller and medium sized medical device manufacturers, when at the same time constraining factors threaten their potential to innovate (van den Heuvel et al., 2018).

Stirling and Shehata (2016) propose that adopting an inclusive approach to innovation, which embraces the principles of open innovation (Chesbrough, Vanhaverbeke & West, 2006), would be effective. This suggestion seems feasible because medical device companies frequently collaborate with a diverse group of partners and could develop a much tighter supply chain that fully integrates suppliers, development partners and medical professionals (Stirling & Shehata, 2016). Hence, firms will need to explore the opportunities and challenges offered by diverse innovation models, which help to deliver a new business model to implement their strategies effectively (Casadesus-Masanell & Ricart, 2010).

The background to the research problem demonstrates that the change in EU regulation is a major issue for SME medical device manufacturers. It also establishes that there are multiple consequences for SMEs associated with making strategic and operational decisions to overcome the new challenges. These strategies must be suitable to ensure that small firms are able to survive and take full advantage of industry growth opportunities. Therefore, the value of this research to organisational and institutional groups can be summarised as shown in Table 1.

Table 1: Research Importance and Value

Practical Value and potential Exploitation	Target Group
• Awareness of alternative concepts and strategies in innovation management • Scientifically oriented decision making • Better understanding of implementation requirements for coopetition	• Senior Management of medical device SME's such as Managing Directors and Head of R&D • Policymakers • Scientific and business researchers of innovation management

1.4 Research Objectives and Questions

As briefly introduced above, under certain conditions and with the right incentive, managers overcome traditional competitive thinking (Brandenburger & Nalebuff, 1996). Coopetition as an innovation strategy is chosen when high development costs are involved (Gnyawali & Park, 2009). Cooperation with competitors may balance a demand for manpower, knowledge, and financial resources (Bouncken, Fredrich, Ritala, & Kraus, 2017). With coopetition resources are shared, knowledge is leveraged, and value creation improved (Bengtsson & Kock, 1999). Such a strategy might come into play when important and game changing changes to the regulatory environment take place and require adequate responses (Tether, 2002). Regarding SMEs in the medical device industry, respective examples do already exist (Bouncken & Fredrich, 2016).

The overall purpose of this thesis is to critically appraise the nature of the decision-making process required for the adoption of coopetition as a business model to accomplish survival and prosperity in the SME medical devices sector. Therefore, the major objectives of the research are to:

- Review existing forms of coopetition in SME innovation practices.
- Contrast existing forms of SME innovation practices to identify advantages, risks, and limitations of coopetition.
- Explore coopetition from the experience of leaders and managers of SME medical device companies.
- Understand which critical success factors lead to success or to failed outcomes of coopetition in medical device innovation management.
- Establish whether coopetition can overcome barriers to innovation in the context of new regulation.

These objectives require the execution of a literature review and the subsequent derivation of research questions, as will be detailed below. Such an approach also informs the nature of the research methods suitable to answer the general research question of this thesis. This can be described as the question regarding the critical success factors for coopetition that will provide benefits to medical device SMEs given the impact of the new European medical device regulations

on time and cost to market. Sub questions (SQ) will be developed to support the thesis goals and the required level of detail in a practical manner (Creswell & Creswell, 2017).

1.5 Structure of the Study

A significant share of this work is dedicated to a thorough presentation and discussion of core literature in the field, as well as developing the appropriate methodological approach used to form new insights.

Regarding the required theories, these are developed from a more general perspective on business models and organisational growth and the consideration of innovation, towards an industry-specific view on the novel regulations, innovation management in medical devices and coopetition as a possible solution to navigate within this new legal context.

This is followed by an in-depth discussion of the research methodology and its underlying paradigm, including a description of the data collection and data analysis approach and the treatment of ethical considerations.

The final chapters detail the applied approach and the resulting findings. It will be explained how the actual data was processed, subsequently interpreted which led to new theory. The conclusions provide insights for leaders in medical device SMEs, policymakers and scientific and business researchers as set out in the research problem, section 1.3.

CHAPTER 2: LITERATURE REVIEW AND KEY CONCEPTS

The first part of the literature review will assist in building a conceptual framework, which is relevant to coding the data gathered in the study (Ritchie & Lewis, 2010; Hart 2010). The major theories critically evaluated relate to the nature of strategy, business modelling, strategies for growth, organisational structure and culture, and leadership. This, eventually, points at coopetition as an important concept, entailing the introduced theories and combining them into a suitable framework for an industry-specific view on medical devices.

The second part of the literature review focusses on the EU medical device sector with its new regulations and what has been published on innovation and coopetition specifically in this industry. Therefore, the purpose of the literature review is to identify gaps in the current knowledge, so that the research question can be developed. The structure of this chapter is visualized in Figure 2.

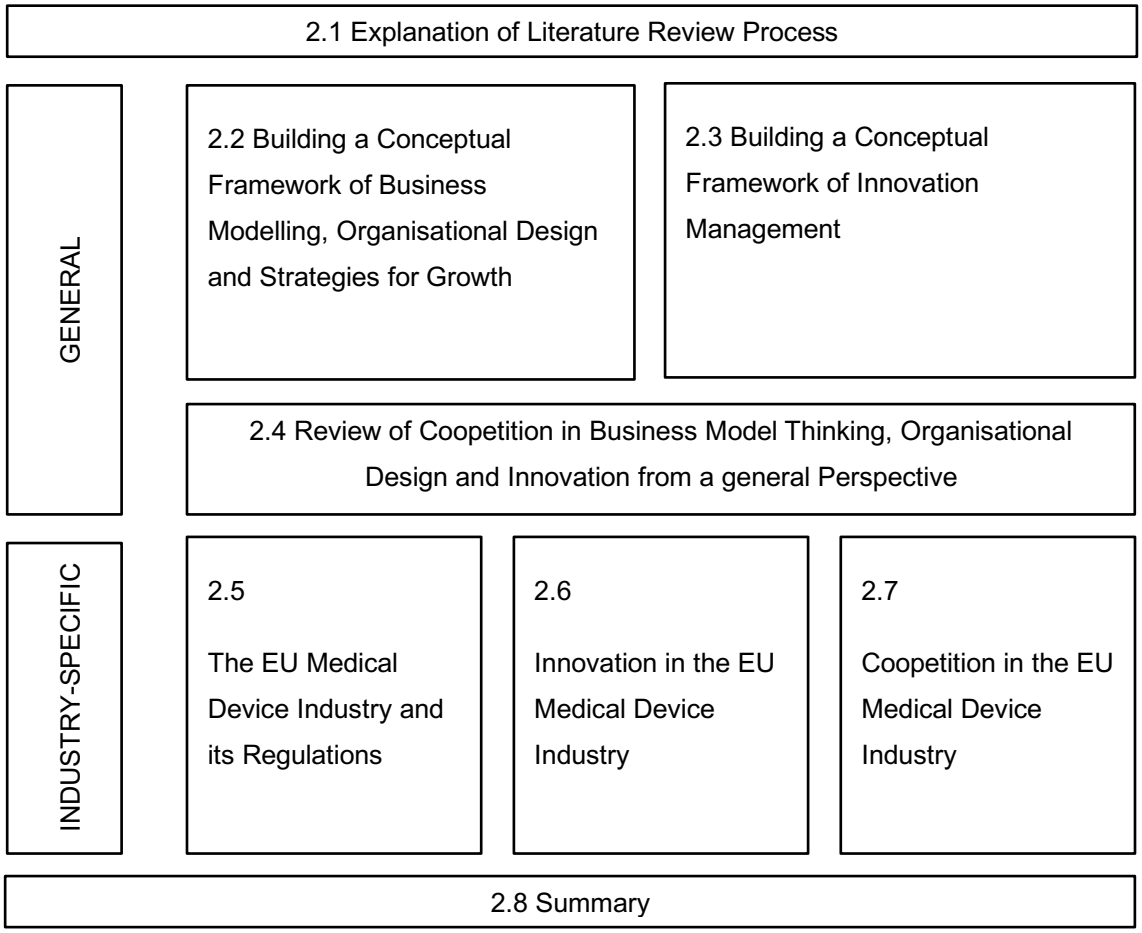

Figure 2: Chapter 2 Structure

2.1 Literature Review Process

Literature reviews provide an overview and synthesis of publications on a topic and describe the status of research and knowledge. A review does not present new data but intends to summarize and crystalize the best currently available evidence on a specific theme (Derish & Annesley, 2011; Pautasso, 2013). Therefore, a review is referred to as secondary research (Bolderston, 2008).

The two standards of reviews are (a) systematic and (b) non-systematic or narrative review (Ferrari, 2015). A systematic literature research is the planned, structured and transparent approach to the search for relevant specialist literature in relation to a research theme with the aim of ensuring the most complete overview possible, while at the same time being comprehensible to third parties (Brereton, Kitchenham, Budgen, Turner, & Khalil, 2007). This type of research is usually a first step in answering a subsequent, and more specific, research question (Kitchenham et al., 2009). Furthermore, systematic reviews tend to use specific search terms and inclusion and exclusion criteria, whereas the criteria for narrative literature reviews may not be as strict.

A narrative review has a broader approach, as it involves gathering, critiquing, and summarising journal articles and textbooks about a particular topic. These are generally undertaken to get an overview of a topic and potentially identify gaps in the literature (Derish & Annesley, 2011; Grant & Booth, 2009). Unlike systematic reviews that benefit from guidelines (…), there are no acknowledged guidelines for narrative reviews." (Ferrari, 2015, p. 230).

For this thesis a narrative literature review approach is chosen, because coopetition between medical device SMEs is an almost unexplored research topic and the ability to conduct a wider exploration could be lost in the restrictive framework of a systematic review. However, certain elements of a systematic review are of value, especially to get the review of existing knowledge started. Based on the research topic, key terms such as "coopetition management", "coopetition and innovation management", "coopetition and SMEs", etc. are applied in various relevant databases, such as Science Direct or Web of Science.

Further search criteria and limiters are set, e.g., articles published within the last 25 years, in English language, peer-reviewed and available in full-text.

The identified relevant articles are used as a preliminary base to identify other related and relevant literature, as followed in below chapters.

2.2 Business Model, Growth and Organisational Design

This section reviews major theories related to strategy, business modelling, strategies for growth, organisational structure, culture, and leadership, to build a conceptual framework for this thesis. The section is followed by major theories in innovation management and coopetition from a general perspective, before reviewing the EU medical device industry, the new regulations and how innovation and coopetition in this sector have been studied so far.

2.2.1 Strategy and Business Model Thinking

Strategy is described as the organisation's purpose, and strategic management as the process of identifying that purpose and devising plans and actions to achieve it (Lynch, 2018). As suggested by Child (1997), strategy should be a continuous process.

This description infers that strategy is developed by analysis of the industry environment, such that Johnson, Scholes and Whittington (2008) portrayed it as the long-term direction and scope that achieves advantage in a changing environment by the manner in which the individual firm uses its resources and competences. These resources (Barney, 1991) and competences (Hamel & Prahalad, 1994) are the means of differentiating the firm from its competitors because they are unique to the firm, developed and adjusted over time to exploit changes in the external environment, and impossible to imitate.

The idea of strategy as a long-term plan has been questioned because the future can be very uncertain. Therefore, Eisenhardt (2002) suggests that strategy is about intuition, exploiting the best opportunities in uncertain situations,

experimenting with different ideas, testing them for a short time and if they are not successful in creating value and competitive advantage, replacing them with new strategies.

In contrast to strategy, the literature indicates that the idea of a business model is not a well-defined term, partly because it is a relatively new concept, which has undergone sparse research (Wirtz, Pistoia, Ullrick & Gottell, 2016). According to Casadesus-Masanell and Ricart (2010) a business model represents the organisation's purpose, because it is associated with the strategic choices made to generate competitive advantage. Johnson, Christensen and Kagermann (2008) also propose that a business model is linked to strategy. They suggest that it cannot be decided until an important opportunity is identified, which will satisfy the need of real customers. As Johnson et al. (2008) claim, strategy is a plan of how the company will fulfil that need, and as a profitable venture. The product or service that can accomplish the end-users' requirements could be new or a suitably modified existing one.

The associated business model comprises four integrated elements that create and release the value required and must be identified by the company executives: the customer value proposition; devising the formula for making a profit from the venture; identifying key resources; identifying major processes. The profit formula is obtained by multiplying the price by expected volume of sales, establishing the direct and indirect costs including economies of scale, calculating the profit margin and the time taken for resources to be used to meet targeted volume requirements. The major resources that will facilitate the defined customer value in a profitable manner are identified as people, technology, information, distribution channels, partnerships or alliances and brand (Johnson et al., 2008).

The business model concept of Johnson et al. is relevant to this research because it specifies the business model elements, which include the critical factors of alliances, skilled and knowledgeable people, partnership, and technology as outlined above. The vital processes include design, product development, sourcing materials, manufacturing and marketing/distribution plus any associated rules including regulation, supplier terms and conditions and size of opportunity required for investment (Johnson et al., 2008).

A similar concept of business model is introduced by Osterwalder and Pigneur (2010). It is presented as a simple description of the activities that the firm must take to create products and services, by means of employing its unique resources and competences to ensure that it has competitive advantage in the related market. These ideas infer a cause-and-effect link between business model development and competitive advantage, in other words performance outcomes (Casadesus-Masanell & Ricart, 2010).

A synopsis of the major elements associated with business model facilitated a definition: business models are ”simplified representations of the value proposition, value creation and delivery, value capture elements and interactions between these elements withing an organisational unit” (Geissdoerfer, Vladimirova & Evans, 2018, p. 402). A sustainable business model is an extension of the standard business model definition in that it includes monetary and non-monetary value for stakeholders in the long term (Geissdoerfer et al., 2018). These definitions of business model suggest that sustainable business models would be characterised by operations, which must be cost efficient, and optimise resources and productivity, and by innovation focused on the identification of new business model characteristics, which are superior to the existing model (Chesbrough, 2010). Large innovation projects, for instance new products or services, require appropriate strategic management to ensure that all elements within the business model are suitably aligned because innovation projects are more challenging than other organisational diversification activities (Mitchell & Bruckner Coles, 2004; Osterwalder & Pigneur, 2010).

Hence the definition of ‘sustainable business model’ for this thesis is the implementation of strategy that has the purpose of managing medical device innovation in a way that is more cost efficient, and optimises internal and external/coopetition resources, productivity, and the opportunities of new EU legislation.

2.2.2 Strategies for Growth

The survival of many medical devices companies, particularly the SMEs which dominate the sector, is dependent on being able to quickly adapt to new regulation, increasingly fierce global competition, and high rate of innovation, as indicated in chapter one already. Companies in the industry employ various strategies to answer these challenges (Fernández et al., 2019). This research focuses on coopetition as the potentially most advantageous type of growth/survival strategy for medical device SME to exploit the opportunities represented by the new legislation and to minimise threats, for instance lack of access to investment and limited knowledge (Miglierini, 2018; EC, 2014).

However, there are several established options for growth and/or new market entry: organic growth, M&A, joint venture, equity alliances, non-equity alliances, and licensing and franchising (Whittington et al., 2019). The selected growth strategy is frequently based on the organisation lifecycle and the perceived level of risk of each alternative, with organic growth being considered the highest risk and export, e.g., of products, the lowest risk (Whittington et al., 2019; Lasserre, 2017). Thus, organic growth generally requires a large investment in resources, especially employee knowledge and skills in the case of the SMEs in the EU medical devices sector, as well as physical resources such as equipment.

Frequently firms open subsidiaries in other countries to accomplish the expansion at lower cost and/or to establish market presence nearer to the end user. The advantages are that the company has complete control of the venture, is able to use the latest technologies, can attract and develop new staff according to its standards, and build its reputation with customers. The firm that decides to expand its operations in another country may also attract tax or other incentives from the host country's government but in this case the major challenges include political risk of asset seizure and government bureaucracy (Whittington et al., 2019; Lasserre, 2017).

In all cases of organic growth, initial performance outcomes are likely to be lower than expected and may cause cash flow problems. A major operational issue in overseas expansion is the cultural difference, for instance difference in workplace practices and expectations, and management (Whittington et al., 2019; Lasserre,

2017; Lynch, 2018). Those issues can prove to be prohibitive for the expansion of SMEs, simply due to the lack of knowledge and resources, regarding coping with related risks.

One of the major strategies employed by large medical technology manufacturing companies to leverage successful innovation outcomes is by Merger and Acquisitions (M&A), an established approach to rapidly leverage innovation rate, speed to market, and profitability (Fernández et al., 2019; Whittington et al., 2019). M&A can produce quicker results than organic growth, especially in fast growing markets, since the M&A partner is already established (Lynch, 2018) and has complementary resources that will enable altering the business model (Johnson et al., 2008). Merger is distinguished from acquisition since it is a friendlier arrangement, in which neither firm has the assets to acquire the other, but the opportunities and risks tend to be very similar (Lynch, 2018).

The cultural differences and hostility associated with some M&A activities have proven to be extremely detrimental owing to different values, beliefs and working practices, so that the acquisition does not produce the forecast financial outcomes, as demonstrated by Porter's (1987) longitudinal empirical research of large company M&A activities and outcomes. An additional aspect emphasised by Das and Teng (2000) is that the acquiring firm or major partner in the merger may acquire skills that hinder growth because they are not appropriate to the new operation.

As presented in Figure 3, from 2013 to 2017, an average of 2,700 M&A transactions occurred in the medical device sector (Medical Device Network, 2017a). Investment in the industry is relatively weak compared with other manufacturing sectors and the activity has declined more recently as private investors and large medical technology companies remain cautious about the return to be gained from either acquiring smaller medical device companies and start-ups, or investing in them (Medical Device Network, 2017a).

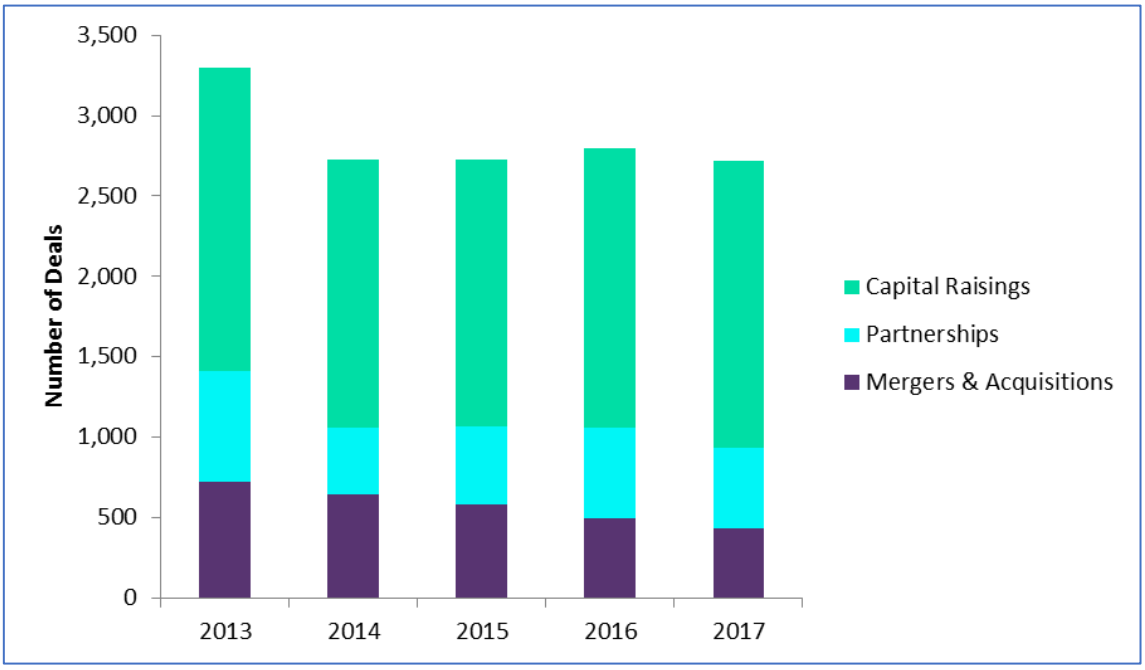

Figure 3: Declining M&A Activity in Medical Device Manufacturing Sector

Source: Medical Device Network (2017a, p. 1)

In Europe, the purpose of M&A activity was not merely innovation but related to access to new brands, products and services and new markets and new verticals (IMAP, 2019). New verticals refer to markets in which a group of companies operate across multiple industries representing vertical integration in the value chain, which would apportion R&D costs across the whole value chain and increase efficiency and purchasing power. Verticals comprises companies that provide “technology designed to improve healthcare outcomes, reduce costs and maximise output” (Pregin, 2020, p. 28) and includes health intelligence platforms, exam room technology, patient wearables and other related solutions (Preqin, 2020). The choice of strategic partners made by some manufacturers may also involve competitors, adopting a strategy referred to as coopetition (van den Heuvel et al., 2018), the major underlying concept of this thesis.

A traditional characteristic of medical device companies is that they are the most likely of all manufacturing companies to prioritise research and development (Stirling & Shehata, 2016) but this has become more difficult with new regulation (De Maria et al., 2018). Brown, Eatock, Dixon, Meenan and Anderson (2008)

forecasted that with regards to new regulation the medical device industry was to innovate new devices manufactured with a lean approach, which would also minimise national healthcare costs (Deloitte, 2018). Therefore, solutions other than M&A are considered.

Joint Venture is a form of strategic alliance, since its purpose is to accomplish agreed goals, and because it is created by agreement of the participating companies, which both own shares in the joint company (Lynch, 2018). Joint venture is one form of strategic alliance, generally referred to as partnerships that may also include equity of non-equity joint working situations (Uddin & Akhter, 2011; Pellicelli, 2003). Strategic alliances may be characterised by weaker contractual arrangements than joint venture, or by minority shareholdings and are developed for a specific purpose, for instance market expansion or access to certain technologies or skills (Lynch, 2018; Whittington et al., 2019).

The advantages of joint venture strategy are that the partners share financial risk. Also, they can access new skills and knowledge, which are especially advantageous when these complements rather than substantially overlap, since the potential for innovation and much increased competitive advantage is higher (Lasserre, 2017; Grant & Baden-Fuller, 2004). The integration of the two companies' employees may be challenging and lead to lower productivity than anticipated, but the most critical disadvantage may be that one partner acquires important skills and knowledge that enable it to become a competitor in the longer term; this is a common occurrence when an organisation expands into a new country and market where the other partner is established (Whittington et al., 2019).

Alliances have the advantage of building close working relations, joint learning and locking out other competitors (Lynch, 2018). However, the acquisition of new knowledge by the strategic alliance, is the means for one or more of the partners to attempt to exploit it for self-interest. In the case of non-equity alliances, this is especially possible, since each organisation retains its independence and competes in the same market (Pellicelli, 2003). Non-equity alliances may be short term arrangements for a specific purpose and include several organisations or business units, a traditional example is outsourcing (Pellicelli, 2003; Lynch,

2018). Additional disadvantages of alliances are that maintaining the relationship requires both organisations to constantly attempt to collaborate harmoniously; progress may be slow and there is little opportunity for economies of scale (Lynch, 2018).

Licensing and franchising tend to have similar advantages and disadvantages. Licensing includes selling the firm's intellectual property rights to an individual or organisation and being an authorised company agent who takes orders for its products and services (Whittington et al., 2019; Lynch, 2018). In contrast, franchising occurs when a company allows an entity to sell its goods/services to the public in the same country or other countries. The major advantage of licensing and franchising is that financial risk is minimised, whilst market awareness of the product/service is enhanced, and/or the firm can test another market. However, the major disadvantages are that the original company gains no expertise in how to market successfully in other contexts, and the franchisees' quality standards may be lower and harm the brand. Agents or franchisees may also copy and/or upgrade the product/service to the local context, locking out the originator (Worthington & Britton, 2009; Whittington et al., 2009; Lasserre, 2017; Lynch, 2018).

Affiliation is a growth concept linked to franchising and licensing, where an established organisation arranges for smaller independent companies operating in the same business sector to offer their products/services under its name (Carney, Gedajlovic, Heugens, Van Essen & Van Oosterhout, 2011); this may be a formal or informal arrangement. Hotel brands have used this concept to increase their available locations, and small hotels benefit from greater scope to attract tourists. The main brand handles all the booking administration, meaning that small companies can access tourists globally (Yakhlef & Maubourguet, 2004).

As can be seen from the literature review above, the position of SMEs in the EU medical devices sector, and the necessity to innovate to survive and prosper, infer that organic growth, licensing and franchising are unsuitable options to resolve their challenges, because SMEs miss operational knowledge and/or financial resources required to cope with risks involved in expanding (Whittington et al., 2019; Lasserre, 2017). M&A and/or strategic alliances are alternative

options, however, while solving many issues, they create other threats for success as outlined above (Fernández et al., 2019; Lynch, 2018; Whittington et al., 2019). The medical device industry is in need for business models and growth strategies that enable the adaption to new regulation, increasingly fierce global competition, and high rate of innovation. Therefore, this research focuses on coopetition as a potential new way to secure survival and growth.

2.2.3 Organisational Structure

The structure of an organisation indicates the way it functions and how it influences the behaviour of individuals working in it. The units comprising the organisation also impact on its efficiency, effectiveness, and employee morale (Dalton, Todor, Spendolini, Fielding & Porter, 1980). Structure is perceived as having two dimensions: one is the physical design, which refers to the organisational dimensions, the other is the management span of control, type of hierarchy and extent of bureaucracy or usage of administration (Campbell, Bownas, Peterson, & Dunnette, 1974). Therefore, organisations can be described as systems characterised by relationships between the various physical and human elements; composed of hard and soft components, where hard refers to the tangible hierarchical units and groups, and soft to features such as human judgement (Tran & Tian, 2013; Ahmady, Mehrpour & Nikooravesh, 2016).

Organisational structure in the context of its size has also been traditionally associated with the extent of a firm's bureaucracy and capacity to change, small companies being far more likely to change than large ones (Zaradis and Mousiolis, 2014). In contrast, large organisations have access to more physical and human resources and much greater capacity to exploit new opportunities and markets. However, the extent that they do so is dependent on the degree of bureaucracy, of structural inertia, and generally organisations are slower to change than the external environment (Haveman, 1993). Organisational size has also been associated with senior management capacity for engendering innovation (Vaccaro, Jansen, van den Bosch & Volberda, 2012). These are important general aspects of organisations that

are relevant to this thesis, as both large and small organisations operate in the medical devices industry, with varying organisational cultures and structures.

Many traditional organisational models focus on functional activities of the company, for instance finance, sales and marketing and manufacturing, or on divisions relating to product groups or geographic regions, using the rationale that key tasks can be divided amongst the employees, coordinated, and accomplished to a given standard. These structures are based on the need for planning, organising, directing, and controlling activities (Mullins & Christy, 2016). The structure chosen must be the one considered to generate optimum performance and competitive advantage, and therefore is a crucial decision, with different criteria as the company size grows (Whittington et a., 2019); structure also determines the lines of communication between divisions or departments, between employees, and the links with senior management (Mullins & Christy 2016).

The design of an appropriate organisational structure to optimise the firm's alignment with the environment and accomplishment of its strategies, was satisfied by the implementation of six objectives according to Mullins and Christy (2016). It must facilitate: achieving the financial objectives by means of efficient operations aligned with resource allocations; monitoring activities regularly and accurately; supervising the accountability of individuals and groups in relation to their organisational responsibilities; coordination of units and their workplaces; future change associated with environmental change or growth plans, and therefore characterised by flexibility; a motivated labour force generated by an agreeable social environment. The social and structural characteristics influence the firm's distinct culture (Schein, 1985), which is reviewed in detail in the next section of this thesis. The characteristics also define the interaction with external forces, which are major success or failure factors (Mullins & Christy, 2016).

A study by Mintzberg (1999) found six typical organisation structural elements as presented in figure 4, which must be organised in a consistent manner based on the nature of the firm.

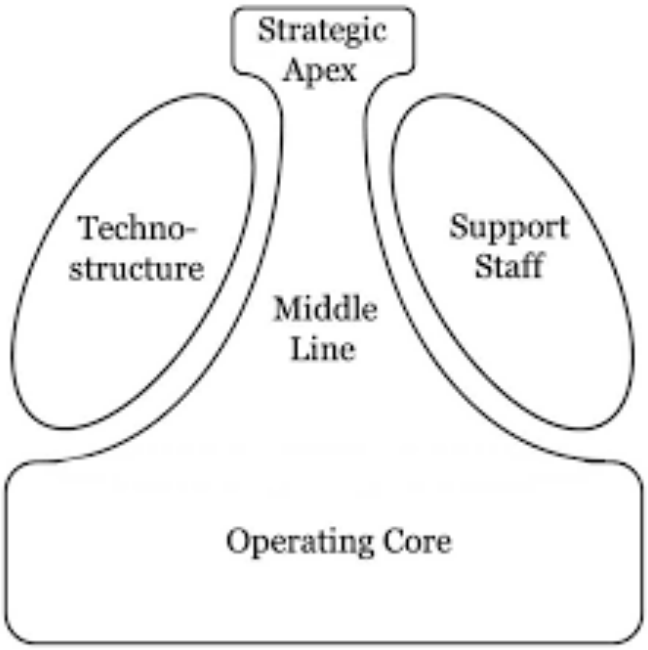

Figure 4: Fundamental Organisational Design Elements

Source: Mintzberg (1999, p. 3340)

The strategic apex represents the formal leader(s) of the organisation, who manage(s) all the activities, one person in a small firm and a senior management team with a person designated as leader in larger companies. Depending on the context, the operating core may report directly to the member(s) of the apex or by means of series of managers who report to the apex; a typical example is a small/micro enterprise of less than 10 people controlled by the owner, growing to a small business of under 50 employees with a small group of middle managers (EC, 2014), the middle line (Mintzberg, 1999).

The technical level and support staff groups are closer to the apex and to middle managers because they both offer specific services to the entire organisation but have no direct influence on the operating core. The technical level monitors and co-ordinates the tasks performed by the operational core and middle managers, and the support staff provide services such as legal advice, catering, and public relations. The sixth element, ideology comprises organisation values and beliefs that characterise it and differentiate it from other firms; its organisational culture (Mintzberg, 1999).

2.2.4 Organisational Culture

With regards to the concept of culture, many interpretations exist, and it is often assumed to be an inherited phenomenon. However, the anthropological perception of culture is that it is not a genetic characteristic but is learnt by individual exposure to other human beings and life experiences (Hall, 1997). Culture is defined by Serrat (2017, p. 32) as the combination of “a society’s distinctive ideas, beliefs, values, and knowledge. It exhibits the ways humans interpret their environments.”

Culture is linked with many academic disciplines, for instance sociology, the political economy and communication, and is applied to make sense of phenomena associated with gender, ideologies, nationality, and social class. An understanding of culture enables development of appropriate management and policies in a variety of contexts including commercial business organisations (Serrat, 2017). Hence culture is linked to a range of human preferences, which also include education and professional disciplines (Doole & Lowe, 2012).

The learnt behaviour associated with culture is compared with software programming by Hofstede, Hofstede and Minkov (2010) who perceive cultures as programming of the mind in a collective sense, but also stress that individuals can reject the ideas, and that culture changes over time as individuals experience new phenomenon. The inference was that the perceptions and behaviours of individuals belonging to a particular group are not always predictable and based on specified norms (Hofstede et al., 2010).

A similar description of culture in organisations is offered by Schein (1985) and outwardly characterised by standardised language and work behaviours, relationships with customers, and processes and procedures that must be adhered to. These characteristics were often attributed to the founder, although some change may have occurred over time, but this would be the result of the formal leaders reshaping the culture to meet changes in the environment, which Schein (1985) proposed was the leader’s predominant responsibility.

Three levels of culture are suggested by Schein (1985). The visible culture of the firm is evident from the symbols and artefacts, for instance the building design,

arrangement of offices, logos, language, and degree of technology employed. The second level is related to corporate values, the actions to be taken in each situation, a new issue, and uncertainty as to the most effective solution. The third level is tacit assumptions, the underlying values, and beliefs (Schein,1985).

When an appropriate solution is developed it would be tested numerous times before being accepted as consistently successful. Hence, once proven, all similar events would be automatically resolved in the same way, in an unconscious manner (Schein, 1985); the accepted solution becomes the theory in use, which restricts learning and adapting to change in new situations (Argyris & Schön, 1978). Sub-cultures also existed within the organisational culture, a consequence of specialist expertise and of geographical locations.

Although Schein's (1985) perception of organisational culture is regarded as a major contribution to understanding the phenomenon and why culture-change in organisations is a significant challenge, the level of detail on how change can be affected is more evident in the cultural web concept of organisation offered by Whittington et al. (2019), which is presented in figure 5. This enables a firm's culture to be scrutinised, by examining each of the elements individually.

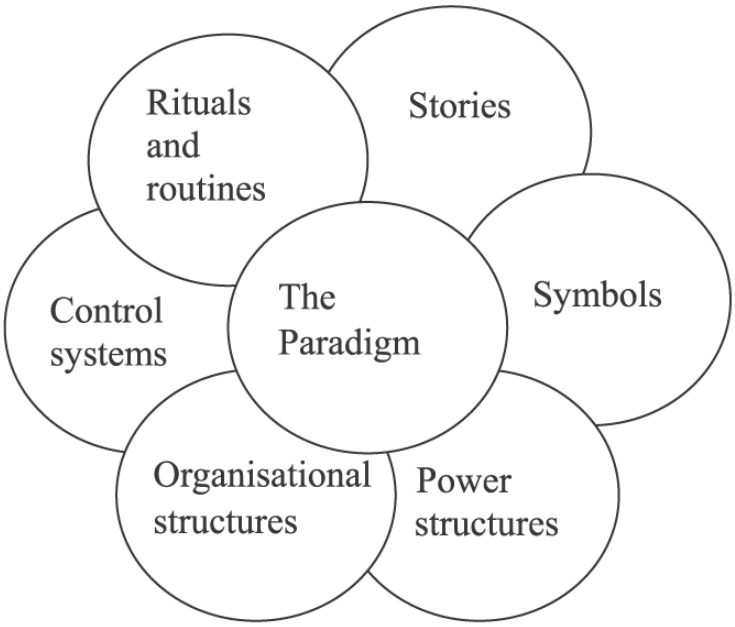

Figure 5: The Cultural Web

Source: Whittington et al. (2019, p. 173)

The paradigm is at the core of all the values and beliefs that underpin organisational behaviour and aligns with the level of basic assumptions in Schein's (1985) model. Stories are concerned with specific, significant historical events, for example the successes of the founder, and are the basis of acceptable corporate values and behaviours, often forming part of new employee indoctrination programmes. Symbols are people or objects with which the organisation identifies, or aspects of its strategy that it emphasises, whilst rituals and routines are the major processes that are emphasised and learnt by employees in development programmes. Control systems, what is monitored and how, but also the extent of control, and organisational structure relates to the formal hierarchy and the informal communication channels, its rigidity also revealing the underlying beliefs of the firm. Power structures, the location of power relation to resources, status, and symbols and, reflect which individuals are able to mobilise activity, and which can prevent it (Whittington et al., 2019). These models enable comprehension of the facilitators for, and barriers to, change which may exist in EU medical device companies.

Organisational culture is also approached from a national cultural perspective by Hofstede et al. (2010), representing an additional perspective, which is particularly relevant to understanding different approaches to medical device design and regulation in the diverse nationalities of the EU member states. This model is empirically based on research conducted in more than 80 countries for over 40 years and comprises six dimensions of culture: Power Distance (PDI), Uncertainty Avoidance (UAI), Individualism (IDV), Masculinity (MAS), Pragmatism or Long-Term Short-Term perspective (LTvST) and Restraint versus Indulgence (RI). Each of these is a continuum, and each country given a score along the continuum (Hofstede, 2020; Hofstede et al., 2010).

Hofstede's research on national cultural differences is of great importance to this study because companies with different national cultural origins have been found to have greater challenges in implementing coopetition (Ritala, 2012). An aspect, that is further reviewed in section 2.4.1.

2.2.5 Leadership and Management

Leadership has been defined in numerous ways. It was described by Stogdill (1997) as being the influential factor that supported an organised group to set and accomplish specified goals by means of completing differentiated tasks. Leadership is also defined in terms of two distinct responsibilities, leadership, and management (Kotter, 2012). The main groups of theories are summarised in table 2, with an indication of what the theory communicates about leadership.

Table 2: Summary of Groups of Leadership Theories

Approach	Predominant Focus	Main Theories
Qualities or Traits	Who the leader is	Great Person Theory, Trait Theory
Functional	What the leaders does and how	Action Centred Leadership
Behavioural	What the leaders does	McGregor: Theory X and Theory Y (1960); authoritarian, democratic and laissez-faire styles; tell, sells, consults.
Style	How the leaders lead organisations	Blake & Moulton (1961); Hershey & Blanchard (1988)
Contingency	When the leader acts, under which circumstances	Fielder (1967), Vroom & Yetton's (1973) contingency models, Path-Goal Theory
Transitional/ Transformational	Who leads, what s/he does and how	Leaders re-energise and transform organisations
Inspirational or Visionary	Leadership and followership	Charismatic/inspirational leadership
Psychological Leadership Approaches	Leadership and followers	Narcissistic, ethical, and authentic

Sources: Mullins & Christy (2016); Adair (1973); Northouse (2021); Rosenthal & Pittinsky (2006); Hernandez, Eberly, Avolio & Joh (2011)

The first five approaches focus on the single leader and describe leadership related features. The first category trait theories are most appropriately represented by Great Man Theory, indicating that leaders were always male, a characteristic that has been revised as Great Person Theory. The focus is on who the leader is and exceptional personal qualities (Mullins & Christy, 2016; Day & Zaccaro, 2014; Kirkpatick & Locke, 1991). These leaders had heroic, legendary status, and comprised great industrial and political leaders. Trait theories generally concentrated on the person rather than the role or the context of the firm and tended to be highly subjective.

Analysis of trait theories over 56 years by Northouse (2019) revealed a change in their nature: in the early period intelligence, extrovert character and masculinity were frequently mentioned, whilst from 1991 to 2004, masculinity had disappeared and cognitive ability, knowledge, emotional intelligence, problem solving, openness and integrity were identified with exceptional leaders (Kirkpatick & Locke, 1991; Zaccaro, Kemp & Bader, 2004). Therefore, the contemporary leadership traits, personal qualities, have relevance to leaders in the 21st century as they are more knowledge and skills based, to enhance relationships and motivation in organisations and in inter-organisational cooperation (Goleman, 2005).

Functional leadership is characterised by what the leader does, the nature of the group and recognises that leadership can be learned and developed (Mullins & Christy, 2016). Since the leader is fully engaged with the group, mutual learning is possible and team members can develop leadership skills. The most frequently employed theory in this category is Action Centred Leadership, a process represented by three overlapping circles: the organisation and its purpose, team building and employee skill development (Adair, 1973). The strength of the theory is its simplicity, whilst its key limitations are that the formal leader must have the skills and motivation to share leadership and leadership power with the team.

The behavioural theories are exemplified by Theory X and Theory Y in which the leader treats employees according to how he perceives their attitude to their job and consequent behaviour (Mullins & Christy, 2016). Theory X leaders assume that employees do not like to work or taking responsibility and must be centrally

controlled to follow a specified system of rules and procedures. In contrast, leaders applying Theory Y consider that the worker is self-motivated, accountable and can be left to organise and complete own tasks effectively. The theory X leader is focused on achieving the task outcomes and performance, whilst theory Y leader considers his role is to motivate. Although these are extreme behaviours, they have practical application in context, for instance a tedious, repetitive unskilled job may invoke a Theory X approach or a version of it. In contrast Theory Y would be a reasonable approach to leading skilled and professionally qualified personnel, a more participative approach (Mullins & Christy, 2016; Morse & Lorsch, 1970; Northouse, 2021).

Both theories have limitations, for instance the theory X manager may exploit workers and/or demotivate them, whilst the theory Y manager could avoid making decisions or fail to support employees to find appropriate solutions to issues that they encounter, in other words, neglect leadership decision making responsibilities and employee support for effective problem solving (Mullins & Christy, 2016; Northouse, 2021).

Style theories of leadership also promote the concept of a best leadership approach and relate to how the leader accomplishes the strategic objectives through the workforce. One of the major examples is Blake and Moulton's (1964) managerial grid comprising two themes: making sure that the employees understand the task to be achieved and developing appropriate relationships to do so; four major situations emerge and imply a similarity to contingency theories of when to apply a certain approach, how to lead (Northouse, 2021).

High concern for people and low task focus is associated with Country Club Management because there is a friendly and supportive atmosphere but low focus on completing the task. Team management was therefore considered the most effective leadership style and is likely to be most appropriate in agile organisational structures (Morris, Ma & Wu, 2014).

Contingency theories are predominantly situational and therefore no specific leadership approach is considered appropriate for all contexts. The leader adopts the characteristics needed to accomplish objectives, inferring that there is a

correct leadership style for a specific set of variable situational factors (Northouse, 2021). The limitation of Contingency theories is that they assume that leaders have the knowledge and skills to practice what is effectively a continuum of leadership behaviour (Mullins & Christy, 2016). The variables associated with contingency theories include the skills of employees and how well they understood their responsibilities, the level of employee commitment, their capacity to work as a team, how the task is organised, availability of resources, extent of coordination with other groups, and the readiness of employees to be led (Northouse, 2021; Mullins & Christy, 2016; Yukl & van Fleet, 1992).

The limitations of this theory are that it is only weakly validated by empirical studies, the concept of maturity is not well defined, and many situational variables are omitted. Consequently, it fails to provide consistency between leadership behaviour and effectiveness as the context alters (Yukl & van Fleet, 1992). However, the idea of evaluating employee readiness for the coopetition situation is a valid leadership approach, provided the leader has the skills to assess them and the criteria on which to base readiness, as highlighted by Yukl and van Fleet (1992).

Transformational leadership is fundamentally associated with culture change, in contrast to transactional leadership, which operates to the existing structure and norms (Bass, 1985); this aligns with Schein's (1985) proposal that leadership is concerned with culture change as the only priority. Therefore, transformational leaders appraise the existing culture in the context of the environment and aim to realign its values and beliefs with future needs (Bass, 1985; Kotter, 2012). Consequently, transformational leadership relies on the concept of leaders influencing employees to accomplish a vision of the future shape of the organisation that the leader creates. Employees become committed to accomplishing the vision on a voluntary basis because they have a highly positive opinion of the leader; he is considered inspirational and employee performance is consequently higher than might be expected (Bass, 1985; Kotter, 2012).

Transformational leadership is characterised by four elements (Bass & Avolio, 1994): idealised influence, motivational inspiration, intellectual stimulation, and individualised consideration. Idealised influence is a consequence of the leader's

charisma, personality traits that attract followers and gain their respect. Charisma comprises qualities such as strong values relating to right and wrong, exceptional communication skills that inspire collective action and achievement, and non-verbal signals that provide authenticity to the message relayed (Antonakis, Bastardoz, Jacquart, & Shamir, 2016; Connelly, Certo, Ireland & Reutzel, 2011). Motivational inspiration is accomplished by leaders providing meaning to the follower's work tasks and making them challenging, so that they remain intellectually stimulated because they understand that the leader expects them to be creative. Individualised consideration is the leadership quality that demonstrates his/her concern to facilitate personal growth and development appropriate to everyone (Bass & Avolio,1994).

Leadership in this sense is also associated with two roles, leadership and management (Kotter, 2012; Mintzberg, 2009). The leadership function, according to Kotter (2012), is to create a sustainable organisation by developing a long-term vision of the future direction that followers can understand and support, whereas the management function is to stabilise the current organisation by ensuring the short-term objectives are met by means of providing resources, appropriate processes and procedures and monitoring and evaluation.

In this context, there is an implication that leader follower relationship must be strong to optimise performance, whilst the term follower could have a weak connotation (Northouse, 2019); five different levels of follower were identified by Gobble (2017) and have relevance to how followers in companies working in coopetitive arrangements might support their leaders and those of other companies in the coopetition.

The five categories of follower are sheep, alienated, yes person, survivor, and effective follower. Sheep tend to be passive and obey instructions, whilst alienated followers are unhappy with most aspects of their leader, and yes-employees follow the leader's decisions and ideas without questioning them. In contrast, survivors are politically motivated and change their views to parallel those of the current leader to gain their approval and, therefore, make little contribution to enhancing organisational performance. The effective follower is a

critical thinker, who expresses their own thoughts and ideas, questions those of the leader in a positive manner, is proactive and self-motivated (Gobble, 2017).

2.2.6 Contemporary Approaches to Organisational Design and Growth

The approaches to organisational structure, culture and leadership as described above as well as the types of growth strategies described in section 2.2.1 are predominantly classical, well established and employed in many firms of all sizes globally (Whittington et al., 2019). However, it is questionable whether they meet the demands of the highly dynamic and fast-moving business environment that prevails in the 21st century (Jackson, 2002). Developments in the information technology space, including high capacity for data processing and ever-increasing quantities of information available have led to new business models in the past 20 years and novel ways of configuring the fundamental elements of organisations (Strikwerda, 2012).

The business environment has moved from the manufacturing age to the information age, in which acquisition and application of knowledge is the means to competitive advantage (Kotter, 2012). Knowledge workers are characterised by their capacity to generate and share ideas and information, are mobile and move from company to company, rather than pursuing career development by aspiring to senior management positions in an organisation's apex (Serratt, 2017). Knowledge workers are important to this thesis since they were identified as being focused on innovation and value creation, especially in conditions of uncertainty (Bryan & Joyce, 2005) when innovative ideas must also be commercialised and brought to market as fast as possible (Hatami, McLellan, Plotkin & Schulze, 2014).

However, the objective to innovate and commercialise new ideas before competitors may be constrained by organisational structure; tall structures inhibit fast communication and decision making (Bryan & Joyce, 2005). Divisional or departmental data often belonged to the unit rather than to the whole organisation and/or the company was characterised by a culture of low cooperation and low collaboration. Structures that facilitate innovation and knowledge transfer need to

be cross functional and flat (Bryan & Joyce, 2005). Moreover, matrix organisations or other semi-traditional cross functional arrangements are not ideal configurations for innovation and knowledge workers, since there may be two or more senior managers at the apex with conflicting ideas, and this reduces the speed of innovation activity (Bryan & Joyce, 2005).

A highly flexible flat generic design, which integrates some traditional ideas, whilst providing for access to resources shared by all employees, is suggested as a solution by Strikwerda (2012) and is shown in Figure 6. As can be seen there, strategy is directly related to the organisational design, internal governance management methods and to the business model, with the objective of successfully generating the targeted profits. Processes are focused on leveraging customer value. Generic resources, especially technologies, are important to the information space so that employees have real-time connectivity and are associated with manufacturing and the assembly of products.

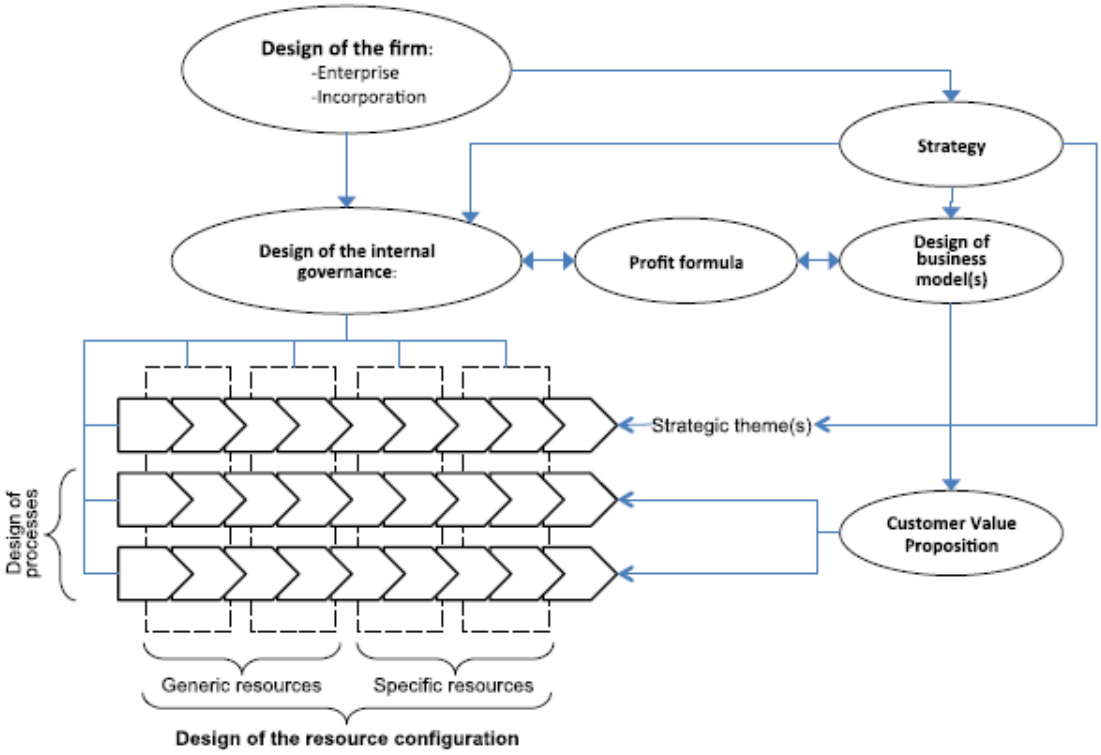

Figure 6: 21st Century Generic Organisational Structure

Source: Strikwerda (2012, p. 148)

The links between the model above and traditional organisational structures is more evident in Figure 7. Here, the business model is concerned with innovation and directly linked to investment in human capital, which links to other business models, exploitation of opportunities and experimentation. Experimental bias, associated with innovation, is focused on technology, markets, products/services, and end users, to quickly identify key business opportunities, which represent to generate revenue streams (Strikwerda, 2012). The firm's assets consisting of intangible information capital represented by knowledge workers, and tangible hardware and software assets that facilitate information and idea sharing. This design intensifies the opportunities for knowledge worker collaboration, and information exchange between all key stakeholders (Strikwerda, 2012).

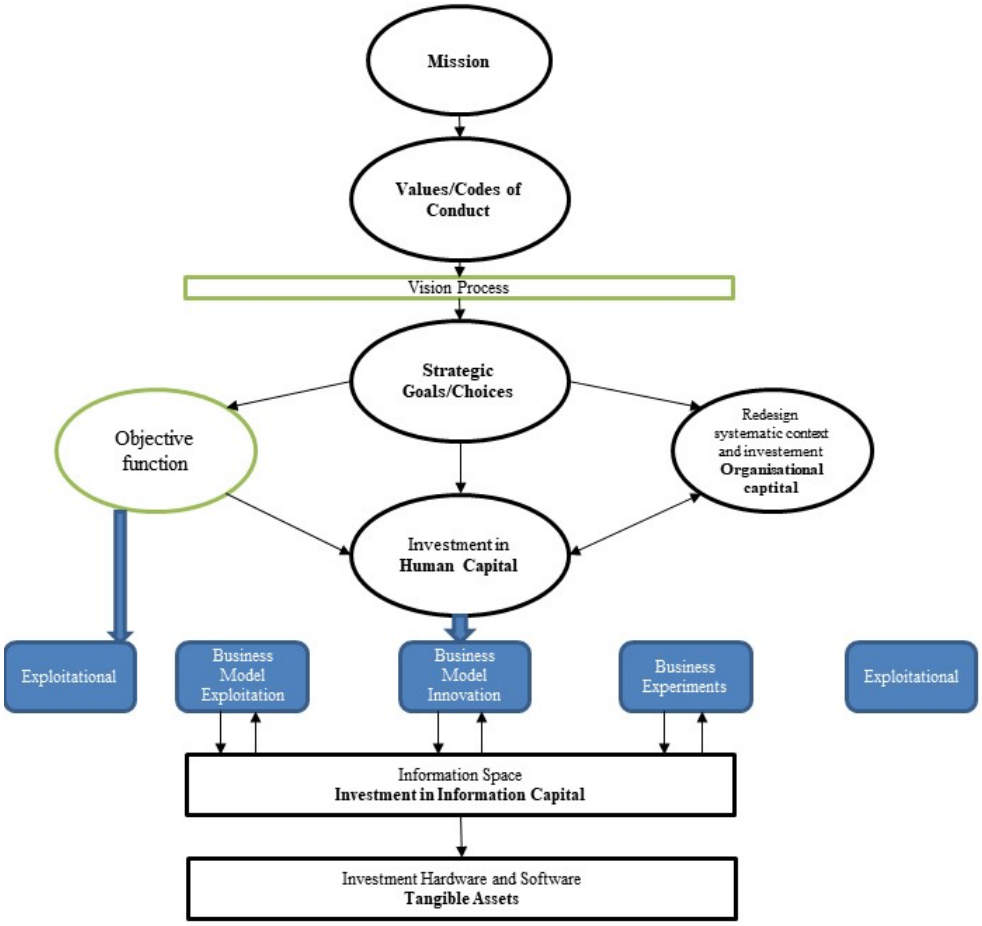

Figure 7: Organisational Design

Source: Strikwerda (2012, p. 154)

Technology development has also driven the growth of the virtual organisation in which leaders and employees are in different spaces geographically but networked into one working space by means of technology; this may occur for most or all working days or periodically (Walker, 2006). Although Walker (2006) found that virtual working was predominantly an extension of the traditional company located in physical buildings, over time technological advances and the recent pandemic have accelerated the growth of virtual companies. Virtual organisations are those in which employees communicate by means of video-conferencing and other tools and may never or rarely meet physically. This is another potential configuration for SMEs to collaborate and cooperate with other firms of varying sizes in a highly cost-effective manner (Walsh, 2020; Newman & Ford, 2021; Burma, 2014).

However, several disadvantages are associated with virtual teams including: the difficulty of managing the team members and measuring their individual performance; preventing employee health from declining as they are isolated; employees having trouble in managing their space to separate work and domestic commitments; working in different time zones.

On the other hand, virtual teams can enable substantial organisational flexibility, higher productivity, and facilitate high levels of cross-functional activity and expertise (Townsend, DeMarie & Hendrickson, 2000; Kniffin et al., 2021). In terms of collaboration with other organisations, firms have the option to employ knowledge workers and/or to work with other companies in lower cost locations (Burma, 2014), which is a potential advantage for medical devices SMEs attempting to innovate at optimum cost levels.

In a general perspective, innovative firms in the 21st century need to be agile organisations, rather than hierarchies (Aghina et al., 2018) and generically the organisational structure should be characterised by: a fundamental structure that facilitates employee interaction and knowledge sharing; shared vision and resources; team composition changing on a regular basis to reflect the task/market, resources are also allocated in a similar manner; team members are highly motivated because task have meaningful and leaders inspirational; internal competition between employees and regular individual and team performance

reviews (Aghina et al., 2018). The inference is that agile organisations tend to operate on new customer focused values, and principles and practices, that eliminate the tradition command and control hierarchy, hence leaders of agile organisations have different mindsets, attitudes and cultural values that focus on innovation (Rigby, Sutherland & Takeuch, 2016).

Open boundary design is a particularly interesting agile organisation concept for SME medical device companies to collaborate and cooperate with others, since it is intended for manufacturing companies, which required alliances with other firms or parts of the product development cycle, and to varying extents (Narasimhan et al., 2012). In the following, three types are described, i.e., hollow organisations – when all operations occur outside the firm, modular organisations – when some operations remain in-house and some are outsourced, and virtual design – when a company is formed outside the main firm on a temporary basis, for example to take advantage of an opportunity (Luthans, Luthans & Luthans, 2021; Narasimhan et al., 2012).

The hollow organisation is illustrated in Figure 8.

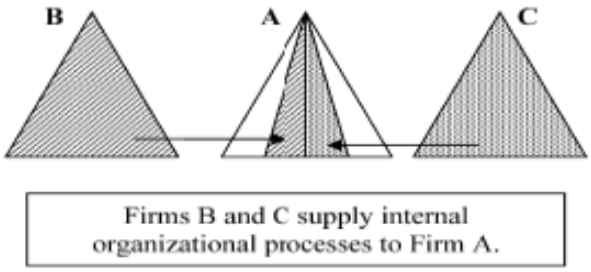

Figure 8: Hollow Organisation

Source: Narasimhan et al. (2012, p. 1)

In this arrangement, the operations outsourced are those that add no value for the customer and are outside of the core competences of the firm, which provide its competitive advantage (Luthans et al., 2021; Hamel & Prahalad, 1994). This might be the entire manufacturing process, whilst marketing and sales and

product design remain in-house (Luthans et al., 2021), an approach that holds a potential for application in SMEs in medical device companies (van den Heuvel et al., 2018).

The company to which the operations are outsourced is contracted to work according to company objectives, whilst the outsourcing company can reduce fixed costs, often gains access to new technologies, and greater expertise for completing these tasks. The strategy tends to ensure that the core business can focus on value added parts of the development process, and is more sustainable, particularly in a difficult economic climate (Luthans et al., 2021). There are major disadvantages, though, such as loss of skills in the non-core processes, potential quality issues as the company does not have control, and gradual price increases, which may render the practice unfeasible, and difficulty in returning the tasks in-house.

Modular organisations (see Figure 9) are concerned with assembly of parts, manufactured by the own organisation and/or different firms. Aeroplane manufacturers, for example, contract many parts, but also produce some of the core elements of the final product (Luthans et al., 2021).

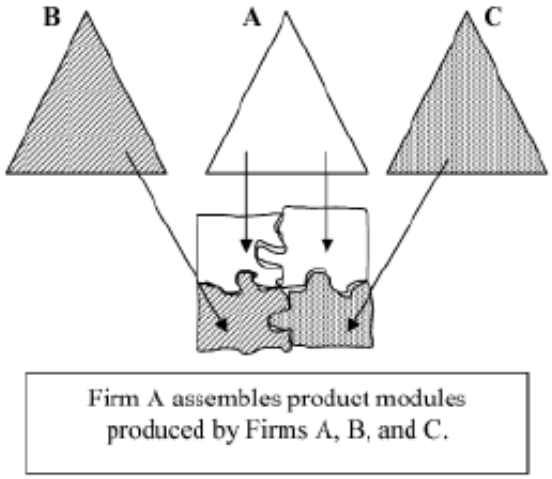

Figure 9: The Modular Organisation

Source: Narasimhan et al. (2012, p. 2)

This type of commoditised production means that it must be possible to divide the final product into several parts, and to decide which parts are best produced outside the company and those that should be manufactured within the firm. This is a common arrangement in medical equipment manufacture according to Narasimhan et al. (2012) and could also have relevance to the research question at hand. The major disadvantages are that modular design is applicable only when the product can be divided into appropriate parts, the parts become standardised so that differentiation is very difficult as competitors can easily copy them, and poor assembly issues will have a negative effect on the firm's reputation (Narasimhan et al., 2012).

The virtual organisation (see Figure 10) refers to setting up a temporary company outside the main organisation to take advantage of a limited market opportunity in alliance with another firm; the term virtual is used in this sense as a new environment not a non-bricks and mortar firm. The purpose is to combine different assets, skills, and ideas and to exploit the opportunity quickly before competitors can produce an appropriate product (Narasimhan et al., 2012).

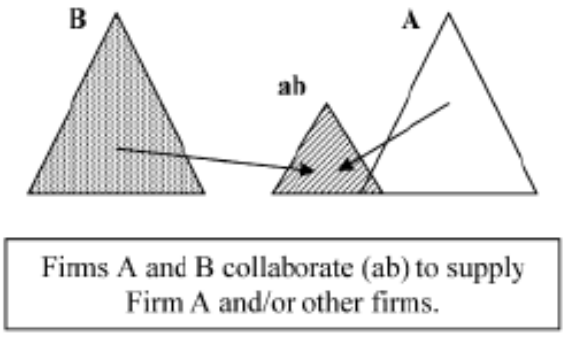

Figure 10: The Virtual Organization

Source: Narasimhan et al. (2012, p. 3)

Virtual organisations rely on five factors for success: technology, opportunism, trust, high quality, and lack of boundaries (Luthans et al., 2021). The technology facilitates instant connectivity whatever the physical distance between the firms and high-quality outcomes from a new group of specialist skills, which provide

competitive advantage by means of synergy. However, trust between the partners is vital to success otherwise the venture will fail for at least one of them. Success is also considerably helped if one of the firms has strong brand presence (Narasimhan et al., 2012; Luthans et al., 2021).

The link between all these new organisational ideas is highly skilled knowledge workers, technology, and innovation but there is sparse literature on the hollow and virtual models. However, Shamir (1999, p. 59) provides a general description of boundaryless organisations, which summarizes the understanding and concept, indicating the usefulness of such thinking to the study at hand: “Boundaryless, flattened, flexible, project-based, and team-based organizations that employ temporary, externalized, and remote workers, whose tasks are more intellectual and less routine and cannot be controlled and co-ordinated by structure or direct supervision, need mechanisms of co-ordination through shared meaning systems, a shared sense of purpose, and high member commitment to shared values.“

With regards to the business model and organisational design, in context of business growth and organisational adaptability, such an understanding highlights the need to literally think outside the box. Coopetition, the main theme of this research, may provide an answer how to remain competitive and respond to environmental changes through thinking across organisational boundaries.

2.3 Innovation

Having built a conceptual framework for this thesis based on strategy, business modelling, strategies for growth, organisational structure, culture and leadership, this next section reviews major theories in innovation management. As already indicated, innovation is key for medical device SME to survive and prosper (Porter & Teisberg, 2004), and this research investigates new ways to stay innovative under the new EU regulations for medical devices.

Innovation is defined in various ways. A particularly relevant description provided by Schumpeter (1947, p. 151), describes innovation as: “Doing of new things or

the doing of things that are already done, in a new way". Innovation perceived in this way is highly relevant to transformation of many global industries, owing to the rate of technological development in the 21st century, which has made traditional practices and skills employed redundant (Deloitte, 2018; Schumpeter, 1947). Disruptive innovation creates new markets and drives organisational growth, as stated by Christensen, Raynor & Anthony (2003).

Creativity is the initial stage of innovation (Amabile, Conti, Coon, Lazenby & Herron, 1996). Therefore, firms are urged to pursue unformed ideas, since most successful innovations begin with a vague idea (Christensen et al., 2003; Downey, 2007). This is reinforced by Hunter and Cushenbery (2011), who suggest that innovation is a process that begins with creativity, which is defined as the generation of quickly developed novel, useful ideas, which are developed to be implemented in a commercial manner. Creativity is also used as an adjective applied to products, inputs, processes, and people. However, not all innovation is successful because it may not match the change in consumer preferences, and/or be associated with organisational efficiency and cost effectiveness and/or post-sales service quality (Vahs & Burmeister, 2002).

Consequently, innovation is described in four contexts by the OECD (2005): a product, which is new or highly improved; a process related to enhancing the quality of a series of activities to better meet strategic goals; marketing that includes involving customers' input; organisational, relating to devising or creating new behaviours or ideas. All four contexts are relevant to medical devices innovation in the contemporary context, and innovation must be managed so that all value chain activities are accomplished as efficiently as possible (Franken & Franken, 2011; Porter, 2008).

Innovation is important to organisations, since new ideas generate growth, market share and success compared to competitors. An organisation's capacity to innovate has become more important than its size, since the capacity to gather and apply knowledge, technological skill, and experience to develop a unique new product/service that creates customer value has become the means to competitive advantage (Tidd & Bessant, 2018). The management of the

innovation process, reviewed in the next section, has led to multiple models of how to best accomplish it (Meissner & Kotsemir, 2016).

2.3.1 The Innovation Process

Innovation is perceived as a four-stage process of: awareness or recognition of an issue to which an appropriate solution does not appear to exist; identification of a potential solution to resolve the gap; implementation of the solution; institutionalisation as the solution is integrated into standard activities (Smith & Kaluzny, 1986).

The process suggested by Tidd and Bessant (2018) of search, select, implement and capture is similar, but the involvement of senior leaders is highlighted as necessary for the selection stage, once the search phase is completed, because a strategic plan must be implemented. Implementation involves commercialising the idea as a new product, process, position, or paradigm. In terms of the healthcare sector the product might be a new medical device or process. Capture is associated with the organisation reaping the benefits of its innovation strategy, which requires substantial management and technical skills gathered during the first three phases and to successfully market the innovation and sustain momentum in the market (Weintraub & McKee, 2019). These options are highly relevant to SMEs, which are the focus of this thesis.

When innovation practices are applied by companies internally, the term intrapreneurship is employed to signal that innovation is entirely internal, often facilitated by a department focused on generating corporate ventures, which are then evaluated for commercial value (Tidd & Bessant, 2018). Innovation generated with external input, is an alternative method of sustaining innovation in all stages of the organisational life cycle (Ozman, 2011).

The type of innovation an organisation is most focused on relates to the organisational life cycle suggested by Tidd and Bessant (2018), where innovation purpose could be to create social or commercial value as outlined in Table 3.

Table 3: Innovation Across the Organisational Life Cycle

Purpose	Lifecycle Stage			
	Start-Up	**Growth**	**Sustain/Scale**	**Renew**
Commercial Value Creation	Individual entrepreneur exploits new technology or market gap	Expanding business by adding new products/services or moving into new markets	Build portfolio of incremental innovation to sustain business and/or to influence or enter new markets	Return to radical frame-breaking innovation like start-up phase to transform business to have different focus
Social Value Creation	Social entrepreneur with passionate objective to alter or improve something in higher environment	Developing ideas, connecting with others in a network for change, for instance in a regional or concerned with a major issue	Diffusing the idea widely to other social entrepreneurs, creating links with major mainstream group such as public sector agencies	Changing the system and then acting as a change agent for future required social change

Source: adapted from Tidd and Bessant (2018, p. 63)

The change in focus of innovation as the organisation moves through its lifecycle is relevant to this thesis in two ways. The commercially focused lifecycle pinpoints the importance of the start-up trying to exploit new technologies and/or market opportunities, often this will be an SME. However, it could be an established SME that needs to renew its product/service in new circumstances. Both contexts are possible in the EU medical devices market in the context of new regulation.

The social lifecycle has links to the regulation aspect of this thesis, so that there may be some advantage in one of the SME medical device coopetition partners being a social entrepreneur focused on driving the proposed changes for the benefit of innovative, safe national social health (Tidd & Bessant, 2018). There is a gap in knowledge as to whether socially focussed partners can influence the speed of innovation owing to their close knowledge of value consumers prefer.

2.3.2 Innovation Models

The meaning of innovation has developed over time and the two major approaches are referred to as open and closed innovation, where the closed innovation process relies on all ideas and their application being generated inside the firm, and open innovation refers to ideas being instigated and/or developed inside and external to the firm (Chesbrough et al., 2006). The closed innovation model is also aligned with traditional vertical integration, where the innovation activities within various elements of the firm produce new products and services; innovation derives from the firm's internal science and technology know-how, with many projects failing to be selected as viable enough to launch in the market (Chesbrough, 2012).

Figure 11 visualizes both closed and open innovation within in a company as closed innovation derives from an internal technology base and open innovation from an external. The open – or external – approach may include 'insourcing', in other words internalizing the source of innovation. Both approaches can lead to bringing new solutions or products to market through the innovating company or through spin-offs or even other companies if the innovation is out licensed.

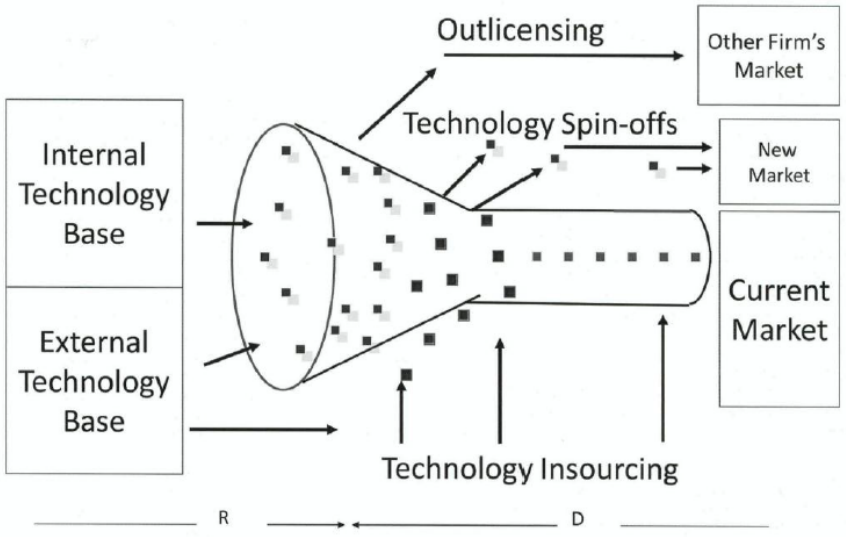

Figure 11: Closed and Open Innovation Models

Source: Chesbrough (2012, p. 23)

Open innovation has the advantage of generating more and potentially better ideas with the involvement of key stakeholders such as customers, suppliers, researchers, and competitors, but a major disadvantage is that one or more of the collaborators could develop the idea as a commercially viable proposition and obtain the competitive advantage and profits.

There are two basic types of open innovation, outside-in and inside out, plus a combination of the two referred to as coupled open innovation. In the outside-in version, external ideas are applied to an internal project and the involvement of key stakeholders supports early detection of issues that could occur in the supply chain (Gassmann & Enkel, 2004). Inside-out innovation occurs when firms produce ideas that are either not used, or under used by them, and are subsequently made available to external organisations, according to Chesbrough (2012).

Inside-out innovation tends to be employed in higher tech sectors, the owner of the idea sells or licences the intellectual property, the patents, to other organisations; the ideas it generates are commercialised by licence holders to provide new products or solutions in their specific markets, to establish technological standards or to support partners with new knowledge and/or technology (Gassmann & Enkel, 2004). Therefore, the inside-out model is characterised by research-orientated companies supporting innovation of companies outside of their industry sector and, selling licences reduces their internal R&D costs (Gassmann & Enkel, 2004; Chesbrough, 2012).

The coupled version, in which both types of open innovation are employed (see Figure 12) enables continuous learning, and the establishment of standards or major influential product/service design in a collaborative network of partners, which may comprise a group of companies, research organisations and other learning institutions or a combinations of these (Gassmann & Enkel, 2004; Lameras, Hendrix, Lengyel, de Freitas & More, 2012).

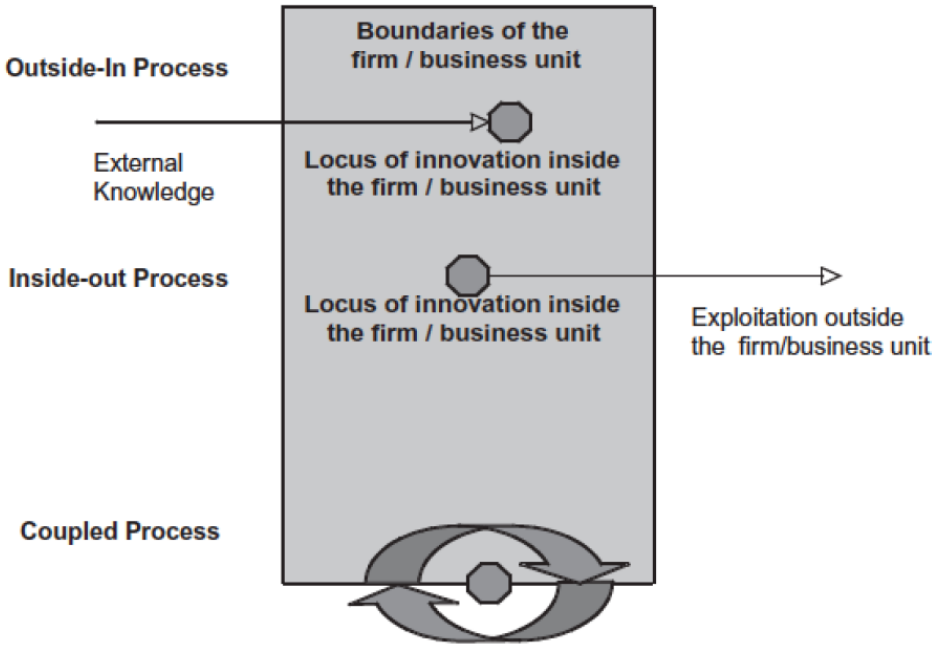

Figure 12: Open Innovation Processes; coupled Version

Source: Conboy and Morgan (2011, p. 539)

Although many stakeholders including customers may continuously participate and provide information in the coupled process and enhance the potential for innovation, the empirical study conducted by Conboy and Morgan (2011) found that competitiveness between different project teams, business units or collaborators could reduce openness between them and if they failed to fully document their procedures and findings. This would reduce knowledge transfer; sharing knowledge by means of regular interactions was vital to optimise the concept.

These diverse concepts of innovation indicate the complexity now associated with the term innovation and suggest that an organisation using innovation to recreate or maintain competitive advantage in the context of new regulation must critically appraise, which method(s) to adopt.

2.3.3 Innovation in SMEs

Prior studies have indicated that R&D is more challenging for SMEs than for large organisations, because they possess lower levels of physical and human resources, particularly the substantial fixed and variable costs and specialist knowledge and skills required (Ortega-Argilés, Vivarelli & Voigt, 2009). SMEs also have lower levels of access to important information, and the venture is associated with high levels of uncertainty about the commercial feasibility of the outcome (Rammer, Czarnitzki & Spielkamp, 2008). The inference is that SMEs must manage innovation in a different, less resource intensive way, for instance by gathering knowledge from the external environment, from customers, suppliers, and competitors, and/or collaborating with other firms. Also, leaders must foster knowledge sharing within the organisation (Nonaka & von Krogh, 2009; Smith, 2001).

This aligns with the concept of innovation management as defined by Downey (2007), a process of developing the innovative product/service, commercialising it and getting it to market. An empirical study of 2841 German SMEs, of which 1047 were innovators, was conducted by Rammer et al. (2008) to determine the nature of their innovation management practices and innovation sources; data was gathered from an official government industrial survey and therefore considered reliable. Only companies providing sufficient data were included. Innovation success was measured through a categorial variable, which assessed the extent to which “an SME has successfully introduced challenging product and/or process innovations, that is, innovations that significantly change the firm’s market position” (Rammer et al., 2008, p. 4).

Therefore, the outcomes of this study have relevance to the SME medical device manufacturers’ potential dilemma in this research. The overall finding is that SMEs, which applied a large diverse set of innovation management tools effectively, such as human resource management focused on cross-functional teamwork and formal collaboration with external partners, were able to match the innovation performance of larger firms with successful R&D outcomes.

The research by Rammer et al. (2008) implies that SMEs operating in the medical devices sector may enhance their potential for success in the current environment

of risk averse investors by implementing a form of open innovation. An additional finding is that in-house R&D was successful only when external knowledge was gathered. Although this study is limited to SMEs in Germany in early 2000s, it is indicative that collaboration with external partners is likely to increase the probability of success.

In contrast the findings of the multi-national SME study by Hossain and Kauranen (2016) failed to demonstrate a definitive link between open innovation and enhanced innovation performance, where external sources included government agencies. However, in Europe, interaction of SMEs with government agencies did enhance innovation outcomes because EU innovation policies focused on the end-users needs, which is a useful finding for this research and will be further evaluated.

Other relevant findings were that the motivation of SMEs for initiating open innovation was most focused on commercialisation of ideas and new entrant SMEs were more likely to adopt it, since established firms obtained lower levels of benefits.

Whilst this snapshot of existing literature suggests that open innovation could support SME EU medical device manufacturers to overcome some of the challenges driven by new legislation, large gaps remain. This research may be able to diminish the gaps because its focus is on the relative success of collaboration with external organisations to increase the rate and commercial value of innovation.

2.3.4 Leadership for Innovation

As indicated in some descriptions of creativity and the innovation process, innovation is often initiated by the ideas of an individual or individuals and presumed to be a consequence of rational thought patterns (Pesut, 2013). Each idea that the team regards as having commercial potential is developed by interaction with other individuals, and a prototype may be constructed (Paulus & Nijstad, 2003). The outputs of this group are indirectly influenced by leaders because they design the organisational environment, recruitment and selection

criteria and rewards and act as role models for employee behaviour, as indicated in Figure 13.

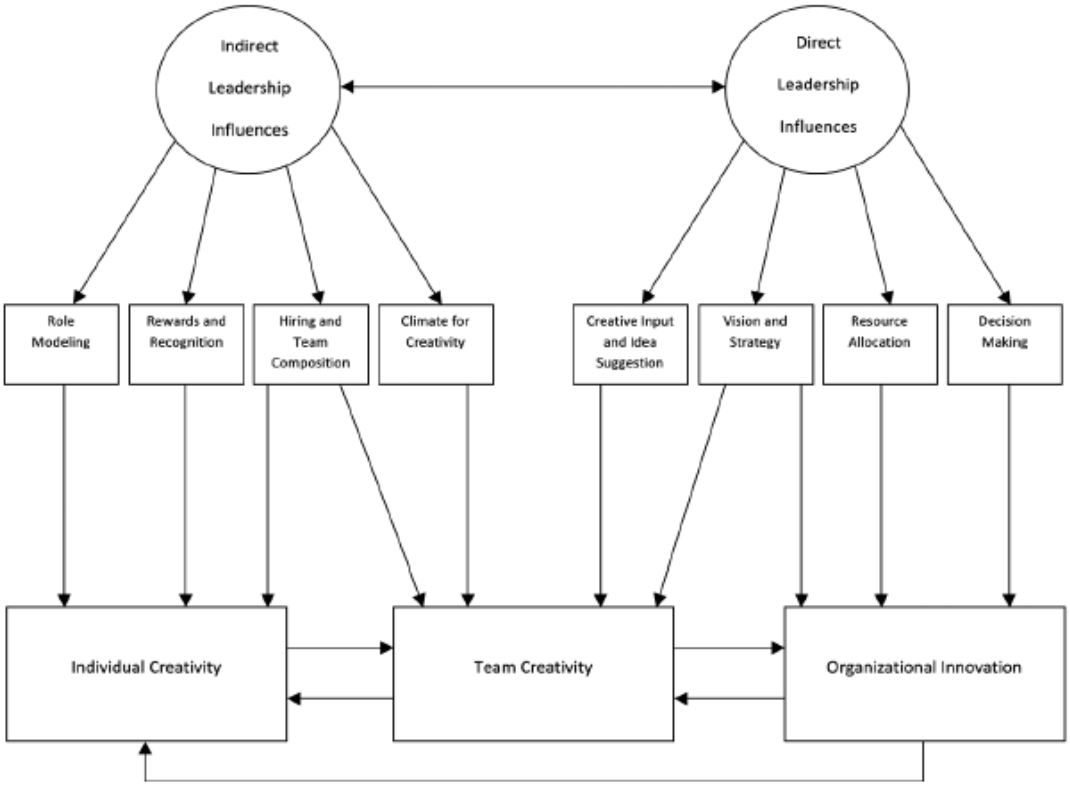

Figure 13: Direct and Indirect Leadership for Innovation

Source: Hunter and Cushenbery (2011, p. 251)

In the context of stimulating innovative activity, the leader who is observed as being a risk taker and acting in an unconventional manner transmits the message to employees that these characteristics are acceptable. Rewards in the context are not based on quantitative output of ideas as the leader is aware of the high failure rate. Recognising the quality of the idea and serious attempts to overcome the challenges of commercialising it is more likely to motivate employees to continue to be creatively.

The leader also needs to consider the employees needed across the whole innovation process from idea generators to designers and market testers (Hunter & Cushenbery, 2011). In recruitment and selection, focus should be on the new

skills required to exploit new opportunities or to resolve threats from forecast changes in the environment, rather than select based on a predefined job role.

The overall workplace environment as a creative space is crucial to successful innovation (Hunter & Cushenbery, 2011) but developing this is challenging. Some firms, such as Google, allow employees time to devote to personal projects during their working hours, which has resulted in new innovations not driven by organisational objectives, for instance Gmail, which the organisation adopted; too much structure stifled innovation according to Google leaders (Auletta, 2009).

In this model the leader becomes directly involved once a propotype or design has been constucted, after which decisions will be made with regard to further development of the idea, which may involve organisational level focus, testing and/or evaluation in the market. The commercial viability will dictate whether it is rejected or returned to the creative team to implement feedback from market and/or internal testing, restarting the process. In reality, the idea is likely to be refined several times before leadership is convinced the product/service has commercial competitive advantage (Hunter & Cushenbery, 2011).

The leadership skills associated with high innovation success are strategic thinking skills and knowledge plus capacity to stimulate employee engagement and behaviours. Creative input by the leader rather than domination of idea generation is also identifed as important to obtaining a wide range of perceptions, and an atmosphere in which they can be challenged (Hunter & Cushenbery, 2011).

The model offered by Stacey (2010) is fundamentally similar in that it suggests the leader has direct responsibility for innovation and indirect influence over how it is generated. For innovation which is associated with high levels of uncertainty and a considerable lack of agreement, decision making is characterised by high complexity. In situations that are familiar, for instance, incremental innovation of existing products, experience supports decision making regarding the most appropriate solution with reasonable certainty (see Figure 14).

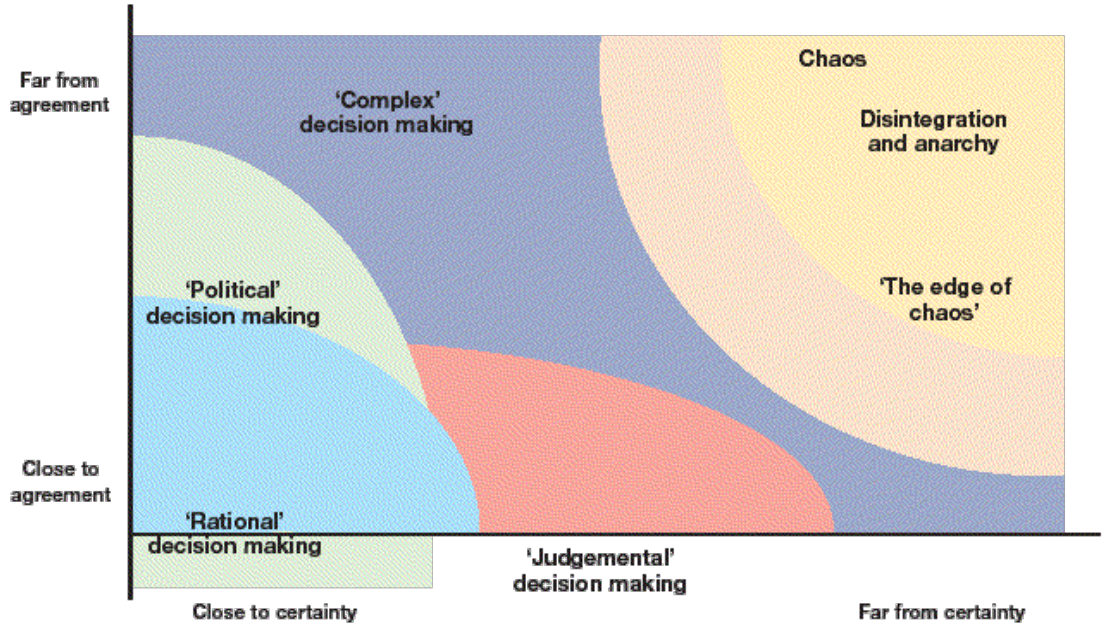

Figure 14: Type of Decision Making and Relative Levels of Agreement

Source: Stacey (1996, p. 47)

When decision making becomes highly complex, traditional leadership methods are not appropriate. Instead of directing the innovation, the leader facilitates or orchestrates the environment and activities needed to foster it. The workplace setting encourages spontaneous interaction between employees with widely diverse perspectives to explore the unknown, the opportunity to exchange ideas, and to question them in a conflictual and competitive manner, in order to develop the optimum solutions; this concept of organisational system is contrary to the ideas of harmony that is traditionally promoted (Stacey, 2010).

This type of leadership requires considerable courage, according to Stacey (2010), since the leader does not directly control the activities and behaviours but influences them by the way he interacts with employees to reflect on ideas using skill and imagination and an ethical approach. Therefore, the leader must trust the employees to generate ideas and select the most appropriate for development into commercial solutions that will meet organisational goals, with minimum input, whilst the leader remains responsible for performance outcomes. This model highly resembles Google's leadership and innovation philosophy (Auletta, 2009).

Despite the expectation on leadership to create a suitable environment for innovation, empirical evidence suggests a gap in practice. A McKinsey survey (Barsh, Capozzi & Davidson, 2008) found that 94% senior executives believed there was no ideal method of designing an innovative environment in companies, and that the workplace setting depended on the people recruited and the organisational culture. The short term performance focus in firms was identified as a barrier to developing a genuine creative environment and culture, and Barsh et al. (2008) perceived that an innovation required implementation of three basic elements of people management: innovation to become an integrated strategic management goal, which was managed, monitored and evaluated; allow dynamic innovation networks to develop naturally to more effectively utilise the skills of existing employees; actively encourage an innovation culture based on trust, risk taking and lack of fear of failure.

A recent literature review survey of leadership for fostering innovation for patient benefit in the health sector, conducted by Weintraub and McKee (2019), found that although it was considered increasingly important, very little research had been conducted to support leadership development and practice. An online search for leadership for innovation in the medical devices sector also resulted in few studies. The survey for Deloitte by Murray, Hakim and Shah (2018) made recommendations for how leaders should approach talent management but made no mention of leadership skills for fostering innovation in the organisation. The implication is that many leaders appear unaware of a type of leadership required for innovation, as expressed by leading innovative technology companies (Auletta, 2009) or academics such as Stacey (1996).

The leadership model for SMEs in this thesis must be one that best supports innovation, but it is also vital to identify to what extent it can co-exist with a leadership framework for coopetition.

2.4 Intermediate Results: Coopetition in Business Model Thinking, Organisational Design and Innovation

The following sections will summarise the so far discussed theories about strategy, business modelling, growth, organisational structure, culture, leadership, and innovation into context with coopetition and to indicate and discuss how such an understanding, in general, might be useful for the stated research problem introduced in this thesis. The industry-specific view on innovation and coopetition will follow in later sections.

2.4.1 Coopetition as a Business Model

As discussed, Johnson et al. (2008) put forward four elements associated with a new business model. The proposed major element of change in the context of this research is resource, where the novel resource could be coopetition, collaboration between competing partners to accomplish faster innovation and time to market.

Coopetition is described by Bengtsson, Hinttu and Kock (2003) as a business arrangement in which two or more competitors collaborate and compete concurrently. However, coopetition may go beyond collaboration to co-existing, may occur between strategic business units in one organisation, between a firm's employees, or between a company and its customers (Walley, 2007; Bengtsson et al., 2003). Coopetition could extend beyond firms, for instance to domestic or foreign governments (Bengtsson, Eriksson & Wincent, 2010) although most research had been conducted on inter-firm relationships (Tidström, 2008).

When a range of organisations is involved, Rusko (2012, p. 65) refers to the phenomenon of collaboration between competitors as multi-faceted coopetition, which might be a relevant context for this research and is defined as: "a contextual coopetition network comprising of two (or more) coopetitive firms in which also at least one or more actor, such as own or foreign government, customers or other stakeholders of the firms are involved." In a different context, the same firms compete rather than collaborate, with another outcome.

Whilst a range of multifaceted coopetitive relationships have been identified, Walley (2007) suggests coopetition was more likely to be found in certain contexts: regulated industries; global businesses and industries; products or service considered essential by the end user; companies with high transaction specific assets; opportunism to accomplish competitive advantage over competitors; by less powerful firms; firms whose core competences would not be lessened by coopetition.

The major advantages of coopetition as identified by Cygler, Sroka, Solesvik, and Debkowska (2018) are the potential to increase innovation between participating organisations, the development of technology that all firms may use in their independent companies, access to scarce resources, creating new products and access to new markets. Coopetition may also enhance business sustainability, in cases in which environmental, economic, and social causes are perceived as an industry concern and require the competitor to cooperate. Pressure from other stakeholders, for instance customers, government institutions, and non-governmental organisations may also strongly influence companies to operate with sustainable practices. (Cygler at al., 2018). According to Doz and Hamel (1998), one of the main reasons for competing firms to cooperate is to eliminate threats that impact on both parties by combining resources.

Simmons (1996) proposed that the usefulness of coopetition as a business model was dependent on the situation. This has been confirmed by Crick and Crick (2020) with a focus on the strategic challenges during the Corona-Pandemic. Crick and Crick (2020, p. 210) take a stance for more collaboration in the pharmaceutical industry by illustrating how US located rival companies were forced to share "… scientific data, such as from experiments and clinical trials to expedite the process of finding treatment options for the disease. […], there are often bureaucratic, political, and legal factors that serve as barriers for the implementation of coopetition strategies during pandemics. In this situation, the facilitation of inter-country-level coopetition has taken place through not only relaxed laws on cooperation versus competition, but also, a common incentive to develop a cure, or at least treatment options as quickly as possible. […] These organisations have demonstrated that despite there being institutional differences

at play, there are short-term cooperative factors that outweigh certain rivalrous behaviours". Also concerned with the impact of the Corona-Pandemic, and how coopetition might be applied to manage related challenges, Talari and Binandeh (2021) indicate that the most relevant strategic drivers will be found in the areas of organisational empowerment and strategic investment.

Some researchers found that coopetition does not always have a positive outcome. Bouncken and Kraus (2013) have named coopetition a double-edged sword when studying 830 SMEs in knowledge intensive sectors. They acknowledge that coopetition has the capability to create a radical level of innovation, while simultaneously might cause negative effects on novel innovations, an effect that, surprisingly, might be strongest in such collaborations where knowledge sharing is intensive.

Ritala (2012) and Bonel, Pellizzari and Rocco (2008) highlight the need to also manage the risks of coopetition. As with other strategic alliances the most frequently cited disadvantages are information security, opportunism arising from self-interest, and the potential loss of a firm's control over a specific technology if inequality exists regarding the benefits derived by participating companies in a coopetition (Cygler et al., 2018). The failure of coopetition is also a threat to the companies' reputations (Cygler et al., 2018). The common secondary effect is coopetitive exclusivity which prevents the participating companies from collaborating with other competitors and therefore losing the opportunity for additional learning, knowledge, and resources (Cygler at al., 2018).

2.4.2 Coopetition and the Organization

As indicated in section 2.2 companies with different national cultural origin have been found to have greater challenges in implementing a coopetitive relationship (Ritala, 2012). Linked to the model and research of Hofstede et al. (2010), and their six dimensions of culture (Power Distance (PDI), Uncertainty Avoidance (UAI), Individualism (IDV), Masculinity (MAS), Pragmatism or Long-Term Short-Term perspective (LTvST) and Restraint versus Indulgence (RI)), it appears that high UAI cultures tend to be process orientated rather than results orientated,

they prefer bureaucracy and standard routines. Therefore, coopetition between companies from nations with highly diverse scores on this dimension may be more difficult initially because coopetition is initially characterised by low UAI, results focused cultures (Luo & Rui, 2009). However, there is also evidence that formal structures and processes are preferable to create a stable coopetitive relationship (Das & Teng, 1997) so that similarities in the UAI dimension have relevance to coopetition.

Power Distance (PDI) reflects attitudes to educational levels, high scores are associated with uneducated employees who receive and implement instructions, whereas low scores imply fewer supervisory categories and more equal sharing of power (Hofstede, 2020). Hence large differences in PDI between firms attempting to be coopetitive, are likely to be challenging as individuals are unable to identify with the new alliance (Mathias, Huyghe, Frid & Galloway, 2018); employees identifying with firms with large power distance will need to be supported to understand the concept of coopetition and the reasons for its creation (Zeng & Chen, 2003).

The PDI dimension is also proposed to be related to the continuum between job orientation and employee orientation, the type of management philosophy regarding employees; in high job orientated environments employee welfare will be less important than meeting work deadlines (Hofstede, 2020). However, since coopetition activity is a short-term arrangement on a limited scale the difference in scores may be less important (Ketchen, Snow, & Hoover, 2004) although Eriksson (2010) found that employee motivation and incentives increased the potential for success.

The mode of communication, which relies on PDI and individualism (IDV), is also relevant to success in coopetition, low PDI combined with high IDV means that the organisation is open to communication with external parties, whilst the high PDI/low IDV is common in a closed culture, where internal communication is valued.

A wide variation in openness can create tension and conflict in coopetition as found by Razah-Ullah, Bengtsson and Kock (2014). The degree of control exerted

in the companies forming the coopetitive relationships is an additional potential issue; this predominantly relies on the Power Distance (PDI), Uncertainty Avoidance (UAI) and Individualism (IDV) dimensions that influence internal structure, discipline/rules and adherence to norms. Lower degress of control are likely to generate innovation, whilst tight control implies high cost consciousness, a serious environment usually unsuitable for improvisation (Hofstede, 2020). Whilst formality may be advantageous for coopetition, too much informality may damage the collaboration between the firms, so that the establishment of formal agreements and structural designs will be required for collaboration by the partners; however, too much rigidity may hinder the integration (Tidström, 2008).

2.4.3 Leadership for Coopetition

Since theory is developing from studies focusing on coopetition as a business model for competitive advantage, the approach taken by this researcher is to determine the leadership skills and knowledge for leadership as a CSF in coopetition.

For coopetition to be successful, the managers of the participating firms must have defined reasons for participating in coopetition, particularly exploiting the opportunity for learning and exchange of knowledge, otherwise the alliance would fail according to empirical research by Winberg and Oster (2015). Coopetition infers those managers acquire legal protection of knowledge and information specific to their firm, while also becoming cognisant of the diverse competitive factors arising in a coopetitive setting and how to manage them during the initial stages of creating the arrangement.

Therefore, the framework for coopetition suggested by Winberg & Oster (2015), as shown in Figure 15, facilitates understanding of the opportunities and challenges, particularly emphasising the important role of management. Values, beliefs, and perspectives of managers have significant influence on how cooperation and competition develop between firms in a coopetitive relationship (Altendorfer, 2019). Also, the framework by Winberg & Oster (2015) outlines the importance to build and maintain a relationship of trust; this was emphasised as

a difficulty of strategic alliances by Lynch (2018). However, studies so far have not examined the concept of 'trust' in detail. This study is aiming to further specify the type of trust necessary.

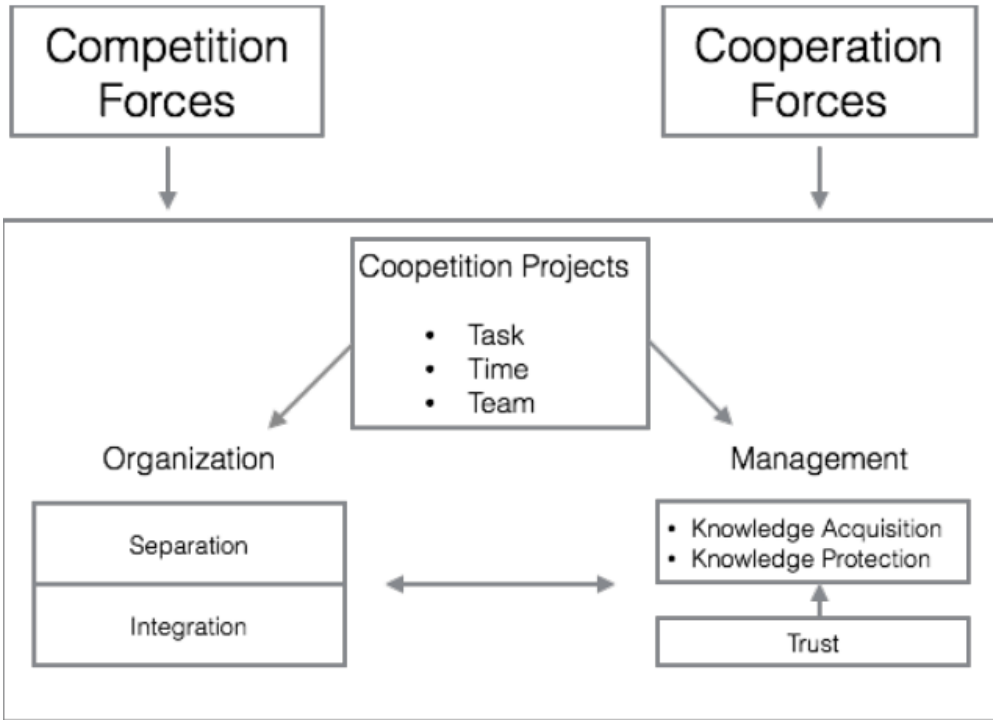

Figure 15: Coopetition Theoretical Framework

Source: Winberg and Oster (2015, p. 21)

A qualitative study by Chin, Chan and Lam (2008) identified that leadership, long term management commitment, and especially degree of trust engendered, were the most important of CSFs for coopetition in manufacturing companies in Hong Kong. The CSF factors comprised three main themes, management leadership, relationship management and communication management; 17 sub factors of which they comprised highlighted specific elements revealing the strategic importance of leadership and that vital leadership qualities were building trust and demonstration long term commitment.

The findings are valuable to this research especially as the sample comprised senior managers with between six- and nine-years' experience of coopetition.

However, a major limitation is the small purposive sample of six semi-structured interviews with industry experts; other limitations of the research include that it focused on firms with a model of coopetition based high competition with low cooperation, the medical devices sector is not represented.

Three case studies of organisations employing coopetition business model were developed by Osarenkhoe (2010) to identify CSFs, based on expert interviews, participant observation and secondary data. Leadership and trust were also the major CSFs identified; leadership facilitating the exchange of tacit and non-tacit knowledge was identified as vital but often neglected, so that fostering knowledge sharing, which also generated new knowledge and practical know-how was crucial. This is an important leadership competence in terms of this thesis, as it promotes competences of knowledge sharing and joint knowledge generation but implies the building trust CSF is also integrated into that competence. The organisations selected were two associations of smaller businesses, and part of a global information and communication technology firms, so that the context is partly valuable to the research since SMEs are involved, but the limitation is that they are grouped as one organisation and none in medical devices. The empirical findings tend to support this in respect of identifying leadership, trust and fostering active employee participations as CSFs for coopetition. Tsai (2002) also suggested that coopetition arises from supportive leadership, which allows employee participation in certain levels of decision-making.

The research conducted by Strese, Meuer, Flatten and Bretel (2016) was concerned with the question of which leadership approaches optimised internal coopetition between the specialist functions within a single firm. The participants representing 234 German firms considered that openness was required to foster an environment of partnership leading to mutual success. High levels of skill in conflict management and fostering trust amongst competing cooperative functional groups were necessary leadership attributes. This concept of partnership would be accomplished by ensuring that functional leaders fully participated in decision making regarding an integrated strategy and how it would be implemented to accomplish the agreed goals. It was also vital for leaders to ensure that employees understood their roles, responsibilities, and contributions

to organisational success of the coopetition approach. The organisational structure selected by leaders also impacted on outcomes, formalising the coopetition principle, and developing an appropriate culture without centralising control were most likely to generate success. This study implies that leadership for effective internal coopetition requires a leader to create a suitable environment, in which direct and indirect leadership activities are shaped to allow competition and cooperation in a positive way, like Hunter and Cushenbery's (2011) framework. Also, an appropriate organisational mindset and culture is needed and must be established through the leader (Crick, 2020).

Leadership concepts for coopetition in a generic organisational context were suggested by Sus and Organa (2020) and emphasised the crucial competence of being able to manage the highly complex situation, with leadership being dynamic, emergent, and interactive; complex interactions to generate a common approach to issues that would necessitate behavioural change and working practices. The specific aspects of complexity leadership also changed with the organisational life cycle. In the context of the network or independent entities formal authority was also associated with leadership, requiring competences such as measured risk taking, generating opportunities, coordination of the entities comprising the firms participating in coopetition to achieve specific goals.

The focus on complexity leadership competence aligns with the approach to leading innovation suggested by Stacey (2010) and is therefore most relevant to this thesis. A gap in the literature regarding leadership competences for successful coopetition is evident as so few published studies focus on its importance in coopetition studies; this research will support diminishing this gap.

2.4.4 Coopetition in Innovation

The role of innovation in coopetition is well established in research. Reiss and Neumann (2013) describe in that context that the idea of collaboration in general is strongly related to concepts such as open innovation, crowdsourcing, co-innovation, co-creation, open-source communities, innovation ecosystems, and strategic innovation partnerships. They see it as a positive strategy with

numerous advantages for both sides. Unused in these approaches, so they argue is the creativity-promoting potential of competition, which is channelled, regulated, and initiated by certain rules (Reiss and Neumann, 2013).

On the one hand, this applies to coopetition as well, in which cooperation takes place during the generation of ideas, but competition takes place during marketing. On the other hand, organised coopetition also occurs as a way of competing among partners, especially in the context of idea competitions. The organisation of competition is intended to increase the willingness to perform of all participants in idea and innovation management and at the same time to curb uncontrolled competitive practices such as poaching, plagiarism, collusion, and bribery (Reiss and Neumann, 2013).

Pekovic, Grolleau and Mzoughi (2020) have studied the question as to whether coopetition might have a positive effect on innovation activities, especially when conducted with actual rivals. They found evidence of a positive and significant relationship between various forms of cooperation. They state that "… that cooperation with rival and non- rivals taken together increases economic performance, but that the impact of cooperation with rivals is lower than the impact of cooperation with non-rivals. Estimation results suggest that reaping the full cooperation benefits is not automatic and requires precision dosing and management" (Pekovic et al., 2020, p. 1).

The analyses by Cygler and Sroka (2017) suggested that the major benefits of coopetition for innovation were perceived as the opportunity to obtain scarce or relatively inaccessible resources, market and technological opportunities, risk reduction, enhanced learning and increased sense of competitiveness and creativity.

However, the literature search for this thesis confirms little focus on coopetition in the medical devices sector and health care generally compared with other sectors (McCarthy et al., 2018), especially related to SMEs. One of the few studies focusing on coopetition in the healthcare industry is the Innovation Learning Network (ILN), which is an international group. This research relates to a project managed by the healthcare company Kaiser Permanente in which eight

large healthcare organisations participated with a common goal of developing and implementing high quality healthcare systems (McCarthy et al., 2018).

Their findings revealed that lack of trust existed between the competing companies because they feared that their ideas would be adopted for advantage by the other partners. This problem led to the development of a legal coopetition agreement in which four areas of collaborative practice were specified in descending order of priority: innovation methodology; processes including workflows; devices and software; the space or architecture in which the collaborative work occurred. Individual network organisations were free to decide on the information they were willing to share, and with which network partners. This set of arrangements was found to strengthen the co-creation process and optimise mutual benefits (McCarthy et al., 2018). The outcomes from this research are useful since they provide ideas for a practical framework that another organisation can customise to own context.

The creation of specific standards for coopetitive projects was also identified by Zakrzewska-Bielawska (2015), in an empirical study of 235 high tech companies, which adopted the coopetition model to mitigate higher competition in the sector, owing to the fast pace of technological change and increasing globalisation. The implication is that changes in the external environment are a major challenge that is influencing the level of coopetition; this conclusion was also drawn by OECD (2001) and UNCTAD (2011).

More than half of the 235 companies in the study of Zakrzewska-Bielawska (2015), 51.9%, were in the mature lifecycle stage, just 8.09% at start-up and 31.9% in the growth stage. The companies predominantly collaborated with competitors, larger firms and with SMEs which were at a similar stage of development and geographical scope, either in Poland or operating globally. Many had coopetitive relationships with two to five competitors, the larger the firm the greater the number of competitors, especially in Research and Development (R&D), identified with statistical significance. The collaborations were for diverse purposes: production or services, sales and distribution, supply and R&D. Innovation was the least important of these factors for coopetition, and small firms were found to be most likely to form coopetitive relationships for R&D purposes

with a domestically located partner, 55.66% of total. All firms in R&D coopetitive relations with a larger or medium sized partner preferred a partner with stronger technological expertise but comparable market position and benefitted from the alliance. The risk of loss was found to be much lower from a relationship with a foreign or regional partner than with a domestic one (Zakrzewska-Bielawska, 2015).

The research is very useful, owing to the level of information generated and suggests that setting agreed, and potentially legally binding standards is crucial. Also, firms in the mature and growth stage are much more likely to participate in coopetition than start-ups, and the coopetitive relationship tends to comprise more than two firms. Although SMEs tend to form coopetitive relationships with local firms, the potential for success if greater with a foreign partner. However, the major limitation of this research is that the sample for coopetition for innovation is not a representative sample, and findings cannot be generalised (Saunders, Lewis & Thornhill, 2019).

A similar quantitative research study into 210 high tech companies in the same region as Zakrzewska-Bielawska's (2015) research, was conducted by Cygler et al. (2018) to gain greater insights into the relative advantages and disadvantages of coopetition; 23% of participants were in the medical devices sector, providing some indicators for this research. In relation to R&D, the duration of the relationship was generally a minimum of 5 to 7 years, and generally enhanced innovation outcomes. However, this finding was not statistically significant, but the implication was that coopetition in R&D increased unique knowledge and reduced costs in long term relationships but that short term coopetition of less than a year had no benefits. Long term relationships were interpreted as being a consequence of the new product development cycle and low predictability of the commercial value of ideas. The sample was not representative in this research either, so generalisability is not possible (Saunders et al., 2019).

Other potential disadvantages of coopetition, which emerged from Cygler and Sroka's (2017) study were that miscommunication, conflict and opportunism greatly impacted on the performance and outcome of the collaboration; these findings align with Kraus, Schmid & Gast (2017), de Resende et al. (2018) and

McCarthy et al. (2018). The risk of information leakage is always a major concern and, for smaller firms collaborating with larger or stronger firms, the possibility of losing organisational independence, especially in decision making is a serious concern (Zakrzewska-Bielawska, 2014).

In a similar context Ritala and Hurmelinna-Laukkanen (2013) state that with regards to managerial practice such "… collaboration is often characterized by uncertainty - the outcomes may not be as originally expected, and flexibility and responsiveness are required. It can also be suggested that companies pursuing innovation-related coopetition should consider replacing IPR [Intellectual Property Rights] strategies (that typically focus strongly on patents, and in some instances trademarks but rarely anything else) with more overarching appropriability strategies. This calls for combining forces from several areas inside the company, such as R&D, HRM, the legal department, and the IPR department. For example, if the firm's own knowledge is secured with patents or copyrights and the collaboration contracts and related nondisclosure arrangements are well developed, the knowledge exchange-hampering tacitness or secrecy can be put aside as protection mechanisms, and the collaboration will be more fluent and less risky for all participants. In such cases, coopetition should be based on mutual value creation rather than suspicion and opportunism" (Ritala & Hurmelinna-Laukkanen, 2013, pp. 166).

Research into coopetition related to new product development found that more new products were developed from coopetitive relations than by firms operating alone, but there were conflicting findings regarding whether it was most effective in terms of radical innovation or of incremental innovation (Bouncken, Fredrich, Ritala & Kraus, 2018). These findings inspired the study of coopetition and innovation in both innovation contexts by Bouncken et al. (2018). The major findings were that coopetition should be limited to the uncertain later stages of radical innovation; this potentially reflects the acknowledged risk of one of the partners in a growth strategy learning from the other and employing it for own advantage (Whittington et al., 2019).

In highly technological innovation generally, competitors still decide, which competitors they want to collaborate with and at which stage of the process they

will be allowed to collaborate and share information (Zakrzewska-Bielawska, 2015). Radical innovation is classified as business model innovation in the context of coopetition (Ritala & Sainio, 2014) with the inference that firms wishing to participate in coopetitive radical innovation must be willing to change their business models, to gain competitive advantage over other companies/alliances operating in their market sector (Ritala & Sainio, 2014).

Radical innovation is characterised by disruptive innovations, those which render previous skills, knowledge, and technology redundant (Schumpeter, 1947). This type of innovation is discontinuous, produces entirely new products and services, which tend to improve operational efficiency and fulfil new end user preferences. Management of radical innovation requires a change of mind set and capacity to forecast independent entities formal authority was also associated with leadership, requiring competences such as measured risk taking, generating opportunities, coordination of the entities comprising the firms participating in coopetition to achieve their specific goal.

This is similar to Ritala and Hurmelinna-Laukkanen (2013) aiming to understand why some companies are more successful than others in collaborations. The authors conclude that it is relevant to consider "… firm-specific appropriability and absorptive capacity simultaneously, and in relation to coopetition in particular. […] In general, the results show that a firm is able to achieve better results from coopetition in terms of innovation when it has a well-developed appropriability regime and potential absorptive capacity. Some differences were also found regarding the importance of these two factors with respect to incremental and radical innovations" (Ritala & Hurmelinna-Laukkanen, 2013, p. 166).

McCarthy et al. (2018) suggest that collaboration between competitors in the medical sector should be limited to additional clinical work submitted to the commission for assessment; coopetition should not extend to customer data and information. These and other studies suggest that coopetition associated with technological innovation is incremental innovation, which proceeds at a slow pace and is the most common type of innovation because it is low risk and related to an existing product/service (Bouncken & Kraus, 2013; Ritala & Sainio, 2014; Ringberg, Reihlen & Ryden, 2019).

The evidence on innovation in the German nanotechnology sector by Blind and Gauch (2009) infers that it would be preferable to introduce coopetition between competitors and other stakeholders in the middle to final stages, to reduce costs associated with regulations, clinical trials, and ancillary activities. The rationale is that the discussions, which occur in the later stages, concern regulatory focused information regarding standardisation and implementation, rather than product centred data.

Winberg and Oster (2015) suggest that coopetition is justifiable in the early stages of innovation, only if coopetition is for a specific purpose, or limited to developing standards and basic research, and strongly agree that the appropriate stage for full coopetition is when original and unique activities commence that will generate the trade secret.

The review of different studies on appropriate stages of innovation for coopetition and whether incremental and/or disruptive innovation is applicable identifies a need for further research, especially at which part of the overall innovation management process coopetition is most likely applicable. Also, this research will influence the gap in knowledge about how coopetition integrates with different types of innovation.

2.5 EU Medical Devices Industry and related Directives and Legislation

After building a conceptual framework for this thesis and reviewing literature on coopetition from a more general perspective, the next sections will focus specifically on the EU SME medical device industry, the new regulations and existing studies on innovation and coopetition within that sector.

Medical devices are included in the healthcare industry sector and have increased in importance owing to the advances in technology that have enabled manufacturers to develop and market health monitoring devices from which health related data can be shared. This has been possible owing to the connectivity afforded by the Internet of Things (IoT). Medical devices of this nature make an increasingly important contribution to improving healthcare

(Dash, Shakyawar, Sharma & Kaushik, 2019). However, medical devices are generally described as comprising the means to diagnose, prevent, or treat medical conditions excluding those that require chemical action on a patient's body, and range from bandages to deep brain simulators (Jin, 2014).

The European Trade Association for medical devices, MedTech Europe (2020), refers to medical devices collectively as medical technologies, which comprise products, services, and solutions, which are utilised with the purpose of saving lives or improving the quality of human life on a day-to-day basis. Four main groups are identified by Torsekar (2018): disposables including gloves, syringes, and bandages; surgical and medical instruments embracing those employed in cosmetic treatments; implantable and non-implantable therapeutics, such as hearing aids and false limbs, ventilators, and infusion pumps respectively; diagnostic devices that are highly complex technological capital equipment.

The medical devices healthcare subsector is characterised by substantial financial investment in research and development (R&D), and a higher rate of new product innovation than the rest of the healthcare market. Medical devices are applied alone or in combination along the entire medical treatment process from diagnosis to treatment, sustaining life (WHO, 2010; ISO, 2016). More recently equipment for remote monitoring of medical conditions has been a major application and vital to providing information on the status of health (Sanders, Stern & Gordon, 2020) and lessening the effects of functional conditions such as pain, disease, and reduced mobility (Charness & Olsen, 2010).

New devices are usually created in the health sector as clinical need arises, motivating their design and manufacture. Once the prototype of the new devices has been developed it may be tested, depending on its perceived risk; those that require evaluation may be initially tested on animals and adjusted as necessary or withdrawn. Clinical trials may follow if the initial tests prove the prototype's capability for the intended purpose, so that humans participate to evaluate the device's safety and efficiency. All devices of any risk level must meet the required current legal standards, and some high-risk devices may be subject to an investigation by the regulatory authority (Guerra Bretaña & Flórez-Rendón, 2018).

2.5.1 Sector Importance

A country's health is directly related to its stage of economic development (Barro & Lee, 1994) since life expectancy is enhanced and the population's active working life extended, but also through preventative health interventions that decrease health costs. In addition, medical devices improve the quality of life for those citizens with an existing health problem, and the effectiveness of the health systems by reducing the frequency of visits to health professionals (Maresova, Penhaker, Selamat & Kuca, 2015).

The European medical devices market is categorised in three ways: by country; by device; by end user (Heneghan, Thompson, Billingsley & Cohen, 2011). The two major end user segments are hospitals/clinical care and home care, whereas the eleven main product sectors include ventilators, various systems for detection, interventions, health monitoring and management, and respiratory care (ASD Media, 2020). The hospital and clinical care sector and orthopaedics sectors are forecast to have the fastest growth in the short to medium term owing to the ageing population (Piuzzi et al., 2019).

The European Medical Devices industry employed approximately 730,000 people in 2021 (MedTech Europe, 2021). Germany is the largest employer with more than 140,000 people employed by more than 1,300 manufacturers (GTAI, 2019). The predominance SMEs with less than 20 employees is illustrated by 95% of medical device companies in Europe being micro or small companies (MedTech Europe, 2021). The sector produces more than 500,000 products, many of which are niche products produced by small manufacturers, who may also be global leaders in that specialist product (GTAI, 2019). The ageing population is expected to be more than one third of the total market by 2035, providing a significant opportunity for all EU manufacturers (GTAI, 2019). Many US large medical device companies operate in the EU market representing almost 40% of market share in Germany alone (GTAI, 2019).

The distribution of employees in the EU medical devices sector is exemplary shown in Figure 16 and represents the relative proportion of each member state's contribution to the total market (MedTech Europe, 2021).

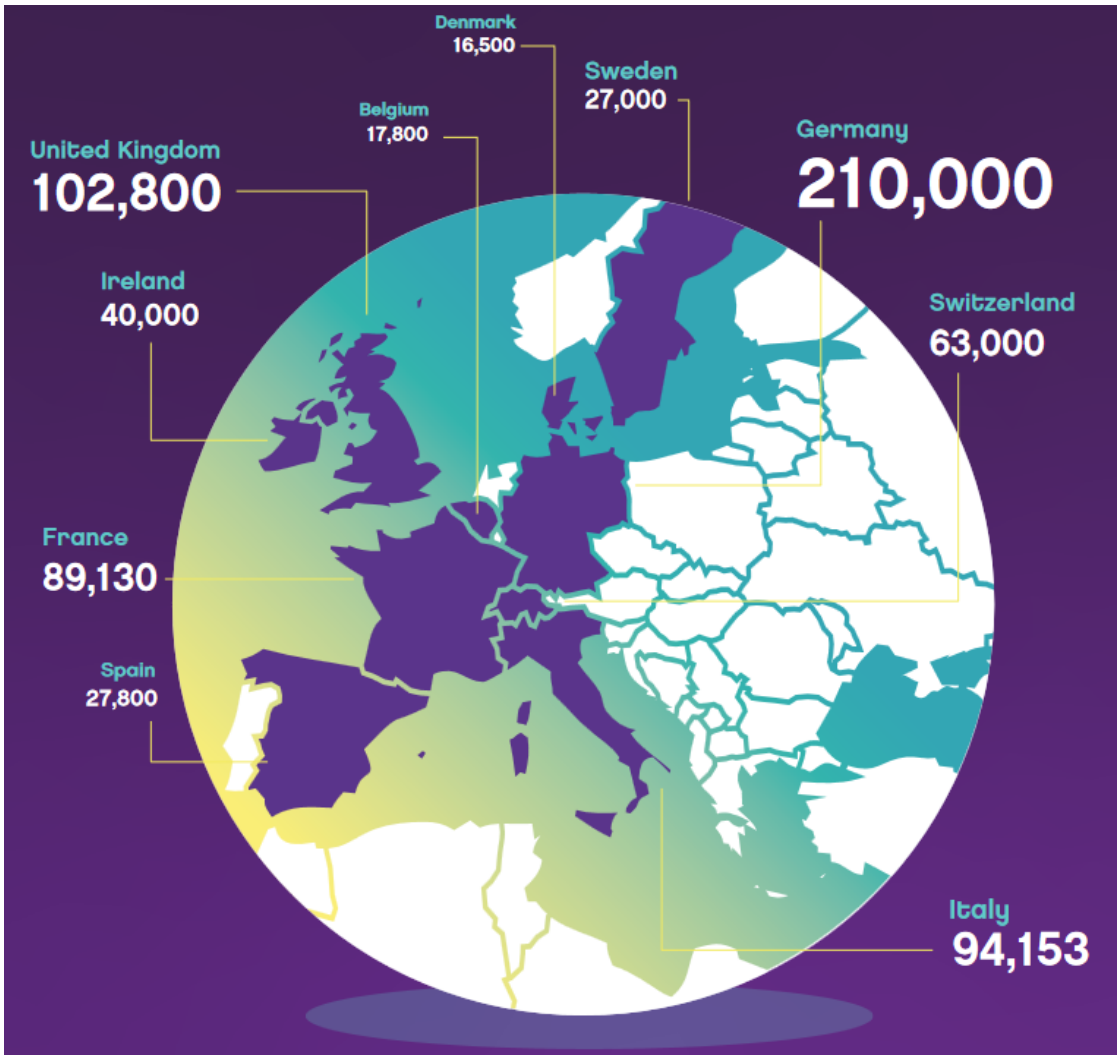

Figure 16: Medical Devices Employment Provision in Europe 2021

Source: MedTech Europe (2021, p. 17)

The productivity of these employees is indicated by the value added they represent, calculated as €160,000 per person, the consequence of their social and economic contribution. The importance of the sector is also suggested by its comparative size to pharmaceuticals, which provides employment for a similar cohort of 765,000 people (MedTech Europe, 2021).

The total value of the European market for medical technologies in 2016 based on manufacturer prices was approximately € 110 billion, representing 29% of the global market and second largest; the global leader was the United States (US) with 43% market share (Miglierini, 2018). The forecast annual market growth to

2025 is 4.7%, when the market value will have increased from $US 48.9 billion in 2020 to $US 61.4 billion. The forecast growth is expected to derive from product innovation (Gerecke, Clawson, Pross, Verboven & Bax, 2020).

The medical devices sector is characterised by constant innovation owing to substantial focus on R&D, which also relies on co-creation with users; 14,000 patents were registered with the European Patents Office in 2019, representing 39% of total patents registered globally, marginally less than the 40% US share.

The importance of medical devices to EU population health and to the economy is also represented by 7.7% of all patent applications deriving from this sector, its 0.9% growth in the year and comparison with only 7,700 pharmaceutical patent applications. The focus on innovation is necessary for competitiveness and survival since the average product lifecycle is less than 24 months, improved or new product offers quickly making existing ones obsolete (Gerecke et al., 2020).

Apart from US firms, the main competitors to European manufacturers, are in China and Japan, which have 6% and 7% global share respectively. China is increasingly participating in this sector and has been focusing on the high value aspects of R&D, Distribution, Marketing and After Sales Service (see Figure 17), owing to the growth in Asian healthcare markets. R&D comprising product design, obtaining regulatory approval, and positioning the price, represents approximately 60% of medical device value chain costs.

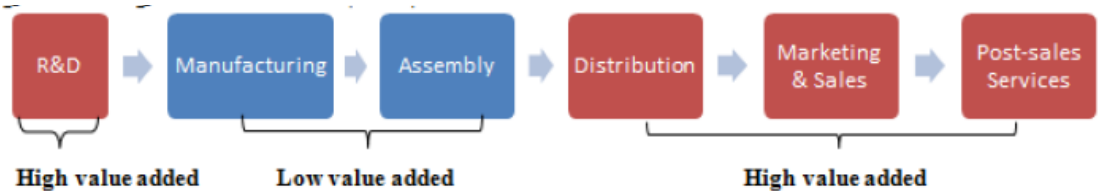

Figure 17: Medical Devices Global Value Chain

Source: Torsekar (2018, p. 5)

The distribution, sales and service activities related to high value products are mainly direct sales to hospitals or specialist care organisations, plus the

associated consultation and training of users to make sure the product is used effectively. Therefore, potentially these value chain elements are highly profitable (Torsekar, 2018), and represent significant competitive advantage by proactive tactics that lock out competition (Brege & Kindstrom, 2020).

The highest level of medical device firms' global Foreign Direct Investment (FDI) has been in China, particularly by US firms. These trends represent increased global competition for EU firms, although the German medical device division of Siemens and Braun, Netherlands based Philips, and Messilor based in France, have all invested in China. China's transition from low to high end medical device producer also shifts its position in global markets relative to EU (Torsekar, 2018).

The forecast major growth areas within the medical technology product/service portfolio to 2024, are indicated as: diabetic care with sales growth rate of 8% and 5% increase in market share; cardiology and in-Vitro diagnostics forecast to experience up to 6.5% sales growth and market share expansion of 14 to 15%. However, growth is expected across all devices, according to MedTech Europe (2021), and IMAP (2019), as presented in Figure 18.

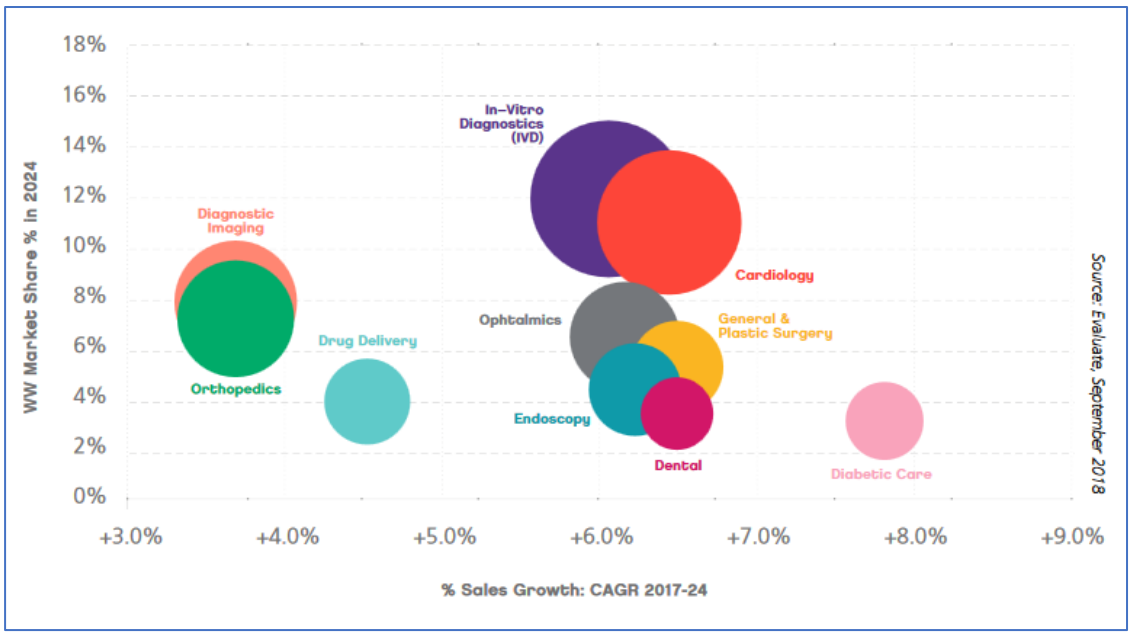

Figure 18: World Medical Technology Market 2017-2024

Source: MedTech Europe (2021, p. 30)

The importance of medical devices to EU GDP is indicated by an average consumer spend of €225 per head (MedTech Europe, 2020) and represented 11.8% of total medical products exports, total value €281 billion; imports and exports were 9.3% of total recorded EU trade (EPRS, 2020). As Figure 19 shows, the most importance export markets were US, China, UK, Japan, and Russia associated with 30%, 12%, 8%, 5% and 4% of total respectively (ERPS, 2020).

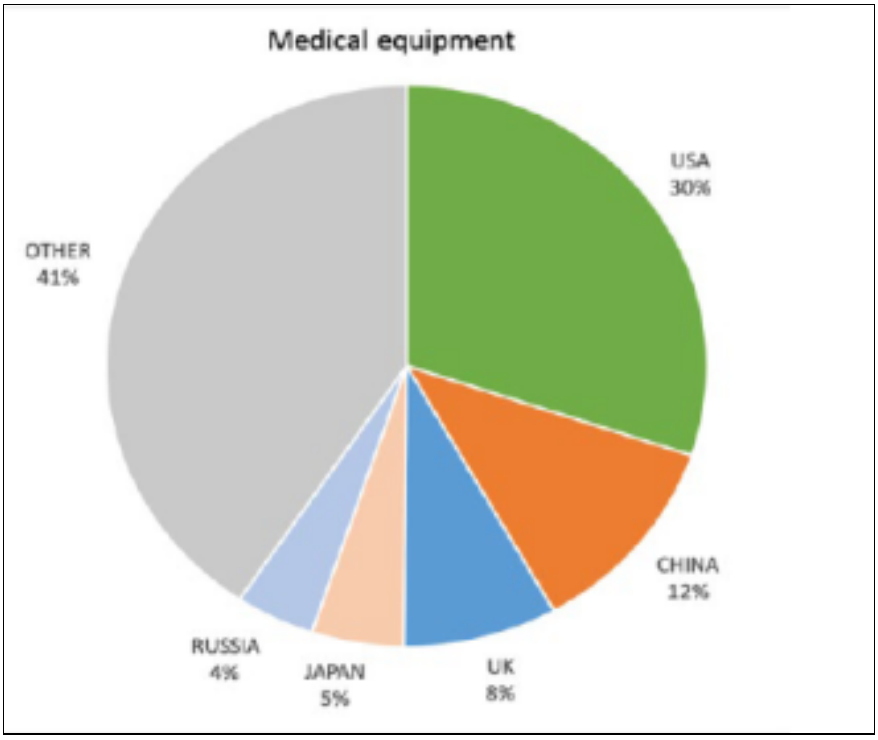

Figure 19: EU Medical Device Exports

Source: EPRS (2020, p. 1)

2.5.2 Classification, Regulation and Harmonisation of Medical Devices

Although the medical devices sector has always been subject to strict regulation, it is forecasted to continue to significantly contribute to the enhanced health of society in the short to medium term. However, the time taken for new products manufactured in the European Union (EU) to reach the market is likely to be increased by tighter regulation associated with new unproven technologies and smart and connected devices (Marketline, 2017).

The impact of regulations on manufacturers varies according to the type of device and, notably, the global region of manufacture (ISO, 2016). This means that the range of products classified as medical devices varies globally, may include human and animal tissue, and some products are difficult to categorise as either devices or drugs (Racchi et al., 2016; ISO, 2016).

EU Medical devices are generally classified according to their perceived level of risk, from class I devices to class III (Guerra Bretaña & Flórez-Rendón, 2018), in four risk categories (Maresova et. al., 2020a; Medical Device Coordination Group, 2021), as illustrated in Figure 20.

Figure 20: New EU Regulatory Classification

The lowest risk class 1 devices are those not regarded as sterile for personal protection reasons (Medical Device Coordination Group, 2021). Whilst class I devices do not need to undergo an external premarket review, they must be registered and are likely to have to pass the US FDA regulations, especially since the US has three risk levels not four as in the EU (Guerra Bretaña & Flórez-Rendón, 2018)

Class II devices represent moderate risks, and each risk level requires specific, mandatory procedures for labelling, which is required for post-marketing monitoring, and is an additional level of control. Class IIa products are classified as sterile or non-sterile, are used for short time periods and indicate low or medium risk, such as hearing aids or ultrasound machines. Different rules apply to each group but a notified body, a legally designated organisation, must certify them as meeting the new legislation. Class IIb devices are utilised for longer periods, are medium or high risk and include surgical lasers or defibrillators.

Class III are high risk products requiring general controls regarding manufacturing and marketing, safety validation, scientific reviews, and manufacturing standard reviews (Guerra Bretaña & Flórez-Rendón, 2018); testing and assessment is extensive and thorough. These highest risk class III products are exemplified by cardiovascular catheters, hip-joint implants and prosthetic heart valves, for instance, which must be monitored constantly. Therefore, more stringent quality assurance audits must be completed by a notified body (Medical Device Coordination Group, 2021).

The degree of control on devices by the notified body is associated with the perceived level of risk of its use on the human body; the notified body collaborates with the national authorities before and after the devices are placed in the market to monitor their on-going level of safety and performance (MedTech Europe, 2021). These procedures, however, might prevent rapid innovation (Jeandupeux**,** 2019**;** Peter, Hajek, Maresova, Augustynek & Penhaker, 2020).

The standards for conformity in most countries are based on the provisions of the International Organisation for Standardisation (ISO) and national medical device regulations. In the European Union, the categorisation and assessment procedures are more stringent because they are not performed by a single government agency but a group of notified bodies (Maci & Maresova, 2022). These are vigilant in pursuing premarket approval and continue to encounter problems with recalls, owing to product safety issues (WHO, 2010; Bergsland, Elle & Fosse, 2014; Guerra Bretaña & Flórez-Rendón, 2018).

The review process has not been perfected and market entry of partially tested devices continues to be a dilemma, whilst harmonisation of regulatory objectives and procedures is currently promoted and adopted (WHO, 2010; WHO, 2011; Guerra Bretaña & Flórez-Rendón, 2018; Maresova et al., 2020b). Effectively, the regulatory process makes it difficult for innovation as it is a bureaucratic, time-consuming process as indicated by Figure 21.

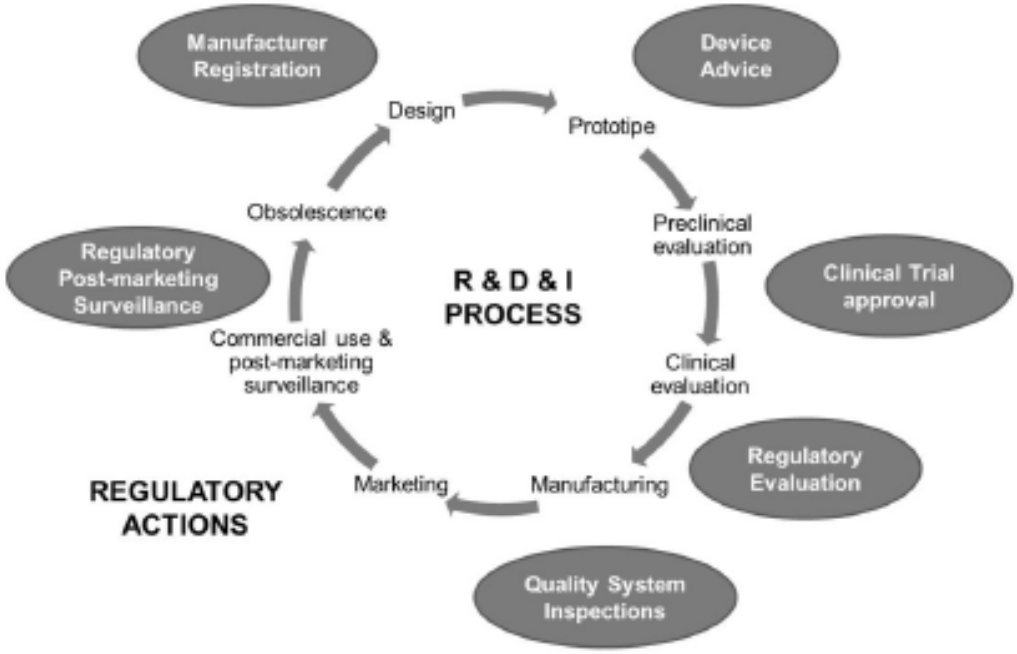

Figure 21: Effect of Regulation on Innovation in Medical Devices Sector

Source: Guerra Bretaña & Flórez-Rendón (2018, p. 361)

The harmonisation of regulatory approaches as a global strategy has resulted in the creation of the World Health Authority's 4As of global healthcare: Availability, Affordability, Accessibility and Appropriateness. Consequently, concepts such as Responsible Research and Innovation (RRI) (Mattke, Liu & Orr, 2016), affordable healthcare, value-based incentives, and payment models (WHO, 2010; WHO, 2011; Mattke et al., 2016; Auer & Jarmai, 2017) have emerged. The European Union, Japan, Canada and the United States supported these activities, with the

purpose of raising the standard of conformity for most medical device manufacturers as a consequence of globalisation (De Maria et al., 2018).

Harmonisation of regulation in the EU continues to be a challenge as the European Commission does not have complete authority over health issues but only creates a directive for guidance, which remains subject to the interpretation of the member states and implementation by them (Altenstetter & Permanand, 2007). The impact of the policies on manufacturers has been to change their innovation strategies to fund prudent designs, which are lower cost than those already on the market (Mattke et al., 2016). The associated global campaign for affordable healthcare, which made healthcare providers, institutions, and their medical staff concurrently responsible for the overall costs of patient health and for improvement of their performance (Mattke et al., 2016), also forced the manufacturers and innovation designers to partner in ensuring the enhanced health results demanded.

The liberalisation of the European market has made the regulatory process for medical devices even more complicated, since every EU member state is required to notify the European Commission of any intention to add requirements of higher standardisation, which are not stipulated in the current EU regulations (Altenstetter & Permanand, 2007).

The procedure is that initially the assessment regulations known as Essential Requirements (ERs), must be complied with, then the diagnostic, therapeutic and medical value analysis can take place. If a member state wishes to insert another layer of requirement, which was not provided earlier, the request must be supported by a report explaining why it is necessary, and this forms the basis for EU Commission approval or rejection (Altenstetter & Permanand, 2007). This process occurs frequently because the EU member states have no common approach to medical devices, despite the prevailing definition under EU law. Additionally, a medical device is not considered to be a human tissue engineered product, an organ, a cosmetic, a transplant or even a blood product, under current EU regulation (Altenstetter & Permanand, 2007); it is merely a device used to support or enhance research, clinical and laboratory procedures, and testing to improve patient health.

The EU directive on medical devices has evolved four times since 1990, with the new directive in 2005 adding tissue and cell treatments. The phase of change began with the Active Implantable Medical Devices (AIMD) legislation emphasis of the 1990 directive and another in 1993, the Medical Device Directive (MDD). In 1998 a much more comprehensive In Vitro Diagnostic Medical Device Directive (IVDD) was presented and by 2005 the proposed EU Medical Devices Directive for advanced procedures and therapies emerged. This was the forerunner of EU 2017/745, which has been implemented in 2022 after a five-year transition period (De Maria et al., 2018). Under this new directive, substantially more devices were moved to the highest category, and manufacturers must also present proof of clinical benefit and design, specific to the patient or user (De Maria et al., 2018).

The new regulations and its consequences on medical device companies are reviewed in detail in the next sections. At this point and from a political perspective it shall be mentioned, that one of the main objectives of EU 2017/745 is to integrate and to consolidate all national approaches to medical devices in the EU into a single framework (European Commission, 2020). However, certain national variations in procedures, laws and institutional implementation still exist (Peter et al., 2020).

2.5.3 EU Directive 2017/745 and its Consequences

Medical devices have previously been perceived as less risky compared with pharmaceuticals and medical biotechnology, historically resulting in less exposure to governmental supervision and regulation (Neeser et al., 2017). The risk profile of medical devices has increased significantly in recent decades as innovation activity increased and there have been substantial incidences of adverse clinical events and high recall rates (Groennvold, 2017). The most prominent example is known as the Poly Implant Prothèse (PIP) scandal, involving a French manufacturer of silicone breast implants, which used cheap industrial silicone instead of the approved material. This practice was not discovered for almost a decade; more than 300,000 women in 65 countries are believed to have received these implants and to have suffered numerous serious consequences (Greco, 2015).

This type of incident raised concerns about the way medical devices were regulated and monitored, so that on May 25, 2017, new regulations came into force in the EU to ensure a consistently high level of health and safety protection for EU citizens (Wagner & Schanze, 2018). These new regulations were intended to replace the existing directives after a transitional period in 2020, respectively 2021. However, owing to the Covid pandemic, the transitional period has been extended to May 2022 (European Commission, 2020).

The main purposes of the change in regulation are “enhancing competitiveness while ensuring the safety and performance of medical devices to achieve this, the Commission regularly liaises with patient and industry associations to explore ways of bringing innovation to patients whilst supporting enterprises and maintaining growth” (EC, 2020, p. 1). In this context, two new regulations are to be enforced:

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

2. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing directive 98/79/EC and Commission Decision 2010/227/EU.

Under Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, a European Conformity (CE) seal or mark will be required as proof of safety compliance (Clemens, 2018; De Maria et al., 2018; Guerra-Bretana & Florez-Rendon, 2018). To acquire the CE mark, manufacturers must implement several procedures, from selecting the assessment route that best conforms to their device, to identifying the device classification and evaluating its risks and benefits. The risks and benefits evaluation will be based on the period, which the device will interact with the body and the technical features of the device on which it is classified, as already indicated above (De Maria et al., 2018).

The EU Commission is empowered to harmonise the different international standards applicable under the new regulation and to formulate or create a unified or common standard for those devices, which do not possess existing standards or guidelines (Clemens, 2018; De Maria et al., 2018). The process for obtaining the CE mark for a class 1 device is illustrated in Figure 22.

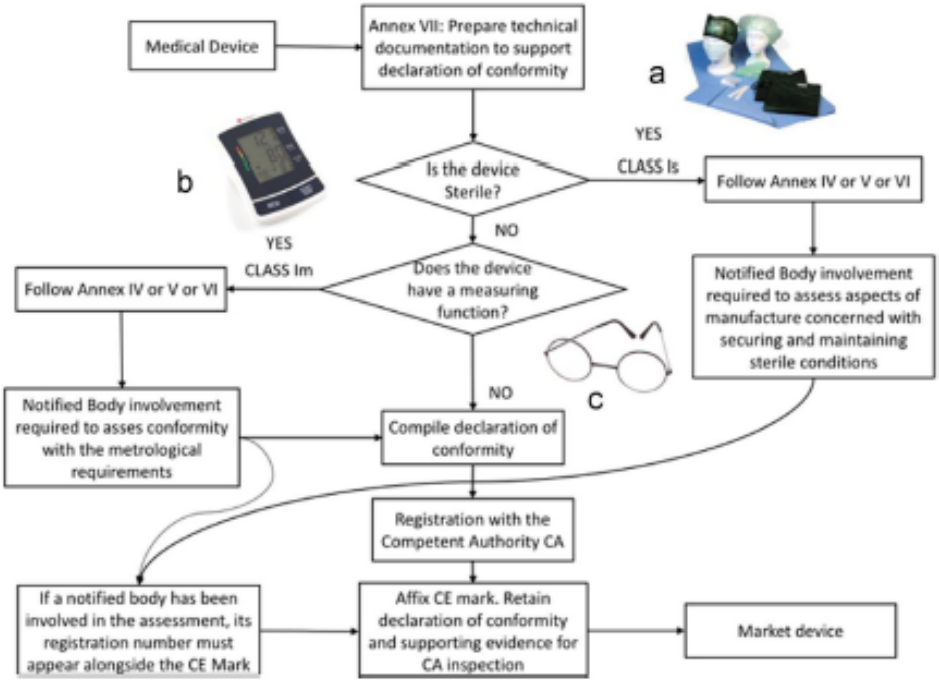

Figure 22: Process for Obtaining CE Mark – Class I Device

Source: De Maria et al. (2018, p. 158)

It is almost immediately evident whether the devices require any external body to provide the declaration of conformity: if it is not a sterile device or a measuring device, self-certification is possible and devices must be registered with the competent body so that the CE mark can be attached, otherwise the notified body must be involved in evaluating its conformity.

Manufacturers of class II devices employ a similar but more complex process, as indicated in Figure 23.

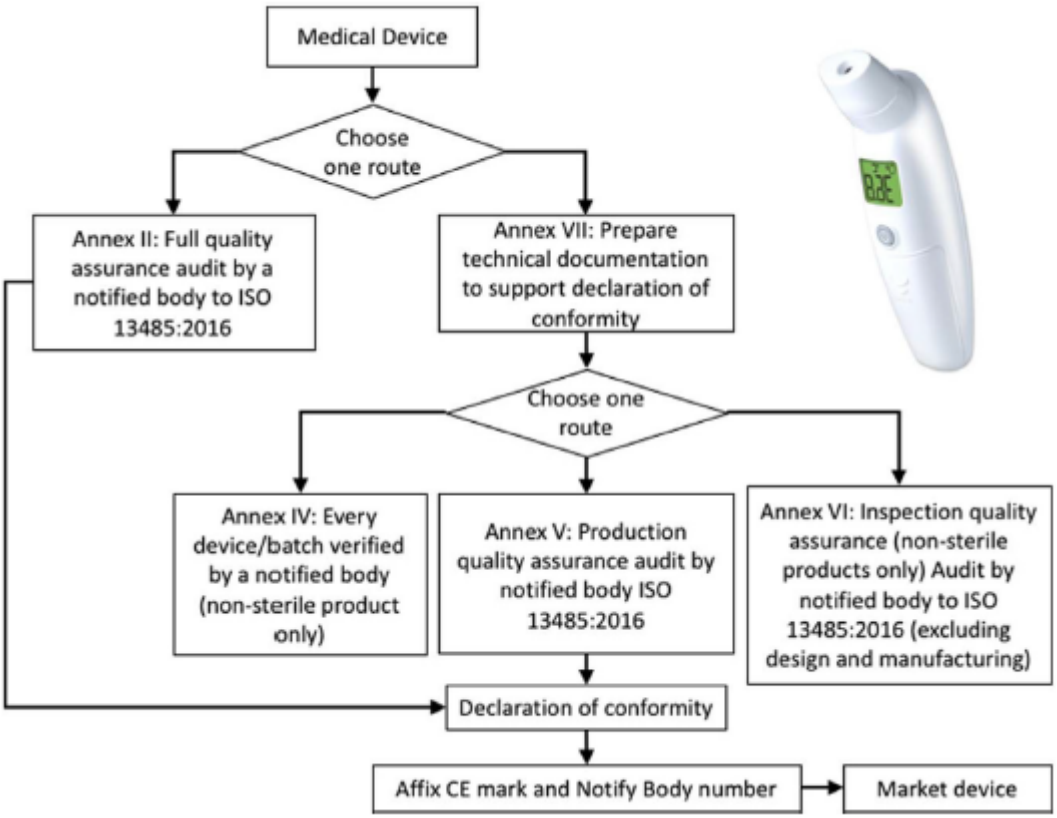

Figure 23: Process for Class II Devices

Source: De Maria et al. (2018, p. 159)

The example here is a contactless thermometer, the manufacturer can choose from two routes: one in which the entire audit is conducted by the relevant ISO or the second in which the manufacturer prepares the full technical statement, and a notified body is involved in assessing conformity (De Maria et al., 2020); it is evident that this will be a costlier route to CE mark than for class I devices.

The class III device is graphically illustrated in Figure 24 with hip joint implant as example.

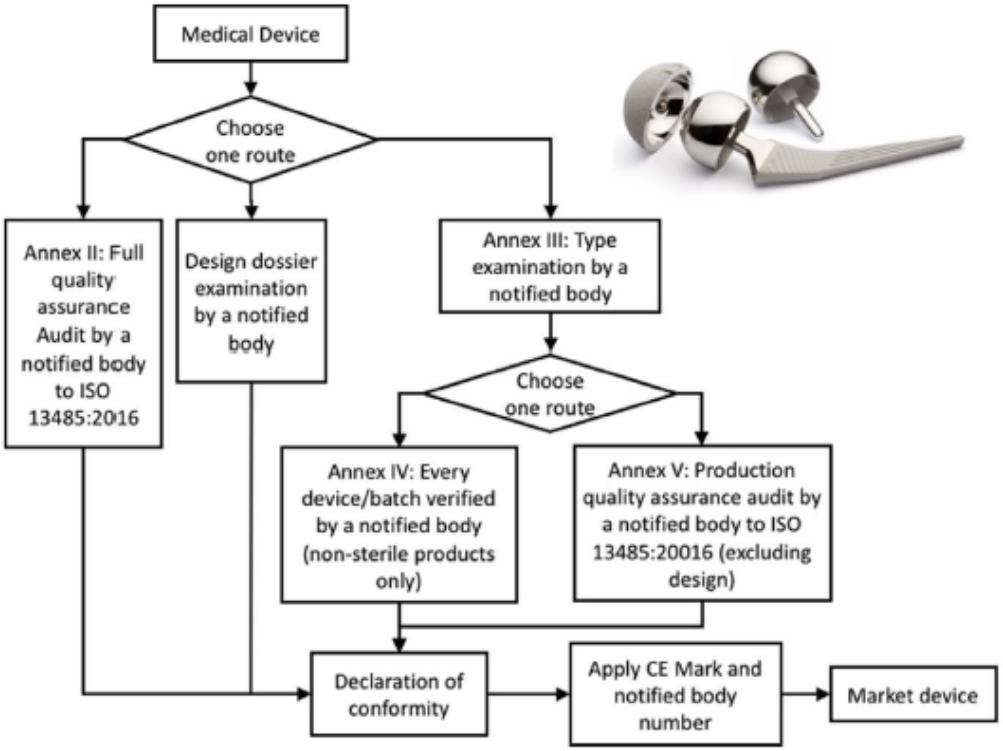

Figure 24: Class III Procedure for CE Mark

Source: De Maria et al. (2018, p. 160)

Three options are available to the device manufacturer, all comprising the involvement of a notified body for all process elements (De Maria et al., 2018).

These illustrations provide a guide to the cost impact of the new processes for launching and marketing the device. All notified bodies which comprise the authorised sector to assess the devices, must be registered under the new Medical Device Regulation (MDR), as well as device manufacturers and all importers (Clemens, 2018).

The devices must also be designated a Unique Device Identification (UDI) as well as the CE Mark, and technical record updates are also mandatory based on the articles added to the regulations for clinical trials and analyses. Additionally, it must be labelled by the manufacturer with advantages and limitations. The extension to the European Database of Medical Devices (EUDAMED) is another change, which is intended to allow access by the notified bodies, the regulatory

offices, and the manufacturers, but also to be available for public information and scrutiny. The Post Market Clinical Follow ups (PMCFs) and other surveillance reports are published and made available to concerned parties (Clemens, 2018).

2.5.4 Practical Issues for Innovators and Manufacturers

The new directive (EU) 2017/745 will force manufacturers to innovate to transform current designs to meet their requirements, with no regard for the proven record of a device but purely on new assessment and procedures (Clemens, 2018; De Maria et al., 2018; Guerra-Bretana & Florez-Rendon, 2018). The number of significant alterations to the previous regulations means that manufacturers can expect far more stringent certification requirements and increased intervention from enforcers (Bach, 2018). These factors will have a substantial impact on time and cost to market the devices, require regulatory knowledge, and bear the risk of products not being approved. Therefore, the changes are perceived as a severe threat to innovation, since SMEs may not have the financial, human and knowledge resources needed to comply with the new regulations (Yeo, 2018). The underlying assumption and a proposition in the literature covering SME is the resource limitations compared to larger companies (Colombo et al., 2012) and the comparably much more intensive competition (Pillania, 2009).

One of the issues for manufacturers, apart from the added bureaucracy and cost of ensuring conformity with the legislation, is that many medical devices have been categorised as a higher risk class than previously, as indicated above. The manufacturer must prove that the device complies with the relevant EU regulation to be market ready. The inference is a longer time gap before entering the market, resulting in higher cost. The SME manufacturer is therefore very likely to lose the competitive advantage or fail to survive, although small and highly agile, and better able to be a first mover in the market than a large company (Maresova et al., 2020a; Tajvidi & Karami, 2015). The consequences are that many small firms would be unable to comply and/or their survival would be uncertain (IMAP, 2019), an issue of attracting investment, to remain a viable business (Mason & Kwok,

2010). This situation could also engender high rates of small business mergers to scale up operations, whilst implementing regulations effectively (IMAP, 2019).

The major objective of the new regulation is to improve patient health at lower cost, which will require medical device companies to collaborate and cooperate with each other and with the regulatory agencies, to accomplish lower testing costs even at the early development stage (Bergsland et al., 2014; Mattke et al., 2016; Guerra Bretaña & Flórez-Rendón, 2018). The regulation centred approach to innovation has made the process extremely time consuming and costly (Ikram, 2015) because the focus is not merely on product development but also in the services related to the innovation.

The tighter regulation might deter US firms from focussing on European markets, which they had previously regarded as easier entry than domestic market (IMAP, 2019), owing to high Federal Drug Agency (FDA) regulatory demands (Janetos, Xu, Walter & Xu, 2018). Instead, they may concentrate on meeting domestic markets as the more profitable alternative (IMAP, 2019), which could be helpful for EU firms' domestic sales prospects as they also try to adjust to the new rules. In contrast, the impact of new regulation in China is considered a potential driver of more innovation in the sector, representing an additional threat to the EU manufacturer, which must spend more time and resources on compliance with the regulation than on innovation (van den Heuvel et al., 2018). Therefore, a significant threat to manufacturers is the slow implementation of the regulation, which for up to 40% of firms is further complicated by their current reliance on UK Notifying Bodies and uncertain consequences of Brexit on the validity of their regulatory status in the relatively short term (IMAP, 2019).

Despite the attempts to harmonise global regulation, the alignment of EU regulation with that of the manufacturers' major export markets is an additional issue, which may impact on the specifications of the products and/or increase cost and time (Medical Device Network, 2017a). The US regulation is particularly important to European Manufacturers since this is the largest export market and is complicated by small market share in other countries and possibly in UK after Brexit. A report by Medical Device Network (2017b) states that UK imported 60%

of total medical devices in 2016, 75% of which were manufactured in the EU, so that EU manufacturers would need to ensure regulations were sufficient for future UK regulations.

The concerns of SME leaders in the medical device industry regarding the impact of the new regulation on their capacity to innovate is critical, as so little empirical research has been conducted on the issue. Also, little conclusions can be drawn from other industries outside medical devices, since in general a gap exists regarding how EU regulations will hinder or stimulate SME innovation (Pelkmans & Renda, 2014). Some research represents the exemption. A systematic literature review conducted by Ashford (2000), for example, suggests that stringent regulation can stimulate innovation and competitiveness. Industrial biotechnology however is an opposite example. Because EU regulations are much stricter than in other global regions, most manufacturing activities have been transferred to other parts of the world (Cantley & Lex, 2011).

The beforehand mentioned studies represent a macroeconomic view and do not necessarily provide answers to the challenges of companies on a microeconomic level. Hence this research is focussed on answering how individual SMEs can overcome the challenges, and it will not try to evaluate the overall impact of the new regulations on innovation and competitiveness in the European medical device industry (Maresova et al., 2020a). Also, this research does not attempt to quantify the impact of the new regulations, neither on a macroeconomic nor on a microeconomic level. An approach to this aspect is made by Maci and Maresova (2022) and recommended for further research.

Whilst not being the focus of this research it shall be mentioned that regulatory approval of products alone is no longer a guarantee of success, especially since reimbursement costs are increasingly difficult to acquire (Medical Device Network, 2017a). The reimbursement procedure also appears complex and is country specific, for instance, a US report (La Pointe, 2019) states that reimbursement can take at least six months, whilst Kuo & Manaker (2019) estimate two to five years. A study by Schaefer, Schnell and Sonsilla (2015) confirmed the range of reimbursement in EU countries. In France, for instance, it could take up to two years for diabetic devices.

2.6 Innovation in the EU Medical Device Industry

Medical device regulation changes have increased the investment of time and money in the innovation and manufacturing of medical devices, especially in the EU. The medical technologies industry is characterised by rapid change, and the additional challenges instigated by the combination of the EU regulations and the diverse requirements of individual EU member, make the launch of new devices more difficult, owing to the inevitable delays of the new testing and certification regimes (WHO, 2010; Akenroye, 2012; Tamsin & Bach, 2014; Ciani et al., 2016; Lee, 2018; Vincent, Niezen, O'Kane & Stawarz, 2015).

The many challenges introduced by the evolving EU directives on medical devices, which now include in vitro diagnostics medical devices, infer that SMEs, investors and other funding bodies are forced to collaborate to control costs related to labour, technological data and information and training. Therefore, the practical outcome has been the adoption of open innovation models (Chesbrough et al., 2006; Guerra Bretaña & Flórez-Rendón, 2018), the establishment of innovation hubs (Meyer, 2015; Arkhipova & Arkhipov, 2016) and other approaches to new product development for instance the stage gate model (Rochford & Rudelius, 1997), multiple convergent process, product and cycle time excellence, the total design approach and third generation new design models (Maresova, 2020b; Owens & Atherton, 2018).

Researchers also established another collaborative approach, which may be more appropriate for medical device innovations involving high costs due to regulatory pressures (Bengtsson & Kock, 2000; Gnyawali & Park, 2009). The concept, denominated coopetition, is characterised by collaboration between competitors, which share the development costs and challenges (McCarthy et al., 2018).

Diverse cooperation and collaboration models, which are utilised by SMEs in the EU are appraised in successive sections as they will be discussed during the interviews. Also, there will be comparison of their strengths and weaknesses with those of coopetition in section 2.7.

2.6.1 Open Innovation and Innovation Hubs

Open innovation in medical devices is characterised by collaboration being established between the device developers and the regulating bodies at an early stage, so that regulators integrate the scientific requirements (Guerra Bretaña & Flórez-Rendón, 2018). This approach provides a good balance between the safety and efficacy of the product, high quality assurance and an efficient assessment and review process that motivates and promotes innovation of medical devices and is especially relevant for newly emerging technologies and scientific discoveries (Guerra Bretaña & Flórez-Rendón, 2018). In some cases, open innovation applies to collaboration between the developers and other stakeholders, for instance patients, doctors, researchers and regulating agencies (Bayon et al., 2016), when consideration must be given to business agreements, IPR and the revenue shares of all collaborating parties.

The creation of innovation hubs was driven by two major factors which constitute supply planning, materials planning and delivery to manufacturing plants (Arkhipova & Arkhipov, 2016). They are primarily important to network companies that benefit from a centralised, efficient procurement system for a continuous, secure supply of materials and/or finished products (Arkhipova & Arkhipov, 2016). The European hub consider the best suppliers to be located at 150 to 250 kilometres because they benefit from lower purchasing rates and less risk of material shortages (Arkhipova & Arkhipov, 2016).

2.6.2 New Product Development Models

The stakeholders in the medical devices sector benefit from gaining an understanding of the new product development process, to be more prepared for the introduction of enhancements and improvements (Owens & Atherton, 2018). This can be accomplished by appraising New Product Development (NPD) models, which identify the issues of the device users, medical staff, and patients, which must resolve by collaborating parties. This will enable the stakeholders to evaluate the suitability of available information to provide a solution to their specified requirements. Therefore, the model supports a formal study of an idea,

identification of specific needs to be integrated and on-going improvements to certain features, as well as its longer-term feasibility as a commercial venture (Owens & Atherton, 2018). An appreciation of the NPD process stages allows the integration of user needs with compliance or regulatory issues and is advantageous to all associated NPD parties. Each NPD model has specific advantages and limitations, which need to be considered so the most advantageous model can be selected for each purpose (Owens & Atherton, 2018).

2.6.3 Stage Gate Model

The Stage Gate Model (Figure 25) presents the product development process in phases allowing the concept or idea to develop simultaneously with the project implementation stages (Owens & Atherton, 2018).

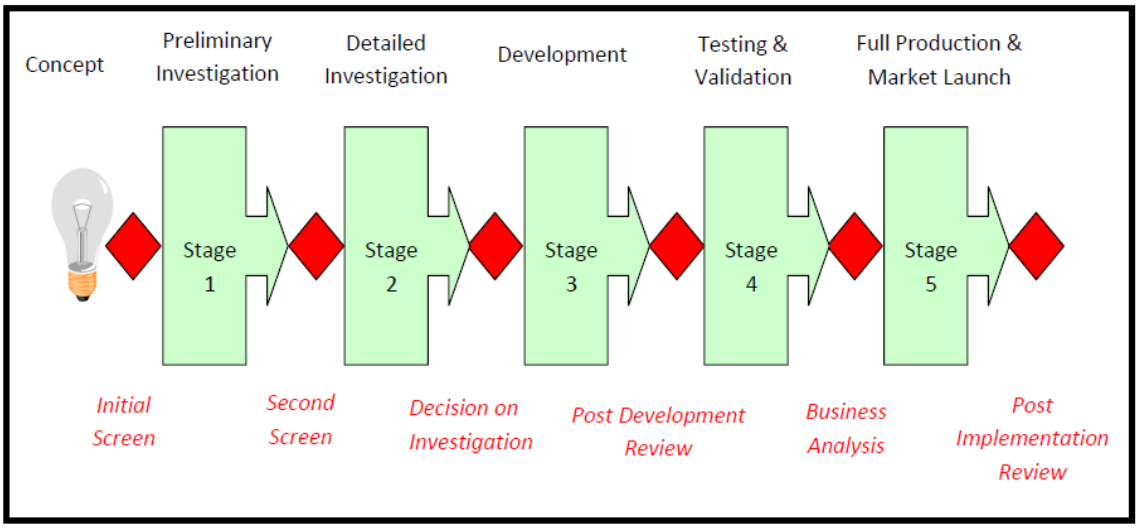

Figure 25: Stage Gate Model

Source: Owens & Atherton (2018, p. 8)

This model primarily functions as an information gathering mechanism to encourage early feedback on an idea and avoids technical and/or financial errors in formulating product development decisions (Owens & Atherton, 2018). The

main limitation is that the focus is on technical design so that end-user needs are ignored (Owens & Atherton, 2018), they are not involved in the R&D process, and the approach would be in misalignment with current healthcare policy focus on value (Money et al., 2011; Mattke et al., 2016).

2.6.4 Multiple Convergent Process

The multi-convergent process integrates the inputs of people involved in the process from multiple disciplines, to establish the successes in each specialist group and the model (Owens & Atherton, 2018). This objective is accomplished by documenting the progress of the tasks associated with each of the disciplines so that aspects that they have in common, convergent points, are identified, enabling factors and conditions to be evaluated in an integral manner (Owens & Atherton, 2018). The major disadvantage is that convergence is limited to the agreed areas relating to cross-functional decisions, whilst the specialist groups work independently on all other activities. Therefore, efficiency levels are poor, and management of the process is difficult.

2.6.5 Product Cycle and Time Excellence

The product cycle and time excellence model are designed primarily to ensure fast time to market, which is the economic result of the process, with decisions being limited to senior managers rather than the NPD team, and who also grant the product approval before it can be utilised by the relevant stakeholders (Ikram, 2015; Owens & Atherton, 2018). The focus of the model is on the development time which is covered by documentation and the allotted budget (Owens & Atherton, 2018). The process is illustrated in Figure 26.

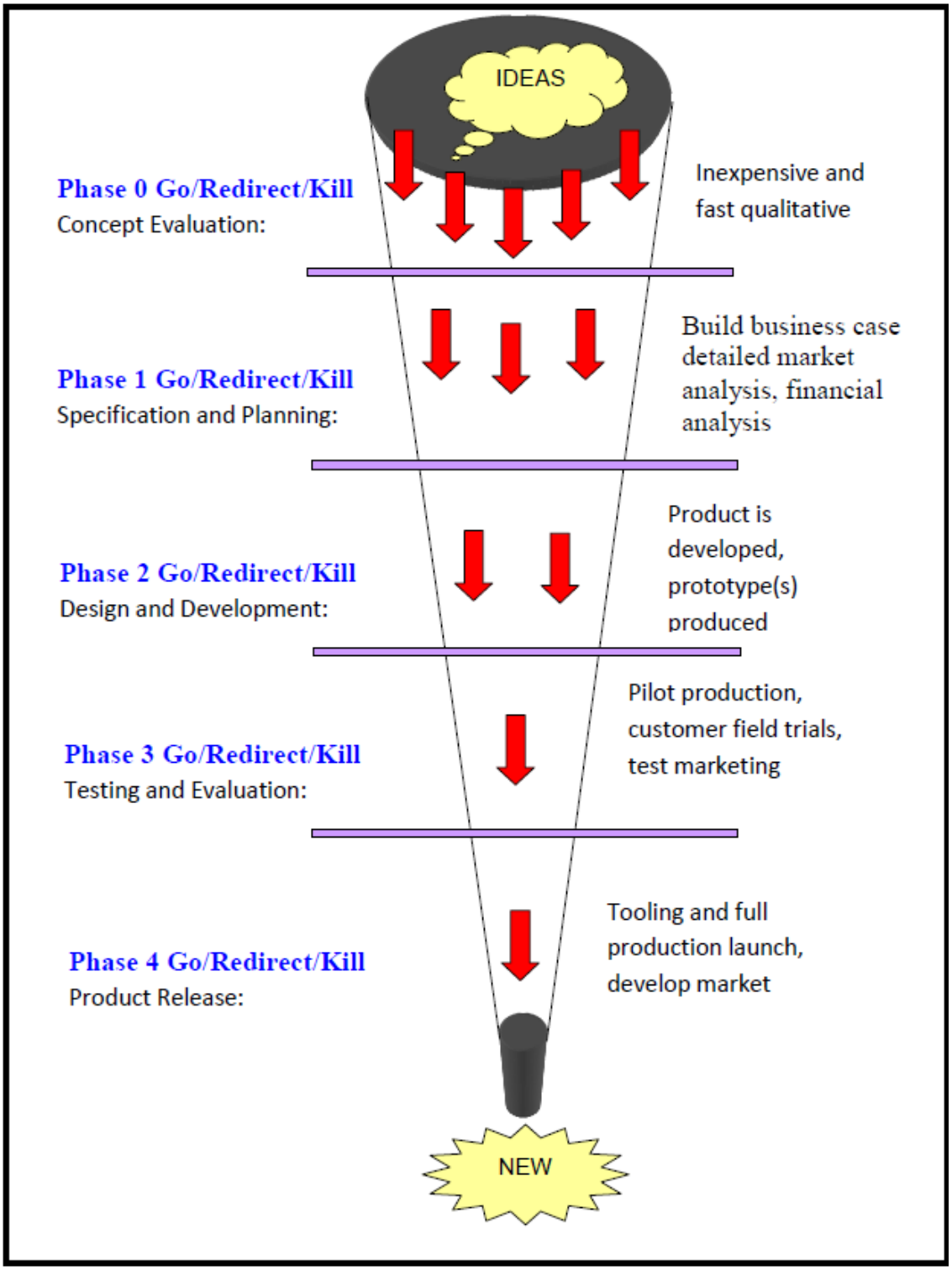

Figure 26: Product Cycle and Time Excellence Model

Source: Owens and Atherton (2018, p. 12)

As the illustration suggest many ideas are created initially and gradually filtered to find the best idea(s) in terms of commerciality and speed to market dimensions,

decisions are made to reject, accept or redirect each idea at each product cycle stage (Owens & Atherton, 2018).

The overall objective is to minimise product development time and to gain competitive advantage (Ikram, 2015). The five phases each have between 15 and 20 steps, each comprising between ten and thirty tasks; each step is timed to determine the total development time for each idea. Although, the core groups or teams are assembled at the introductory stage, it is the senior managers who decide the product strategy, select the technology, implement, and eventually decide if the project is submitted to cross project management (Ikram, 2015; Owens & Atherton, 2018).

Whilst the advantage of this model is that it enables manufacturers to focus on delivering high return on investment during the first market launch of the product (Ikram, 2015), it tends to integrate early 20th century scientific labour practice in the timing aspect and deters team innovativeness. The fast development of technology infers that the new product life cycle will be increasingly shorter resulting in lower profits, owing to the high cost of development. Therefore, large medical devices companies tend to focus on late-stage strategies, such as adding valued-added services, and developing newer and advanced devices (Ikram, 2015). In this context, the collaboration between the developers, manufacturers and medical practitioners is deemed very important.

2.6.6 The Total Design Approach

In contrast to the before mentioned models in this section, which tend to focus on development as a series of independent stages, the total design model is perceived as a continuous process in which stakeholders collaborate to gather information and ideas, develop them, and manufacture the product: user support being a major input (Owens & Atherton, 2018).

The design begins with a market study, establishing market needs, and ends with the market launch, and actual sales. In this perspective it is similar to the product cycle and time excellence model, as well as also being economically motivated or business oriented. The design evolves during the time of development and is

established by dividing the process into stages according to the problems that must be resolved (Brown et al., 2008; MacCormack, 2012; Owens & Atherton, 2018), as presented in Figure 27.

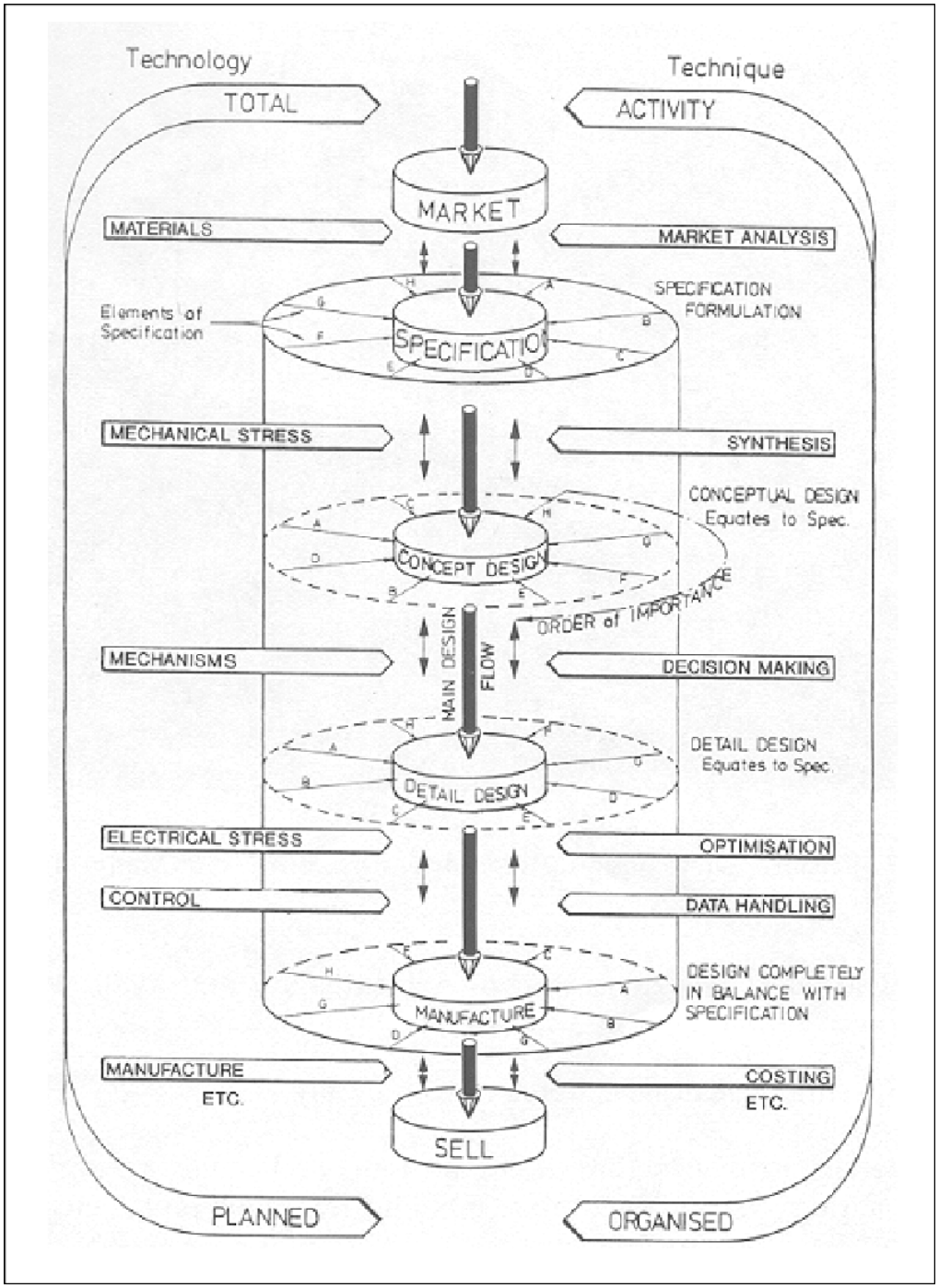

Figure 27: Total Design Approach

Source: Owens and Atherton (2018, p. 16)

The approach resembles a spiral process in which the design evolves in four major phases of formation, evolution, transfer of technology stage and reaction stage, which leads back to the formation stage until the desired outcome is achieved (Owens & Atherton, 2018). Since the process is interactive, overlaps may occur as it evolves but, although promoted by UK higher education engineering institutes, its disadvantage is that too technical for stakeholders other than engineers and technical specialists (Owens & Atherton, 2018). Other limitations are the lack of emphasis on gathering data on user preferences and soliciting input from other specialist disciplines.

2.6.7 Requirements Capture Process Model

The requirement capture model emphasises the value of the development team insights and understanding of the issues and their significance to the end user. Its advantages are that it gathers multiple perspectives on the same data and recognises that activities and events generate changes in how user requirements are perceived; these two initiatives are vital to accurately defining the required product features. Hence, its effectiveness depends on the expertise and motivation of stakeholders involved (Owens & Atherton, 2018).

2.6.8 Third Generation Process

The third-generation process model integrates hardware, software and human intervention to identify and characterise issues of fluidity, focus, flexibility and fuzzy gates, which mean that every decision made is based on the particular context (Owens & Atherton, 2018). Its major limitation is the resulting complexity associated with decision making at every stage and, consequently developer, technicians and senior managers must be involved in every decision, which slows the pace of development (Zollo, Reuer & Singh, 2002).

2.7 Coopetition in the European Medical Device Industry

Chapter 2.4 introduced the concept of coopetition from a general perspective and linked it to organisational theories and general innovation management. After reviewing the EU medical device industry, the new legislation and innovation in the industry in chapters 2.5 and 2.6, this section now will investigate the actual application of coopetition in the medical device industry, especially with regards to SMEs.

2.7.1 Coopetition as SME Growth Strategy

The high cost involved in the regulatory processes associated with design, manufacture and certification of medical devices combined with high taxation and an extremely complex reimbursement scheme have resulted in innovation becoming very challenging in the EU medical device industry (Bergsland et al., 2014, Mattke et al., 2016). As a highly relevant aspect, the new EU MDR has expanded the definition and classification of medical devices and this factor may enhance medical device firm costs because it is likely to reclassify some existing devices (Bergsland et al., 2014, Mattke et al., 2016). Coopetitive arrangements may help to minimise these additional costs especially by being responsible for conducting clinical trials, defining the device benefits and associated evidence, which are a huge challenge of the new MDR as demonstrated in section 2.5.

The MDR also focuses on the device life cycle, which is a highly significant change from the previous legislation; in the past approval was a single occurrence but in the new regulatory regime the medical device SMEs must conduct post market device performance reports including technical documentation. This is an extremely costly process, as it consumes employee time and related expenses, coopetitive alliances could be organised to significantly reduce the financial impact for SMEs with limited resources and reduce delays in commercialising devices. This arrangement negates the need for employing external professionals to help with the pre-assessment, whilst allowing SMEs to share those costs without loss of device innovation quality (Bergsland et al., 2014, Mattke et al., 2016).

Therefore, the coopetition strategy for survival and growth can be an attractive alternative for medical device manufacturers, as demonstrated by previous studies. One is the reported success of the coopetitors comprising the Innovation Learning Network (ILN) associated with Kaiser Permanente (McCarthy et al., 2018). The major advantages in this coopetitive group are access to information, data and knowledge, faster resolution of problems, a sense of community belonging and individual firms gaining a reputation as being a part of a positive movement (McCarthy et al., 2018).

Previous studies have also shown that the most advantageous time to introduce coopetition between competitors and other stakeholders is between the middle and final stages of innovation to minimise the costs associated with regulation, clinical trials and after sales responsibilities. These stages, after the device has been classified, are the ones that are most concerned with regulation, have the least risk of one or more of the coopetitive group being untrustworthy in terms of self-interest such as developing the idea alone (McCarthy et al., 2018).

Three types of innovation are applicable to medical devices: incremental, minor changes to the present device; radical innovations characterised by major discoveries; transformative innovation which refers to changes that affect the organisational structure (Akenroye, 2012). Coopetition tends to be associated with the external factors of innovation and development such as market behaviour and changing customer needs (Kraus et al., 2017), however, technological knowledge acquired during the process may generate minor or incremental changes to devices of individuals as they share information on market responses. It may also lead to a change of mindset (Ringberg et al., 2019), which brings about incremental changes in the design.

Therefore, successful innovation to generate the value-based healthcare demanded by public policymakers relies on the need for collaboration and cooperation between the three major groups with that common objective, the SME innovators, the regulators, and manufacturers (Bergsland et al., 2014). The EU medical device industry is mainly comprised of SMEs as a governmental social pre-requisite for innovation (Akenroye, 2012) but their participation is predominantly in the design and innovation stage, whereas manufacturing and

patenting of the design is usually awarded to larger firms that fund the research and development (Auer & Jarmai, 2017).

SMEs are motivated to innovate to satisfy consumers changing preferences not merely to improve a previous model (Auer & Jarmai, 2017). Medical device innovation combines technological processes and advancements in medical knowledge, which means that the medical purpose is validated by qualified medical personnel and the technical component by specialists in engineering designs and functionality (Tamsin & Bach, 2014); clinical trials demanded by regulators are the point of the device innovation process when both parties validate the applicability of the product (Auer & Jarmai, 2017). This means that researchers and manufactures perceive innovation to establish influence and credibility in the market, rather than merely focussing on the economic outcomes.

In contrast, the position of regulators in medical device innovation is to create and implement policies, which ensure the appropriateness of the innovation regarding its technological features or the advance in treatment it signifies, plus global accessibility, affordability, and availability (WHO, 2010). The major responsibility of the regulator is to ensure the suitable quality, safety, and effectiveness of the medical device within their jurisdiction and on a global scale (WHO, 2010; WHO, 2011; WTO, 2020). Therefore, regulators must satisfy the demands of policymaker's emphasis on cost effective, affordable innovations, whilst taking a realistic perspective on the costs of developing the device and subjecting it to clinical trials (Mattke et al., 2016). Concurrently they are responsible for facilitating the harmonisation of global regulations and approaches.

Manufacturers have traditionally been the primary source of funding and their concerns are development cost and a commercial product that can be marketed successfully in the shortest possible time. The manufacturer perception of the product benefits is purely economic, and contrary to that of regulatory bodies, which focuses on human factor engineering, user-centred design methods and ethical authorisation of medical devices that manufacturers consider costly, tedious, and constraining on their activities (Money et al., 2011). An additional concern for manufacturers is speed of technology change that is in imbalance with the slow process of user participation in authorisation, which may lead to

loss of opportunity, pricing problems and the level of return of investment (WHO, 2010; Money et al., 2011; Bayon et al., 2016; Auer & Jarmai, 2017).

In addition to the existing challenge of reducing the cost of innovation, which is associated with expensive engineering technology, manufacturers also have to be prudent about which innovations align with affordable healthcare, whilst also observing suitable quality and safety standards (Mattke et al., 2016). The value approach to health care has redefined the way manufacturers and financial investors produce their innovations. The manufacturers perspective on innovation continues to be commercial superiority, increased sales and a worthwhile return on investment or capital gain, whilst in contemporary terms superiority has become associated with producing a competitive alternative brand which costs less than the leading brand in the market and ensures global acceptance (Mattke et al., 2016).

In the absence of collaboration between these parties, it will be difficult to motivate SMEs and manufacturers to innovate in the near future, whilst coopetition between them would facilitate sharing the cost of trials, research and learning (Gast, Filser, Gundolf & Kraus, 2015; McCarthy et al., 2018). Time to market is critical for technology focused organisations to profit from their investments, because of the rapid nature of technological advancement means short product lifecycles.

Collaboration between coopetitive partners is not necessary in the product design but more concerned with safety data and user requirements deriving from clinical trials and post purchase feedback. Therefore, the collaboration required is limited to information to assist the regulators to integrate science and technology into associated laws and procedures for more realistic, effective product review and assessment, the middle and final stages of the innovation process. Consequently, coopetition is an appropriate strategy for innovation in the EU medical device industry, and to counterbalance the increased time and costs of regulatory processes and increased competition (Brandenburger & Nalebuff, 1996; Bergsland et al., 2014; Guerra Bretaña & Flórez-Rendón, 2018).

An important factor in the coopetitive arrangements of EU medical device SMEs is the duration of the coopetition because the fast technology changes may necessitate medical device companies accessing new knowledge or technology. The coopetitive relationship should, therefore, be agreed on a project basis, to enable flexibility and access more learning, knowledge, and resources for small and large companies. This arrangement will also lessen the occurrence of bigger companies dictating the coopetition goals and smaller SMEs losing their sense of being decision makers in the coopetitive process. In R&D, a longer coopetitive relationship initially accounted for a reduction in transaction costs, especially for acquisition of new knowledge or technology, since the innovation period is longer (Cygler et al., 2018). The scope of the coopetition in medical device innovation is also related to its potential success and benefits from financial management, market entry and development and technological advances (Cygler et al., 2018).

For SMEs in specific, several success factors for coopetition keep quoted in the literature to be potentially more relevant than others. Thomason, Simendinger and Kiernan (2013), for example, suggest a coherent model of such factors, reaching from the individual, i.e., company owners and/or managers level, via the firm level to dyadic as well as triadic relationships amongst firms. According to these authors individual levels of trustworthiness will positively relate to successful coopetition, as will levels of imperfect knowledge. Firm financial resources and perceptions of market entry difficulties are negatively associated with the successful application of coopetition. Moreover, the presence and valence of incentives might be able to improve the dyadic relationship between the partners (Thomason et al., 2013). Particularly in the case of small firms with limited financial resources.

Additionally, with regards to the triadic relationship and the organisational stress coopetition might cause, (Thomason et al., 2013, p. 23) suggest "…that [value creation] should be handled either by creating two teams, one involved in collaboration, and one involved in the competitive aspects, or by using an intermediary to coordinate the relationship. Either choice allows individuals to behave in a manner that either promotes collaborating or competing but does not have to balance both simultaneously. Either choice also helps to establish control.

The trust, commitment, and mutual benefit aspects of a successful coopetitive relationship may require monitoring and the adoption of various ethical and strategic policies, procedures and control systems designed to build and maintain social capital over the long term."

Research on coopetition between SMEs so far has stayed on a rather superficial level. Bengtsson and Johansson (2014) tried to understand how coopetition enables SMEs to create entrepreneurial opportunities in complex business environments. They studied SMEs managerial challenges when collaborating with larger competitors, especially, how such an approach could create new business opportunities.

The main challenge encountered by the companies they studied was their liability of their actual, relative smaller size. Their goal was to enter a market in the first place, and straight-forward collaboration with a larger competitor appeared, in some cases, a viable option to do so (Bengtsson & Johansson, 2014). Very important was the need to create legitimacy by means to being considered worthwhile to partner with a larger, potentially incumbent corporation.

Other issues relevant were role flexibility and agility to sustain opportunities (Bengtsson & Johansson, 2014). The authors explain both terms as being about speed needed to develop and exchange relationships on the one hand, and the ability to manage several relationships at the same time and coping with potential issues that might arise from this challenge. More explicitly they state that these "… two capabilities are closely related; as firms develop simultaneous capabilities for flexibility and undertaking different roles in relations with competitors and customers, and to be agile in building and reconfiguring their relations over time, in order to sustain their opportunities. […], by developing these capabilities, they manage the challenge related to large firm tendencies to lock in or control successful small suppliers and balance the coopetitive relationship" (Bengtsson & Johansson, 2014, p. 415).

2.7.2 Comparison of Open Innovation and Coopetition

The purpose of open innovation is to accelerate innovate outcomes. In relation to medical device innovation, open innovation may be applied to the collaboration between device developers and regulating bodies to formulate regulatory science or parameters combining science and legislation (Guerra Bretaña & Flórez-Rendón, 2018). Hence, collaboration occurs between competitors of devices, which have similar classification and purpose to reduce the cost to market and after sales controls, without share original ideas and/or patented products.

A quantitative study conducted among Malaysian high-tech SMEs, established that open innovations founded on coopetition have a positive effect on the company's open innovation performance (Hameed & Naveed, 2019). A survey was conducted, and the data analysed using Partial Least Square (PLS) Structural Equation Modelling (SEM), by Hameed and Naveed (2019) to establish the major characteristics of coopetition in context. The three major findings were that: coopetition represents collaboration with competitors to accomplish a common objective; successful coopetition requires interpersonal and inter organisational trust and dependency as mediating variables to establish its effect on the company's open innovation performance; the company's open innovation performance is measured in terms of its awareness of open innovation principles, communication between internal and external colleagues, and readiness to acquire new learning.

The study findings indicate that open innovation founded on coopetition will succeed to improve the company's open innovation performance only when the factors of trust and dependency are fulfilled and requires an associated effective mechanism such as a legal agreement (McCarthy et al., 2018). Therefore, coopetition cannot be directly compared with open innovation, rather the two concepts are interrelated in the sense that coopetition improves open innovation, because of the combined human capital capacity of the participating firms.

Innovation hubs are created primarily for facilitating material acquisition and storage (Arkhipova & Arkhipov, 2016) or to provide a central common area for coopetitors to learn without the need for individual disclosure to the entire group. The arrangement is secured by pre-arranged legal agreements between the

participants in coopetition (McCarthy et al., 2018). They are fundamentally the asset sharing arrangements associated with the coopetitive relationship, which may have a significant impact on the industry or the region where coopetitors are located (Bengtsson et al., 2010).

2.7.3 New Product Development Processes and Coopetition

New Product Development (NPD) models do not compete with coopetition as a business approach in any way but are relevant regarding the stage at which a coopetition effort may be effective, for instance for enriching technical knowledge (Owens & Atherton, 2018), or external conditions including regulations and laws (Dorn, Schweiger & Albers 2016).

Product development processes demonstrate that coopetition is a deliberate strategy at the company level and concerns the flow of development, enabling individual companies in a coopetitive relationship to define the participating actors, their point of entry to product development and the extent of information, which may be released to optimise advantage for the company (Tidström & Rajala, 2015). In this perspective, coopetition becomes a spontaneous rather than a pre-arranged status or one directed by managers of the larger participating firms or institutions (Della Corte, 2018). Therefore, product development processes and coopetition can be distinguished by former associated with how products are developed, whereas the latter refers to a business specific strategy between competing companies (Della Corte, 2018), with the purpose of maximising benefits from shared knowledge and scarce resources. These processes introduce the ideas of “technovation”, defined as coopetition taking place during the innovation process (Gast et al., 2015).

2.7.4 Coopetition and the other Strategies for Innovation in the Medical Device Industry

The new EU medical device regulations combined with increased taxation necessitate a strategy that will enable the co-existence of the stress on safety with the need for more effective health care at lower cost (Bergsland et al., 2014;

Ikram, 2015; Mattke et al., 2016). In relation to innovation, the EU's RRI strategy integrates a policy of involving more stakeholders in medical device research and has the purpose of lowering the cost of medical devices, whilst their effectiveness remains equivalent to those offered to medical practitioners by large medical device companies (Ikram, 2015; Iordanou, 2019).

The principle is implemented by requiring medical device manufacturers to observe RRI in processes, and to strictly adhere to ethical business practices (Iordanou, 2019). Ethics has become a major concern owing to the level of corruption in the sector (Bergsland et al., 2014) and is believed to be driven by high levels of competition and the existence of monopolies, which exist because the large companies protect their products with very wide-ranging patents that prevent further innovation by SMEs. In the context of reducing the cost of medical devices to make them more widely available in poor countries, this practice is undesirable (Bergsland et al., 2014).

The EU regulation is the means to reduce the influence that medical device companies exert with medical practitioners regarding the type of device to use or endorse (Ikram, 2015) and especially important in the context of health care budget reductions and the emphasis on value for service. In the pharmaceutical industry generic drugs have become the preference because the EU encourages purchase of cost-efficient supplies and products (Ikram, 2015). The RRI strategy lengthens the period for innovation and the associated costs because it is focused on product features and services (Ikram, 2015). Study findings suggest that SMEs are reluctant to undertake research involving patients, especially in the early stages and in the innovation process, frequently because of concerns regarding the danger of raising expectations they cannot meet, whilst others are apprehensive about increasing costs and producing less competitive products.

2.7.5 Coopetition in the European Medical Device Industry: Advantages, Limitations and Future Direction

The medical device sector is classified as a technology industry, characterised by rapid technological evolution and predominantly SME firms. However, lack of

funding and available resources has induced coopetitive arrangements with other SMEs, which has become important to enhancing innovation activity (Gast et al., 2015). A quantitative study, relying on regression methods, conducted by Quintana-Garcia and Benavides-Velasco (2004) found that cooperation among competitors greatly influenced their innovation capacity, especially regarding individual SME product development. The reasons identified were that sharing of managerial and marketing skills, financial acumen, and technological resources strengthened the participating SMEs' individual innovation performances. The phenomenon was explained by Gast et al. (2015) as being a consequence of the small size of SMEs contrasting with certain external factors and conditions, which necessitated the need for coopetition.

In the EU, the increasing imposition of new medical device regulation and its rigidity, necessitated cooperation amongst SMEs, even those competing, owing to the higher cost, certification and time to market (Clemens, 2018). The effects of the MDR are exacerbated by the requirement for EU member states to harmonise procedures and, therefore, to eliminate different approaches to implementing new medical device directives (WHO, 2010; Bergsland et al., 2014; Guerra Bretaña & Flórez-Rendón, 2018). Additional complications are: the withdrawal of Great Britain from the European Union in 2019, referred to as Brexit (Clemens, 2018) requiring member states, which dependent on the services of UK notified bodies to renew their certifications with the EU and the U.K. for post Brexit implementation; a new scrutiny procedure for devices in the EU regulations that notified bodies may impose for higher risk devices (Clemens, 2018), representing additional regulation even before the product may be launched.

A fast-emerging trend in the high technology industry, which may support SME innovation, is software projects moving to the open-source arena, rather than being an in-house activity (Teixeira et al., 2015). The inference is that software develops sophistication from a network of groups or individuals, even rival companies, gradually improving its effectiveness; this fact is exemplified by smartphone operating system software webkit, a collaboration between Apple and Samsung (Teixeira et al., 2015). Whilst coopetition characterises R&D,

marketing remains highly competitive and focused on the purchaser (Teixeira et al., 2015).

Europes adoption of open innovation models and other collaborations are strategies intended to eliminate the barriers to medical device innovation (Bayon et al., 2016; Guerra Bretaña & Flórez-Rendón, 2018; Forsberg & Groenendijk, 2019). Collaboration has also been applied in the European wireless telecommunications industry (Yami & Nemeh, 2014), and in implementation of RRI principles among EU SMEs to diminish the gap between the needs of the society and the economic goals of manufacturers and developers (Auer & Jarmai, 2017). This is a strategy adopted in the EU programmes Horizon 2020 and FP7, with funding initiatives linked to the implementation of RRI principles, to ensure that innovations are socially and environmentally sustainable (Auer & Jarmai, 2017). However, despite its introduction in the 1990s, very few companies remain aware of either RRI or the incentives, which the government has formulated for their observance (Auer & Jarmai, 2017).

Therefore, the factors of higher cost and time associated with implementing EU medical device regulations, the lack of funding for individual SMEs, their limited technological knowledge, skills and resources, and the gap between science, technology and research combine to justify coopetition as a requirement for the survival and on-going prosperity of medical device SMEs. The introduction of post sales device controls is a user related factor, medical device companies in a coopetition may wish to exclude from the arrangement, to retain their close relationship with consumers, a competitive advantage. However, all other factors infer the effectiveness of coopetitive efforts as an inter- or intra-organisational strategy to generate successful innovation to manage the challenges of the new EU medical device environment.

This strategy is especially important to the EU because SMEs in the healthcare industry generally operate at member state level, and 70% of the EU population favour the intervention of the EU Commission in health matters owing to the rapidly ageing population demographics (Gast et al., 2015). These factors justify the establishment of a common approach to healthcare product development and regulation, without compromising safety and quality and including medical

devices. Since the EU Commission supports the production of less expensive, quality medical devices (Mattke et al., 2016) coopetition among medical device SMEs will optimise shared knowledge and learning, access to scarce resources and avoid potential legal conflicts between member states and the EU Commission.

The EU published an article defining medical devices in two ways, custom made, and mass produced (EU, 2020). A custom-made devise is defined as being manufactured according to a written instruction by a qualified professional for the use of a specific person and their particular needs. In contrast, mass produced devices, which are adapted to the requirements specified by a professional, include device version manufactured for a larger market. It also promotes the non-industrial production and modification of medical devices by health institutions in house for a specific group of people, when there is no equivalent on the market to meet the particular needs of specific group. In this context, health institutions are not limited to hospitals but include public health centres and laboratories, which are not obliged to directly treat patients (EU, 2020).

The EU Innovative Medicines Initiative also refers to collaboration between different stakeholders. These developments imply that innovation may develop outside of the standard hospital setting and may redefine coopetitive relationships in the health sector, indicating the future direction of coopetition for innovation in the medical device industry.

The European technological industry comprises 90% SMEs, which also represent two thirds of the labour market, suggesting that coopetition has an important position to counterbalance the challenges of high cost and time lag for obtaining approval for new products and innovation. This collaboration could include other stakeholders, for instance universities and research centres, and curb irresponsible research and innovation, which often occurs when large firms conduct R&D internally and deprive the industry of greater opportunities for learning and development. It will also further limit unethical practices of medical practitioners receiving financial support for their studies, or for personal consumption, in return for endorsing medical devices manufactured by large companies (Dalsing, 2011; Muth, 2017).

Medical practitioners and clinicians are expected to provide clinical evidence of the efficacy and superiority of a medical device used in their patients based on professional principles. This task is considered to contribute to their continuing education and to advance research into the diagnosis, treatment and management of certain diseases and medical conditions. Despite the frequent unethical principles involved in current practice, it has been difficult to resolve because large medical company donations may also benefit medical institutions in which the medical practitioners are employed. The EU's policy of value-based health care, implementation of the initiative and RRI, support coopetition as a strategy to accomplish this goal, and to lower the cost of research, clinical trials, and continuing studies. Coopetition motivates the adoption of RRI, which values user involvement in medical device development by use of human engineering methods (Money et al., 2011); the objective of RRI being to ensure that R&D is aligned with the needs, expectations, and values of European society (Forsberg & Groenendijk, 2019).

Coopetition among EU's medical device SMEs will be instrumental in creating effective policies, particularly as policy makers aim to influence the direction of medical device development. This frequently results in a gap between what is required in practice and the associated policy, whilst coopetitive research data is a source, which determines how affordability and quality can be integrated into policy creation. Therefore, coopetitive research data will help to establish, which policies should be expanded, amended, or removed, and facilitate how incentives can be formulated to achieve the purpose of the policies (Petersen, Adams & DeMuro, 2015).

In the EU context, there has been a significant increase in funding research and development to support SMEs and established to be a common feature of coopetitive arrangements. This funding strategy accomplishes the goals of the policymakers and the firms because they receive the coopetitive research data to formulate more appropriate policies regarding medical devices innovation. This connection should be particularly emphasised in relation to reimbursement methods to be applied across the EU because disparity is a major cause of many

SMEs' business failure (Horgan, van Kranen & Morré, 2018), which also impacts negatively on the labour market.

Another potential advantage of coopetition, the anticipated decline in the number of notified bodies conducting the assessments owing to the stricter requirements and higher qualifications (Maresova et al., 2020b), implies that coopetitive arrangements will reduce their assessment and review workloads because the coopetitives are composed of several competing SMEs working on the same technological idea, financial management or market study. Therefore, notified bodies can be more focused on concepts and principles rather than on the companies undertaking the innovative product development.

Coopetition has also become the EU's strategy to enhance SME scientific capability; The European Strategy Forum for Research Infrastructures (ESFRI) officially extends the environment of interdisciplinary innovation in health and sciences (Horgan et al., 2018). Research Infrastructures (RIs) provide open access to the latest technologies and scientific data for innovate researchers and companies working in life sciences and health research. They afford an opportunity for SMEs to participate in research promoted by global industry leaders by means of the open access RI (Horgan et al., 2018). The RIs also enable the SMEs to introduce European products and resources to the global market, which may facilitate wider collaboration, and possibly coopetition with global competitors in the medical device industry (Horgan et al., 2018).

The EU predicts that RIs will reduce the gap between research and medical application, by means of training and medical technology services. The existing European RIs, such as the European Clinical Research Infrastructures Network (ECRIN), the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) and the European Advanced Translational Research Infrastructure in Medicine (EATRIS) are expected to enhance the competitive advantage of EU medical devices SMES and to motivate them to develop high quality instruments. The RIs will provide access to healthcare, genetic and other relevant databases developed by EU states and encourage knowledge transfer to increase the competitiveness of the EU medical devices sector (Horgan et al., 2018). Therefore, coopetition in the EU medical device industry is forecast to align EU

and member state objectives, the needs of society and the economic goals of the manufacturers (Forsberg & Groenendijk, 2019).

2.8 Summary

Coopetition, the relationship between competition and cooperation has gradually become the preferred option to increase the innovation performance of SMEs in highly technological projects, which include medical device innovation (Nieto & Santa Maria, 2010; Teixeira et al., 2015). The success of coopetition has been determined as dependent on collaboration to leverage innovation performance of all participating organisations, and that the greater the level of agreement on common objectives and of trust, the higher the SME innovation performance (Hameed & Naveed, 2019).

This review has indicated that coopetition is an effective strategy for innovation also in the medical device industry because it allows participating SMEs to successfully implement a strategy that is a balance between competition and cooperation, to increase their capacity to innovate and exploit new market opportunities. This proposal is strengthened by the fact that coopetition is a strategy, which the EU promote for innovation by means of the growth of SMEs because they have high R&D capability and can make rapid decisions.

There is also some empirical evidence of the beneficial effect of coopetition among EU's medical device SMEs for example the study of Cygler et al. (2018) of 120 high technology Polish companies and Pullen, de Weerd-Nederhof, Groen and Fisschers' (2012) research into medical device SMEs in the Netherlands. The Cygler et al. (2018) study established the benefits of coopetition to be an increase in the innovation performances of participating firms, development of new technology which all participants may utilise in their own companies, access to scarce resources, access to additional complementary resources creating new products and access to new markets.

Many of these advantages were also revealed by Pullen et al. (2012) and the later research conducted by Hameed and Naveed (2019), which also highlighted

the impact of coopetition on open innovation. The study by Hameed & Naveed's (2019) also confirmed that collaboration to accomplish a common goal was ranked the highest success factor in open innovations founded on coopetition. However, Pullen et al. (2012) also revealed that, whilst complementary objectives were a critical success factor for coopetition, a professional business approach, fairness, and trust towards collaborating companies or project partners, was required to achieve high innovation performance.

The researchers admit that medical device SMEs in the Netherlands, which comprises 80% of the industry, practice coopetitive open innovation activities with other network partners extensively but also experienced barriers to doing so. Additionally, SMEs need to be decisive, and companies of the same size and innovation accomplishment were most likely to be successful in this type of alliance; also confirmed by Cygler et al. (2018) and Hameed & Naveed, 2019).

However, a substantial gap in the literature remains regarding the efficacy of coopetition as an innovation strategy for EU medical device SMEs because Pullen et al. (2012) is the only research that focuses solely on EU medical device SMEs and the survey participants were from the Netherlands alone and was conducted prior to the release of new EU directives. The limitation of Cygler et al. (2018) is that medical devices companies are one of the technology industries studied and it is limited to Poland.

The following chapter will address the methodological considerations and research approach applied in this thesis.

CHAPTER 3: RESEARCH METHODOLOGY

In this chapter the qualitative research approach chosen to address the issues under scrutiny will be elaborated and formulated in detail. This is explicitly based on the previously described research problem and theoretical context. Amongst other things it will be explained how techniques enhance reliability and validity of findings appropriate to qualitative research recommended by Ritchie and Lewis (2010).

The overall methodological approach relies on a specific research stance taken, influenced also by the researcher's perspective on the research at hand (Crotty, 1998). It is based on a set of assumptions about three aspects of the research, the ontology, the epistemology, and the axiology respectively. When the stance applied is strictly objective, the research is based on a hypothetico-deductive approach (Godfrey-Smith, 2003) determining the methodological choices. These selected methods include explanatory design and specific systematic methods and data analysis, based on deduction or theory testing (Grix, 2002). The alternative traditional approach is the subjective stance that relies on induction or theory building. Whereas the hypothetico-deductive method relies on statistical inference drawn from observation, qualitative approaches accept the inner subjective world of a respondent influences their beliefs and what they give significance to. It is a more flexible exploratory approach to research that enables the researcher to gain in-depth understanding of a range of human perceptions of the phenomenon (Saunders et al., 2019).

The research at hand is predominantly influenced by the subjective stance for which acceptable knowledge is assumed to derive from a range of sources. It is shaped by diverse subjective human interpretation of an identical phenomenon. The assumption about how the world works, the ontology (Fleetwood, 2005), is that there are multiple ways of explaining the same phenomena, which are influenced by personal human experiences that differ considerably between individuals.

As discussed in the literature review chapter, the following is the main research question posed within this thesis:

What are the critical success factors for coopetition that will provide benefits to medical device SMEs given the impact of the new European medical device regulations on time and cost to market?

To approach this broad question, it is necessary to specify the relevant and critical elements of a complex amalgamation of latent constructs by means of sub questions. These are drawn out of theory and summarized implications derived from the literature review, and following the author's own interpretation of how to gain knowledge that will be necessary to approach the general research question:

SQ1: What are the critical success factors involved in adopting the new legislation in relation to innovation management?
SQ2: How will established success factors need to be adapted and into what form?
SQ3: What does coopetition mean for these SMEs?
SQ4: How has coopetition been approached/considered in the context of innovation management, if at all?
SQ5: What aspects of innovation management or stages of the innovation process are suitable for coopetition, based on the experience of these SMEs?
SQ6: What are the challenges of implementing coopetition from the SME perspective view?
SQ7: What strategic changes are needed for coopetition?
SQ8: What organisational structure/changes are required for coopetition?
SQ9: What role does corporate culture play?
SQ10: Which management and leadership characteristics support the application of coopetition?
SQ11: What other critical success factors for coopetition have been identified?

As indicated by a qualitative research approach, the derived sub questions are, in nature, subject to both the respondents and author's own subjective interpretations and knowledge in the field as well. A model known as "The

Research Onion", Figure 28, explains how the approach taken in this thesis relates to other worldviews and research approaches.

The Research Onion is used to guide the development of the research methods in a systematic manner, where the layers of the onion represent the elements of research design (Saunders et al., 2019). This diagram is used to position research methodologies from a philosophical stance perspective, through approaches, methodological choices, strategies, techniques, and procedures. This encompassing view provides a useful way to discuss the relationships between different elements within the act of doctoral research.

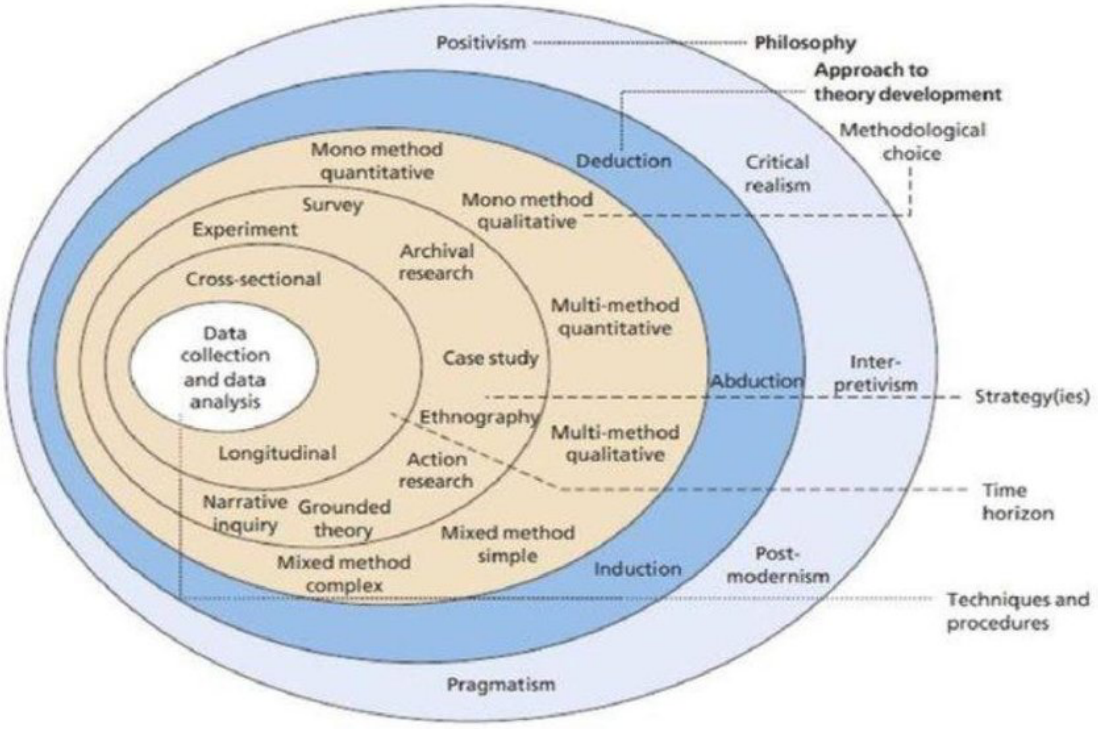

Figure 28: The Research Onion

Source: Saunders et al. (2019, p. 130)

Therefore, the research methodology commences with a discussion of philosophical stances that underpin research, the associated research design, and demonstrate how that research design determines the choice of subsequent methodologies (Saunders et al., 2019; Creswell & Creswell, 2017).

3.1 Research Stance, Research Design and Approach to Theory Development

The stance selected influences the research with regards to the epistemology, ontology, and axiology (Crotty, 1998; Saunders et al., 2019; Collis & Hussey, 2014). This includes the idea that a defined set of assumptions guides the research, to generate a valid explanation of the phenomenon being observed (Cooper, Schindler & Sun, 2006). Therefore, epistemology is concerned with assumptions leading to the recognition of acceptable knowledge, whilst ontology refers to the view of extant reality used in the study. In other words, how reality works and how we know it epistemologically.

Consequently, for the intended research design, understanding epistemology, and how it related to the overall methodology, is of the utmost importance. The link between epistemology and the entire research process in the thesis is diagrammatically represented in Figure 29; it demonstrates a circular link that enables new knowledge to be created at the end of the research process (Carter & Little, 2007).

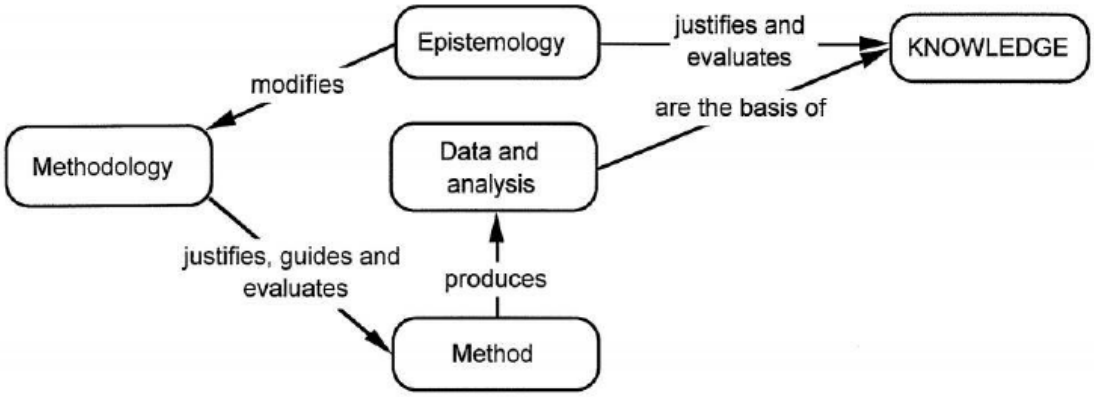

Figure 29: Relationship Epistemology, Methodology and Data Analysis

Source: Carter and Little (2007, p. 3)

In the objective stance, cause and effect links are identified with an approach like scientific enquiry (Grix, 2002), relying on facts that can be proven and a conviction

that these are generated independently of human interpretation (Letherby, Scott & Williams, 2013). The epistemology assumption is therefore that acceptable knowledge is derived from a single source of evidence, which is observable and measurable phenomenon under observation. Therefore, the assumption is that one reality exists, which is independent of the observer. Also, the hypothetical-deductive method believes that objective knowledge can be drawn out of a literature review, hence the presumption of knowledge comes before research considerations.

Whereas the objectivist stance tries to ignore the inner subjective experience, in the subjective stance the role of human values and beliefs in explaining phenomena is given more priority and emphasis (Cooper et al., 2006). Subjectivist epistemology is associated with diverse human understanding of an event, multiple explanations of the same observation, which are based on reflecting on what was observed and articulating its meaning by applying individual values and experiences (Ritchie & Lewis, 2010; Collis & Hussey, 2014).

The two stances are based on different assumptions. They are useful in different contexts and yield different outcomes and, according to Jean Lee (1992), most researchers have affiliations with scientific and humanist approaches rather than extremes. This is also emphasised by Collis and Hussey (2014) who propose that contemporary research is much more likely to adopt an approach that incorporates a proportion of each stance, the amount of objective and subjective input varying with the subject of the research. Consequently, one could argue that the most important factor in selecting a stance to research is that it is the optimum choice for answering the research question, according to Creswell and Creswell (2017).

Following the above theoretical considerations with regards to theory, the author of this thesis chose an exploratory approach, as the knowledge sought after is difficult, if at all, to quantify. That is, the research context was so complex that it was difficult to presume knowledge purely from a Literature Review. A purely objectivist perspective on methodology appears insufficient when attempting to gain an in-depth knowledge of the contextual concept of coopetition, how it is perceived by medical device companies and for what reasons, based on

secondary data alone. An additional objective is to assess how viable the company executives consider coopetition as a strategy to overcome issues related to implementing the new EU regulations, gaining competitive advantage, and generating sufficient financial profit, which also is not presented in prior research and thus calls for an exploratory approach.

Moreover, the subject of coopetition is a relatively new consideration in the literature, which is poorly understood within the sector. Exploratory design is suitable for gaining a much more detailed knowledge of the perceived opportunities and threats for medical device companies. It allows patterns to be developed for better understanding the phenomenon as well as verifying these with experts who participate in the study (Saunders et al., 2019; Collis & Hussey, 2014).

In summing up the above, this thesis will additionally apply an inductive approach to research. Table 4 compares the inductive approach used in this research with deduction that starts with theory and uses data to test it, and from that develops a conclusion through reasoning and abduction which develops several possible conclusions then seeks to identify the best one. It was decided that induction would allow a more informative and reliable understanding of the concept of coopetition in this context to emerge

Table 4: Approaches to Theory Development

Aspect	Deduction	Induction	Abduction
Approach	Based on scientific principles	Understanding the meaning humans assign to phenomena	Explaining an unexpected, surprising event
Process	Moving from theory to data	Gathering data to develop new theory	Begins with surprising observation develops theory and tests theory, Process many occur several times
Purpose	Explain cause and effect relationship between variables. Theory testing.	Gain a deep understanding of the research context. Building new theory.	Deciding the most probable inference from observations. Theory modification integrating existing theory as appropriate
Data	Gather quantitative/numerical data	Collect textual, spoken, and other descriptive data	All data types
Structure and data collection	Highly rigid, systematic, Quality of data is ensured by suitable controls	Flexible to changing direction and explore unexpected information	Collection of data to explore themes and patterns, flexible
Values	Researcher independent of the phenomenon studied	Researcher is an integral part of the research	
Demonstration of rigour	Large sample that allows generalisability of findings	Consistency, credibility, and confirmability	The findings can be generalised or are consistent, credible, and confirmable

Source: Saunders et al. (2019), Ritchie & Lewis (2010)

3.2 Research Philosophy and Strategy

In the last section the general research stance and paradigm of this thesis was discussed, to provide the reader with more orientation as to why a certain methodology is chosen. Now, the focus moves towards the outer ring of the before mentioned Research Onion (Figure 28) to explain the underlying research philosophy.

The author's ontology is rooted in social constructivism as described by Searle (1997). Searle proposed ontology as comprising two levels, lower-level facts that are independent of humans and institutions, for instance that the universe exists, and higher-level facts that are dependent on humans and institutions. Since, institutional facts are constructs of reality or truth, they can be interpreted, and the interpretation used to discover an underlying meaning.

This epistemological approach of interpretivism is often associated with social constructivism (Creswell & Creswell, 2017) and its origins are in the concept that understanding knowledge related to human and social sciences cannot be the same as its usage in physical sciences. This is explained by humans interpreting their world objectively and more importantly also subjectively, and then act based on such interpretation whereas the physical world does not (Hammersley, 2013). Therefore, the researcher approaches this study understanding that each participant will have their own perception of reality, although the phenomenon studied is the same (Collis & Hussey, 2014). In the following section, related research strategies will be discussed.

3.2.1 Research Strategies

The research onion (Figure 28) suggests four possible research strategies for this study: ethnography, action research, narrative enquiry and grounded theory (Saunders et al., 2019). Ethnography is concerned with gaining an in depth understanding of people, described as naturalistic research, because it usually occurs within the context in which the phenomenon can be observed (Hirsch & Gellner, 2001). This strategy involves long term study of participants in their environment, making observations and developing theories about them, which

focus on interpreting their world in the same way that they do (Collis & Hussey, 2014). The objectives of this research strategy do not align with the aims of this thesis and so will not be used.

The focus of Action Research is research in action. It is generally conducted within the researcher's context (e.g. the firm they work in), and is longitudinal and requires long periods collaborating with colleagues and contacts, in contrast to researching an action that has occurred (Cohen, Manion & Morrison, 2017). This approach is usually associated with organisational change within the researcher's organisation, very often an educational setting, and comprises fact finding and analysis, taking actions and reflecting on the outcomes in order to instigate new actions (Newman, 2000; Saunders et al., 2019). The key issue is the researcher is not neutral but participates in influencing the action. Therefore, it is not suitable to answer the research questions associated with this research, which has the purpose of gathering a range of opinions to solve a key issue as effectively as possible.

Narrative enquiry involves collecting data as stories recounted by the participants about the phenomena, so that they recount experiences over a period and make connections between them; the researcher's role is to listen rather than to collect specific facts (Saunders et al., 2019). This strategy is unsuitable for this thesis since participants are senior executives in the firms concerned, many of which are very small, and the time consumed by them to support this type of research strategy would be unreasonable.

The fundamental purpose of the research is to establish an emergent theory from systematic comparative analysis of human perceptions of the observations of coopetition and to interpret them (Patton, 2002). Hence, grounded theory is the most suitable research strategy for answering the research question of this thesis, fundamentally because it is an established method for developing new theory without assuming prior knowledge gained from other sources and used frequently in business research to explain organisational behaviour (Bryant & Charmaz, 2007; Glaser & Strauss, 1967). Grounded theory comprises the researcher deriving a general, abstract theory of a process, action, or interaction, which is grounded in the views of participants (Creswell & Creswell, 2017).

All data will be recorded in this research as the conversations take place, so that they are available for scrutiny by others. This will also serve as an audit trail so that eventual conclusions can be tracked back to annoymised responses. The time horizon for the research is understood as a cross-sectional snapshot in time (Saunders et al., 2019).

3.3 Reliability and Validity

Reliability and validity are terms developed by researchers using the objective stance to research, with the purpose of demonstrating its rigour (Balnaves & Caputi, 2001). High reliability is fundamentally associated with the ease of reproducing the research and obtaining similar outcomes. This stance is driven by testing known theory, and calculating statistical coefficients to demonstrate reliability, for instance Cronbach's alpha with a value greater than 0.7 (Saunders et al., 2019).

Validity in quantitative research is concerned with how well a study accomplishes the objectives set, known as constructive validity, and with the generalisability of findings to the whole population, accomplished by using large samples and demonstrating that outcomes are statistically significant because the p value is <0,05, for instance (Balnaves & Caputi, 2001).

However, since every qualitative research study is relatively unique and many have the objective of developing new theory, these definitions are not appropriate (Ritchie & Lewis, 2010). The reliability of a qualitative study is focused on consistency and its validity relies on trustworthiness and confirmability of the findings (Gliner, 1994). The similarity of the characteristics of the two concepts in qualitative research are noted by Lincoln and Guba (1985) who propose that if research has high validity, it will automatically have high reliability within similar contexts.

This research is characterised by transparency in relation to the analysis of the data which undergoes six methods of coding, recorded in detail in the appendices and explained at length in this chapter. This is guided by the methodology

recommended by Saldana (2016). Hence, the replicability of this study is as high as possible from a quantitative perspective, and the validity is proven by providing copies of all the interview transcripts, recording the methods of analysis and associated findings in the Coding Master and Code Book, as well as a detailed diary of the process and reflections on the data before conclusions are drawn.

The use of thick description in the findings and discussion chapter is another means to demonstrate trustworthiness and confirmability (Lincoln & Guba, 1985; Gliner, 1994). Reliability and validity are considerably strengthened by the fact that all participants checked the interview transcripts, to confirm their accuracy and provide approval for inclusion in the research (Ritchie & Lewis, 2010). This check reduced the risk of researcher bias and misunderstanding.

3.4 Approach for Data Gathering and Analysis

Given the selection of grounded theory, qualitative methods are used for data gathering and analysis (Ritchie & Lewis, 2010; Creswell & Creswell, 2017). Data is gathered using semi-structured interviews (Hammer & Wildavsky, 2018).

The alternative data collection methods for qualitative research are structured and unstructured interviews, a qualitative survey, which is constructed in a similar manner to the interview question option, observation, and focus groups (Saunders et al., 2019).

Focus groups are a well-established method of gathering insightful data, and usually comprise small groups, which are presented with a range of themes developed by the researcher and asked to provide their opinions (Cyr, 2019). In contrast to interviews, which are one to one conversation between participant and interviewer, focus groups enable participants to listen and respond to the views of other participants so that difference frames of reference are presented. The limitation is that the data gathered in focus groups may be even less objective as that produced in interviews because the researcher has less control over the interactions and outcomes (Ritchie & Lewis, 2010). Given this research took

place during the Covid pandemic, gathering respondents, busy executives, was not feasible.

A qualitative survey comprises a range of predominantly open questions, which the participant completes and returns to the researcher. This type of approach is often facilitated by online survey facilities (Saunders et al., 2019). Although this option offers the participant considerable freedom to complete and return the responses and reduces the time and cost of data collection, the lack of opportunity for the researcher to also observe participant's body language and to ask additional questions to clarify comments made are its main disadvantages. Survey's risk low response rates (Sahleh & Bista, 2017) and with online surveys there is an addition risk around data security (Buchanan & Hvizdak, 2009).

However, online data collection in all its possible varieties is a possible option. Especially when there are restrictions that prevent direct contact such as the Covid-19 legal guidelines in force at the time of this research. Face to face interviews is difficult, if possible, at all. The widespread adoption of video conferencing technology (e.g., Zoom or Microsoft Teams) has alleviated this problem and brings efficiencies by enabling remote face to face dialogue (Archibald, Ambagtsheer, Casey & Lawless, 2019; Gray, Wong-Wylie, Rempel & Cook, 2020).

The major challenge with Microsoft Teams may be technical issues of connectivity or of participant skills or interview preferences (Archibald et al., 2019.). The Microsoft Teams technology was applied for interviewing to collect data for this thesis, which was conducted in the period of Covid restrictions, especially appropriate as many of the participant companies were high tech focussed. Therefore, semi-structured interviews were conducted as the most efficient alternative to face-to-face interviews and allowed the most realistic alternative available. Details on this approach will follow below.

Semi-structured interviews are preferred to structured and unstructured interviews in this research because they relax the assumption of prior knowledge allowing unconsidered data to surface. They also have some high-level structure to enable comparisons between interviews and enable the researcher and

participant to conduct a conversation in a more relaxed manner (Gill, Stewart, Treasure & Chadwick, 2008). The interviewer prepares a logically sequenced group of open questions, to gather facts and opinions related to opportunities and challenges associated with the implementation of new EU directives in the medical devices sector. The interviewer is also able to ask further questions when the participant provides a response that requires further enquiry.

In contrast, a structured interview comprises development of the same set of questions, but the interviewer does not deviate from the questions prepared (Gill et al., 2008; DiCicco-Bloom & Crabtree, 2006), which may deter the participant from providing additional detailed information (Briggs, 1986). The unstructured interview is characterised by no preparation by the interviewer, who subsequently has no control over the interview and therefore is likely to fail to gather the data required to answer the research questions.

The participants in this research needed to represent a medical device SME in a country which falls under or applies the medical device regulations of the European Union (EU). Beside EU member states, this was Switzerland, Norway, Iceland, and some EU candidate states. The interviewees needed to oversee innovation management in their respective companies (e.g., Head of R&D, product management, CTO) or have general management responsibility including product innovation, development, and portfolio management. Potential participants emerged through the researchers' professional network within the medical device industry and were approached personally through telephone and/or email. As an exclusion criterion, only representatives of companies were selected in which the author has no vested interest or commercial bias stemming from his own profession.

The participants received an information sheet prior to consenting to take part in the research; the information comprising risks and benefits of participation and data management techniques to be employed. The interviewees are also advised that they can withdraw from the research at any time (Ritchie & Lewis, 2010) and asked to give their permission for the interview to be recorded (Saunders et al., 2019), which will increase the reliability of the findings (Ritchie & Lewis, 2010). This procedure is also vital to ensure that ethical standards are maintained in the

digital context (Jirotka, Grimpe, Stahl, Eden & Hartswood, 2017) and to the validity level of the findings (Ritchie & Lewis, 2010).

Fifteen senior executives from a range of medical devices companies participated in this research, and their suitability in terms of knowledge, experience and firm types is demonstrated in Table 5. The participants were interviewed between July and September 2020, due to the covid-19 pandemic using Microsoft Teams; the actual interview document is attached as Appendix 1.

During the subsequent transcription process all interviews were fully anonymized, with the participants being pseudonymized from P1 to P15 in the sequence of their interviews. To establish internal validity, the transcriptions were shared with the interviewees to allow them to correct the interpretation of their words if needed. Two participants (P4 and P6) asked for minor corrections. To further enhance validity, confidence and stability, a synopsis of the coding results later was shared with the participants also. All participants but one (P15 did not respond) confirmed the synopsis, so that reliable conclusions could be formed.

Initial data and voice recordings of the interviews are stored securely on the University's research store, where data are automatically backed-up. All data with participants' identity on it will be destroyed when the DBA is completed and only ever be visible to the principal investigator and the two university DBA supervisors. All pseudonymized data after the research completes will be securely stored in the University's research data archive and retained for a period of 10 years after the DBA thesis is published.

Table 5: Participant Profile

Participant	Position in Company	Location, Established	Employees	Major Activities	Turnover
P1	CEO and Co-Founder	London, UK, 2016	4	Drug releasing polymer system related to eye health	Not given
P2	COO and Co-Founder	Aix-en-Provence, France, 2010	5	Bone graft	Development company, no turnover yet
P3	Founder and owner	Ellesmere Port, UK, 2010	24	Implants for orthopaedics and trauma	€6 million
P4	CEO and Co-Founder	Pessac, France, 2010	4	Implantable medical devices for orthopaedic surgery	Early stage, turnover very low
P5	Co-Founder	Cambridge, UK, 2015	3	Analytics for running technical development and clinical validation of medical devices	€90,000
P6	Co-Owner	Decines-Charpieu, France, 2010	3	Spinal implants, cervical and lumbar implants	Not given
P7	Head of Global Product Development	Frankfurt, Germany, 1988	28	Biomaterials and other medical devices for bone and tissue regeneration	€6.5 million
P8	Founder and COO	Paris, France, 2017	7 plus 30 freelancers	Software solution to aid critical decision making for critically ill patients	Very low, at first pilot stage

P9	CEO	Dresden, Germany, 2001	9	Bone substitution and regeneration materials	€1 million
P10	Founder and Part Owner	Piascezno, Poland, 2002	25 to 30	Medical devices for optometry/ophthalmology.	€3 billion
P11	COO	Geneva, Switzerland, 2005	250 globally	Mainly spinal implants	$US 70 to 100 million
P12	CEO	Helsinki, 2018	42	Class II ophthalmology data system	€2 million
P13	Senior Manager Quality & Regulatory	Schlieren, Switzerland, 2012	8	Bone fixation technology	None, still in development stage
P14	Head of Innovation	Tuttlingen, Germany, 1954	40	Surgical Instruments	€6 million
P15	CEO and Co-Founder	Cologne, Germany, 2018	7 plus freelancers	(Medical) Software development and web applications	€300,000

3.4.1 Coding Master Framework

The following sections will focus on elaborating on the actual coding procedure applied for the collected data, i.e., the coding sequence recommended by Saldana (2016). The first stage is to create a Coding Master and Code Book (Appendix 2a and 2b) and to commence a Coding Diary (Appendix 2c) with the purpose of recording all the coding processes, the main findings, and reflections on them for a series of 6 coding cycles, as recommended by Saldana (2016).

Developing the Coding Master framework comprises creating a series of tabs in Excel that parallel the main questions and topics in the interview master. These consist of sections and subject matter as recorded in Table 6. The responses relating to each subtopic are recorded in the diary by participant number so that, for example, the position and company of each participant is recorded from P1 to P15 in the first part of the company information tab in column A for company number and column B for participant descriptions, and the company products and services in column E. The use of Excel facilitates easily adding extra columns to add further analysis types without losing the original structure.

Table 6: Format of Coding Master

Tab Settings Excel	Sections
Company Information **General Features**	Participant Job Title Year Established Company Size Main Activities Annual Turnover Organisational Structure &. Culture Management and Leadership Style
Company Information on Innovation	Critical Success Factors for innovation in your company Differences between innovation in medical devices and other sectors Who is responsible for innovation in your organisation

Company Information on New Product Development (NPD) and Innovation	Internal Factors most important for innovation in your organisation Does company organisational structure support or hinder innovation
Company Information **Leadership for Innovation**	How does company leadership assist or hinder innovation? How does your company culture assist of hinder innovation
New EU Regulations	What impact will the new regulations have on innovation in general Do you have the financial resources to innovate? Do you have the knowledge resources to innovate? What elements in the new EU regulations will help the company to innovate?
Coopetition	Participant familiarity with coopetition Opinions on whether coopetition is a possible solution to resolve the challenges of the new legislation Company experiences of coopetition, opportunities, and challenges Aspects of the business operations suitable and unsuitable for coopetition Changes the company had to make to implement coopetition The operations coopetition would be limited to

The Code Book (see Appendix 2b) commenced with definition of the main themes of conceptual framework that would guide analysing the findings from the coding cycles that followed. These codes, which also reflect the different areas of interview questions, were organisational structure, organisational culture, strategy, leadership, and innovation.

The six coding techniques employed were divided into first cycle coding and second cycle coding, moving from the larger number of first cycle codes to a few major themes, which is a recoding process, following the guidance provided by

Saldana (2016). The first cycle of coding comprised: In Vivo Coding (codes derived from actual spoken/used terms), Process Coding (codes to communicate an action in the data) and Initial Coding (open codes providing a label, description, definition, or category name), whilst the second cycle incorporated attention to the focused coding method and then application of the axial and theoretical codes (i.e. the sorting and organizing of codes, as well as relating them to each other to create new categories). This coding process is summarised in Figure 30; all coding methods are explained in detail in sections 3.4.2 to 3.4.8.

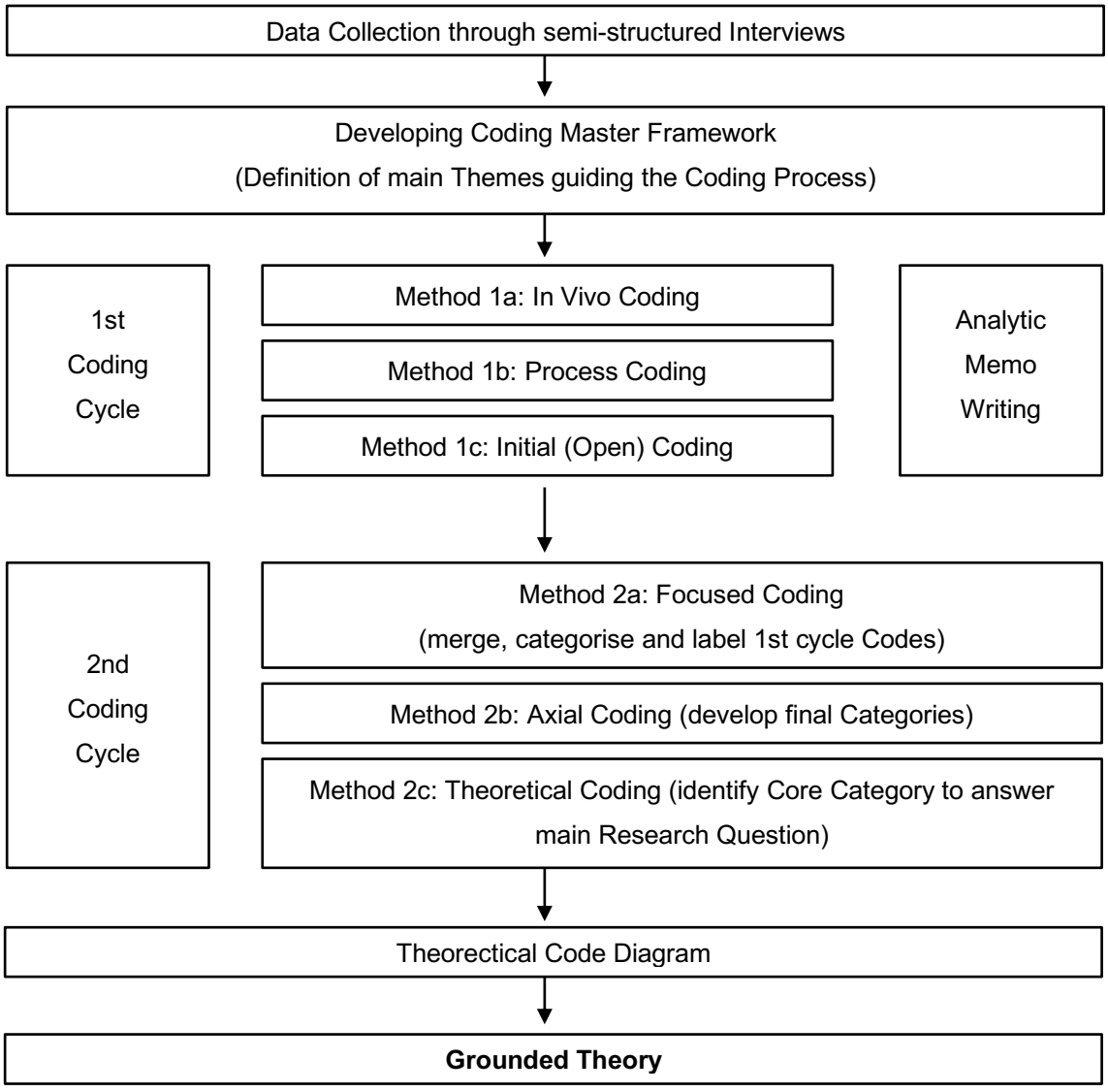

Figure 30: Coding Process to identify new Theory

Source: Author, following Saldana (2016, p. 56)

3.4.2 In Vivo Coding

The In Vivo Codes are the first ones determined by the process of carefully reading of approximately 200 pages of interviews, which are divided by topic or sub-topic and therefore it is easy to compare responses from the 15 interviewees. The researcher can gain a holistic view of all the data gathered, with key words and phrases identified to align with the themes that are outlined in the Code Master. This process facilitates a broad view of all the facts the participants know, and how they perceive them in relation to their organisation and to the opportunities and issues they have with the EU regulation, and eventually to what extent these facts and options align with existing knowledge.

The In Vivo codes can be determined for each question, from the words expressed by the participants, and the specific words or phrases are highlighted in the scripts. An example of this coding is given in relation to organisational structure in Table 7. The lumper code, characterised as more holistic and expedient (Saldana, 2016), is “some sort of tiered system”, and other expressions associated with this but offering additional perspectives are designated splitter codes. All the In Vivo codes are recorded in the Code Book.

Table 7: Sample of In Vivo Codes

1	"Some sort of tiered system" (Organisational Structure)
1a	"Not underneath me, but work alongside me"
1b	"Organize in a very short step”
1c	"As little corporates as possible"
1d	“You're at the bottom. You're at the top, you've set into stone a set of representations about value and worth”

The master coding document in Excel is updated with all In Vivo codes against the phrases that had been identified. As recommended by Saldana (2016), Analytical Memos are written once the required codes are determined, to reflect

on how they are identified. This is followed by writing a critical discussion relating to the words and phrases of interest. These have significant value to developing the concluding chapters, which present the findings and analysis, and discusses the findings as they relate to existing theory to highlight new perspectives.

3.4.3 Process Coding

The second set of codes are Process Codes that identify situations in which the participant has naturally described a step-by-step process, which evolves over time. Saldana (2016, pp. 110) describes process coding as associated with: actual and conceptual doing; conflicts experienced by the participants; what events evoked, slowed, changed, accelerated, or stopped the action from evolving. The process coding is restricted to the interview questions that directly relate to answering to the main research question and the eleven sub questions.

As the Process Codes are identified, they are categorised by a name, for instance "innovation related to EU regulations" was labelled a process of choosing and learning, whilst leadership for innovation is labelled as "behaviours". The process stages of each code, as identified by each of the 15 participants, are transferred to the Code Book. An example is provided in Table 8.

Table 8: Sample of Process Coding

Process Code	P1	P2	P3
Code: Innovation related to EU regulations			
Labelled as "choosing and learning"	exciting people	comparing potential projects	providing an alternative
Code: Leadership for innovation			
Labelled as "Behaviours"	explain why everything is as important	you need a leader one for the innovation, another one for the operating	anybody who sees a good idea should bring it forth to the management

The Analytical Memos, which are written after each coding action are the most important part of the coding process according to Saldana (2016). They facilitate categorising the coding according to content and help the researcher to begin the process of documenting the themes that will form the discussion chapter. This researcher applies this advice for each coding sequences, as can be observed in the Coding Diary in the appendix. Therefore, a summary according to the theme is constructed, allowing eventual merging to create comparisons and a holistic interpretation of the data leading to identifying the grounded theory.

3.4.4 Initial (Open) Coding

This is the final first coding method applied to the same set of original data and is analysed by question and/or sub question except for those responses that are related to company information and irrelevant to answering the research questions. Initial Coding is also referred to as open coding, but Saldana (2016,) prefers the term initial because it is a first cycle method and was nominated by Charmaz (2014).

The procedure for Initial Coding is to divide the responses into discrete parts; closely examine those parts for similarities and differences; for the researcher to stay open-minded about every theoretical possibility that interpretation of the data may generate; to profoundly reflect on the contents of the data. The advice given by Charmaz (2014) relates specifically to interview transcripts, stating that they should undergo a line-by-line analysis.

Initial Coding in the way Saldana (2016) describes is using a process code and then identifying related relevant sub codes, which resemble the splitters in In Vivo coding. Saldana (2016) provides guidelines for coding with examples but no rigid rules. He also emphasises that there is no rigid framework for coding and that every researcher code in a unique way. For this thesis, the researcher examined Saldana's examples (Saldana, 2016) to identify initial codes that would be appropriate to this thesis.

Table 9 provides an example how the codes developed based on the data. As the coding proceeds codes are merging because substantial similarity becomes

evident, and with the purpose of finishing the coding with a few broader themes that integrate the earlier ones.

Table 9: Sample of Initial Coding

Question on internal factors helping/hindering innovation	
Initial Code	**Splitters from In Vivo Coding**
qualifying	P1: three maximums too many opinions can kill it; P8: flat organisational structure helps innovation at some levels. We share.at our level--but not with everybody in the company P9: I think for us the organisational structure is not that important P10: they generate some noise too, but if it comes to innovation, I think this is very good ... if you ...
critical success factors	P1: a good set of cofounders; get your team together...same sort of work ethic as you; P10: because the organization is very small, then communication goes quick. P1: critical success factor: chairman and board sometimes to help direct it; barrier to success: you can have the odd board member who doesn't ...understand the research space and will just ..... and try and derail it. ….
Barriers to success	P5: silo thinking really starts to limit the ability to see an integrated solution/innovation
Choosing	P3: you've got identify definitely applications and the need for it (talks about heavy and lighter metal frames for glasses)
Labelling	P11: structure as empowering P15: everyone should think about it then people feel committed to it P2: best structure organization would be an ambidextrous organization; P3: consultant...bit of a radical thinker at times; critical success factor: see something in our organization or outside of our organization... they think needs changing, then they come to us and we'll discuss it P5: soloing - people who stay too long in one division, one area of the company;
Quantifying	P13: when you have flat organization...people are encouraged; P1 quantifying: (org structure) supporting innovation, if didn't have a board and a chairman to speak to, we could go off tangent quite quickly; P3: (innovation) product just going to be unique enough but there's also going to be a definite need;
Dispelling stereotypes	P13: this is bad (idea), no such thing. Ideas are open and invited

The results are initially fully recorded in the Code Book (Appendix 2b) under Initial Coding and transferred into the Coding Diary (Appendix 2c) in tabular form. This facilitates scrutiny by other researchers of the way interpretation of data has occurred and is also providing thick description, transparency that enhances the validity of the findings (Ritchie & Lewis, 2010). This coding and the Analytical Memos are especially useful in revealing emotions, particularly the uncertainties about the impact of the regulation and coopetition as a solution for medical devices firms to survive and to gain competitive advantage.

3.4.5 Transitioning to Second Cycle Coding

The procedure for transitioning to the second cycle is carefully studied (Saldana, 2016) and the intended recoding employed to tighten and reduce the codes developed in the first cycle, as required. It is a process of revisiting the first set of codes, reorganising and rearranging the codes to prepare for additional coding and analysis with fewer themes; focusing on rationalising them. This process facilitates the emergence of possible axial codes, to which the relevant categories can be attached relating to the original theoretical base of the work and, more importantly, discovering how they are applied to the coopetition aspects of these theories.

3.4.6 Focused Coding

Saldana (2016, p. 240) states that Focused Coding follows first cycle grounded theory coding methods to develop the “most salient categories in the data corpus”. To develop these codes, the previous interview question coding, relating to the participants and characteristics of the firm such as organisational structure and culture, was included. Consequently, the five focused category codes resulting from focused recoding of In Vivo codes are: (i) representation of values, beliefs, and aspirations; (ii) behaviours; (iii) What’s at stake? /Outcomes; (iv) choosing and learning; (v) minimising barriers/creating agility. A sample of the Focused Coding applied to In Vivo codes is provided in Table 10, the full details are recorded in the Coding Diary (Appendix 2c).

Table 10: Sample of Focus Coding

In Vivo Codes		New Code
2	**" We do everything"**	
2a	"I think you always need clear roles, responsibilities and clear person where the buck stops with who has to make the decision"	Behaviours
2b	"The structure is me"	
2c	"we three together, we consider as a management team which handles and, of course, responsible for all signatures and all our responsibilities covering all which is related to the company."	
4	**"Free on their way of thinking"**	
4a	"You will have to think differently"	Choosing and learning
4b	"Good perspective on reality"	
4c	"The culture is complete mix culture... with different qualification"	

These Focused Codes are found to be easily transferable to the outcomes of the other coding methodologies. Hence, the eight final Process Codes were merged, recoded, and recorded in the Code Book, in red text (Appendix 2b). An example of merging and recoding is provided in Table 11.

Table 11: Reducing/ Focusing Process Codes

Process Code	Recoded
Qualifying (Quantifying/qualifying and some hypothesising merged into this code)	What's at stake?
Barriers to success (Stereotyping merged into this code)	Minimising barriers

This process is a preparation for revealing the Axial Codes, and the subsequent identification of associated subcategories of each main Axial Code (Saldana, 2016).

3.4.7 Axial Codes Revealed

Axial coding is suitable for analysis of interview transcripts. It tightens the original coding and is the means to "crystallise your analytical work even further" (Saldana, 2016, p. 245). Saldana (2016) also states that Axial codes are generally derived from Initial Codes, which provides confidence that an appropriate method of transitioning into the second coding cycle is applied when utilizing initial codes in Focused Coding as a preparation for Axial Coding. The Axial Codes and the respective subcategories, which are determined from the first cycle coding, are shown in Table 12.

Table 12: Axial Codes and Associated Sub-Categories

Axial Codes	Sub-Categories with examples
Representations of values, beliefs, and aspirations	Culture for innovation – team first
	Structure small, start-up agile v large dominant
	Aspirations – competitive advantage/stay in market v independence

Behaviours	Failure – control of certain resources, stealing assets
	Success - openness, trust, empowerment
	Compromise - flexibility
Choosing and Learning	Which partners? Size of company, competitor, or non-competitor
	Which mindsets? Open/closed innovation, degree of legislations
	Which strategy? Type of alliance, business model
	Which aspects of coopetition? Technology, regulations, innovations, stages from development to market launch
What's at stake/outcomes	Time
	Competitive Advantage
	Financial costs, profits, transfer pricing, registrations
	Markets
	Secrets, uncertainty – fear of sharing
Minimising Barriers	Regulation – in house shared
	Eco-system – getting resources
	Legal rights agreed
	Get to market - compromise markets/product lines

These categories are informed by revisiting the research questions to confirm that the final objective is being met accurately. The full process is reported in the coding diary (Appendix 2c).

3.4.8 Theoretical Coding

Theoretical coding is the core category of the research which has the purpose of answering the research question: What are the critical success factors for coopetition that will provide benefits to medical device SME given the impact of the new European medical device regulations on time and cost to market?

The Theoretical Code, the central or core category (Saldana, 2016), must answer how the phenomenon of coopetition work, why it works, and under what conditions. This is accomplished by considering each of the axial code categories in fine detail, for instance, representations of values and beliefs are reliant on organisational culture, structure, and aspirations. Comments regarding opportunities and challenges that these represent for successful coopetition are identified from the Coding Master and Coding Diary. A small sample from values and beliefs is presented in Table 13 and illustrates the in-depth process that is applied to ensure all the necessary objectives of theoretical coding are met; a full account is available in Appendix 2c.

Table 13: Representations of Values Beliefs and Aspirations

	Supportive of coopetition/innovation	Hindrances to coopetition innovation
culture	I do everything Formal leader takes responsibility when things go wrong Understanding why Unstructured collaboration internal Free thinking – blind alley innovation Thinking differently Certain rules for guidance Cope with uncertainty	Blame Insufficient information available Too much structure Certainty Repeating the same mistakes Chaotic Need for certainty

The Theoretical Code integrating the main themes is then determined and represented by a Theoretical Code Diagram, in this case Figure 31; the full process will be reported in below.

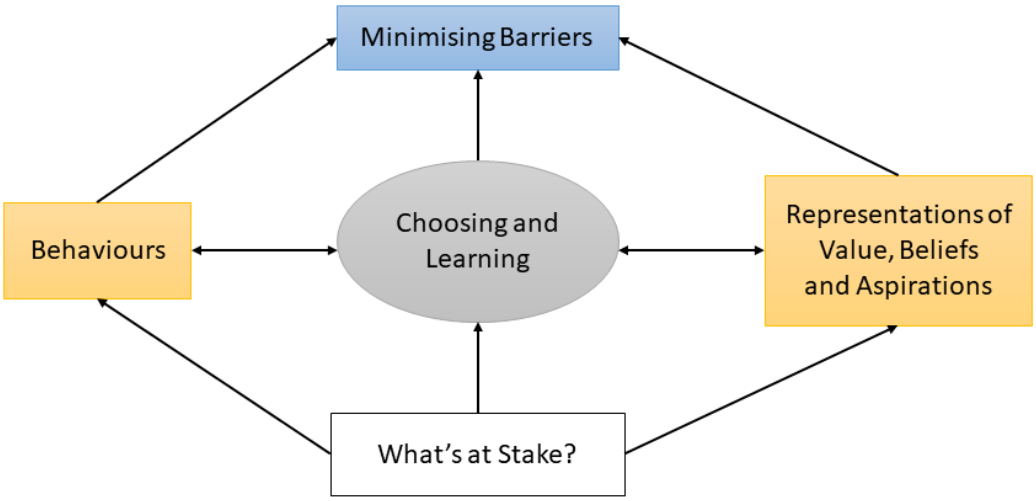

Figure 31: Theoretical Code Diagram

The category code of the Theoretical Code for this research is Minimising Barriers and represented by the category code diagram that integrates the main themes underlying it. The grounded theory is developed from the diagram and documented in chapter four.

3.5 Ethical Considerations

The ethics of social science research have been adhered to and the data management plan was approved by the university. The participants were senior managers and/or part owners of the companies and were invited to take part in the research, the findings from which are highly relevant to resolving their challenges in implementing the new EU regulation successfully.

Prior to the interviews being arranged, the participants received an information sheet, which explained the purpose of the research, the risks and benefits and

details of how the data would be managed. They all signed a consent form. The researcher explained the purpose of the research and assured confidentiality and anonymity regarding the identity of participants and their firms before commencing the interviews; this is evident from the transcripts in which personal details have been excluded. Interviewees were also advised that they could withdraw from the research at any time (Saunders et al., 2019). The researchers attempt to minimise bias in the interpretation of the findings is also evident owing to the systematic way in which they interview transcripts have been analysed. The advice offered by Saldana (2016) to reflect deeply on the findings before drawing conclusions is applied to diminish bias.

3.6 Summary

This chapter discusses the fundamental philosophy adopted by the thesis and the research methods. A relatively high level of detail is provided in this chapter because the methodology makes a very large contribution to the thesis by means of the analysis of the data gathered during the primary research.

This research is predominantly supported by the subjective stance for which acceptable knowledge is assumed to derive from a range of sources. Grounded theory appears to be especially apt for this research because the researcher derives a general, abstract theory of a process, action, or interaction grounded in the views of participants (Creswell & Creswell, 2017).

Two cycles of coding are employed to reduce the initial multiple codes to a small number of categories so that new theory emerges. The coding process relies on implementing the advice of Saldana (2016).

The following chapter represents the detailed application of this process with regards to the research question under scrutiny and analysing the actual data collected.

CHAPTER 4: FINDINGS, ANALYSIS AND DISCUSSION

The previous chapter has shown the complexity developing grounded theory through qualitative research by applying semi structured interviews and coding the data following the advice of Saldana (2016). In this section it will be explained how the actual data was processed accordingly, subsequently interpreted and finally led to new theory.

The first part of the chapter is structured according to the applied coding methods and the respective findings, then identifies the main results and the emerging grounded theory. Finally, the content analysed is discussed in relation to the research questions and in relation to its correspondence with existing studies, which isolates the new items of theory that have emerged (Saldana, 2016). Figure 32 describes the approach, contents, and structure of chapter 4:

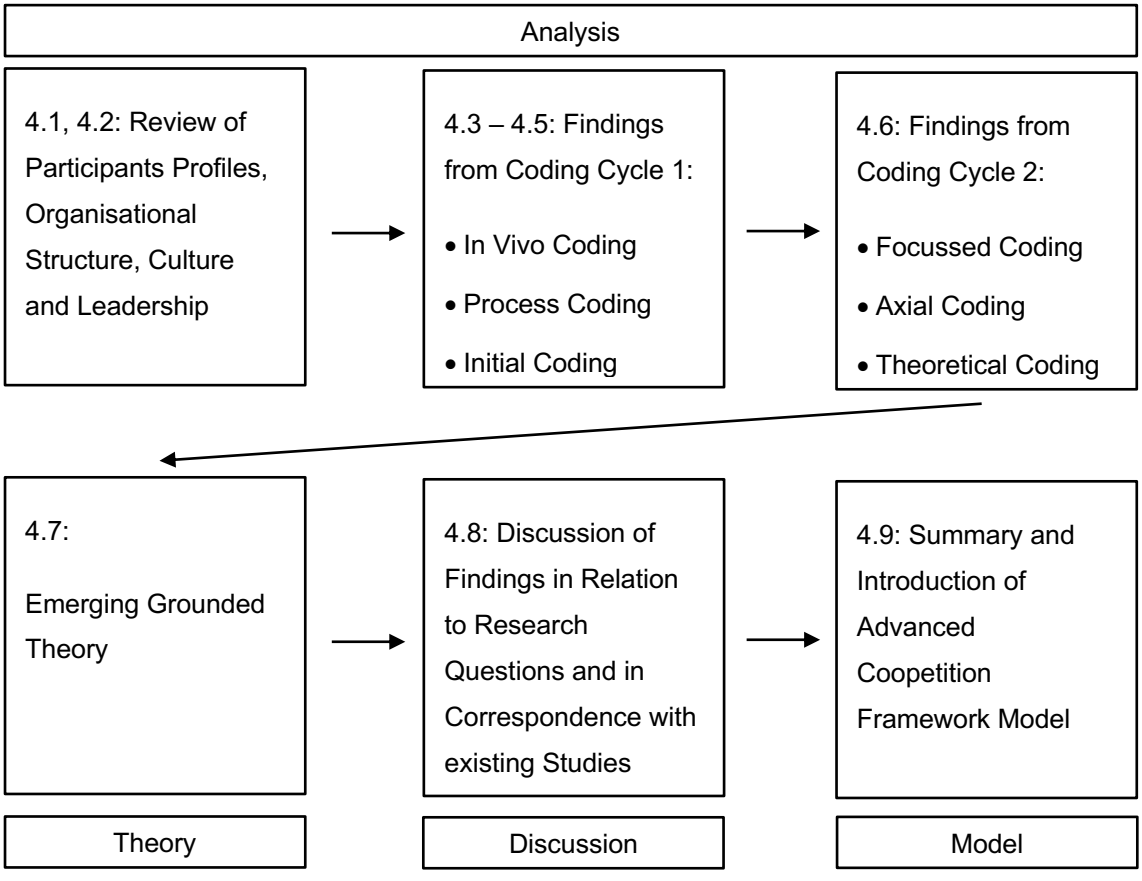

Figure 32: Chapter 4 Structure

Thus, the analysis of the interview data is documented in this chapter in a highly transparent manner. Direct quotes are particularly valuable in qualitative research and integrated sparingly to illustrate the meanings participants associate with specific social phenomena. They are also used to enhance the text, to provide diversity and to demonstrate the richness of the feedback (Ritchie & Lewis, 2010).

4.1 Participant and Company Profiles

The fifteen participants who took part in this study provided considerable information regarding their roles, responsibilities, organisational structure, organisational culture, and approach to innovation. Therefore, this evaluation of the participant profile is concerned with documenting these features and identifying patterns in them.

The main roles of the participants in this research are presented in Table 14, almost one third were either founders or co-founders of the firm, but of those only two stated that they were the owners or co-owners, only one co-owner did not state that he founded the firm. The main characteristic of this group of participants seems to be that they are employees of the company, eight having senior board status.

Table 14: Participant Role Pattern

Participant	Owner	Founder	Co-Founder	CEO	COO	CTO	Head of Function
P1			1	1			
P2			1		1		
P3	1	1					
P4				1			
P5			1				
P6	Co-Owner						
P7							1
P8		1			1	1	
P9				1			
P10	Part	1					
P11					1		
P12							1
P13							1
P14							1
P15			1	1			

One of the founders, P8, occupies two major roles, and founders that have a top-level position are CEOs or COOs. The group also incorporates four senior managers, which gives a more rounded perspective on how inter-firm coopetition

might benefit a company than singularly only taking the views of senior Board level personnel and founders. The degree of autonomy to make decisions for each of the participants is indicated in Table 15.

Table 15: Power and Decision Autonomy

Participant	Ultimate Authority	R&D	Sales	Product Development	Partnership Development	Quality and Regulation	Raising Finance
P1	1					1	
P2				1			
P3	1			1			
P4							1
P5	1			1	1		
P6	1	1	1			1	
P7				1 (Global)			
P8			1				
P9	1						
P10		1	1				
P11			1			1	
P12			1	1			
P13				1		1	
P14			1	1			
P15	1		1	1			

The six individuals who have ultimate authority in the companies are almost all owners, founders, or co-founders. Only P9 declared that he is not a company owner or founder. As is expected of SME enterprises many of the senior managers fulfil several significant responsibilities in the company, P5 and P15 in three roles and P6 occupying four. Given the counts in each column in table 15, product development and sales are given priority with quality and regulation also being important enough to be a major senior management responsibility. The implication is that this group will have deep insight into the issues of developing and selling the reconfigured products within the legal constraints of the EU regulation.

4.2 Participant Organisational Structure, Culture and Leadership

Organisational structure, culture and the leadership approach have a significant influence on innovation as discussed in chapter two. The organisational framework associated with these interviewees is summarised in Table 16.

Table 16: Organisational Features

Participant	Size (according to participant)	Company Stage	Structure	Management/and Leadership Style	Culture
P1	micro	commercial	Hierarchy	Open	fun, work hard
P2	micro	development	Flat	empathy trust empowerment	collaborate work hard
P3	small	commercial	Flat	open, flexible	-
P4	micro	commercial	Flat	Communication, open transparent	teamwork
P5	micro	commercial	Flat	-	open, respect, empathy

P6	micro	commercial	Flat	-	accept failure but learn from it
P7	small	commercial	Hierarchy	CEO makes decisions	Responsibility of top management
P8	micro	Piloting first product	Flat	collegial, agile	Transparency
P9	micro	commercial	Flat	open collaborative decision making	Open, transparent, share information
P10	small	commercial	Flat	Decision making two owners, cooperative	-
P11	medium	commercial	Flat	transitioning	-
P12	small	commercial	Flat	Trust mentoring	start-up, employee perspective of owning mini company
P13	micro	development	Flat	collaborative	start-up
P14	small	commercial	Flat	group decision making	diverse origins and qualifications
P15	micro	commercial	Flat	Open	**-**

This summary demonstrates that the participants are all derived from SMEs, with 9 participants working in micro size companies, 6 in small businesses and only 1 participant in a medium size company, which confirms that the focus of this research is satisfied.

Most companies are no longer in the development stage of their business lifecycle and therefore are likely to have existing products that they will need to

adapt to meet the regulation. The inference is that this aspect of the research is important, and a short analysis of the products may be useful to inform further comments.

Only two organisations are described as being hierarchical, the remainder are flat structures, which is typical of SMEs. This corresponds with the most likely structure to drive innovation according to Bryan and Joyce (2005) and Strikwerda (2012) as outlined in the literature review, chapter 2.2.2. The feedback from P10 of being a flat organisation but decisions being made by the two owners seems contradictory, but the company has 25 to 30 people so the description may be apt.

Most firms operate in an open, collaborative manner with substantial trust being common and a hard-working culture also characterises them. The culture generally corresponds to the comments on structure, openness, and collaboration although P7's natural response was to associate culture with leadership responsibility in alignment with Schein (1985). P14 linked culture with ethnicity and professional qualifications (Doole & Lowe, 2012).

The underlying answers around the organisational structure, culture, and leadership of the participants presented in the tables above were also subject to In Vivo coding, which revealed substantially more detail. In contrast to the remaining interview questions no other coding techniques were applied to the initial questions on structure, culture, and leadership since they were not directly concerned with answering the research questions.

The main findings from these general company questions, which were analysed using lumper and splitter codes, are presented and discussed hereafter. Lumper codes are characterised as more holistic and expedient, whereas splitter codes split the data into smaller codable and nuanced moments (Saldana, 2016).

4.2.1 Organisational Structure (OS)

One lumper code, presented in bold, was identified to combine all the diverse comments (splitter codes) regarding organisational structure (see Table 17).

Table 17: In Vivo Code Organisational Structure

Lumper Code 1:	"Some sort of tiered system" (OS)
Splitter Code 1a:	"Not underneath me, but work alongside me"
1b:	"Organize in a very short step"
1c:	"As little corporates as possible"
1d:	"You're at the bottom. You're at the top, you've set into stone a set of representations about value and worth."

The concept of organisational structure was encapsulated in the phrase "some sort of tiered system" (P1) and was ideal to summarise the various expressions made about it. Whilst P5 described the company structure as flat, this was qualified in relation to the perceived need to have a defined leader with roles and responsibilities. The description of organisational structure given by P3 was also illuminating: "Organised in short steps and works alongside me not under me." This conveyed a lack of 'chain of command' arrangements and the feeling of working together to ensure that the objectives were achieved. The large firm scenario was openly expressed as being totally unsuitable for the type of tasks and work environment in these firms due to high complexity and different interests within the same organisation. These descriptions of the small organisations not only convey the physical framework but offer a sense of employee emotion and pride in how it impacted on morale, which aligns with Dalton et al. (1980).

The roles that individuals undertook within the participant firms were identified by the In Vivo Code 2 and seemed best expressed by the lumper code: "we do everything" (P3) as presented in Table 18.

Table 18: In Vivo Code Roles

Lumper Code 2:	“We do everything.”
Splitter Code 2a:	"I think you always need clear roles, responsibilities and clear person where the buck stops with, who has to make the decision."
2b:	"The structure is me."
2c:	"We three together, we consider as a management team which handles and, of course, responsible for all signatures and all our responsibilities covering all which is related to the company."

Roles were often not well defined, and how they were shaped varied. The CEO of P3 with 24 employees for instance captured the spirit of the SME with the expression: “the structure is me” (P3). The inference is that he did everything or had participated in every functional role in the company at some time; all elements described by Mintzberg (1999), see chapter 2.2.3, merged into one.

In contrast P9, working in a company that had 9 employees, was organised so that three people had designated themselves a management team. They shared all the key tasks, inferring that an apex and operating core existed without a middle line, and technical and support staff were merged into the whole organisation, rather than sharply defined. This structure reflects the perception of the small firm having a higher proportion of leadership capacity than larger companies as expressed by Vaccaro et al. (2012). In other cases, roles and responsibilities were more well-defined and considered important. They inferred a sole final decision maker at the apex, who was accountable for consequences if something went wrong, as expressed by P5 with 3 employees. This aligns with the idea of leadership expressed by Stacey (1996).

These responses demonstrate that ideas of organisational structure vary considerably even within micro and small firms, and that traditional and contemporary ideas of structure and relationships within the firm are often combined.

The third OS concept focused on the size of the company and its relationship to its stage of development, the code for this was “an early-stage company” (P2). The expressions regarding the stage in the company’s business life cycle were implying the simplicity and division of labour that was occurring. There are 5 employees in a 2:3 arrangement: “we are only one floor and two guys on top” (P2). The frequent merging of the structural dimensions in various degrees is well described by: “unstructured collaboration system… comparable to a start-up” (P13).

The participants provide a description of organisational structure that strongly matches existing theory but is surprising because there is substantial variety in the way the elements of structure are arranged. In case of P3 a fluid structure could be envisaged, with the CEO formally at the apex representing different elements at various times (Mintzberg, 1999); this is also inferred in many other firms. A gap is evident because P11 provides minimum information about the structure, merely expressing a belief that it is flat. However, when P11 discusses higher responsibilities, it is evident that there is a complex functional arrangement and that he is at the apex of that function within a larger structure, comprising a headquarters structure reproduced in divisions each with the same functions (Mintzberg, 1999; Whittington et al., 2019).

4.2.2 Organisational Culture

The associated organisational culture was less well described by participants. However, two lumper codes were identified from the responses that were provided.

Later questions which are more focused on culture required for innovation, enabled some expansion of knowledge on culture in these firms to supplement initial feedback. The first lumper code focused on organisational culture as a mind-set, see Table 19, and the second was associated with the perceived purpose of culture, see Table 20.

Table 19: In Vivo Code Organisational Culture I

Lumper Code 4:	"Free on their way of thinking"
Splitter Code 4a:	"You will have to think differently."
4b:	"Good perspective on reality"
4c:	"The culture is complete mix culture... with different qualification."
4d:	"A blind alley is explored in a way that I'm not sure it's that feasible to do with the pressure of a big team and big financing."

The free-thinking culture expressed in the lumper code was also associated with the "blind alley" in one of the splitter codes, which also inferred uncertainty and a risk-taking attitude. This characteristic differentiated the micro firm from large organisations that would be too bureaucratic to enable this culture to operate (Haveman, 1993). There was also a strong inference that being an SME, especially a micro-organisation, had an emotional impact on employees, because they had direct knowledge of the firm's opportunities and challenges and understood the reality of their situation (Rammer et al., 2008; Ortega-Argilés et al., 2009).

The concept of culture conveyed in this series of expressions very much aligns with Serrat's (2017) definition of culture as distinctive and relating to how humans interpret their environment. The splitter code expressing culture as a complete mix, referred to the organisation comprising individuals with different disciplines and backgrounds (Hall, 1997; Doole & Lowe, 2012).

Table 20: In Vivo Code Organisational Culture II

Lumper Code 5:	"There's so much at stake."
Splitter Code 5a:	"We like very much to interact with either insiders or outsiders of the company."
5b:	"Collective shared responsibility and objective"
5c:	"They have no time to develop it in their own R&D and there's already a CE mark."

The lumper code in Table 20 related to a comment by P8 that suggests that the organisation interacts with its environment in a certain manner because there is so much to gain or lose by its decisions and actions. Culture is therefore characterised by shared responsibilities and focuses strongly on accomplishing objectives (P5) and gathering information from inside and outside of the organisation (P8).

In some cases, firms have established collaboration with others, and are sharing responsibility with them to achieve joint objectives, as is the case with P6, which stated that it has the CE Mark and know-how that the partner wished to acquire. The inference is that each partner has a great deal at stake and adapts its culture to optimise outcomes, as is required in coopetitive relationships (Ritala & Sainio, 2014).

4.2.3 Leadership and Management

The participants were asked two types of question regarding leadership and management in the initial phase of the interview: what the terms meant organisationally and if they perceived their role as leader or manager. The responses to the questions revealed six aspects: meaning of leadership; traits of leaders; leadership stye; meaning of manager; the leader's work; feeling of being a leader.

The lumper code most associated with leadership in the companies was represented by the expression **“**give power to the people” (P2) and expanded in four additional expressions. The first two offered by P2 were leadership expressed as trusting employees and empowering them to manage and solve the problems that they encountered. Other examples of this type of leadership were organisation-wide discussions that satisfied the entire team of 9 employees and expressed as usually producing the optimum solution (P9). The concept of leadership as predominantly a mentoring activity by P12 was relatively unique, especially as this company comprised 42 employees. However, all these responses tend to align with less classical leadership theories; a delegating leadership approach because the motivated employees have the appropriate skills and aptitudes (Yukl & van Fleet, 1992; Mullins & Christy, 2016), or are perceived as effective followers (Gobble, 2017).

Table 21: In Vivo Code Leadership

Lumper Code 6:	**“Give power to the people.”**
Splitter Code 6a:	“Trusting them”
6b:	“Give them the opportunity to manage their problem and their solution by themselves."
6c:	"Typically, we do have a discussion with a consent which makes everybody happy and which in most cases is the best solution."
6d:	"Mentoring orientated"

The mentoring reflects the coaching and developing employee’s aspect of Adair’s (1973) Action Centred Leadership Theory and transfer of tacit knowledge (Smith, 2001). The trait theory of leadership was also evident in responses of leadership being open as the main code, and empathy (P2), communication (P4) and leader by example (P3). These tend to match the contemporary traits identified by Northouse (2019) and Zaccaro et al. (2004); ideal for enhancing relationships and motivation (Goleman, 2005).

Leadership style in the organisations was characterised by readiness to always discuss issues openly with employees by P1, P3, P5 and P9. There were expressions of a collegiate relationship (P8), somewhat reflecting the concern for people and task team management leadership (Blake & Moulton, 1964). Also, leadership was perceived as most effective and suitable in agile organisations (Morris et al., 2014). These comments reinforced the trait theories and leadership as empowerment in contrast to a top-down leadership approach mentioned by P7: “decision making comes from the board of directors and the CEO”. This style is associated with large firm structure and culture, which P7 experienced.

The first lumper code identified with the term manager was “it’s a big extension on project management” (P1) emphasising the day-to-day duties of leaders (Kotter, 2012), which are essential to ensuring that short term objectives are accomplished. The leader as communicator, who constantly interacts with employees, motivating and mentoring them (Mintzberg, 2009) is also expressed by “somebody who is interested in what they are doing and who is interested to interact and to discuss things and really gives feedback about how to do it “; “really hearing people”; “encouraging the people to be happy in their job” (P9).

Table 22: In Vivo Code Manager

Lumper Code 9:	**"It's a big extension on project management."**
Splitter Code 9a:	“To make sure that everyone comes into deadline on time.”
9b:	"I am involved in all processes to discuss things and really gives feedback about how to do it."
9c:	"Somebody who is interested in what they are doing and who is interested to interact and to discuss things and really gives feedback about how to do it."
9d:	“Really hearing people”
9e:	"Encouraging the people to be happy in their job"

The implication of the two major participants providing the expressions in Table 22 of leader as manager is that differentiation of the two roles is noticeable in these two organisations. However, many respondents did not consciously separate the responsibilities of leaders from managers as Kotter (2012) emphasised, but perceived the functions as being integrated and hence the additional lumper code: “Leader manager not a leader” (P2).

Other descriptions provided by participants enunciated the two aspects being combined as presented in Table 23: “good leader needs to be close... the frequency [of meeting] at least one time per week, close to the team and just to get a report from them… to be reassured about what they are doing” (P2). This first splitter code reflects the more day to day approach of the management part of leadership (Mintzberg, 2009), whereas needing to get a report on how the employees are progressing more reflects the anxiety of leadership, described by Stacey (2010).

Table 23: In Vivo Code Leader vs. Manager

Lumper Code 10:	**"Leader manager not a leader"**
Splitter Code 10a:	"Good leader needs to be close- close, the frequency at least one time per week, ...close to the team and just to get a report from them…to be reassured about what they are doing."
10b:	"I'm a leader, but I'm a manager also."

The last leadership lumper codes identified from the interviews, was concerned with the leader’s perception of higher role: “Leader… implies a tribe” (P5). This is an aspect of leadership that is relatively neglected by academic theory, with Stacey (2010) being one of the relatively few authors emphasising how the leader feels responsible for developing the strategy for the future. As reflected in P5’s comment about his feelings as a leader, this can be an unknowable future: “trying to find a path through this forest… focused on an objective beyond themselves”

(P5). The stress being that the task was not easy personally, and further challenging because he felt responsible for encouraging followers to help accomplish the goal (Kotter, 2012): “and help other people through them” (P5).

Table 24: In Vivo Code Leadership Self-understanding

Lumper Code 11:	"Leader... implies a tribe"
Splitter Code 11a:	"Trying to find a path through this forest, focused on an objective beyond themselves"
11b:	“Going through personal pain"
11c:	"Help other people through them"

In these responses, the observer can sense and empathise with the leaders, who are evidently experiencing considerable challenges with the uncertainty of the legal changes in the medical devices sector (IMAP, 2019), and subsequent long-term viability of their businesses (Mason & Kwok, 2010). In relation to answering the research questions for this thesis, these features of leaders and leadership are useful for answering research sub question number 10: Which management and leadership characteristics support the application of coopetition?

4.3 Findings from In Vivo Coding (Cycle 1)

After reviewing the participants profiles, organisational structure, culture and leadership, the next part of this analysis and discussion chapter concentrates on the main body of questions from the interviews on innovation, the new EU regulations, and coopetition.

The analysis follows the advice of Saldana (2016) for coding qualitative research with the aim of developing new theory. The coding therefore contains two cycles with three different coding methods each, so in total 6 rounds of coding were

applied. The first cycle of coding comprises: In Vivo Coding (codes derived from actual spoken/used terms), Process Coding (codes to communicate an action in the data) and Initial Coding (open codes providing a label, description, definition, or category name)

The methods of the second cycle (focused, axial and theoretical coding) aim to condense and crystalise the findings of the first cycle, ultimately shaping a new theory. The findings are reported in the sequence in which the coding occurred which is documented in detail in the appendices.

Analysing the same set of data with three different methods in cycle one is like looking at the same object from different perspectives. These different methods can reveal different findings, but also show the same results. In terms of presenting the findings some are therefore mentioned multiple times in the next sections. This shall not be seen as repetition and redundancies, but triangulation that strengthens the validity of the respective results.

The results start with reporting on In Vivo Coding before introducing Process Coding findings in the next section. Subsequent sections report on Initial Coding, Transitioning to Second Cycle Coding, and the emerging grounded theory.

4.3.1 Innovation – In Vivo Coding

The importance of innovation to organisational success was determined by asking the direct question whether it was a Critical Success Factor (CSF) for the participant firms. Innovation is generally regarded as the source of competitive advantage and the most vital CSF for sustainable organisations (Tidd & Bessant, 2018). Therefore, it is surprising, that only P11 rated innovation the most important success factor, whilst P2, P4 and P14 rated it second and P15 third. Two participants, P1 and P12, stated “really high” and P8 suggested recruiting the right people was equally important. Other aspects perceived as of prime importance to business success were Sales (P4), team first (P2), and the new regulation (P13). In summary innovation was still seen as highly important across the participants, but not the most important success factor for medical device

SMEs currently. This could be the case because of the new regulations requiring other resources than innovation to be managed and needs to be analysed further.

Whilst not answering the question directly two other aspects of innovation emerged, qualifying innovation as being either incremental or disruptive and distinguishing innovation from creativity: **“**incremental technology and not disruptive technology” (P2). The difference between creativity and commercialised ideas was expressed by P12 and P8: "I would rank it high… but at the same time it needs to be implemented… not just prototypes, demos and so on” (P12); “innovation which can come from laboratories usually state-owned and it's very much research rather than development… we're rather much more on the development phase because we co-develop our solution with users… it's innovation that they can put money into" (P8). These responses about the incremental and disruptive innovation align with existing theory (Christensen et al., 2003), and with an understanding of innovation as the stage of product/service development when creative ideas are commercialised (Amabile et al., 1996; Hunter & Cushenbery 2011). Therefore, the In Vivo Code 17 emerged as:

Table 25: In Vivo Code Innovation

Lumper Code 17:	**”Secret of our success is innovation.”**
Splitter Code 17a:	“Area innovation appears to add value."
17b:	“Incremental technology and not disruptive technology”
17c:	“Innovation... from laboratories. Very much research rather than development... we co-develop our solution with users... it's innovation"

The participants were asked their opinion on whether innovation in medical devices was different from innovation in other contexts, and then other related sub questions were posed to them to determine the reasons for the expressed

differences. There was very high convergence of opinion that innovation in the medical devices sector was different from that in other sectors, 13 participants suggested this, mainly because of the regulatory requirements specific to medical devices.

However, P6 and P8 disagreed with this convergence. P6 perceived that innovation was the means to higher profit margins through product differentiation, and P8 focused on the mind-set of the user of the medical device. The medical staff who implemented the innovation had considerable control over device success and this was the differentiating factor rather than the product: "what needs to be very, very clear is that not only do you need to bring the product, which is in itself innovative, you also need to bring the mind-set, you know, for the change to occur"; "maybe one of the differences I see with other markets, is getting people involved in innovation themselves and being able to change their practice" (P8).

This response is one of the major factors that generated the In Vivo lumper code 18 “bar is much higher” (P5). It reflects the general perspective of respondents that it was more difficult to innovate in the medical devices sector owing to boundary conditions being referred to as “toxic” (P5), the difficulty of changing the user’s mind-set (P9, P8, P10), and that the medical device instruments were in contact with patients (P14, P15).

Table 26: In Vivo Code Medical Device Innovation

Lumper Code 18:	**”Bar is much higher.”**
Splitter Code 18a:	“Boundary conditions for innovation are toxic in medical devices.”
18b:	“Getting people involved in innovation... being able to change their practice"
18c:	"Instruments…. in contact directly with the patient”

The remarks reflect the definition of innovation and creative destruction in which new ways of doing old things are discovered, making previous skills and mind-sets redundant (Schumpeter, 1947). The implication of the bar being higher was that firms needed to be more responsible (P10) and were subject to higher hurdles (P9). Regulations, restrictions, and changes in medical registration (P12) were some other barriers, as was the tracking capacity of devices, owing to data privacy issues (P12, P15).

The new regulations were referred to as: “that kind of brutal regulation make it impossible for small companies to really come up with new innovative products in a financeable way" (P13). This remark captures the emotion of personal anxiety and risk that was expressed previous about the learning culture required for innovation (McCarthy et al., 2018). Also, the responses externalise many of the fears and frustrations within senior management of medical devices companies, which cannot be easily expressed by quantitative research methods; they are therefore valuable examples of the multiple emotional issues the sector is currently experiencing. They add new insight to the gaps in knowledge identified by Pelkmans and Renda (2014) regarding the general effect of new regulations.

A diverse range of boundary conditions were cited that hindered innovation or limited innovation drastically. According to P13, these limitations are particularly true for disruptive innovation; these made the industry rather “conservative” (P10), and software innovation lagged other sectors by five years (P12). The remark relating to software is also associated with potential for failure in smart devices and privacy concerns, corresponding to Marketline (2017). This emphasised that the time taken for new products manufactured in the EU to reach the market would be considerably lengthened by the new regulation.

Medical device companies were described by P2 as generally more associated with open innovation (Chesbrough, 2012), as stated by Guerra Bretaña and Flórez-Rendón (2018), because the risk of producing nothing after up to 4 years of research was too high. P5 also mentioned that risk added tolerability for failure, which was much lower than was the case in pharmaceuticals. The constraints on innovation in the medical device sector were increasing according to P4, but P7 stated that when innovation was successful in this sector it held potential for

higher profits and quick time to market for new products. The contrast in focus of different SMEs seem to reflect the stark difference in organisational context that was evident in P7s culture and leadership remarks. It confirms the strategies of larger companies to rapidly leverage innovation rate, speed to market, and profitability and to achieve this by acquisition, merger or other means of capturing SME innovative capacity, as highlighted by Fernández et al. (2019) and Whittington et al. (2019).

Several additional questions on innovation were posed to the participants, the first being, which person in the organisation was in charge of innovation: five responded that it was the senior management team or specific members (P2, P7, P9, P11, P13, P15); P1, P5 and P10 had sole responsibility and P4 and P6 shared it with an engineer; P3 did no inhouse design; P14 customers and company; P8 and P12 no answer. The pattern of innovation responsibility is revealed as innovation being the responsibility of senior managers alone or with other senior managers, rather than a whole organisation decision. This tends to confirm the theory that innovation is orchestrated by leadership (Stacey, 2010), but there is no evidence that it is optimised by whole firm involvement from these responses.

Seven participants were asked directly if their firms practised open innovation (P1, P3, P7, P8, P11, P12, P13) but only P1 and P13 responded that they currently did so, P13 providing a description of the external entities participating and describing partnerships and knowledge transfer (Chesbrough et al., 2006): "with automotive, with engineers developing automotive applications or aeronautic applications or in the watch industry"; "there is knowledge transfer between different applications in different fields" (P13). Liaison with individuals in diverse engineering specialisms was also mentioned by P3 but less detail was given.

Three participants were asked if they were involved in an innovation hub, only P1 confirmed. These responses tend to reinforce the lack of open innovation in these participant companies expressed previously; contrary to other industries (Arkhipova & Arkhipov, 2016).

There also was agreement about innovation being a structured process from five participants who were directly asked another question about how innovation occurred in their company. This motivated an additional splitter code, which was added to innovation lumper code 17 secret of our success is innovation**:** 17d structured with scarce resources and learning internal/externally. The details of structured innovation varied somewhat but one theme was scarce resources and being asked to justify how value was added by investors, for instance: "It's very structured because we have very scarce resources"; "We are going to have investors who are going to ask us: where do you invest your money? What do you get from your money? Do you make some intellectual property out of it?" (P8).

Structure described by P10 was about the learning from the creative idea until the point of commercialisation: "A little bit of everything… we plan... we build the base... we test different possibilities... then life brings new idea... we are learning some things that were never expected... we are also learning that's something we expected... So, it's a lot of learning curve".

There was "beginners' luck" associated with the structured process (P11), structure also involved learning but using a different resource pool: "strong exchange with clinical specialists... constant monitoring of publications... a very well-organized database of publications strong connections into the industry outside of medical device... there is influence coming back to us" (P11). The degree of structure in innovation in the company of P11 was a consequence of an engineer being involved, previously it had been more unstructured.

In contrast structured innovation with P6 and P13 was driven by customer input, P6 gained the data from its sales and marketing personnel and P13 from conversations with surgeons. Hence innovation was "not an accidental process, it is really by observing and researching what is happening in the field and outside of the field of medical devices" (P13). Therefore, the structured process mirrors both the learning by experimenting to find a commercial solution (Hunter & Cushenbery, 2011) and open innovation (Chesbrough et al., 2006).

Some participants were asked additional questions, which yielded a few other insights about innovation in the organisations. The first related to experience with New Product Development (NPD) models, but P14 was the only respondent who was attempting to develop one. The motivation was that the firm currently had a partner, which sold its product and required that product to have a certain specification. However, P14 was developing its own version to sell direct to the market and withdrawing from a collaborative relationship, dispelling a coopetition relationship.

The internal factors leading to successful innovation, or hindering it, were identified in three sub questions posed to some participants; the first two questions were based around organisational structure and culture, although leadership also became a large element of those responses. The third question was about leadership for innovation and generally triangulated the features of leaders and leadership for innovation in early questions so that codes could be assigned to these ideas.

The emphasis from P5 was that appropriate organisational structure and culture were vital to facilitate innovation, in strong agreement with theory (Dalton et al., 1980). Contrary to theory, P9 suggests it was not that important to higher organisation, but this may be a consequence of the open, shared decision making that occurs in the workplace environment described earlier, which is not perceived as a contrived structure and culture.

The small size of the participant organisation and a flat structure were both repeated as providing an excellent context for innovation (P3, P5, P8, P10, P12, P13, P14, P15). P11 reemphasised the belief that innovation was more likely with fewer organisational layers and by empowering people, which increased their commitment to it (Kotter, 2012), again linking leadership to culture (Kotter, 2012; Stacey, 2010).

The declarations by P11 were matched by other participants who frequently stressed that capabilities for innovation were associated with organisational size, which tended to foster an innovation culture: “that’s a lot to do with the size of the organization” (P1). This general remark is justified by emphasising the highly

flexible approach possible because the team was small (P1, P10). They could swap tasks from a vital administrative role such as applying for funding, to working a long day in the laboratory: “good at being flexible because we’re still quite a small team” (P1), “can swap to writing a grant one minute or they can be doing a 12-hour day in the lab next” (P1). A learning culture and transfer of knowledge are both evident in these firms, and characteristic of an open innovation environment (Gassmann & Enkel, 2004; Lameras et al., 2012).

The perception of individuals in the small team was that they were developing and managing their own business. They inferred that start-up culture must be maintained (P1), because being a small team made decision making easy. “Wanted to keep this Start-up culture... everyone feels that they are responsible of their own mini company area” (P12). “We are growing. We can see that we are transforming into much less movable object … we have become rather slow and not so quick learning as we used to be” (P12).

Two remarks were made by P5, which emphasised the relative lack of speed and capacity to experiment associated with multinational companies, aligning with Zaradis and Mousiolis (2014): “multinational there’s hard steps there, but zero to something… they’re very rarely focused on”, “a blind alley is explored in a way that I’m not sure it’s that feasible to do with the pressure of a big team and big financing” (P5).

The lumper code 14 “team first; people first” captured the culture of the people resources required for innovation, and four splitter codes were also identified. There was awareness of the resilience needed to work in an SME and of recruiting employees with similar mind-sets and values, which was expressed in various ways by the participants: “It is quite tough to our people, and we want to be sure that at the end, people we hire are in the same cultures as ours and the same values” (P2).

P1 suggested that too many founders could destroy innovation because of not coming to conclusions and that choosing co-founders with a similar work ethic was important to support it, which matched the lumper code 14 of people and team first: "a good set of cofounders to start"; "you don't need too many

cofounders, you need like three maximum"; "too many opinions can kill it"; "you need to have people... equally as efficient... the same sort of work ethic as you" (P1).

The implication is that the choice of members of the founding groups is a Critical Success Factor (CSF) for successful innovation and that conflict regarding work ethic is a Critical Failure Factor (CFF); this belief has some alignment with workplace culture of high job orientation (Hofstede, 2020), in which individuals with lower levels of it will not be considered a good organisational fit.

Table 27: In Vivo Code Human Resources for Innovation

Lumper Code 14:	**“Team first; people first”**
Splitter Code 14a:	“It is quite tough to our people, and we want to be sure that at the end, people we hire are in the same cultures as ours and the same values."
14b:	“Error of this kind... Okay, no problem. We're going to redo this thing"
14c:	"Inform them what's going on, what is current status.”
14d:	"You need good cofounders… not too many - too much opinion kills it."

The only individual who raised the cultural value that making errors was acceptable was P10, but this was qualified by the necessity to learn from them rather than repeat them, so that overall performance improvement is accomplished. There was also a cultural acceptance that creating a new idea or product was challenging, expressed by P3, and providing In Vivo code 15 “zero to something is the hard step” (P3). In this code, the diverse challenges of legislation in the current SME context are exposed. The code represents a new finding about the diverse personal struggles endured by leaders and employees; it is a painful learning process that the team must sustain and reinforces the

emotion of leadership expressed as personal pain by P5. Therefore “hard work” is an essential cultural attribute in these firms according to P1 and P2, and a realisation that “system needs to be changed… so we need to invest” (P3).

Table 28: In Vivo Code Culture of painful Learning

Lumper Code 15:	“Zero to something is the hard step”
Splitter Code 15a:	“System needs to be changed. So, we need to invest."
15b:	“Work hard”
15c:	"But if we redo it, you need also to improve something.”
15d:	“When it becomes difficult, some people prefer their own interest… this is very disappointing.”
15e:	"Finances limit you and the rules limit you. That is what we have to learn in the company."
15f:	"Trying to learn from all the difficulties and experiences"

The cultural understanding of the boundaries of possible solutions owing to lack of resources is captured in an expression by P13: “finances limit you and the rules limit you… that is what we have to learn in the company”. This demanding situation is reinforced by P5, who expressed the potential of personal risk involved, and by P10 that the cost of errors needed to be understood and “if we redo it, you need also to improve something.” Other difficult steps were mentioned for instance: “trying to learn from all the difficulties and experiences” (P12) and realising that “when it becomes difficult, some people prefer their own interest… this is very disappointing” (P4).

Therefore, P10 proposed that the cultural value of people first was associated with sharing full information relating to the firm’s progress and status with all team members. The implication is that this is an aspect of the workplace that underlies

the cultural understanding of the threatening nature of the environment on survival. Uncertainty as a cultural element in these SMEs is also demonstrated by the elements of In Vivo code 16 (see Table 29), and directly refers to the situation that has been driven by the new EU regulations.

Table 29: In Vivo Code Regulations

Lumper Code 16:	**"We always have alternatives."**
Splitter Code 16a:	"We always bear in mind that a contract that we have signed with a company, a third-party company, might end."
16b:	"a lot of collaboration"
16c:	"Have to adapt to this different way of doing business nobody knows what the new normal is going to look like."
16d:	"agile"

Uncertainty is best expressed by P3 in not having any idea what the new normal will be when the regulations come into force, and P6 envisaging that substantial collaboration will be required. Agility is linked to the capacity to make very quick decisions, always having alternatives because the signed contract may not provide any assurance of stability (P8), so that being good at changing partners was an essential characteristic. In relation to 'people first', code 13, agility is expressed by P10 and P11 as finding a solution by changing the company's direction if needed, although P11 suggests structural agility is important. This capacity for change is also dependent on recruiting highly talented flexible people who even have the capacity to change industry (P10) and linked to being very good at learning (P1). These remarks on agility somewhat align with the findings of Rigby et al. (2016) and Aghina et al. (2018). The comments open new understanding of the emotional aspects and challenges for SMEs in the medical devices sector under the new regulations.

All responses confirmed that leadership was important to supporting innovation in their organisations (Hunter & Cushenbery, 2011). A variety of reasons were expressed, for instance: everyone needed to understand why they were asked to do certain tasks and why there were changes in patterns (P1, P8); leaders needed to encourage constant two-way dialogue (P1), and to facilitate equal participation in innovation by all employees (P3, P7, P9).

The leader as responsible for culture as emphasised by Schein (1985) is confirmed in this thesis by the lumper code: “Thanks to the senior guy” (P2), which is reemphasised in the large organisational sense by P7: “has to be addressed by top management”. The influence of top management is also inferred in seeking to create value rather than satisfying political motives by “not doing something for a political reason but because they have a business value” (P15).

Table 30: In Vivo Code Leadership for Innovation

Lumper Code 12:	**“Thanks to the senior guy”**
Splitter Code 12a:	"Has to be addressed by top management"
12b:	"Not doing something for a political reason but because they have a business value"
12c:	“You've got a much longer journey through a lot more forest with much fewer resources and much less help.”
12d:	"It has to be agile leadership and management."

Leadership allocating rare resources (Barney, 1991) whilst understanding the uncertainty of outcomes (Eisenhardt, 2002) is characterised by P5 in “you’ve got a much longer journey through a lot more forest with much fewer resources and much less help”. Leadership and management of innovation are expected “to be agile” and were linked to empowering employees to be creative by P7.

The tribe concept of leadership, lumper code 11, also re-emerged regarding leadership openness, but with the warning that sometimes openness should be restricted (P8): "I think, well, innovation can backfire if you don't keep it within the walls of the companies. So, it needs to be secretive in some way". This is a particularly important observation in the context of coopetition, which is of ultimate interest to this researcher, and reinforces existing empirical research of caution in revealing too much know-how. (McCarthy et al., 2018).

The main outcomes from the questions on leadership and culture for innovation are summarised in Table 31, demonstrating perceived leadership attributes and work tasks that is creating agility and culture for innovation.

Table 31: Summary of Leadership as Driver of Innovation and Culture

Feature	Factors
Leadership for Innovation Culture	Leader responsibility (P2, P7) Maintain start-up culture/size (P1, P2, P10) Slow innovation by allowing growth in size – cannot do zero to something (P2, P5, P7) Agile (P7) Create business value (P13) Long term focus (P5)
Agile for innovation	High capacity to rapidly switch task (P1) Quick decision making (P8) Change partners (P8, P10) Change sector (P10, P11) Recruit talented flexible people capable of sustaining these changes (P1) Resilient (P2) Good at learning (P1)
Learning culture	Mistakes accepted if you learn from them (P10) Understand the cost of errors (P10) Painful experience (P3, P5) Personal risk (P5) Uncertain future (P3) Hard work (P1, P2) Investment needed (P3) Finances limit you (P13) Individual self-interest disappoints (P4)

4.3.2 Impact of new EU Directives – In Vivo Coding

The participants were asked three questions concerning the impact of the change in EU regulation for the Medical Devices sector; its effect on innovation, whether the company had the required financial resources, if the company had the appropriate knowledge for implementing the regulation. A lumper code associated with the effect of the regulations on innovation emerged from In Vivo coding of the responses; it was generated by P12: "raising the barrier of entry".

This expression can capture diverse inferences for the medical device companies and aligns with the findings of recent studies on its impact on the sector, for instance Maresova et al. (2020a). The impact most often cited was that small companies will find it much more difficult to continue to participate in the sector: "getting through every regulatory hurdle and not running out of cash" (P1); “no resources for really new developments… companies do not have enough resources to pursue new projects” (P9); “it's going to destroy innovation, to avoid innovation to go in the market... at least, in orthopaedics. It may be different in other fields, but in orthopaedics... because it's very difficult to raise money in orthopaedics” (P4); “it cuts off innovation, maybe not in total but at a very certain level" (P9).

The last comment was reiterated by P7, who proposed that new regulation would have a “fundamental impact on the innovation pipeline”. From the larger company perspective, P7s remark is likely to be partly driven by its reliance on SMEs to generate the necessary R&D which they can then acquire (Fernández et al., 2019).

Table 32: In Vivo Code Impact of EU Regulations

Lumper Code 19:	**“Raising the barrier of entry”**
Splitter Code 19a:	"More valuable innovation"
19b:	"Rethink how to work"

The concerns expressed by the participants regarding resources confirm earlier studies, such as Ikram (2015). In contrast to the dominant focus on resources being a barrier to the innovation required to comply with the new regulations, P12 proposed that the quantity of innovation might not be decreased but redirected instead. It was suggested that bigger companies, which had more market power would be the main sources of future innovation in the medical devices sector. This is an interesting observation by the Head of Function of a small company currently in the commercial stage, and possibly taking a difference perspective than owners or co-founders focusing on resource challenges.

Three participants, P7, P11 and P14, proposed that the value of innovation would be enhanced, because the ideas generated have a higher potential for commercialisation and only good quality instruments would enter the market; this viewpoint reinforces the findings of Mattke et al. (2016). These remarks are indicated in splitter code 19a “more valuable innovation” (P11).

"There's also an upside... I believe that the new European medical device regulation will lead to longer product life cycles... products can also be cashed out longer... definitely beneficial especially for the small and medium size companies" (P7).

There was considerable evidence that firms would need to “rethink how you work”, (see splitter code 19b (P11)), and comprising aspects such as: partnerships; changing the length of the small company innovation cycle by only partially developing the idea and then selling it; focusing on the regulatory aspects for some products; "our only option, really is to partner with one of the key manufacturers" (P1); "we probably see a lot of new start-up company selling their technology before clinical trial to these big companies" (P2); "Smaller companies will need to put heavier emphasis on solid clinical dossier for class three and implantable products. It will also require extra time and investment to put those dossiers together" (P7).

The comments about start-ups selling ideas at an earlier stage in product development tend to confirm research by Deloitte (2017), which revealed that investors had concerns that their return from start-ups would be too low because

they were already considered to take too long to reach the commercial stage of an idea, before the new rules were introduced.

Most innovative R&D projects would also be cancelled according to P9, and focus would move to ensuring that the existing product portfolio would be suitable for aligning with the new regulation. The cost of entering the sector would increase because of the tighter regulation (P10), inferring those potential new entrants would consider their options in new ways; one option was to examine the alternatives, was the firm able to continue alone or did it need to consider searching for funding (P11).

These challenges reflect the findings of Gast et al. (2015) but also the requirement to become more aware of potential investor concerns and have higher probability of obtaining investments. In addition, companies would need to rethink how to compete with advantages the US market might have rather than trading in the EU. "It will prioritize more the US market versus the European market, while historically it has been the opposite" (P11). These remarks illustrate the complexity which has been invoked by the new directives, multiple potential issues and solutions, and considerably increased bureaucracy (Guerra Bretaña & Flórez-Rendón, 2018).

The participants were specifically asked whether their companies had the financial and knowledge resources to implement the new EU regulations. The responses were mixed, as indicated by direct quotations. Some were finding the required resources difficult to generate but were rethinking their position (P1, P2, P9) whilst others had resources or intended to divert resources to ensuring compliance (P3, P8, P10, P11, P12, P14), but some did not (P4, P6). In terms of financial resources, for instance: "Definitely not we have to face the requirement to perform clinical studies… and difficult to set up and to organize and in principle, finance that… we look for a collaborator who is willing to get a product into the market“ (P9).

"We will target mainly US, South America or the countries where you don’t need to have CE… for the new one, we don’t plan to get a CE mark… we don’t want to get a CE mark just because at the end... as you know, the price is quite low

and the expense or the budget to get a CE mark or in one year will be so high" (P2). In this case, the company would exit EU markets and trade in other export markets only, and the implied intention was that all new innovations would also be excluded from EU markets. The additional inference from these remarks is that in developing new strategies, the companies had identified some products, which had such a low sales price and/or margin that adapting them to meet new regulations was not profitable, would inhibit company growth (Johnson et al., 2008), and that they would no longer be available in the EU.

In contrast other firms related that: "We have the money... we will return level and come off... with all the restrictions that the new medical directives have placed upon us" (P3); "Yes, because for us, it's not a big difference comparing to the previous registration procedure" (P10). Most of the group recognised that need to obtain knowledge regarding the regulation by seeking guidance (P1, P3, P7, P9, P10, P13) or appointing internal regulatory responsibility to employee(s) (P2, P7). There was also recognition that acquiring knowledge could represent a high-cost factor: "we certainly have the knowledge after having a consultant... charging us £1000 day" (P3).

"Definitely, yes… we have our own medical and regulatory department… we are also working with external consultants" (P7). However, P4 made a conscious decision to delay full implementation: "we have the knowledge, but we did not implement yet all the requirements because... strategically, we don't want to go there". A concern expressed by P10 was the additional time the regulatory procedures added to the product to market timescale especially when: "there are very few notified bodies" (Jeandupeux**,** 2019; Maresova et al., 2020b; Peter et al., 2020).

The comments indicate very different financial readiness/capacity, which may be a consequence of specialism, size and business lifecycle but also demonstrate that most companies understand that knowledge of regulation must be acquired. The diverse contexts of these companies in respect to MDR is also evolving, with approximately half changing their previous approaches to ensure they can comply, but others finding the financial challenges too great. It is evident that firms regard possessing the required regulatory knowledge of high importance,

with P13 suggesting it took precedence over engineering knowledge or creativity (Money et al., 2011).

It was evident that medical device companies were rethinking their approach because of the impending implementation of the legislation, for instance P2 stated that the regulatory authorities engaged in open dialogue with them regarding changes.

The companies were also being proactive in identifying positive outcomes on a personal business basis: “as a small company, maybe we are more able to get innovative products in the market or to maintain our innovative products in the market better than the big players" (P9); "it will allow you to push through more valued innovation" (P11); "maybe become more... outcome-based innovation-driven than just bringing innovation with some incremental, you know, feature" (P11).

A particularly positive response from P2 was that the regulatory requirements would reduce external competitors from trading in EU markets. These remarks, in contrast, appear to support the EU position that regulation change would enhance innovation and competitiveness (EC, 2020a; Maresova et al., 2020a). “If you have the CE mark, it is because you have the clinical trial and... evidence-based... to increase a bit the barrier at the entrance for competitor wanting to target Europe, at the end, the effort for that will be quite huge to compete against us" (P2).

4.3.3 Coopetition – In Vivo Coding

The first question relating to coopetition was exploratory, its purpose to obtain an understanding of the extent of knowledge of the concept, and opinion on how it might support innovation in the context of new EU regulations. Most participants understood the term coopetition despite some having no personal experience; the perception was that the arrangement had advantages and pitfalls and that compromises were required for it to be successful, as suggested by Simmons (1996), reinforced for coopetition by Ritala and Sainio (2014). The lumper code

20 “ecosystems for innovation” (P7) emerged from the range of comments, which provided a framework for a range of interpretations of the terms. The splitter codes that fulfilled a similar purpose but represented specific aspects of the ecosystem were: “deliver value” (P7); “resource sharing and compromise” (P1), which embraced both human and physical asset exchange and behaviours; legal side kills the innovation (P10).

Table 33: In Vivo Code Coopetition

Lumper Code 20:	“Ecosystem for innovation”
Splitter Code 20a:	"Deliver value"
20b:	"Resource sharing and compromise"
20c:	“Legal side kills the innovation”
20d:	"That’s a secret"

Coopetition was described as collaborating with the competition (P1, P2), which was likely to be a much bigger firm with more resources (P1) and for a specific project (P2); the coopetition might include “suppliers, customers, and firms producing complimentary or related products" (P7). However, P4 identified the challenge of finding a suitable partner, which it has not been able to achieve so far, because no one wanted to release control of their own business as indicated by Razah-Ullah et al. (2014).

A major purpose of coopetition was to help small and medium sized companies to deliver value in the complex medical devices market, which was characterised by high consolidation and regulation, according to P7, and where a single stakeholder would find it difficult to innovate in all the required aspects (P1). Hence, P10 suggested coopetition was an enforced collaboration. This is an interesting perspective which has not been found in the existing literature.

The need for resources was accompanied by the requirement to compromise to obtain them (P10) but this could be disadvantageous for small companies who might ultimately experience proportionately much less benefit from the arrangement than large company partner (P10).

The resource needed for Intellectual Property (IP) or associated licences might be a limiting factor (P11) as would fear of the competitor poaching talented employees (P15) so that if companies were unable to compromise and agree a contract, the legal side “kills the innovation" (P11). Small companies would therefore be cautious about how much they were willing to compromise to form a coopetitive relationship (P12, P13, P15).

Whilst many of these perspectives may have been derived from personal experience, the participants were asked to relate actual experiences, which provide some additional insight into the viability of coopetition as a solution to complex challenges from the new regulation, the focus of this research.

A few of the participant firms were able to provide examples of when coopetition has been successful, for instance P7 had employed the model many times. Its experience had been that by providing its partner with its major product had facilitated product enrichment and accelerated the CE certification process. P7 also intended to find a coopetitive R&D arrangement to enhance its innovation.

Partner behaviours in both firms were the key aspect of successful coopetition in the perspective of P10, who had participated in several arrangement in the past five years; the partners produced the same products in the same market. Different skills sets had been the basis of success for P13, whose company knew little about cutting metals and relied on the partner, whilst the companies were able to share the costs of packaging, biological testing, sterilisation, and cleaning which was extremely expensive.

Similarly, P14 shared expertise, some manufacturing activities were beyond its competence, but the arrangement worked by mutual transparency of design and product information. A unique approach in this research was revealed by P2, which had a German partner, a direct competitor producing the same level 1 product. Their development partnership worked because ultimately, they would

sell the product in different markets, P2 outside of Europe and without the CE mark.

Although perceiving coopetition as a positive strategy to overcome the innovation challenges, P1 found that the IP issue was the most difficult aspect of the agreement because of the restrictions it would place on future use of this asset. Consequently, inability to reach legal agreement prevented the coopetition proceeding. According to P6, exchange of technical information required to adapt to the new regulation in a coopetitive arrangement could be protected by a contract relevant to the whole process. The alternative to coopetition was to maintain independence by identifying a funding source so that it could meet the new regulatory requirement (P1).

Although P5 has no experience of coopetition, he felt that most companies would not agree to work in collaboration with a competitor because of their own “ruthless competitiveness”. They were: "anti-collaborative, especially with competitors" (P5). If they were to collaborate with a competitor, it would be at very early-stage work only and on condition they could compete in the same market afterwards (P5). A similar restriction in agreeing any arrangement was promoted by P4, who suggested the deadlock might be overcome by limiting its input assets to manufacturing and the quality system but retaining design change, improvement and critical data. The cited limitations may also account for the inability to find a suitable partner.

The mutual exchange of resources, even if limited, could form the basis of successful coopetition according to P9, which had assets such as an IP package registered in several patent categories, R&D packages that it would be willing to share with the appropriate partner who was interested in investing in development. The firm would retain its status as the contract developer, and the legal contract manufacturer and the legal manufacturer. The resulting medical device would be exclusively available to the partner who would be responsible for its sales and distribution, whilst P9 received the transfer price. Whilst these intentions are useful in principle, since no coopetition has yet occurred, it is not possible to forecast how well this would work.

Therefore, whilst coopetition aided innovation for these firms, focus was on acquiring the resources they did not have to ensure they could meet the regulation, and on continuing the relationship for a limited time related to access to them, so that the knowledge/skills/assets that represented their competitive edge remained under their control (Bouncken et al., 2018; Zakrzewska-Bielawska, 2015).

Table 34 summarises the main success and failure factors for coopetition specified by the participants. Also, Table 34 names those aspects of the business which participants would not share in a coopetition, with the rationale for that decision.

Table 34: Perspectives on Coopetition

Success factors	Failure Factors	It's a secret
• Specialist equipment or knowledge possessed by partner (P1, P2, P9, P12) • Potential to work with different partners in diverse business fields (P9) ➢ companies not in the same market field, which have expertise for instance in machine learning (P8)	• Skills of partner were not as described (P10) ➢ Programming issue (P10) ➢ Different working speed and priorities regarding regulatory approval (P12) ➢ Refusal to share IPR so no working product evolved (P12)	• Work with a competitor limited to early stage and each partner then further develops separately (P5) • There can only be one legal manufacturer (P9) • Never share know-how (P11) • Never share source codes as it cannot be patented in EU (P12)
• Added value for both partners (P1, P9, P6) a) Examples ➢ manufacturing ➢ partner wants to – substitute a new product in existing portfolio) ➢ product validation (P6) ➢ sharing cost (P6) ➢ sharing regulator (P6) ➢ shared technology and IP (P9) ➢ will to share benefits (P6, P13, P14) ➢ share information (P6) particularly preliminary scientific results (P6)	• Partner without honest intent (P8**)** ➢ Access to employee talent (P8) ➢ Documentation ➢ Software	• Never work with a competitor in any aspect involving company's clients (P8)

• Collaboration in the early stages (P1,) of R&D projects (P7) • Collaboration at the same level, defined short- and medium-term objectives (P6, P7) • Compromise that accepts some processes take longer than expected (P9)	• Collaboration in later stages (P7) ➢ Lose important information/ resources for success(P7) • Partner wanted to own product (P12) • Misunderstanding, misinterpretations (P13)	• When the partner wants to invest in company (P14)
• Complete transparency in all matters (P9, P10, P11, P14) ➢ Expectations of both parties recorded (P11, P15) ➢ Legal agreement quickly made (P1, P8) ➢ Simple contract as every potential issue cannot be determined (P6) ➢ Mutual trust (P1, P10, P13) • Communication (P10)	• Lack of transparency ➢ Legal agreement takes too long (P1) ➢ No legal agreement (P2), partner makes new demands as success is identified (P2) ➢ Partner gains access to technical product documentation -lack of legal contract (P7) ➢ Partner does not adhere to legal contract (P15) • Lack of trust everything must be in contract (P15)	• When the potential partner does not agree to share everything (P15)
• Size of partner (P11) ➢ Similar size (P11, P13) same pressure, regulatory wise, timewise, financially (P13) • Small size trust not legal contracts		• No coopetition with bigger companies (P11)

• Co-design means sharing IP (P8)		
• No major changes to the company needed (P1, P2, P7, P10, P13) ➢ Outsource regulatory affairs but not distribution (P7) ➢ Must protect partner's IP even more than own (P10) • Train partner employees, insurance adjustments (P13)		
• Impact on IP ➢ None (P1) ➢ Based IP strategy mainly on partner IPs all managed legally (P2, P10) ➢ Liaison with independent consultant eliminated any IP effects (P7) • Contract specified use of own IP (P9)		• Use of our patents (P13, P1, P2, P7) ➢ Including capacity for someone else to use it (P1) • Patents and technical files (P7)

4.4 Findings from Process Coding (Cycle 1)

After the In Vivo Coding, Process Coding was the next coding method of the first cycle applied to the main body of questions from the interviews. Again, the findings are reported in the sequence in which the coding occurred and is documented in detail in the appendices. As already stated with In Vivo Coding, analysing the same set of data with different methods can reveal new findings, and/or confirm results. Repetition is possible and seen as triangulation that strengthens the validity of the respective results.

4.4.1 Innovation – Process Coding

Participants generally failed to directly rank innovation as a CSF. However, responses were useful in providing their processes for innovation, which were analysed in the stage process coding sequence: first step; second step, turning point; continue; don't continue, outcome.

The participants' starting points varied from having a team to having a project idea, a new material or clients, to identifying a high priority or world class product need, to the realisation that they were in a competitive market. These remarks reflect the breadth of interest of the companies operating in the medical devices industry (MedTech Europe, 2020; Torsekar, 2018). The second stages were equally diverse, from planning to launch or to create a product and investing in it, to adding value, making sure it is relevant as a response to the new regulations, following the rules and applying experiences from other industries.

The decision to continue or to discontinue usually occurs soon after this stage, which could be considered the turning point. Motivations to continue included exciting people about the product, knowing it will make money, attracting funding, implementing the prototype/idea, doing an investigation, the team's effort. Reasons to discontinue varied from not knowing/predicting if innovation has succeeded, reaching the prototype stage only. Hence examples of key outcomes were getting funding, returning high profit on investment, competitive advantage, obtaining the required clinical data and fulfilling the new medical device regulations.

The responses reflect the pride and satisfaction when desired outcomes are reached, but the huge uncertainty and tensions from innovative intention to success are apparent. These responses reinforce IMAP (2019) and Mason and Kwok (2010) regarding the anxiety about being able to obtain investment to survive or remain viable. This situation could also engender high rates of small business mergers to scale up operations, whilst implementing regulations effectively (IMAP, 2019).

The participants confirmed that, in their opinion, innovation processes in the medical devices sector are different from those in most industries and that mostly the required processes inhibited innovation. The dominant difference cited were safety and security issues, particularly those associated with medical devices which functioned by means of contact with patients. The inference of manufacturing devices that has contact with patients, was that manufacturers needed to act more responsibly and ensure that appropriate data collection policies were devised and implemented (Deloitte, 2018).

When the device was ready to be implemented, medical staff and patient demonstrated substantial inertia to change, so that the industry is characterised as conservative. These factors slow the innovation and change process. Innovation in medical devices of this type was expressed as being too fast for the market mind-set, it is therefore disruptive innovation (Christensen et al., 2003). Consequently, the legal issues associated with this innovation process, which include regulation and notified body evaluation, slow time to market (Vincent et al., 2015; Tamsin & Bach, 2014). The inferences for medical device companies and targeted users are that some very good innovations take a long time to be fully commercialised, which implies that innovation in medical devices is high risk (Lee, 2018; Tamsin & Bach, 2014; Yeo, 2018). In the medical device industry toleration of failure is much higher and riskier, which reduces motivation to innovate; market structure is changing, consolidation meaning higher profits; higher costs limit small companies from innovating (Yeo, 2018).

The initiation of the innovation owing to interaction with others is emphasised by P3, P13 and P15 as direct exchange of information initiating an open innovation approach (Chesbrough, 2012). Innovation in medical devices by transferring

knowledge from other sectors is also emphasised by P3 and P13 and is an interesting prospect for other manufacturers. This finding warrants more investigation in further research to identify the exact areas of shared interest, and how and where the practices could be applied throughout the sector.

In contrast P6 gains ideas from the responses of users to sustainable practices “saving the planet” which drives the innovation in single use instruments made from plastic waste. These instruments save users cleaning time, whilst providing company with a new highly profitable source and less effort because the regulation class is lowered, and certification made easier. These are very new important findings that may have implications for many medical device manufacturers.

Choosing innovation projects very carefully is a strategy adopted by P8 owing to possessing scarce resources and being asked by investors to justify how the company uses funds. The capacity to generate intellectual property appears to be a vital decision as to whether the project proceeds or not. It also seems that P8 uses closed innovation but gains information on algorithms from medical institutions, in other words accesses outside knowledge without needing to form formal partnerships. This tactic may also be useful in other contexts where small companies attempt to avoid risks of information sharing; the organisation’s attitude to forming formal relationships reflects its core beliefs and the position of powerful investors (Whittington et al., 2019). It also emphasises that decisions taken by firms regarding innovation is organisation centred and not totally transferable to other similar firms, as has been demonstrated by the responses in this research.

In contrast to other firms, P10 and P15 appear to adopt a more closed innovation approach, which is very reliant on internal information exchange and the classic innovation approach of idea generation leading to prototype, experimenting, gaining new ideas and modified approaches to old ideas, and testing (Hunter & Cushenbery, 2011)

The internal factors, particularly organisational structure and culture that supported and hindered innovation were also discussed, and the process coding

examined these two aspects from the responses that were generated in the interviews.

The flat organisational structure generates a process of innovation comprising fast communication, empowerment, generation of multiple ideas that can be applied to engage employee commitment, and beneficial outcomes (P10, P11, P12, P14, P15). This description is intensely people related in contrast to stage related as cited by Smith and Kaluzny (1986) and Tidd and Bessant (2018). The inference from the cluster of firms supporting this process, is that the formal size of the organisation is not an issue, as the sole large company reports the same characteristics. However, since companies in the development and piloting business lifecycle stage did not focus on this innovation, the business lifecycle stage may have more influence on the innovation process. However, P14 focused on customer ideas as the means to initiate this process (Weintraub & McKee, 2019) suggesting that the type of device influences the process stages, and who is involved. It is also demonstrating similarities in open and closed innovation processes.

In terms of organisational structure for innovation, P1 suggested that three factors were important. A limited number of co-founders was advisable, so as not to kill innovation, the co-founders should have a similar work ethic that supported innovation and the board was important as a reference point to prevent innovation being misdirected. The board initiated thinking about the product that should be innovated and about how to get it into the market. However, board members could hinder innovation if they did not understand the research process and tried to prevent the progress of innovative product. These ideas of organisational structure comprising hard and soft aspects, as influencers on innovation, are like those of Ahmady et al. (2016).

The process of innovation related to company structure described by P3 is useful to this thesis because it infers the huge uncertainty associated with it. In this company advisers were retained, and initiated the process of innovation, either by observation of something inside or outside the company that needed changing, or by identifying new products externally. This would be followed by the advisers discussing the matter with founder who made the decision, based

agreement there was a need for it. However, in order to get consumers to buy the device, the final stage was to ensure the message reached the potential customers. In this case the outside-in model of open innovation (Gassmann & Enkel, 2004) appears to be employed and deliberately controlled by the owners with individuals they know and trust. This has not been mentioned in the empirical part of the thesis, neither did it emerge in the in vivo coding process.

In contrast, the requirement for successful innovation in P5, which seemed to prefer closed innovation, was a process of first creating a culture and structure to attract innovative employees, cultivating, and moving them around the company to prevent silo thinking that would be a hindrance to developing innovative solutions. This was a tactic to sure that employees integrated and generated their ability to try new things (Ahmady et al., 2016; Tran & Tian, 2013).

In P9, innovation was hindered by unsuitable internal structure but in this case, it was the internal structure of the collaborating company, which was large and hierarchical. This comment reinforces the ideas that the internal structure is an important factor. The company of. P9 made use of its innovative process to produce innovative products, but time to market was often hindered by waiting for the partner to complete the process of getting the project approved by a series of managers in that company. The issue was that no one understood what caused the delay, a phenomenon that did not happen in P9. The inference is that organisational structure and culture of collaborative partners are additional potential sources of uncertainty for medical device companies to manage. This is a phenomenon, which was not very apparent from the previous coding activity.

These examples are interesting since they reveal diverse innovation processes, multiple scenarios of open innovation, as well as closed innovation, characterised by structural and/or cultural support or prevention. Collaborative open innovation may be hindered by partner organisational structure and culture, which reinforces the relationship between the two concepts and their strong influence on company preferences for innovation types (Campbell et al., 1974; Dalton et al., 1990). Risk is also implied by the uncertainty of these contexts.

The specific question on leadership for innovation did not generate very informative responses, the main themes emerging were: providing information to create awareness of objectives throughout the company and ensuring the information stayed with the company to prevent ideas being implemented by others; appropriate leadership style and structure so that both innovation, operations, and open communication were optimised and focus was on delivering products aligned with client needs which might also be revealed by observing products in complementary sectors. These themes align with indirect leadership for innovation, creating the climate, and direct actions, such as leadership vision and strategy which combine to develop individual and team creativity leading to organisational innovation (Hunter & Cushenberry, 2011).

It was also considered advisable that leaders explained the importance of the entire innovation process and the end goal, including why specific partners had been chosen (P1, P6, P8) because failing to be open caused employee anxiety (P1) and hindered them from operating at their optimum performance level (P9). None of these firms were still at the idea stage of the business lifecycle, but in the process of converting to commercialisation or had reached it, when the company had taken a different focus. The transition to commercialisation is a new risk in the process, so that more conscious fear of failure may have required leaders to reassure employees. However, leaders also needed to be advised that retaining information within the company was a vital factor to ensure that sharing know-how with potential competitors did not have negative outcomes on the firm (P8). This retention of the means of competitive advantage links to the danger of the idea being implemented by competitors first, in alignment with the findings of Zakrzewska-Bielawska (2014). This fear of information leakage may have been of more importance to P8 because it was the only company currently piloting its idea.

Two types of leadership were required for innovation in medical devices according to P2, who suggested one for leading innovation and the other to head operations, and both leaders reporting directly to CEO. Therefore, shared leadership was the implied theme in the sense of Stacey (2010), the formal leaders directly responsible for innovation, but having indirect influence over how

innovation is generated. In addition, open communication between the teams was vital to developing a product that clients needed (P2, P3, P9, P14). Leaders should also encourage (P9, P3) anyone who observes a good idea in a related part of the sector to discuss it with management, this approach had already produced new products in recent years (P3). Therefore, very agile leadership and management is vital to drive innovation (P5), requiring free exchange of ideas without restriction (P13) and respect for all ideas and a philosophy that there is no bad idea (P13).

The importance of focusing on objectives and not spending too long discussing ideas was important to P4. These remarks capture the importance of exchanging ideas emphasised by Stacey (1996), but hardly reflect any complexity of the process or conflicting views and questioning of ideas expressed that might improve the final innovative output (Stacey, 1996). However, they do emphasise the many roles of direct and indirect leadership to drive individual and team creativity and organisational innovation (Hunter & Cushenbery, 2011). The inappropriate leadership for innovation was highlighted by P12 as strict formal management “army style managers” that suppressed innovative ideas; this aligns with too much structure being damaging to innovation (Auletta, 2009).

In these companies, the range of leadership qualities expressed is very limited, and may be a factor that hinders optimising the innovation that could be accomplished. The inference for the leaders of SMEs in the medical devices sector is to review their leadership attributes against a wider range of potential attributes and learn and implement new complementary approaches, including appropriate aspects of emotional intelligence (Goleman, 2005), and developing effective followers (Gobble, 2017) that could enhance innovation success.

4.4.2 Impact of new EU Directives – Process Coding

The reflections from this set of codes are that a unique and critical factor was associated with the new regulations by P1 and P9, namely the cost of implementing them, which would prevent commercialisation owing to lack of funds. Therefore, the sole alternative to ensure that the process was completed

was by partnering with a major manufacturer, also selected by P9 to ensure commercialisation.

The change associated with the new regulation represents a new strategic direction and new business model, a similar response is cited by P6, P7 and P9 for several reasons. These firms were all at the commercialisation stage, but a range of new processes was evolving within firms driven by new regulations and infer that the new regulation has created unexpected difficulties.

Consequently, strategic change in the form of new business models, product portfolios, distribution markets and processes are also proposed as CSF responses to the new EU regulations. Some big companies were likely to abandon innovation in favour of ensuring that their current products were prepared to meet the new market regulation (P2). Financial and other resources needed to be focused on accomplishing that objective (P2, P6, P9); rationalisation of product portfolios cited by P6 and focus on the most profitable items by big companies at the expense of innovation (P9). Generally, innovation would slow and be more valuable innovation (P11).

In P2s case its distribution market would be outside Europe to avoid obtaining CE certification and optimise its financial resources, and P11 proposed that some EU based companies would focus on the US rather than the EU market. Less competition in the market was forecast because of the regulations, including a decline of up to 40% of small companies (P6), and of business model and market changes. Consequently, there was forecast to be an increase in the value of the technological abilities for companies remaining in the market (P6), but little change in consumer demand or in product prices (P6). Longer product lifecycle and cash returns were predicted (P6, P7), particularly as distributors would interpret the CE mark as representing high quality. The strategies tend to confirm Brown et al. (2008) that the response of firms to changing regulation in the sector was to adopt lean management to minimise costs and resource use, and with Deloitte (2018), that actions selected were those most likely to attract investors.

A substantial change in the product development process was forecasted owing to the requirement for an acceptable clinical dossier that would allow companies

to gain the CE mark; this change was greatest for small companies and consumed their scarce resources of time and money. An additional barrier to getting the product/service to market before competitors, was the lack of notified bodies to approve the product/dossier (P7). These issues had forced P9 to change its business model to collaborative practice, whereas P2, P10 and P11 invested substantial sums internally to gain competitive advantage from the speed at which it could make the product market ready. P10 and P11 already had personnel with relevant experience who became the dedicated employees responsible for clinical dossier matters, and P2 created a new employee position. Similarly, P9 held in-house training programmes and seminars so that it could work more effectively with the notified bodies.

These findings demonstrate the application of diverse solutions by participant companies all representing strategic change and associated implementation by application of new business models (Casadesus-Masanell & Ricart, 2010). All business model change focused on minimising the potential impact of new regulation reducing competitive advantage in the global medical device market (Money et al., 2011; Bayon et al., 2016). The expressed need for collaboration with competitors by two participants is of particular value to this research but, since the number of responses to these questions was limited, the extent of financial and knowledge acquisition anticipated necessary for innovation is not fully evident. The implication is that an accurate indication of the pressure for coopetition as a response to the challenges of implementing the legislation successfully is not known. This may be an issue that participant companies did not consider but one that managers should be advised to explore to reduce costs, and to access greater expertise and speed to market.

4.4.3 Coopetition – Process Coding

Initially the researcher investigated the participants' current knowledge of the concept and underlying reasons for adopting coopetition. Changing market forces were the driver according to P7: "very consolidating and highly regulated market". This change had encouraged strategic alliances, with the rationale for delivering higher value-added propositions and innovative solutions to be able to gain

competitive advantage (Clemens, 2018) like that possessed by the big companies. The inference was that speed could be accomplished by smaller companies initiating collaboration (Clemens, 2018).

In contrast P8, P13 and P14 described the concept of coopetition in relation to the need to share knowledge and resources including IP to innovate, or to access the manufacturing stage, on a contractual basis in an affordable manner, in other words a microeconomic rather than macro sense of the term. Additionally, P14 added the macro aspect of keeping market opportunities open. Coopetition was also the opportunity for the collaborating companies to grow together according to P14. Hence all the processes described have a similar structure: a context is provided; action(s) are taken, a rationale for the action is described with the desired outcome from the coopetitive relationship, which was perceived as being achieved more quickly by small companies than their large competitors, size was a factor.

When participants were asked to relate their actual experience of coopetition or how they envisaged it might happen, the tensions surrounding it and how specific factors affected the speed of outcomes became more evident. Several dilemmas occurred in the process, usually concerned with IP rights (P1, P2) or other legal rights (P1). The consequence of a partner wanting the IP rights eliminated the possibility of a coopetitive relationship for P1 unless it could be agreed in legal terms that the partner did not insist on those rights (P2). The preoccupation of participants with legally ensuring IP rights when considering coopetitive relationships, reinforces the importance the legal arrangement to initiating coopetition emphasised by McCarthy et al. (2018).

Another dilemma was that the partner would try to acquire the company, especially critical for an SME (P3), or had the motive of identifying its know-how (P3). If the potential partner was a direct competitor, there was concern that there might not be enough market demand for both partners to sell sufficient volumes of the product to make coopetition worthwhile financially (P3). In addition, P8 would be cautious of any partner wishing to be publicly endorsed by it, if the coopetition had proved successful. This was because it’s worried that its reputation could be damaged by association if the partner’s business

products/methods were found to represent poor quality in some way. Both comments are understandable since the companies are in early stages of the start-up lifecycle and uncertain about their survival (Deloitte, 2017).

Therefore, unless a legal agreement was either agreed early (P1, P6), the firm decided to remain independent of any coopetitive arrangement (P1). Consequently, legal agreements appear to be a CSF when management considers coopetition as a solution for innovation as indicated by McCarthy et al. (2018).

The type of reasons for adopting coopetition were to gain resources such as R&D partnership contracts (P1, P9) (Gast et al., 2015; Zakrzewska-Bielawska, 2015) and other expertise (P1, P2, P7, P13, P14), for instance a stage in the process that could not be accomplished in-house (Gast et al., 2015; Zakrzewska-Bielawska, 2015). Other reasons were cash (P1, P9, P13) (Gast et al., 2015; Clemens, 2018) and investment in the development stage (P9) (Quintana-Garcia and Benavides-Velasco, 2004). The ability to comply with new regulations was a motivator for coopetition (P6, P7, P14), or for the partner to gain exclusive rights to the product (P8).

In this study, partners were usually identified by being previous customers (P2), long term customers (P10), or a competitor, which would sell the product co-developed in other markets. Coopetition was speeded up when there had been a long-term relationship (P10) and a continuous partnership (P10). The qualities of the partners were the basis for success (P10), as well as openness and sharing of documents and feedback from partner (P14). These comments confirm the necessity for trust to motivate coopetition, stressed by McCarthy et al. (2018).

Complementary questions revealed other major success factors and possible reasons for proceeding or not proceeding with coopetition. A major reason was the added value accomplished from the arrangement, for instance increased flexibility in product portfolios; the partner was able to upgrade a current product with a more innovative version or add a product to its European portfolio to strengthen its market presence by sharing information (P9, P11) (Smith, 2001; Nonaka & von Krogh, 2009). In one case (P9) the single technology could be

shared successfully with a range of non-competing medical device customers (Nonaka & von Krogh, 2009), which is a new finding. When both partners benefitted from the coopetition and reflected its success the arrangement was most beneficial (P1, P9, P10, P13); this could be accomplished when companies had strategic similarities (P13).

The major obstacles to coopetition were: (i) fear of a competitor inside coopetition; (ii) inability to pre-empt risk; (iii) coopetition itself is slower than exiting routes to market. Fear arose owing to the partner wanting to own the IP (P12), and by inability to agree a legal contract, written by a lawyer that avoided issues at the end of the agreement (P2, P7). There was also anxiety about the potential to be forced to instigate legal proceeding if there were issues during the coopetition period (P2). A different concern related to a situation when sales were much higher than anticipated and the competitive partner demanded an increase of the transfer price of its components or threatened to cease providing them (P2). Risk was pre-empted by P7, employing external consultants to ensure that partner did not have direct access to certain know-how in the technical file. However, three companies stated conditions in which they would not form a coopetitive relationship: when the partner wanted to invest in the company or share certain costs such as machining (P14), if the partner wanted access to the company's customers (P8), or if the partner was not willing to share everything (P15). Hence, power structures within the proposed coopetitive relationship were a major facilitator or barrier, as suggested in the corporate context by Whittington et al. (2019).

Therefore, the main limitation of coopetition practice/sharing is IP rights. Frequently no coopetition proceeds if all or the majority of the company's IP must be accessed by partner. The terms of the legal agreement generally are also a potential limitation or motivator for coopetition (P9) (McCarthy et al., 2018).

There was an additional comment that coopetition should be restricted to the early stages of development when knowledge is weak and both parties are incentivised to share results (P5). This partly aligns with Winberg and Oster (2015), which found restriction to early stage preferable when there was a specific purpose for the coopetition. However, P5 suggested that the coopetition should

cease at a certain knowledge stage, unless the partners did not have the resources/knowledge to continue alone or agreed to split sales/distribution geographically or by product line. The implication for this thesis, and for managers of medical device companies, is that the stage at which coopetition should occur is when it is appropriate to accomplish the company's purpose, and this idea is strengthened by feedback from some of the participants stating that they had developed internal regulation expertise or employed consultants so that middle or final stage coopetition may be less required, than at the development stage where technology could be more important.

A general perspective on the context of the new regulation by P11 was that it had forced the company to identify what operations it was possible to accomplish internally, to question its assumptions about acquisitions, strategic partnerships and internal practices such as how it innovates, and which products were marketable. This prioritisation was primarily driven by the higher investments required to progress ideas to commercial products. Hence the limitations to coopetition could be interpreted as dependent on type of innovation considered, in the perspective of investment cost and market changes. The questioning of assumptions evident in P11 suggest it had attempted to change the organisational paradigm (Argyris & Schön, 1978), trying to become a learning organisation to accomplish its objective of innovative practice when applying new regulations.

These responses provide an overall rationale for coopetition as the market changes. Macroeconomic reasons to keep market opportunities open and microeconomic reasons to make innovation/manufacture more affordable for each partner, provide added value and enable company growth. Success and potential failure factor are summarised in Table 35:

Table 35: Enablers and Barriers to Coopetition

Facilitators	Potential Barriers
Long term collaboration between partners	Partner wants to share or buy company's IP
Partners know the business well and have more impact	Other legal issues such as licensing Reputation risk if partner's technology/contribution not optimum
Both/all partners benefit	Partner wants to invest in company or buy it
Company able to use its technology with several non-competing partners withing medical device sector	Partner wants to increase transfer price when it observes high sales or threatens to stop supplying components
Complete transparency	Partner wants exclusive rights to products or markets
Quality of partner technology	Potential partners operate in same markets
Only small parts of company technology are shared	
Sharing expertise and company learning from expertise	
Company has a stage of development/manufacture unavailable in-house	
Cash or investment in development	
Resource gain generally	
Help with regulatory issues	
Partners agree to or already operate in different markets and or product lines/regulatory classes	

Therefore, the evidence suggests that there are more reasons for coopetitive partnerships to be successful and to develop quickly than hindrances, but that intellectual property rights and fear of the partner stealing ideas/ technology/products are the most likely obstacles to preventing or destroying coopetition.

4.5 Findings from Initial Coding (Cycle 1)

The last coding method in the first cycle applied to the main body of questions was Initial Coding. Initial coding, sometimes referred to as open coding, focuses on dividing the responses into discrete parts, with each participants response being listed and analysed line by line, to identify for similarities and differences, to consider all theoretical possibilities whilst interpreting the responses (Saldana, 2016).

Initial Coding in the way Saldana (2016) describes it, is using a process code and then identifying related relevant sub codes, which resemble the splitters in In Vivo coding. This way the Initial Codes finally provide a label, description, definition, or category name. In this research there was a focus on identifying CSFs and CFFs because these are most relevant to answering the research questions. Tables are used showing similarities and differences to demonstrate the relative strength of opinion on specific theories and concepts.

Initial Coding in this research can reveal new findings and/or confirm findings already presented through In Vivo coding and/or process coding. Looking at the same set of data, repetition is likely to occur and strengthens the validity of results.

4.5.1 Innovation – Initial Coding

The responses to the first question were demonstrating that innovation was not the major CSF for success in these companies, it ranked in the first three for few participants. However, verbose responses to the question were a barrier to identifying where innovation factored in the overall company success. People

were subsequently recognised as the key factor, although this is not stressed in the existing studies but alluded to by Eriksson (2010). Other success factors were quickly establishing the new product; transition to the prototype stage; attracting finance and making profit. Considerable diversity is evident in the position innovation holds in company success, and which other elements must be combined to optimise it.

The responses to the difference between innovation in medical technologies and other sectors generated other CSFs and CFFs, including highly emotional expression of the high risk involved in this industry, which was more apparent than found when using In Vivo and Process Codes. Quantifying remarks generally compared the difference between innovation in medical devices with pharmaceutical companies, and P12 and P14 suggested that regulation was much less limiting in other sectors, for instance the automotive and aeronautics sectors.

The medical device industry was characterised by continuous new products on the market because medicine was “always moving forward” (P3) and new regulation meant that industry constraints were always increasing (P4) and had made it more difficult to innovate over the past 20 years. Increasing regulation meant that the software sector in medical devices was five years behind software sectors of other industries (P12). These remarks confirm the perspectives on medical devices regulation expressed by Bergsland et al. (2014) and Mattke et al. (2016).

Innovation in medical devices was generally open innovation (P2) and tolerability for failure was lower than in pharmaceuticals (P5, P6). If the innovation fails in medical devices, “we're not just out of business but parent company is gone probably as well” (P5).

The degree of difference between medical devices and other industries was captured by qualifying remarks, for instance: “working on a person” (P15); “much more difficult... especially in the start-up sector” (P12); “brutal regulation”, which was a barrier to affordable innovative products by small companies (P13). However, P1 considered that the effect of new regulation was different mainly

because the timeline upset investors and others (P1), and P14 further qualified the relative impact of the regulation in the long-term reflecting that there were regulations throughout Europe that initially sound strict. “But afterwards... they have common sense about how they reinforce them” (P14). The extent of difference in medical devices was also qualified positively by P7 in terms of that high-performance innovation generating higher speed to market and profit.

The answers revealed the emotional and cultural perceptions of how innovation in the sector differed from that of other sectors, to an extent not evident in the first two coding methods: “coopetition is incestuous” (P3); “the bar is much higher” (in med tech) (P5); “boundary conditions... really toxic for real innovation” (P9); “the industry is conservative” (P10); “Med-Tech industry is maturing and consolidating” (P7).

Remarks on the acceptance of new technology generally related to the user: “new generations tend to be very much more open-minded” (to change) (P8); “the older people, they have problem using it” (P10). These remarks reflect the concern for manufacturers cited by WHO (2010), Money et al. (2011), Bayon et al. (2016) and Auer and Jarmai (2017) that the speed of technological advance and slow user participation creates an imbalance, which may negatively impact user participation in product authorisation, loss of opportunity, pricing issues and return of investment levels.

Two sub questions focused on positive and negative impact of internal factors and organisational structure on innovation. The main factors were that the number of people involved in innovation should be limited: P1 and P8 suggested a maximum of three because more people would “kill it” because there would be too many opinions to decide; P3, P10, P11 and P15 preferred most employees to be involved. A positive impact was to have a flat structure supporting innovation according to P5, P8 and P15, whereas P9 expressed organisational structure as not important for the company. The rationale for a flat structure was quantified by P13 as “people are encouraged”.

The internal factor chosen by P2 qualified innovation as being most successful when two separate divisions were created: an innovation department to explore

ideas and an operating team to develop them. However, an internal culture in which employees strictly adhered to a job specification was unlikely to be innovative.

The CSFs for structure to support innovation were expressed as: a good set of cofounders and same work ethic (P1); small organisation for fast communication (P10); structure supporting an appropriate culture (P3, P5): gathering internal and external intelligence and discussing need for change. In reference to attracting new talent: “provide a culture and organisational structure that will first attract them ... and probably more importantly, cultivate them” (P3, P5).

Organisational structure was labelled as empowering (P11), and innovation labelled as influencing people to be committed to it (P15). The best structure for innovation was labelled ambidextrous by P2 although this was not defined but implied as having thinkers and doers. Similarly, P3 labelled consultants as radical thinkers. An inappropriate organisational structure was labelled as enabling siloing generated when employees stayed too long in one organisational division; P5 stating that silo thinking was a CFF because it limited the capacity for developing integrated solutions required for innovation. Board members not familiar with innovation and research were additional organisational factor that could “derail” innovation as they opposed approving some options (P3). This is an interesting remark, conflicts between Board rarely being evident in this research and potentially a greater failure factor than is admitted. These feelings and opinions were not evident in other coding, demonstrating the additional perceptions obtained by analysing feedback in several ways.

Therefore, hard and soft elements of organisational structure are emphasised (Tran & Tian, 2013; Ahmady et al., 2016). Hard elements were number of people, small size of innovative team to minimise bureaucracy (Vaccaro et al., 2012), or including all employees for more ideas, but most companies were small so that similar perception is evident. Other hard elements for innovation were flat structure (Bryan and Joyce, 2005), board and chairman to provide guidance (Stacey, 2010). The soft elements referring to people comprising of thinkers and doers, who did not adhere strictly do the job specification or work in silos; cross functional collaboration (Bryan & Joyce, 2005) and open mindset (Argyris &

Schön, 1978). The link between organisational structure and its culture was evident and interestingly regarding the company board, which either enabled it or restricted it (Dalton et al., 1980).

Leadership for innovation was qualified by several participants as supporting innovation by making sure that everyone was aware of why the company was engaged in certain tasks (P1), what the company's aspirations were (P8), and it was important for start-ups (P2). Leadership was linked to innovation by the type of management structure it comprised, open, flat management in which everyone has an equal say (P3), it was positive (P4), and it must be impactful (P12). The major barriers to innovation represented by inappropriate leadership were failing to keep employees informed (P1) attempting to manage both the innovation and commercialisation phases (P2), failing to confine the details of the innovation to inside the firm (P8) and "strict management" military style which would inhibit expression of ideas (P12).

In contrast CSFs for leadership, included ensuring open dialogue always (P1, P2, P9), explaining the end goal, making sure everyone's activities were aligned and focused on the objective (P1, P4) and that activity patterns changed based on market research (P1). The separation of leadership roles to two divisions of innovation and commercialisation was reemphasised by P2. Leadership should encourage anyone observing a good idea to freely discuss it (P3, P9, P13, P14, P15). Leaders also needed to appoint a decision-making team, not everyone should be involved (P14).

Labelling leadership occurred in a few cases; leadership for innovation should be agile management and leadership (P7), somewhat secretive (P8). These labels reflected some of the previous ideas of leadership for innovation but emphasise behaviours and context. Leadership behaviours of hypothesising and choosing were also revealed as important for innovation, for instance hypothesising on the division of the leadership roles by P2: "once you sell a product you need a leader, one for innovation and the other for operating". Hypothesising was associated with considering an idea (P3), reinforced by P9 stating that ideas may not always seem useful at first: "but finally, of course... fruitful".

Making leadership choices embraced decisions regarding reporting lines for P2 and choosing to respect all ideas (P13) and: “there are so many questions every time and that is why it is very important that the management is open” (P14).

The R&D staff were stereotyped by P9 as idea generators that leaders should allow to express their ideas, the inference being that other organisational functions were much less important to leaders in this respect. Leaders with directive style were also stereotyped as suppressing ideas by P12.

The importance of leadership to accomplishing successful innovation, to guide and involve employees is evident from these responses. Handling uncertainty is evident as a leadership attribute, reflecting Stacey (2010) and leadership for innovation as characterised by agility (Aghina et al., 2018) and by hypothesising on different ideas, as making choices, and changing patterns as a consequence of market research (Eisenhardt, 2002).

Through summarising and clustering the Initial Coding on innovation four main categories developed: Critical Success Factors, Barriers to Success, Making Choices, and Identifying Opportunities/Issues. These Codes on innovation are presented in Table 36.

Table 36: Initial Coding for Medical Device Innovation

Category	Aspect
Critical Success Factors	Well-designed innovation management system (P7) Having both a product which is innovative and being able to generate the mind-set of change (P8) Providing ... tools to bring teams to evolve positively, to work differently (P8) getting people (users) involved in innovation ... and being able to change their practice (P8) be more responsible, think about the patient, think about the user, maybe that the device is too advanced; device use must be easy (P10) everything has to be secure and must work, implying link to human health associations with med tech devices (P15)
Barriers to Success	Giving too many details to notified body slows process (P6) “I gave explanation of all the differences in the changes. I shouldn't have done that because. Asked many questions. and that postponed the study file by... eight months” (P6) “Healthcare stakeholders are not very keen. changes in the way they work” (P8) re-certifications ... more difficult under MDR conditions (P9) change in product registrations (P10) smaller manufacturers are very concerned... they are not used to these changes (P14) Data policy in reference to tracking devices (P15)
Making Choices	Creativity and trying new things but worried about this blowing up in their face (P5) it's me and my partner who are taking the decision... we are the ones who are taking the risk (P6) What I share… always choosing the pros and cons P6 some questions. we know we should do something, but we are not going to do it now (P6) Taking the risk of having a good Notified Body (P6)
Identifying Opportunities/ Issues	Increasingly demanding healthcare sector (P7) innovative products difficult to get into this market (P9) should respect (conservative) when we build a product (P10) identifying medical device legislation is limiting innovation (P13)

4.5.2 Impact of new EU Directives – Initial Coding

The impact of the new EU directives, or regulation in general, on innovation was qualified as generally negative, making innovation more difficult. The difficulties expressed confirm those found by Tajvidi and Karami (2015); uncertain survival (IMAP, 2019) and financial difficulties for the business to remain viable (Mason & Kwok, 2010). Therefore, when directly asked the most serious barriers to innovation associated with regulation, similar responses confirmed the major issues of bureaucracy, insufficient financial and knowledge resources to implement regulation and market the product. Hence associated labelling was captured in the barrier to success being much higher, and negative consequences of being a small company.

The success criteria derived from implementing regulation cited: less competition so that the value of existing technical files would increase; large companies reduce their product portfolio to old products; new start-up companies should sell their technology to big companies before the clinical trial stage; the CE mark would be recognised by distributors in other countries as representing high quality (P6). Little change in demand was envisaged but innovation might be concentrated in bigger companies, implying consolidation or small business failure, as suggested by Fernández et al. (2019).

Leaders were forced to make choices on specific markets to target based on regulations in US remaining unchanged, EU market regulation being stricter, and on which products to eliminate from the current portfolio selected on minimum sales revenues. Other selection criteria were whether to focus solely on current product portfolio if there were no resources for new development, in these circumstances a critical leadership decision was whether to form an alliance.

The negative effects of the EU regulations were cited more often and in greater detail than potential benefits. There was also considerable hypothesising regarding the regulation, reflecting the uncertainties that companies considered it represented to their businesses. The responses provided indications of medical device companies being forced to make choices about future strategies/products for diverse reasons, which are of major importance to this thesis.

The financial consequences of the new regulations and the capacity of the companies to fund them were varied, for instance P4 and P9 said they were not able to do so, and the financial resources were considered high by P2, P9, P14 and P11. The difference implementation had on net profit was significant. The increase in expenditure was generally a consequence of employing someone to do the extra work (P3) or of the clinical trials (P9, P11); P3 stated additional costs of € 30,000 to € 40,000 per year, but that it would be able to recoup the expenditure. Some firms were not concerned about these costs, P12 and P9 suggested they would be paid for by companies which would make profit from the innovation. This implies that cost is a big issue for those companies who market the product, whilst others in the supply chain are not impacted.

However, the regulations could be a CFF if the firm did not know how to apply them effectively, P15 stressed that the clinical data must be accurate so that the CE mark is retained. Hence, the notified body must be competent to support the firm to develop the device to comply with the rules in the simplest possible manner (P6), alternatively the firm needs its own regulatory experts (P12). In some devices defining the algorithms in the appropriate way was vital for certification (P8). The timing of completion of all regulation related to products before the deadline was the major factor for P11. These barriers align with those suggested by De Maria et al. (2018).

Hence, some firms found alternatives to implementing the regulations, for instance P2 chose to export exclusively to countries that did not demand them. The other major solution was collaboration (P6, P9), so that they could collect clinical data and market their products. P8 and P11 decided to implement the rules, which meant substantial investment. The hypothesis was that companies applying the regulations are investing in competitive advantage (P10).

The inference for this research is that some companies may choose coopetition solely for implementing the regulations, but it is not the only option to either obtain the financial or knowledge resources.

The impact of regulation on innovation in the sector is summarised in two CFFs and four CSFs which summarise participant comments. The main barriers to

regulation supporting success were the burden for a small company (P4), which would force companies that could not comply to become insolvent (P9). Conversely, regulations could drive innovation that represented added value for patient and surgeon (P2), generate corporate agility and higher levels of innovation than incremental improvements (P11), and facilitate market share growth (P9).

A great deal of uncertainty and hypothesising existed about the positive impact new regulation would have on innovation; firms being forced to quantify the options and to make choices but the overwhelming perspective that small firms would not generally gain innovation-related benefit from the regulations. Generally, these uncertainties and challenges for small firms correspond with those expressed by Al Nassir (2020). The major remarks qualifying and quantifying the impact on regulation are summarised in Table 37.

Table 37: Impact of New Regulation

Impact of Regulation on Innovation	Quantification of Impact
Innovation more difficult (P1, P2, P4, P10)	Force new working practices and business models including working with partner (P1) 30% to 40% small companies will disappear (P6, P7) 50% of product portfolio content eliminated (P6, P7) Companies will favour US market over EU (P11) Companies will have a longer period to develop ideas owing to lower competition (P11)
Slower (P11)	
Discourages innovation (P4); especially some devices (P1)	Orthopaedics (P4) Destroy innovation (P4); or have negative impact on innovation pipeline particularly R&D activity in big companies (P9)
Small companies blocked from market entry (P7, P10); regulations tighter and stricter (P4, P6)	Higher barrier to entry for new companies owing to high costs (P10, P12) Higher focus on Clinical dossiers (P7, P10) and post purchase follow up Additional costs of CE Mark (P4, P6); €250,000 (P6); Appointing a specialist (P6)
Longer product lifecycle (P7)	Beneficial to small and medium companies (P7)
Quality will be very much higher (P8, P14)	Commercial barrier to competitors (P8)

4.5.3 Coopetition – Initial Coding

As with the In Vivo and Process coding, the responses summarised in this section relate to participants' understanding of the concept of coopetition and its suitability as a solution to resolving the challenges of implementing the new regulation. Many participants demonstrated some knowledge of coopetition, which varied considerable with P7, P8 and P10 describing coopetition as a combination of competition and cooperation of diverse activities or strategies; companies could benefit from the concept to implement the regulations more effectively in a customised manner. Several firms had already used this strategy and business model and coopetition was considered important: "because for a little company like us, you only have one person working on regs" (P1); "it (regulation) will enforce such cooperation" (P10); "important for the future" (P14); "getting more difficult for smaller companies to carry the load of regulatory requirement; quantifying: the regulatory burden is high" (P13). These perceptions tend to confirm coopetition as an inter-firm phenomenon in medical devices rather than intra-firm as suggested by Tsai (2002) and Strese et al. (2016).

Coopetition was also quantified as being temporary, a relationship for a specific project by P2, for sharing resources (P4) and beneficial to both companies (P7). The description by P8 of coopetition as an eco-system was also interesting because this was explained as needed in situations when a single stakeholder finds it difficult to do innovation in every field, suggesting that innovation was not merely happening in one process but in multiple terms, which is a new description.

Three models of coopetition were described by P11: "we are seeing it in small companies in three ways, one model, where investing in… resources behind regulatory, and not being able to invest in go-to market investments... they are much more open seeking exclusive distribution or licensing rights (…) I also see companies, that have several innovations, but... need to focus on the few, they are being more open to… technology, large companies are… acquiring other companies, who have some technology registered… because of the lifecycle becoming longer".

A single growth strategy of coopetition but three different business models, which is also a relatively unique way of expressing the concept: getting to market associated with acquiring licences, acquiring technology to develop innovations and big company acquisitions of technology companies to enhance lifecycles. However, these perceptions confirm Das and Teng (1997) that successful coopetition is generally facilitated by formal structures. These are major findings that were not so evident from the other two types of coding implemented in this research.

However, coopetition success was hindered if a suitable partner could not be identified (P4), if the competitor wishes to take over the company (P10), or their IP (P12, P15) and acquire their most talented employees (P15). The factors that were critical to successful coopetition could be summarised in Table 38.

Table 38: CSFs for Coopetition from Initial Coding – Part 1

CSF	Participant(s)
Collaborating with a much larger competitor	P1
Forming strategic alliances especially for small and medium size firms	P7
Share resources particularly IP but contractually, knowledge, experience and for accessing necessary procedures/processes to fill gaps in own operations to go to market	P8, P13, P14
Compromise especially small company when coopetitive with big company	P10
Small business must rethink the level at which they need to be coopetitive	P11

The remarks also reveal the underlying rationale and emotions being experienced by the firms as they make such decisions: “competition who is a lot bigger than you, it has an entire team... more brains... really useful... you need that sort of extra lift” (P1).

The formation of strategic alliances is required to gain competitive advantage over the big companies and to get to market faster according to P7. However, P10 highlights the potential for conflict between small and very large coopetitive partners such that the small company may have to compromise on some of its beliefs and values (Eriksson, 2010). The small company must also carefully consider to what extent it is willing to collaborate with a partner (P11). The emotional experience is that the new regulations are a “burden” to be shared between the partners, and that coopetition “has less impact on your financial structure and on head count… we benefit from each other’s experience, knowledge, findings" (P13). Coopetition was vital to success in the context of “cannot cover all steps by themselves” and of being able to “grow together” (P14).

This remark by P14 implies that coopetition is critical to survival of both organisations and to their future growth, which appears rather strange in the context that coopetition is usually considered in the context of a specific project or projects at a given time. The comment represents a somewhat different mind-set, although like Hamel (1998), that a major for competing firms to cooperate is to eliminate threats that impact on both by combining resources. The remarks also align with Simmons (1996) that the mode of coopetition is selected according to the specific situation, owing to new regulation and to eliminate its threat (Doz & Hamel, 1998).

The emotional response to considering a coopetitive relationship were captured in the hypothesising by three of the participants, for instance anxiety: that it might help when the partners have different notified bodies, or one partner already has an accredited notified body (P9); conscious of lacking resources and knowledge to enter the market “without a stronger partner” (P1O). However, P12s anxiety is ensuring that there are specific criteria for each company’s contribution to the collaboration. As in other aspects of these interviews, small companies, particularly start-up companies, are again stereotyped, as being afraid of coopetition (McCarthy et al., 2018), in this case that they might give away too much the bigger companies (P10).

Some participants related their experiences of coopetition, which provided additional perceptions of it. Coopetition was qualified in terms of specific

activities: the partner had offered R&D contracts to P1; P3s partner needed a spectacle frame but did not want to develop it internally; P9 was to be the manufacturer of a product; P13 lacked experience in cutting; P2 and partner developed a v1 product, which they would both sell in different geographical locations. The commitment to coopetition was often limited to certain stages, for instance P5 would only consider it in the early stages of development and P14 to access manufacturing, but also by concerns regarding IP rights, which had been identified as a critical factor in the other coding types. The comments are further evidence that cultural differences can be managed in the short term, whilst longer term relations can be hindered by them (Ketchen et al., 2004).

Many factors were cited as critical to success in coopetition, revealing the perceived objectives for the relationship and the specific criteria that were considered as beneficial. The categorized remarks are summarised in Table 39.

Table 39: CSFs from Initial Coding – Part 2

Category	Aspect
Behaviours	trust and communication (P4) openness (P14) motivation of partner to make it work owing to investment made (P9) joint commitment to making the coopetition successful (P10) learning (P13)
Legal context	terms of agreement defined from the beginning (P4, P8, P6, P9) receiving transfer price whilst partner sells the product (P9)
Gaining required expertise	technical file (P6) innovation (P7) enriching the product (P7) required documents for customer (P14)
Outcome	sharing costs, reducing overall fixed costs (P14)

Success in coopetitive relationship was hindered by not being able to use the same technology in any other context/relationship by P1, which meant that the opportunity for innovation was eliminated. IP rights were also an issue for P3, whilst no longer having full control of the business was the concern for P4, also implied by P5 who foresaw individuals being too competitive to collaborate.

These CSFs and CFFs provide the key aspects for successful coopetition as limited to four distinct categories. IP is vitally important as is feeling in control. Whilst Pullen et al. (2012) also found trust and fairness to be CSF in the empirical study it conducted in medical devices companies, in agreement with this research (McCarthy et al., 2018). The other success factors were not revealed and represent new findings in the medical device context, specifically other behaviours, legal agreements, and outcomes.

Making suitable choices for success is inferred as being vital to success and some choices are implied by participant remarks: how to speed up the research phases, identifying and selecting resources such as finance and access to innovation (P2), core developments (P9) and markets (P10).

The process of identifying whether coopetition was a suitable strategy for the firm also involved hypothesising about the benefit of an early agreement or being independent and raising funds to complete the regulatory process instead (P1). There was also a practice of assessing the outcomes and associated incentives (P8), including the threat of small companies working together as possibly lower than when there was big size difference (P15).

The logic of coopetition for sharing resources was agreed but the implications of doing so caused much uncertainty owing to potential unacceptable behaviours, lack of any legal agreement and uncertainty of outcomes, despite companies understanding what resources they lacked and/or were willing to share.

The sub question on the limitations to collaboration envisaged by the participants, very much revealed that these were based on choosing and hypothesising: “what we have available in our portfolio... can be suitable to be used for their product idea” (P6). A remark made by P9 implies that coopetition based on one partner managing the regulatory aspects was unlikely and a limitation to coopetition:

“nobody wants to have anything to do with the regulatory stuff because everybody is happy when somebody else is doing that... so, this is a part which we do quite on our own”.

These barriers to success of coopetition, generally expressed by participants as limitations to coopetition, are presented in Table 40.

Table 40: CFFs from Initial Coding

Category	Aspect
Regulatory burden	much larger investment to bring product to market (P6, P11) the time taken for the notified body to pass the technical files (P6)
Partner behaviour	partner acquiring the company’s resources, including knowledge (P2) lack of top management awareness of the regulation and capacity to ask right questions (P6) partner wishing to invest in/acquire the company (P14)
Resource sharing	access to IP (P8) access to the customers (P8)
Outcome	limitation of no recognisable competitive advantage (P2) length of innovation time and associate cost (P6)

4.6 Second Cycle Coding

Summarizing the above, it can be concluded that coopetition is not a new phenomenon in the medical devices sector, but the term is new. Coopetition is a viable option to consider for managing the challenges of adhering to the EU regulations and gaining certification and was often considered a temporary arrangement. The idea of coopetition being an ecosystem seemed to align with participant perspectives on applying it successfully in their companies. Coopetition was revealed as being an interesting concept to the companies,

despite expressions of fear, uncertainty, and loss of identity, because all companies lacked specific resources. In addition, small companies could accelerate their speed to market compared with large companies and subsequently their competitive advantage. Since survival was important for both partners, it was a major incentive for collaboration. The participants' descriptions fit the definition of coopetition as being dependent on a specific situation (Simmons, 1996).

These aspects demonstrate that coopetition in the medical device sector is likely to be a strategy of choices (Child, 1997) that minimise anxiety and doubt but offers the potential of future survival and prosperity. The success or failure of coopetition in the medical device sector depends on specific behaviours, legal context, access to resources and accomplishing specific outcomes. The inference from the first cycle coding analysis is that these should be the major codes used to build the grounded theory, thus this will impact the second cycle coding, as will be elaborated below.

4.6.1 Results of Focused and Axial Coding (Cycle 2)

The transition to the second cycle coding was accomplished by focused recoding of the first cycle codes and identifying the Axial Codes and associated categories and most importantly how they could be applied to the coopetition aspects for which the theory needed to be realised. The coding methods are explained in detail in the research methodology chapter and full details of transition are attached in Appendix 2c.

The five Axial Codes that emerged were those in Table 41, and names reflect the merging of lumper and process codes with initial codes.

Table 41: Axial Codes and Categories

Axial Code	Categories with Examples
Representations of values, beliefs, and aspirations	Culture for innovation – team first Structure small, start-up agile v large dominant Aspirations – competitive advantage/stay in market v independence
Behaviours	Failure – control of certain resources, stealing assets Success – openness, trust, empowerment Compromise – flexibility
Choosing and Learning	Which partners? Size of company, competitor or non-competitor Which mind-sets? Open/closed innovation, degree of legislations Which strategy? Type of alliance, business model Which aspects of coopetition? Technology, regulations, innovations, stages from initial development to market launch
What's at stake/outcomes	Time Competitive Advantage Financial costs, profits, transfer pricing, registrations Markets Secrets – fear of sharing Uncertainty
Minimising Barriers	Regulation – in house shared Eco-system – getting resources Legal rights agreed Get to market - compromise markets/product lines

These criteria were used to develop the analysis of the Axial Codes, which were then summarised to identify the central or core code. However, the Axial Codes

were characterised by overlapping data categories, hence the analysis relied on revisiting all the interview scripts and coding and identified the aspects supporting coopetition and hindering coopetition. These are reported in Table 42 to 45.

Table 42: Representations of Values, Beliefs and Aspirations

	Supportive of coopetition/innovation	Hindrances to coopetition/ innovation
Culture	I do everything Formal leader takes responsibility when things go wrong Understanding why Unstructured collaboration internal Free thinking – blind alley innovation Thinking differently Certain rules for guidance Cope with uncertainty	Blame Insufficient information available Too much structure Certainty Repeating the same mistakes Chaotic Need for certainty
Structure	Small, start-up Works alongside Small steps Flat Fast communication through flat organisation As little corporate as possible Similar size for coopetition Partner has similar organisational structure and culture Board to refer to helps avoid misdirection Consultants and other external links as part of informal structure – advice/collaboration	Large Hierarchical approach Longer chains of command hierarchy Slow communication Big team, big finance Much bigger partner Partners have highly dissimilar structures and cultures No Board may increase tendency for misdirection Internal focus

Aspiration	Mutual survival/prosperity Independence - each partner able to achieve own objectives Seeking to create value/innovation adds value for user Stay flexible and agile Innovation as finding new ways of doing old things	Acquisition Fear of being swallowed up Focus only on business value/Innovation does not focus on user Inertia sets in Failing to observe what is happening externally in own and other fields

In the case of behaviours, the continuum is between the two categories of success and failure, so a third column hindrances was not required. Also, on reflection it was evident that behaviours and choosing and learning could be merged because choosing and learning were behaviours.

Table 43: Behaviours

	Supportive of coopetition/innovation
Failure	Partner's objective to control of certain resources such as IP or to acquire the company Partner stealing assets such as employees and know how Losing control of the business General lack of transparency and trust, including everything must be contracted Silo thinking and lack of cooperation Skills of partner are not as described Employees and teams strictly adhere to own job description hinders innovation Management is formal, strict and hinders innovation Insufficient talent Healthcare stakeholders unwilling to change -includes developing innovations that are too advanced for user and add no value Top management fail to understand the implications of new regulations

Success	openness, listening, trust with employees and partners, innovation controlled to coopetition with trusted long-term partners empowerment of employees, full involvement in decision making recruit and nurture talented employees with similar work ethic employees include thinkers and doers being more responsible for instance -think of end user needs and competences Keeping secrets such as know-how, customers/client data Gathering and discussing internal and externally generated ideas Leaders able to handle uncertainty Agile, flexible approach to leadership and management Decide which types of innovation, open or closed, incremental or radical Develop strategic objectives for the coopetition/innovation with teams Consider regulation needs from the beginning of the coopetition Selecting which aspects of coopetition to contribute – stages of the process, for instance regulation/clinical trials Decide which coopetition business model allows all partners to benefit/added value Select the resources the company is willing to share and under what conditions, technology, finance, know how/validation
Com-promise for Success	Some degree of flexibility in how company should act Agree with competitors to operate in separate geographical markets and/or product lines so that coopetition is possible Identify a range of non-competitive partners in different industry subsectors with which company can share same technology

Table 44: What's at Stake/Outcome

	Success of Innovation/Coopetition	Failure of Innovation/Coopetition
Time	Coopetition reduces time to market Competent notified body and/or regulatory expertise	Conflicts, poor collaboration/resource use add time to market
Competitive Advantage	Added value for both partners Real innovation adds value Better products, less competition, higher profits Redirecting innovation to existing selected products in portfolio- especially big companies Assess low profit products consider exiting owing to higher cost factor	One partner has most/all the benefits Products do not meet the new requirements Insufficient resources because attempt made to retain full existing portfolio and/or continue R&D activities
Finance	Sharing of resources generates cost savings and/or increases profits	Partner changes agreed rules for instance withholds components/transfer price in order to increase financial outcome Issues with new registration rules
Markets	Competitors in coopetition, markets and product lines agreed where/what to compete and not to compete	
Secrets – fear of sharing	Transparency and trust	Partner has hidden agendas
Uncertainty	Leaderships managing uncertainty orchestrate relationship	Lack of appetite for uncertainty, too many restrictions

Table 45: Minimising Barriers

Key Barrier to Innovation/Coopetition	Positive Outcome	Negative Outcome
Regulation	In house expertise developed External expertise accessed Part or all processes shared with coopetition partner Competent notified body aids companies Able to access one of the limited numbers of notified bodies Understanding the implications of changing global healthcare policies and constantly updating knowledge	Insufficient financial and/or knowledge resources, leave market or product to market too late to compete Failure to understand new value focus on healthcare policies No/little access to competent notified body
Accessing resources	Understanding limitation of company resources Mindset change – openness to other ideas Concept of sharing to access process/technology/knowledge gaps to fulfil new regulatory requirements. Observing practice in other sectors and applying it	Failure to understand the complexity of the issues Partner acquires resources such as employees or technologies by means of the coopetition
Legal rights agreed	Limits of technology rights agreed contractually	Partner demands full rights and/or ongoing after coopetition completed or acquires them illegally
Get to market	Coopetition objectives to get to market quickly fulfilled by shared responsibility for accomplishing them After agreed stage of coopetition ends, all parties able to proceed with own further development	Neither partner nor just one accomplishes market entry with relevant products/services

4.6.2 Developing the Theoretical Code (Cycle 2)

The Theoretical Code, the central or core category (Saldana, 2016) must be combining all the products of analysis in a few words to explain the meaning of the research, the main study themes, and key words or key phrases that trigger discussion of the theory.

Also, it was shaped by ensuring that it aligned with answering the research question: What are the critical success factors for coopetition that will provide benefits to medical device SME given the impact of the new European medical device regulations on time and cost to market?

Therefore, the theoretical code answers how the phenomenon of coopetition works, in other words under 'what' conditions and 'why'. The theoretical code is represented graphically by the category code diagram below.

4.6.3 Developing the Category Code (Cycle 2)

The category code within the theoretical code for this research is 'Minimising Barriers' and represented in the category code diagram (see Figure 33). Minimising Barriers thus integrates the main themes that are underlying it.

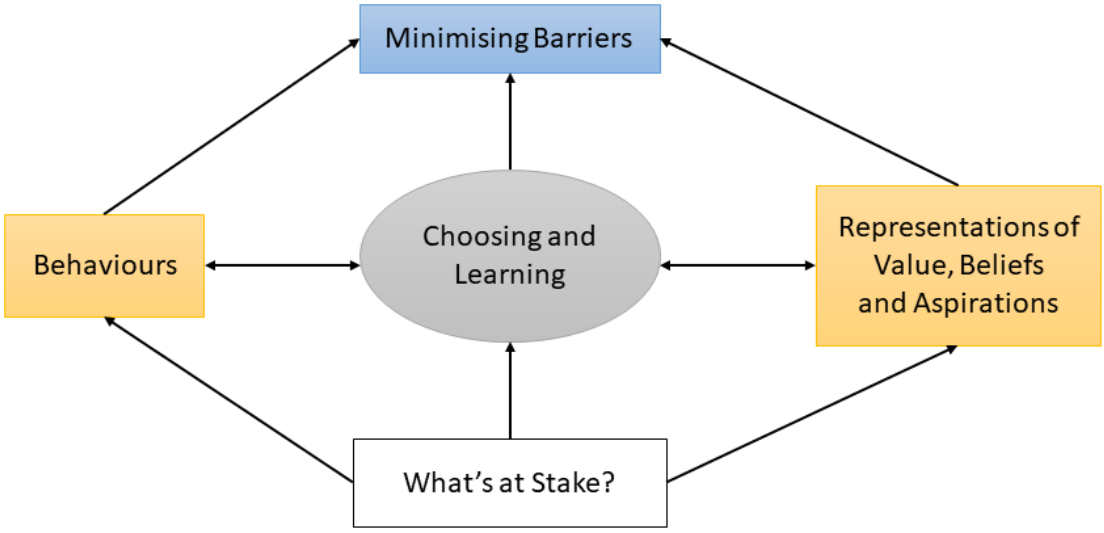

Figure 33: The Category Code Diagram

For coopetition to be a successful business model for SME in the medical device industry, those using coopetition must overcome and minimise certain barriers.

This research identified four main categories of barriers (table 45): expertise to deal with the new medical device regulations in the EU; access to resources required for coopetition; protection of legal rights and intellectual property; getting innovation to market in a timely acceptable manner.

The companies can minimise these barriers by defining what's at stake (table 44), which includes a clear definition of desired outcome of the coopetition and agreement between the partners. Based on the objectives they must go through a process of choosing and learning to determine the most appropriate representations of values, beliefs, and aspirations (table 42) as well as associated behaviours (table 43) that together enable a successful coopetition.

4.7 Emerging Grounded Theory

The theory emerging from this research, based on the theoretical code, and expressed through the category code diagram above, answers the research question as follows:

Coopetition can be a successful business model for small and medium size companies in the medical devices sector as it will help to overcome challenges imposed by the new EU regulations, when such companies are able to minimise key barriers towards collaboration with a competitor.

Whilst the barriers will be similar for all variations of company in the sector, their context will be different, dependent on the area of expertise; previous experience of collaboration that could be positive or induce further uncertainty and fear; which stages of development coopetition comprises.

The detailed analysis of all axial codes (see Table 42 – 45) clearly demonstrates the critical success factors as well as failure factors for coopetition of SME in the medical device industry. Amongst others these are: lack of resources including gaps in processes; understanding the limitations and the need for a different

mind-set; establishing legal rights; being able to move from the early stages of creativity to commercialising.

Companies must make go through a process of choosing and learning how they will manage aspects, such as which part of the entire process from idea to market will use a coopetitive arrangement. Aligned to this is positioning the organisational culture, structure and leadership that will lead to successful outcomes. They must determine the appropriate representations of values, beliefs, and aspirations, as well as the behaviours, for instance communication, team first, empowerment, ability to compromise and trust.

Amongst the different success factors for coopetition, that surfaced in this research, a very dominant one and very much stressed by the participants is ‘trust’. The companies must handle uncertainty and fear with a new business context and work with a partner whose motives may not be sincere, whilst adopting a collegial approach which enables a collective shared responsibility.

Whilst stressing the need for trust, most participants in this research described a more conditional type of trust instead of just believing the other party, linked to legal agreements, balance of power and mutual guarantees. This description of trust adds new theory since literature so far does specify the requisite type of trust necessary in a coopetitive relationship.

4.8 Discussion of Findings in Relation to Research Questions

After presenting the findings from the two coding cycles and the emerging grounded theory, the results are now discussed in relation to the research questions and in correspondence with existing studies. In doing so, the findings and results of this thesis can be evaluated with regards to their actual contribution to management, as well as to management science.

The previously introduced research question together with the sub-questions are guiding the discussion in the section. Because the main research question shows a significant overlap with sub-questions number one, two and eleven, the findings in relation to these four questions are first discussed concertedly, before

evaluating the results in correspondence to the remaining sub-question one by one.

4.8.1 Discussion of Critical Success Factors (SQ1, SQ2, SQ11)

The main research question of this thesis is: “What are the critical success factors for coopetition that will provide benefits to medical device SMEs given the impact of the new European medical device regulations on time and cost to market?”. Sub-questions number one, two and eleven were looking into specific aspects of the main question (SQ1: What are the critical success factors involved in adopting the new legislation in relation to innovation management; SQ2: How will established success factors need to be adapted and into what form; SQ11: What other critical success factors for coopetition have been identified?). Therefore, this section 4.8.1 is merging the discussion of findings on critical success factors (CSFs).

It can be stated at this point of the thesis that coopetition can help to overcome the challenges imposed by the new regulations, but SME need to develop strategies and tactics for minimising the barriers towards working with a competitor. Barriers to such achievement are manifold and include, especially for SMEs, the lack of resources, a limited understanding of further limitations, and an appropriate organisational mind-set to allow coopetition in the first place. Again, this might be all rooted in the earlier discussed limitations that are inherent to SMEs in the first place.

The CSFs for innovation management related to adopting the new legislation were associated predominantly with acquiring the resources required to generate ideas, to commercialise them, and to ensure that they complied with the regulatory requirements. The inference was that firms required mostly financial and knowledge resources, where tangible knowledge included aspects, such as identifying the gaps in its current operations that needed to be addressed.

Intangible knowledge resources could be regarded as a set of CSFs relating to leadership mind set, organisational design and the associated culture for innovation in the new regulatory context. These CSFs were encapsulated in

comments such as “rethinking how you work”, partially developing an idea and selling to another company earlier than had previously been the case. Consequently, identifying appropriate types of collaboration with other organisations, and specifying the parts of the entire supply chain, from creating the idea and identifying resources to placing the product/service on the market, was a major CSF to manage innovation related to the regulation. Other solutions relating to mind set and organisational structure included:

- adding new departments and competences to the existing organisation, which may require a change in organisational culture
- working with partners with similar mind-sets and work ethics
- identifying partners that could be trusted, which were usually long-term contacts and collaborators
- establishing a project and arrangement that represented added value for both partners
- willingness to adapt values and beliefs to ensure the collaboration was viable
- identifying other markets and ceasing to operate in the EU markets so that no new resources were required, but enabling survival
- exploiting the opportunity to communicate with regulatory authorities to gain better understanding of the requirements.

However, retaining the agility of a small company was also vital to innovation management in the new regulatory context. Therefore, the production of high-quality products was a CSF for medical device companies, which relied on these other CSFs being implemented appropriately otherwise the CE mark would not be obtained and market entry impossible.

The most important of these potential CSFs depended on the companies concerned, is that the first stage of innovation management in this context is to identify the organisation’s characteristics, the gaps it has that would prevent innovation and survival. It would then establish, which of these factors is most

critical to retaining competitive advantage in the new market environment. The findings suggest that managers must question their current assumptions about how to prosper in the context of the new regulations; they should reassess all these aspects of the current business model and the underlying values and beliefs that are externalised by their organisational structure and culture.

In addition, compromise was vital especially in small companies forming competitive relationships with larger companies; the SME would need to be willing to adjust its values and beliefs. An associated CSF was the small companies needed to change their mind-set about the level at which coopetition was considered, inferring that they adopted too narrow a focus owing to fear of giving away too much to the larger partner. In some contexts, SMEs would need to consider collaborating with a much larger organisation; this might be abhorrent to SMEs given previous concerns about losing agility and start-up mind-set as the SME grew.

An alternative acceptable coopetitive relationship for small and medium sized companies was likely to be forming strategic alliances so that they could gain competitive advantage over larger competitors. In all cases, appropriate partner behaviours in both firms were a CSF in coopetition. Therefore, a general CSF was that the arrangement must be perceived as being of mutual benefit and the type of coopetition selected depended on the specific requirements of each partner so that it was a strategy based on choices. Developing legal agreements to reduce uncertainty and enhance trust was a CSF that was mentioned most frequently throughout the interviews.

Matching the findings discussed above with existing studies, there is consistency on the basic understanding of CSF for innovation and coopetition. Moreover, with regards to the success factors that might lead to leveraging on advantages of coopetition, it could be deducted by the interviewees responses that it is important to rethink the ways of collaborating and competing in the first place to allow the success factors to really take ground (Chin et al., 2008). The new EU legislation might force SMEs to choose a new way of engaging within their immediate business environment, moving beyond previous fears of losing knowledge or sharing resources which are unique.

For SMEs in specific, several success factors keep quoted in the literature to be potentially more relevant than others. Thomason et al. (2013), for example, suggest a coherent model of such factors. According to these authors individual levels of trustworthiness will positively relate to successful coopetition, as will levels of imperfect knowledge. “The trust, commitment, and mutual benefit aspects of a successful coopetitive relationship may require monitoring and the adoption of various ethical and strategic policies, procedures and control systems designed to build and maintain social capital over the long term” (Thomason et al., 2013, p. 23).

With regards to innovation specifically, research supports the notion that these factors have an indirect impact on innovativeness and innovation performance, especially in a business environment with a relatively low competition complexity (Ritala, 2012). Ritala and Hurmelinna-Laukkanen (2013) also support that a company’s ability to acquire knowledge from outside and to protect its own innovations and own knowledge against imitation are relevant in increasing the innovation outcomes of collaborating with its competitors. They conclude that in terms of “… incremental innovation, a firm-level emphasis on knowledge sharing and learning will positively affect the results of coopetition, as will an emphasis on knowledge protection. Thus, when incremental developments are pursued in coopetition, firms should not only seek to exchange knowledge to create value but also remember to secure the firm-specific core knowledge within the firm's borders to stay competitive. On the other hand, when the firm is pursuing radical innovation with its rivals, the heaviest emphasis should be on protecting its existing core knowledge and also emerging novel innovations and market opportunities” (Ritala and Hurmelinna-Laukkanen, 2013, p. 154).

Summarising the above, the findings of this thesis in line with existing studies have shown that issues regarding the protection of critical knowledge and general issues regarding trust and control of one’s own organization are the most critical factors and valid managerial concerns regarding coopetition. In the medical device industry, the legal protection of innovative achievements is a major competitive advantage and neither easy to be obtained, nor willingly foregone. Actual solutions to overcome the barriers towards coopetition are scarcely

presented in the literature, mostly being too general to be applied in a medical device organization without further input. Therefore, this thesis closes gaps in knowledge and contributes to actual management, as well as to management science.

4.8.2 What does Coopetition mean for these SMEs? (SQ3)

Coopetition is a reality for some firms that have been practising such relationships prior to the new regulation being introduced, others knew the meaning of the term but not the word coopetition. Perhaps the broadest understanding was “ecosystems for innovation” suggested by the CEO of a small company; the implication was that innovation was not merely happening in one process but in multiple processes.

Coopetition was understood as collaborating with competitors, typically with two companies; the partners could be suppliers, customers, firms producing complementary or related products. The partner firm was perceived as being larger by some SMEs. Coopetition might be an arrangement for a specific project or several projects and its extent limited, so that highly valuable aspects remained secret by excluding these stages in the collaborative processes. Therefore, coopetition would relate to specified processes, such as manufacturing or sharing costs or regulator. Coopetition was also the means to deliver value by resource sharing and compromise, involving exchange of the capacities of human and physical assets, and success dependent on appropriate behaviours from the parties. Coopetition was also associated with quicker speed to market and perceived as a temporary arrangement, important for the future, and an inter-firm phenomenon.

Successful coopetition was hindered if legal agreements were required between the parties, the legal aspects would “kill innovation”. This was particularly relevant to many companies, which possess IP rights to technology, for instance, and feared loss of competitive advantage. However, the potential for the partner to identify talented employees and attempt to recruit them was an additional hindrance to agreeing a coopetitive arrangement. A successful coopetitive

arrangement was characterised by the two partners feeling able to give up sole control of the business. Therefore, finding a suitable partner was a major barrier to coopetition, and highly competitive firms were unlikely to form coopetitive arrangements.

To summarize what coopetition means for the studied SMEs facing the new EU regulation, the findings of this thesis show that the subject is addressed roughly in three different ways: investing in resources permitting more openness and the chance to secure exclusive distributing and/or licensing rights, thus managing limited financial resources; focusing on innovations related to open innovation; the acquisition of smaller corporations by larger ones.

Research on these aspects so far has stayed on a rather superficial level. There is little practical information about how to engage into the necessary management of coopetitive strategies. Therefore, chapter five of this thesis, the contribution to management, is deemed to help closing the gap.

4.8.3 How has Coopetition been approached/considered in the Context of Innovation Management, if at all? (SQ4)

As outlined above in detail, and as the focus of sub-question four, coopetition and innovation management are intercorrelated with each other. At times, enhanced innovativeness is the main purpose of coopetition in the first place, especially for SMEs. In the medical device industry, a focused issue could be accelerated CE mark approval, due to quicker time to market and a subsequent competitive advantage.

For some of the companies interviewed in this research, coopetition had aided innovation management because the partner selected provided skills that it did not have, whilst the sharing of costs has allowed innovation to proceed to marketable products/services. In one case the partners managed joint innovation, to serve different geographical markets, the EU requiring the CE mark and non-EU country that did not; this prevented direct competition and generated mutual benefits.

The role of innovation in coopetition, supported by the thesis at hand, is well established in research. Relevant studies of e.g., Reiss and Neumann (2013) and Pekovic et al. (2020) have been reviewed in chapter 2. However, it is clearly also confirmed by other researchers that coopetition might be a "double-edged sword" (Bouncken and Kraus, 2013) and negative effects on novel innovations are possible.

Again, it might require a completely different mind-set, away from viewing coopetition as a threat for the own organisation, towards a more open collaboration and willingness to share. This notion is supported by Kraus et al. (2017), stating that for SMEs in the financial sector they were able to observe that trustees' conservative attitude turns out to be a barrier to coopetition. Mostly owning to the fact that they feel responsible to protect their own business, perceiving collaboration with the potential competition as a threat rather than an opportunity.

4.8.4 What Aspects of Innovation Management or Stages of the Innovation Process are suitable for Coopetition, based on the Experience of these SMEs? (SQ5)

In the experience of the SMEs participating in this research, the aspects of innovation management suitable for coopetition were:

- a cash investment.
- that the partner had specialist knowledge or expertise.
- there was potential to work with partners in non-medical device industries which had relevant knowledge or technology such as machine learning.

If the coopetition facilitated a more flexible product portfolio, for instance to add a product or to upgrade an existing product, this would be motivation for the collaboration. The type of coopetitive relationship considered was inferred as dependent on the type of innovation considered, the market changes and investment cost.

There was some agreement that the coopetitive arrangement would be restricted to distinct stages, such as: any stage which could not be accomplished in-house; a part of the process the company did not wish to complete; the early development stage when knowledge was weak and both parties incentivised to share results; manufacturing, quality, and/or regulatory stage which might be outsourced.

While it is difficult to identify distinct stages of the innovation management process and to identify literature which is dealing with specific stages in detail, Yami and Nemeh (2014) discussed innovation in high-tech industries to shed light on which form of coopetition favours which type of innovation. Their results permit the conclusion that multiple coopetition can be applied for radical innovation and dyadic coopetition for incremental innovation. They propose a conceptual model linking coopetition strategy motives to the types of coopetition, as well as radical or incremental innovation (Yami and Nemeh, 2014).

4.8.5 What are the Challenges of Implementing Coopetition from the SME Perspective? (SQ6)

The biggest challenges to implementing coopetition from the SME perspective are the loss of IP rights, either to partner and/or its contacts, talented personnel being encouraged to join the partner company, and the partner wishing to acquire the business or its IP, any form of dishonest intent on the part of the collaborating firm. There was also a fear of reputation loss if the partner's technology or other contribution was not of the expected quality described, and/or the partner demanded exclusive rights to products or market, or it operated in the same market as the SME. An additional issue was a situation in which the partner supplied a key component at an agreed price but, on realising the demand/profitability of the product demanded a higher transfer price for the components and/or threatened to suspend supply.

Additional literature on related concerns, challenges or even the potential downsides of coopetition appear to be scarce. In that context the before mentioned Ritala (2012) states that market uncertainty, network externalities and

competition influence the implementation and eventual success of coopetition. Moreover, they support the notion that a corporation needs to overcome any concerns regarding coopetition to reap the potentially positive effects on corporate performance. For management this would mean that they need to assess before expansion whether there are competitors pursuing the same strategy and carefully avoid any potential issues in advance (Ritala, 2012).

4.8.6 What strategic Changes are needed for Coopetition? (SQ7)

The participants, who had experience with coopetition stated that few strategic changes were needed for coopetition to take place. In one case regulatory processes were outsourced to an independent party, which became the certification holder. The reason for this strategy was to ensure that the coopetitive partners, which were private label customers or distribution partners in China and EU countries, did not gain access to the technical file. The other changes mentioned were the initiation of legal agreements and once organisation obtained an exclusive licence for the required technology. The implication for management practice is that generally few strategic changes are required to apply coopetitive arrangements into business strategy.

In some contrast to these findings, literature proposes that new ways of collaboration, which coopetition is for many firms, are often competing with daily business and traditional patterns (Suhm, 2005). Therefore, transformation might be needed. More recently concerned with the impact of the Corona-Pandemic and related challenges, but also how coopetition might be applied to manage related challenges, Talari and Binandeh (2021) indicate that the most relevant strategic drivers will be found in the areas of organisational empowerment and strategic investment. With a similar focus on the strategic challenges, Crick and Crick (2020) found that there are short-term cooperative factors outweighing certain rivalrous behaviours during the Corona-Pandemic.

4.8.7 What Organisational Structure/Changes are required for Coopetition? (SQ8)

This research highlights that a flat organisational structure and a small size supports innovation. The flat organisational structure generates a process of innovation comprising fast communication, empowerment and generation of multiple ideas that can be applied to engage employee commitment. This finding corresponds with Bryan and Joyce (2005), Strikwerda (2012) and Kotter (2012), that a flat structure and empowering people is the best set up to drive innovation.

With regards to collaboration and coopetition, the inference of this research is that different organisational structures between the partners are an additional potential source of uncertainty for medical device companies to manage, especially if the collaborating company was large and hierarchical. This adds an interesting aspect to previous studies on sources of tension in coopetition like Bengtsson et al. (2016).

4.8.8 What Role does Corporate Culture play? (SQ9)

The culture of people resources for innovation to occur in an organisation were initially captured in the expression “team first; people first”, sharing knowledge and expertise. Employees needed to be resilient to work in a medical device SME because creating something from nothing was a very hard objective to accomplish. The challenges of the work environment were lack of physical and financial resources, the need for hard work, constant uncertainty, and a painful learning process: “finances limit you… and the rules limit you”.

The new regulation had created greater uncertainty because the employees were working in an unknown environment of “not knowing what the new normal will be”. The culture needed to be agile to constantly change direction as internal direction/ideas changed, and/or the external environment altered. This was also taken in the context of having the agility to quickly change partners to achieve goals, a highly applicable strategy for management practice in the current medical device scenario. Highly talented flexible individuals should be characteristic of the learning culture because they can adapt to change quickly and were a part of the

SME's structural agility; a nurturing culture was also required to cultivate talented employees and motivate them to remain with the firm.

Personal risk was also experienced by all employees, who regarded working in the SME as creating their own business, errors were costly. Errors were tolerated if individuals learnt from them and did not repeat the same mistake; a learning culture is evident in successful SMEs. Innovation was successful when all employees freely shared information and there was transparency in all matters, a vital aspect of corporate culture for innovation.

The high importance of management practices to shape the culture in appropriate ways, creating a climate that embraces these features, is evident from these remarks. Therefore, managers are advised to critically appraise current values and beliefs in relation to the workplace environment and employee motivation and engagement.

Crick (2020) suggests that management should manage assumptions, values and beliefs that are mainly aiming at the benefits of coopetition. What he basically is trying to emphasise is the role the proper organisational mindset, or rather organisational culture is playing when adopting coopetition as a strategy to improve innovation performance.

In this thesis, even though focused on SMEs and the medical device industry, it has become clear that one needs to consider an agile and flexible organization to cope with related challenges, basically carried and expressed by an appropriate organisational culture. The employee culture should be characterised by thinkers and doers, rather than individuals who strictly adhered to their job specification and hindered agility.

4.8.9 Which Management and Leadership Characteristics support the Application of Coopetition? (SQ10)

The leader must be courageous, able to manage the constantly changing challenges encountered in the SME environment and guide the company to find appropriate solutions. This critical leadership attribute was described as a painful

process that was like leading a tribe “trying to find a path through this forest, focused on an objective beyond themselves”. It fully reflects the meaning of leadership in the context of new regulation, which is recognised as an unknown future context for the business.

The ‘senior guy’ is referred to as the person taking the ultimate responsibility for any mistakes, despite involving all the employees in decision making. Therefore the formal leader is the orchestrator of the SME’s strategy and outcomes, adopting an approach of total transparency in actions and motivations, in order to optimise the potential for innovation and create the environment for informal discussions and exchange of ideas The leadership attributes should therefore include openness within the organisation, whilst being cautious about revealing the means of competitive advantage to external contacts, in order preserve and constantly develop it. The leader is also responsible for creating the climate for innovation and coopetition by direct actions, such as leadership vision and strategy, which combine to develop individual and team creativity. In the context of coopetition and SME operations generally, leadership openness is vital to facilitating the entire innovation process and ensuring that desired outcomes were enunciated and understood by the whole team, including why specific partners had been chosen for coopetition.

Leadership and management for coopetition should be characterised by an agile approach and responsiveness to new ideas from the whole team, including observation of innovative ideas/practices external to the firm; conflicting opinions and ideas should be encouraged, to question assumptions and generate the best options. The inappropriate leadership for coopetition was strict formal management that suppressed innovative ideas.

The relevant issues around leadership are another important issue with which this thesis can present a relevant new impact in managerial practice and future research alike. So far very little has been published recently regarding related issues.

4.9 Summary

The analysis of the interview findings has been documented using two cycles of coding, which allowed the grounded theory to emerge.

Coopetition can be a successful business model for small and medium size companies in the medical devices sector as it will help to overcome challenges imposed by the new EU regulations, when such companies are able to minimise key barriers towards collaboration with a competitor. The barriers are similar for all SMEs in the sector.

Based on clear objectives for the coopetition, SMEs must go through a process of choosing and learning how they will manage aspects, such as which part of the entire process from idea to market will use a coopetitive arrangement. Aligned to this is positioning the organisational culture, structure and leadership that will lead to successful outcomes. They must determine the appropriate representations of values, beliefs, and aspirations, as well as the behaviours, for instance trust, communication, team first, empowerment and ability to compromise.

The results have been discussed in relation to the research questions and from a broader literature perspective. It has become obvious that amongst the different critical success factors ‘trust’ plays a dominant role. This finding confirms existing literature; however, studies so far have not examined the concept of ‘trust’ in detail, let alone specify the requisite type of trust necessary in a coopetitive relationship. This research identifies the trust involved as ‘conditional trust’, clearly linked to legal agreements, balance of power and mutual guarantees. That is, the very idea of trust in coopetition starts with agreeing rules and boundaries before the coopetitive relationship deepens.

Based on the framework for coopetition suggested by Winberg & Oster (2015), as presented in chapter 2.4.3, an adjusted model now including conditional trust looks as follows:

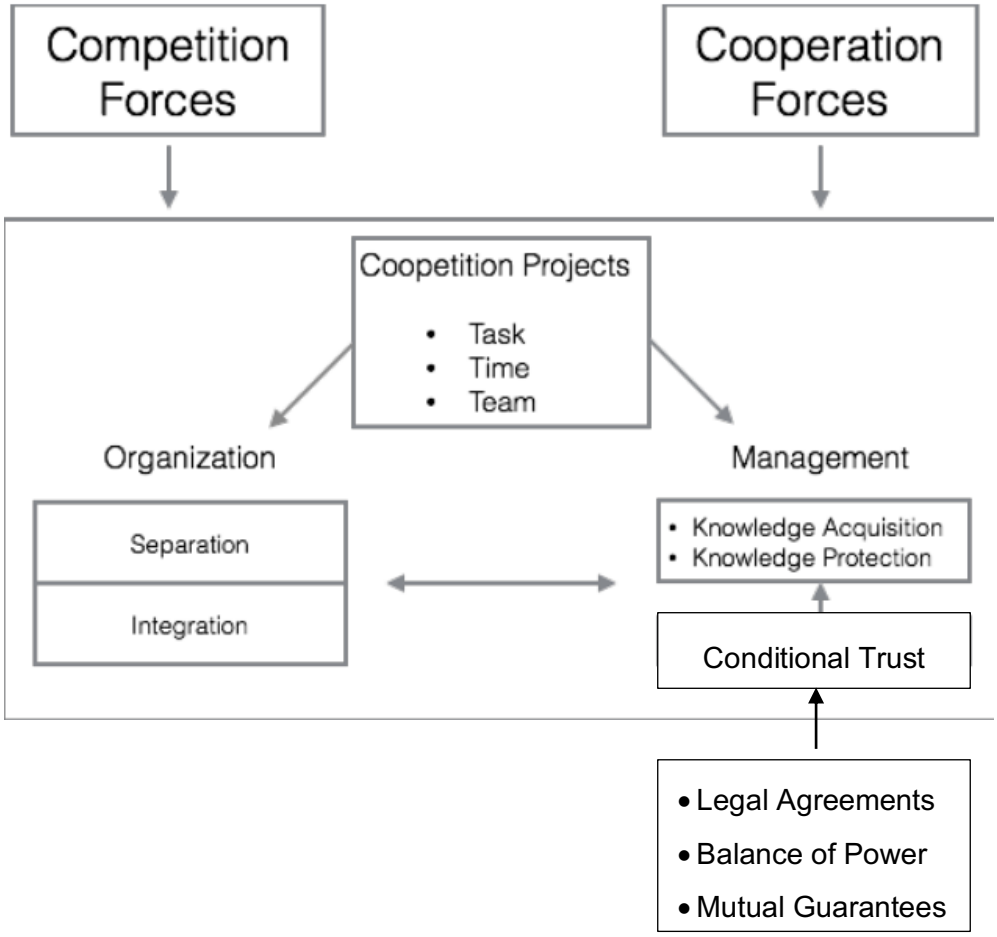

Figure 34: Conditional Trust in Coopetition (based on Winberg & Oster)

The findings of this research can now be concluded with regards to their actual contribution to management. In addition, the final chapter discusses the limitations of the research and gives recommendations for further research into the success factors for coopetition in the medical devices sector.

CHAPTER 5: CONCLUSIONS AND RECOMMENDATIONS

The final chapter highlights the major findings and conclusions of this research. These conclusions provide insights for leaders in medical device SMEs, policymakers and scientific and business researchers as set out in chapter 1.3., where the research problem was defined.

The limitations of the research are explained in the second part of this chapter, and the final section comprises recommendations for further research regarding the impact of new EU regulation on SMEs in the medical devices sector.

5.1 Contribution to Management Theory

The findings of this research and contributions to management theory are structured in four sections within chapter 5.1. They begin with the impact of the new EU medical device regulations on SME in the sector. The next section concludes on coopetition as a business model to overcome the challenges of the new legislation, followed by critical success factors for successful implementation and execution of coopetition. The last section presents relevant findings on innovation management in medical device SME from a broader perspective, partly beyond the new regulations and coopetition.

5.1.1 Effects of the new EU Medical Devices Regulations

This research, based on in-depth interviews with 15 senior executives of different European medical device SME, confirms the new regulations (EU) 2017/745 and (EU) 2017/746 being a threat to the innovation capacity and therefore survival of SME in the sector. Along with decreasing sector investment and rising global competition as outlined in the introduction and literature review, this research revealed substantial challenges for European medical device SME that require new ways of doing business.

The new legislation was referred to as “brutal regulation” in the interviews, making it very challenging for small companies to come up with new innovative products

in a commercially viable way. The impact most often cited was that small companies will find it much more difficult to continue to participate in the sector. Uncertainty and tensions from innovative intention to success are apparent, as well as anxiety about being able to obtain investment to survive or remain viable. The findings are therefore valuable examples of the multiple emotional issues the sector is currently experiencing.

Surprisingly, innovation has not been rated the most essential success factor for companies in this research, which contradicts some views in the literature (e.g., De Bes & Kotler, 2011). People, sales, and regulatory knowledge are believed to be more important success factors currently, which can be interpreted as a consequence of the new regulations, because human, financial and knowledge resources are needed to manage these regulations.

Additionally, the findings confirm that innovative R&D projects in this sector would likely be cancelled, and a strategic focus would move to ensuring that the existing product portfolio meets new regulations. This lack of focus on innovation can create future issues since the literature and research strongly suggests that without innovation companies have no future, which is especially true for SME in the medical device industry. Therefore, leaders of medical device SMEs need to carefully balance todays focus on the new regulations and future needs for innovation to remain competitive.

On top of delayed or cancelled R&D, the new regulations will make a certain number of products disappear from the EU, because companies are not re-certifying them under the new medical device directives. Companies are forced to make choices on which products to eliminate from the current portfolio selected on minimum sales revenues. This confirms the challenges for SMEs, imposed by the new regulations, to continue business as usual as suggested by Clemens (2018), Groennvold (2017), Wagner & Schanze (2018) and Yeo (2018).

Besides the direct impact of the new legislation on companies, special notice was given to the limited number of notified bodies being certified under the new regulations. This creates a potential bottleneck and adds to the work of Jeandupeux (2019), Maresova et al. (2020b) and Peter et al. (2020) regarding

the additional time the regulatory procedures add to the ‘product to market’ timescale. As a conclusion, management not only needs to secure working with an EU notified body, that has been certified under the new regulations, but also to consider extended timelines when planning for (re-)certifications and product approvals.

As concluded so far, the new regulations are making it much more challenging to commercialise new products for SMEs. However, innovation that finally is commercialised under the new regulations, is expected to have increased value. The new regulations are assumed to increase the quality of products and also to extend product lifecycle and cash returns due to higher market entry barriers especially for competition from outside the EU, which adds to the suggestions of Gerecke et al. (2020) and Maresova et al. (2020a). These findings support the EU position that the new regulations will increase competitiveness in the industry (Ben-Menahem et al., 2020) and reinforce earlier findings of Mattke et al. (2016).

From a broader perspective and beyond the medical device industry, the findings of this research contribute to a systematic literature review on the impact of regulations on innovation conducted by Ashford (2000). Also, the fears and frustrations being externalised add new insight to the gaps in knowledge identified by Pelkmans and Renda (2014) regarding the effect of new regulations in general.

Table 46 summarizes the conclusions on the effects of the new regulations and links the conclusions to the respective analysis chapters.

Table 46: Effects of the new EU Medical Devices Regulations

Conclusions	Analysis chapter(s)
The new regulations (EU) 2017/745 and (EU) 2017/746 are considered a threat to the innovation capacity of SME. Small companies will find it much more difficult to continue to participate in the sector.	4.3.2, 4.4.2
Because of the new regulations innovation has not been rated the most essential success factor for companies in this research, since human, financial and knowledge resources are currently more important to manage these regulations.	4.3.1, 4.3.2 and 4.5.1
R&D projects in this sector would likely be cancelled, and a strategic focus moves to ensuring that the existing product portfolio meets new regulations. Leaders of medical device SMEs need to carefully balance todays focus on the new regulations and future needs for innovation to remain competitive.	4.3.3
The new regulations will make a certain number of products disappear from the EU, because companies are not re-certifying them under the new medical device directives.	4.5.3
Limited number of notified bodies being certified under the new regulations creates bottleneck and increases ‘product to market’ timescale.	4.3.3
The new regulations are assumed to increase the quality of products and to extend product lifecycle and cash returns due to higher market entry barriers especially for competition from outside the EU, which increases the value of innovation commercialised under the new regulations.	4.3.3, 4.4.2 and 4.5.3

5.1.2 Coopetition as a Business Model to overcome new Challenges

As described in the literature chapters 2.4 and 2.7, previous studies have found coopetition to support companies to overcome resource difficulties. However, with Pullen et al. (2012) being the only research on coopetition so far that focuses solely on EU medical device SMEs, with survey participants being from the Netherlands only, the applicability of coopetition to medical device SME in the context of major regulation changes was uncertain and needed to be addressed in research. One of the major findings and emerging theory from this research is, that coopetition as a business model can help to overcome the challenges imposed by the new EU regulations, when the small and medium size companies in the sector are able to minimise key barriers towards collaboration with a competitor. The four main categories of barriers identified in this research are: expertise to deal with the new medical device regulations in the EU; access to resources required for coopetition; protection of legal rights and intellectual property; and getting innovation to market in a timely acceptable manner.

Whilst the barriers will be similar for all SME, their relevance will be different, dependent on the area of expertise, previous experience, resource limitations, capacity to adjust mind-set and how legal rights will be shaped. The companies can minimise barriers by establishing a clear definition of desired outcome of the coopetition and agreement between the partners. Based on the objectives they must go through a process of choosing and learning, determining the most appropriate representations of values, beliefs and aspirations and associated behaviours that together enable a successful coopetition.

Coopetition was revealed in this research as being an interesting concept to the companies, despite expressions of fear, uncertainty, and loss of identity, because all companies lacked specific resources. In addition, small companies could accelerate their speed to market compared with large companies and subsequently their competitive advantage.

Most participants knew the term coopetition and had an opinion on how it might support innovation in the context of new EU regulations, despite some having no personal experience. Coopetition was described in different ways, including a suggestion that it is enforced collaboration by the new regulations. This is an

interesting perspective which is hardly evident in the existing literature, because most researchers understand coopetition as a voluntary decision. This finding adds new insights to Fernandez et al. (2014), who found aspects of enforced coopetition in the telecommunications satellites manufacturing industry.

Also, the participants, who had experience with coopetition stated that only a few strategic changes were needed for coopetition to take place. This had not been found in the literature and conflicts with a general understanding, that new ways of collaboration, which coopetition is for many firms, require significant changes in the organisation.

When discussing at which stage of the innovation process coopetition might be useful, participants of this research stated that they had developed internal regulation expertise or employed consultants so that coopetition in the approval phase of the product may be less necessary than at the front-end development stage where technology could be more important. There was an additional comment that coopetition should be restricted to the early stages of development when knowledge is weak. This partly aligns with Winberg and Oster (2015), which found restriction to early stage preferable when there was a specific purpose for the coopetition.

Coopetition does not always have a positive outcome. It is clearly also confirmed by other researchers like Bouncken and Kraus (2013) that coopetition might be a double-edged sword. Ritala (2012) and Bonel et al. (2008) make a similar plea for becoming aware of the management of potential downsides of coopetition.

In addition, participants in this research highlighted, that in case of successful coopetition, the speed of technological advance may create an imbalance with user acceptance, because of slow user adoption of new medical devices. These remarks reflect the concerns cited by the WHO (2010), Money et al. (2011), Bayon et al. (2016) and Auer and Jarmai (2017) on technology adoption in medicine.

A summary of the conclusions on coopetition as a business model for SME is provided in Table 47.

Table 47: Coopetition as a Business Model to overcome new Challenges

Conclusions	Analysis chapter(s)
Coopetition as a business model can help to overcome the challenges imposed by the new EU regulations, when the SME are able to minimise key barriers: expertise to deal with the new medical device regulations in the EU; access to resources required for coopetition; protection of legal rights and intellectual property; and getting innovation to market in a timely acceptable manner.	4.7
Companies can minimise barriers by establishing a clear definition of desired outcome and agreement between the partners. Based on the objectives they must go through a process of choosing and learning, determining the most appropriate representations of values, beliefs and aspirations and associated behaviours that together enable a successful coopetition.	4.7
Coopetition in the approval phase of the product may be less necessary than at the front-end development stage where technology could be more important.	4.4.3
In case of successful coopetition, the speed of technological advance may create an imbalance with user acceptance, because of slow user adoption of new medical devices.	4.3.2

5.1.3 Critical Success Factors for Coopetition

This research finds that amongst the different critical success factors ‘conditional trust’ linked to legal agreements, balance of power and mutual guarantees plays a dominant role. Further important success factors for coopetition of SME in the medical device sector are leadership characteristics, organisational structure and organisational culture, knowledge around the new regulations and resources needed for coopetition.

Trust borne out of longer-term relationships is a very critical success factor for successful coopetition. The qualities of the partners were the basis for success, as well as openness and sharing of documents and feedback from partner. These comments confirm the necessity for trust to motivate coopetition as described by Cygler et al. (2018) and stressed by McCarthy et al. (2018). However, studies so far have not specified the requisite type of trust necessary in a coopetitive relationship. This research identifies the trust involved as ‘conditional trust’, clearly linked to legal agreements, balance of power and mutual guarantees. That is, the very idea of trust in coopetition starts with agreeing rules and boundaries before the coopetitive relationship deepens.

Leadership is another very critical success factors for both, coopetition and the innovation capacity of SMEs. This confirms studies by Chin et al. (2008) and Hunter and Cushenbery (2011). The interview responses also clearly show that leaders are experiencing considerable challenges in the medical devices sector, and subsequent viability of their businesses in the future. Leaders are forced to make choices on specific global markets to target, based on EU market regulation being stricter, and to select products to eliminate from the current portfolio based on minimum sales revenues as already described in the previous section.

Also, the leader as responsible for culture, emphasised by Schein (1985), is confirmed by the findings. This is highly relevant since a free-thinking and open-minded organisational culture is a very important element for the success of coopetition. Therefore, the importance of leadership for the success of coopetition is not only linked to direct decisions regarding the work with a competitor, but also indirectly through the creation of a specific intra-organisational corporate culture and promotion of innovation activities within the company.

Most responses within in this research tend to align with a delegating leadership approach because the motivated employees have the appropriate skills and aptitudes or are perceived as effective followers. Self-driven and loyal team members are especially valuable, given the uncertainty about the future because of the new regulations. In addition, a high need for agile leadership was expressed to manage uncertainties and changes because of the new regulations

and implementation of new business models. These remarks on agility align with the findings of Rigby et al. (2016) and Aghina et al. (2018).

Some responses were also concerned with the leader's responsibility for the team. This is an aspect that is relatively neglected by academic theory, with Stacey (2010) being one of the relatively few authors emphasising how the leader feels responsible for "his" people. Within the context of this research, it underlines the tensions, anxiety, and emotional issues the sector is currently experiencing and how the leader is expected to provide stability and guidance in these turbulent times.

Next to leadership this research highlights the importance of organisational structure and culture for both innovation and coopetition. As proposed in the literature, a flat organisational structure and a small size supports innovation. The flat organisational structure generates a process of innovation comprising fast communication, empowerment and generation of multiple ideas that can be applied to engage employee commitment. This finding corresponds with Bryan and Joyce (2005), Strikwerda (2012) and Kotter (2012), that a flat structure and empowering people is the best set up to drive innovation.

Beyond the understanding of flat structures supporting innovation, the ideas of organisational structure vary considerably between the participants in this research. The conclusion is that in the light of innovation there is not one ideal organisational structure, and that structure needs to be shaped according to the needs of the organization.

With regards to collaboration and coopetition, the inference of this research is that different organisational structures between the partners are an additional potential source of uncertainty for medical device companies to manage, especially if the collaborating company was large and hierarchical. This adds an interesting aspect to previous studies on sources of tension in coopetition like Bengtsson et al. (2016).

Organisational culture supporting innovation was characterized as free-thinking and risk-taking. These characteristics differentiate SMEs from large organizations that would be too bureaucratic to enable this kind of agile culture to operate.

There was also a strong inference that being an SME, especially a micro-organization, had an emotional impact on employees, because they had direct knowledge of the firm's opportunities and challenges and understood the reality of their situation, confirming existing literature like Rammer et al. (2008) and Ortega-Argilés et al. (2009).

There was awareness of the resilience needed to work in an SME and of recruiting employees with similar mind-sets and values. This workplace culture of high job orientation corresponds with Hofstede (2020), where individuals with lower levels of it will not be considered a good organisational fit. As per the discussion of the research questions in chapter 4.8, the employee culture should be characterised by thinkers and doers, rather than individuals who strictly adhered to their job specification and hindered agility. The concept of culture very much aligns with Serrat's (2017) definition of culture as distinctive and relating to how humans interpret their environment.

As with organisational structure, this research claims that different cultures of collaborating companies are a potential source of uncertainty or tension to manage, and therefore supports previous studies on this aspect of coopetition like Bengtsson et al. (2016).

Besides conditional trust, leadership, organisational structure and organisational culture, the following key success factors for coopetition evolved from the research:

Expertise to deal with the new medical device regulations in the EU is a critical success factor for coopetition, which is not evident in the literature so far. A successful outcome will be enabled through the internal development or external access to the regulatory knowledge required. Also, access to one of the limited numbers of notified bodies is needed, ideally the notified body provides certain guidance to the company. In a broader sense the company must understand the implications of changing global healthcare policies and constantly update its knowledge.

Companies need to have access to the human and knowledge resources required for the coopetition. In addition, management needs to understand the

limitations of the company's resources and acknowledge that achieving innovation is a challenge. A potential change of mindset is required, especially being open to other and new ideas. Ideally an eco-system of sharing concepts and knowledge is created. Coopetition will have a negative outcome if management fails to understand the complexity of the issues. Also, coopetition will not lead to success if the partner acquires resources such as employees or technologies by means of the coopetition. These findings add substance to previous studies of Zakrzewska-Bielawska (2015).

Intellectual property management and delineation before coopetition commences is highly important to avoid future disagreements. Frequently no coopetition proceeds if all or the majority of the company's IP must be accessed by partner. The terms of the legal agreement generally are also a potential limitation or motivator for coopetition. This is similar to the findings of, for example, de Resende et al. (2018) and McCarthy et al. (2018).

Table 48 summarizes the critical success factors for coopetition.

Table 48: Critical Success Factors for Coopetition

Conclusions	Analysis chapter(s)
This research identifies the trust involved as 'conditional trust', linked to legal agreements, balance of power and mutual guarantees. That is, the very idea of trust in coopetition starts with agreeing rules and boundaries before the coopetitive relationship deepens.	4.4.3, 4.7, 4.9
Leadership is one of the most critical success factors for both, coopetition and the innovation capacity of SMEs. Leaders are forced to make choices on specific global markets to target, based on EU market regulation being stricter, and to select products to eliminate from the current portfolio based on minimum sales revenues as already described in the previous section.	4.3.1, 4.3.2

The importance of leadership is not only linked to direct decisions regarding the work with a competitor, but also through the creation of a specific intra-organisational corporate culture. Most responses align with a delegating leadership approach because the motivated employees have the appropriate skills and aptitudes. In addition, a high need for agile leadership was expressed.	4.2,3, 4.3.1 and 4.4.2
A flat organisational structure and a small size supports innovation. Beyond, the ideas of organisational structure vary considerably. The conclusion is that in the light of innovation structure needs to be shaped according to the needs of the organization. With regards to coopetition, different organisational structures are an additional potential source of uncertainty to manage, especially if the collaborating company was large and hierarchical.	4.2, 4.3.2, 4.4.1 and 4.5.2
Organisational culture supporting innovation is free-thinking and risk-taking. There was awareness of the resilience needed to work in an SME. The employee culture should be characterised by thinkers and doers. As with organisational structure, different cultures are a potential source of uncertainty or tension to manage.	4.2.2, 4.8
Another critical success factor for coopetition is expertise to deal with the new medical device regulations in the EU. Also, access to one of the limited numbers of notified bodies is needed. In a broader sense the company must understand the implications of changing global healthcare policies and constantly update its knowledge.	4.6.1
Companies need to have access to the human and knowledge resources required for the coopetition. Also, a potential change of mindset is required, especially being open to other and new ideas. Ideally an eco-system of sharing concepts and knowledge is created.	4.6.1
Intellectual property management and delineation before coopetition commences is highly important to avoid future disagreements.	4.4.3

5.1.4 Innovation Management in Medical Device SME

Innovativeness plays a major role in the survival, growth, and prosperity of SMEs, especially in the medical device industry. There was high convergence of opinion in this research that innovation in the medical devices sector is different from that in other sectors. Also, there is a general perspective that it is more difficult to innovate in the medical devices sector, which supports perspectives expressed by Bergsland et al. (2014) and Mattke et al. (2016).

This research found that the perceived responsibility for successful innovation belonged to senior managers alone. More junior managers did not see it as their responsibility, even in an SME. There was agreement innovation not being an accidental process, rather a structured approach of learning by experimenting to find a commercial solution and co-creation with customers and medical professionals. This tends to confirm the theory of Stacey (2010) and Tidd & Bessant (2018), that innovation is orchestrated by leadership. The structured process mirrors both the learning by experimenting to find a commercial solution (Hunter & Cushenbery, 2011) and open innovation (Chesbrough et al., 2006). In the light of evaluating coopetition as an appropriate business model, it is important for management to have a good understanding of how innovation happens within their organisation since different approaches between the collaborating firms may hinder success.

This research found that independent board members with no medical device background could derail innovation because of not understanding the specific dynamics of this industry. This leads to a conclusion of the managerial capability of board members being a relevant factor in the success of innovation and coopetition.

The idea of transferring knowledge from other industries is another interesting and valuable finding of this research. Also, the challenges imposed by the new regulations motivated participants to investigate sustainable practices, for example innovation in single use instruments made from plastic waste. These instruments save users cleaning time, whilst providing a new highly profitable source and less effort because the regulation class is lowered, and certification

made easier. As a conclusion, SMEs should think beyond traditional patterns for solutions as this opens the possibility of low-cost innovation.

A summary of the conclusions on innovation management in medical device SME is provided in Table 49.

Table 49: Innovation Management in Medical Device SME

Conclusions	Analysis chapter(s)
Innovation in the medical devices sector is different from that in other sectors and it is more difficult to innovate. Innovation is not an accidental process, rather a structured approach of learning by experimenting to find a commercial solution and co-creation with customers and medical professionals. It is important for management to have a good understanding of how innovation happens within their organisation since different approaches between the collaborating firms may hinder success.	4.3.2, 4.4.1 and 4.5.1
Independent board members with no medical device background could derail innovation because of not understanding the specific dynamics of this industry.	4.5.2
The idea of transferring knowledge from other industries is a valuable finding. Also, the challenges imposed by the new regulations motivated participants to investigate sustainable practices. SMEs should think beyond traditional patterns for solutions as this opens the possibility of low-cost innovation.	4.4.1

5.2 Limitations of the Research

A severe limitation of this research was the inability to conduct face to face semi-structured interviews owing to the restrictions of the Covid-19 pandemic, a factor which also impacted on availability and contact times with the respondents. The

interviews were undertaken over the video conferencing media Microsoft Teams, which sometimes interrupted the communication flow. Stop and restart was a major characteristic of the conversations, which resulted in the participants substantially diverting the conversations from the main questions. Therefore, the focus of responses was not always well related to the questions posed. In some cases, parts of questions were not answered at all. Hence the timing of this research was a major limitation as participating companies were also trying to survive the Covid-19 pandemic, in which the working environment had altered beyond recognition. In many cases operations were suspended, but firms needed to continue preparations for the changes to regulation.

The restriction of data gathering to interviews is another limitation as qualitative data, subjective views, and opinions, was the sole data source and restricted to 15 firms. A more representative sample is therefore recommended to obtain the perspective of the impact of new regulation in companies throughout Europe, which infers the design and distribution of a quantitative survey instruments, a questionnaire.

5.3 Recommendations for Future Research

The limitations suggest that this research should be extended using mixed methodology, with a representative sample of firms in the EU medical devices sector participating in a questionnaire survey, and additional firms being asked to contribute to qualitative research by means of semi-structured interviews that will complement the current knowledge obtained in this study.

The findings from this research generated several recommendations for further study relating to coopetition in the medical devices sector. A suggestion was made that the quantity of innovation in medical devices might not be decreased by the new regulation but redirected instead, with bigger companies that had more market power being the main sources of future innovation. This has at least two implications: if the trend were to occur, SMEs could be at higher risk for their survival and perhaps be more willing to form coopetitive relationships; smaller companies would be even more attractive targets for acquisition. Therefore,

research is required to identify the major risks associated with larger companies increasing their focus on innovation in the medical devices sector and the potential responses of SMEs to secure their longer-term survival.

Also, the responses in this research externalised many of the fears and frustrations within senior management of medical devices companies currently, providing multiple examples of the tensions, anxiety, and emotional issues the sector is experiencing. More research is recommended to understand the emotional aspects of the response to the major change in regulatory requirements.

One participant in this research suggested that coopetition was enforced collaboration, so that this perception requires further investigation; what are the underlying reasons for this viewpoint and what evidence is there to support this proposal. Future studies might also identify the value of knowledge transfer from other industry sectors to support innovation by medical device companies, so that they are able comply with new regulation, including potentially initiating new cross-sector coopetitive relationships. Integrating sustainable practices into medical device development was highlighted as a possible motivation for coopetition that would generate higher levels of competitive advantage in the context of compliance with new regulations. Since sustainability is of increasing interest in other industries owing to economic, social, and environmental pressures, research into this concept would enhance existing knowledge.

‘Trust’ being an important element of coopetition confirmed existing literature. However, studies so far had not examined the concept of ‘trust’ in detail. This research identified the trust involved as ‘conditional trust’ and specified the type of trust necessary in a coopetitive relationship. More research is required to further explore what specific aspects condition trust and to what extent they determine the success of coopetition. Also, it will be necessary to understand if the impact of conditional trust is the same in all coopetitive situations or case-specific, and if the findings apply to medical device SMEs only or across industries.

Leadership for coopetition was another major success factor in this study but the lack of leadership approaches and identification of key attributes was evident, so that research is required to identify which leadership characteristics and approaches are most important to accomplishing successful coopetitive relationships in the medical devices sector. This is important since legislation changes are frequent in medical device businesses and coopetition is likely to be a growing trend to comply, compete and survive.

'Incentives' surfaced as a trigger to enter and to participate constructively in a collaborative relationship. It remains unclear whether these would be generalised incentives for SMEs or if they are particular to individual or clusters of SMEs. Further research is recommended for this aspect, that was initially addressed in the early work of Brandenburger and Nalebuff on coopetition in 1996.

This research clearly identified consequences of the new regulations on SMEs in the medical device industry but did not measure it. Assessing the economic impact through a cost-effectiveness analysis or an adequate method will help to better understand the severity of the impact. Also, this research applied a microeconomic view on individual companies. Further research will be needed over the next years to evaluate the overall impact of the new regulations on innovation and competitiveness in the European medical device industry.

5.4 Summary

This thesis has answered the main research question: "What are the critical success factors for coopetition that will provide benefits to medical device SMEs given the impact of the new European medical device regulations on time and cost to market?". Also, it met its objectives as outlined in chapter 1.4:

- Review existing forms of coopetition in SME innovation practices
- Contrast existing forms of SME innovation practices to identify advantages, risks, and limitations of coopetition
- Explore coopetition from the experience of leaders and managers of SME medical device companies

- Understand which critical success factors lead to success or to failed outcomes of coopetition in medical device innovation management
- Establish whether coopetition can overcome barriers to innovation in the context of new regulation

The theory emerging from this research and a major result of the study is that coopetition can help to overcome challenges imposed by the new EU regulations, but for coopetition to be a successful business model between SME in the medical device industry, they must overcome and minimise barriers. These key barriers that hinder competitive advantage were identified and measures to minimise their impact in a range of SME scenarios.

The critical success factors for coopetition were analysed and concluded, and one that stood out throughout most interviews was ‘trust’ between the partnering companies. Studies so far have not examined the necessary type of ‘trust’ in detail, this research however identified the trust involved as ‘conditional trust’ that starts with agreeing rules and boundaries before the coopetitive relationship deepens.

By identifying ‘conditional trust’ and other conditions in which coopetition is most likely to be productive for companies in the medical devices sector, the findings from the study have contributed to existing knowledge. The conclusions provide valuable insights for leaders in medical device SMEs, policymakers, and scientific and business researchers.

In addition, this thesis has generated several ideas for further research, which is important as the issue of new regulation in medical devices is on-going, and the industry generally is experiencing transition driven by macroeconomic factors beyond its direct control.

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APPENDICES

Appendix 1: Interview Guidelines & Questions

Guidelines

To explore coopetition in medical device SME and to identify factors enabling or hindering the success of coopetitive innovation (research aim) the following guidelines have been set for the interview process:

a) Data collection will be based on semi-structured, in-depth interviews, conducted one-to-one and online due to constraints imposed by the Covid-19 pandemic.
b) Interviewees need to represent a medical device SME (in line with the "SME" definition of the European commission these companies employ less than 250 people).
c) The interviewees need to oversee innovation management in their respective companies (e.g., Head of R&D, product management, CTO) or have general management responsibility including product innovation, development and portfolio management.
d) Potential participants will be approached personally through telephone and/or email. Given their interest in participating, they will be provided an information sheet and will be asked to sign a consent form.
e) As an exclusion criterion, it will be necessary to select only representatives of companies in which I have no vested interest or commercial bias stemming from my own job.
f) Selected SME need to fall under or apply the medical device regulations of the European Union (beside EU member states this can be Switzerland, Norway, Iceland, and some EU candidate states).
g) Participating medical device SMEs must also be categorized as (i) those having actual coopetition innovation projects or (ii) have collaborated in the past with other similar SMEs or (iii) those which have not really experienced any coopetition endeavours. The rationale for this is to clearly identify factors which may promote or discourage coopetition as an

innovation model or strategy for medical devices amongst SMEs based on actual experiences.

h) SMEs shall likewise be categorized as novice or mature businesses or firms.
i) Information and data shall include all types of innovations from minor to radical to transformative and shall be categorized accordingly to establish which stage of innovation best suits coopetition as an approach or strategy for both technical enhancement and financial advantage.
j) Research and data information shall include both public-funded and private-funded research and development for a wider scope of comparison on factors affecting coopetition in innovating medical device for SMEs.
k) Presented data and information must be categorized as a) used in related interviews in the past; b) an offshoot or an innovation based on previous research or c) new discovery or concept, to guarantee the authenticity as well as novelty and newness of ideas and concepts subject to analysis.

Questions

The interviews aim to address the research objectives identified as:

- Explain why innovation in the medical device industry is different to most industries
- Review existing forms of coopetition in SME innovation and contrast against other, established innovation models to identify upside, risks, benefits, and downsides of coopetition
- Explore coopetition from the experience of leaders and managers of medical device SME
- Understand which critical success factors lead to success or failed outcome of coopetition in medical device innovation management
- Establish if coopetition can overcome problems to innovation in the light of new EU regulations

Based on these research objectives the following set of longitudinal oriented interview questions has been developed:

1. Introduction of interviewee and company
    a. Please state your name, your job title and the name and location of the company you are working for.
    b. What products or services does your company develop and commercialize?
    c. When was your company established and how many employees does it have?
    d. What is the annual turnover?
    e. How long have you been employed by the company?
    f. What are the main tasks and responsibilities in your current role?
    g. Who do you report to?
    h. How many people and what functions report into you?
    i. Do you consider the organizational structure of the company as hierarchical or flat?
    j. How would you describe the management/ and leadership style in your company in general?
    k. Do you consider yourself to be a manager or a leader?
    l. How would you describe your personal management or leadership style?
    m. How would you describe the culture in your organization?
    n. Can your company adapt to new situations? Is it flexible?
    o. Does your company easily learn from new experiences?
2. Innovation
    a. Thinking about the most critical success factors of your company, what ranking does innovation of new products or services have?
    b. Do you think that innovation in medical devices is different from innovation in other industries and if yes, why so?
    c. Who in your company is responsible for innovation?
    d. How does your company drive innovation? Which approaches and initiatives have proven more successful than others?

i. What experience does your company have with Open Innovation?
ii. What experience does your company have with innovation hubs?
iii. What experience does your company have with New Product Development models?

e. From your experience, what internal factors are most important for the success of innovation?
i. To what extend does the organizational structure of your company support or hinder innovation?
ii. To what extend does the management and leadership style in your company support or hinder innovation?
iii. To what extend does the culture in your company support or hinder innovation?

f. What will be the impact of the new EU medical device regulations (Regulation (EU) 2017/745) on innovation in general for all medical device SMEs?

g. Do you see a risk that the new regulations may hinder innovation in your company?
i. Do you think your company still has the financial resources needed for innovation under the new regulations?
ii. Does your company have the required knowledge for innovation under the new regulation?

h. How could the new regulations help your company's innovation efforts?

3. Coopetition
a. Are you familiar with the term coopetition and the concept of competitors working together for a specific purpose?
b. How would you describe coopetition?
c. Do you think coopetition could help to continue delivering innovation given the challenges the new regulations bring?
d. Has your company and/or have you personally been engaged in collaborating with a competitor?

i. If so,
    1. has this been around innovation? Was the coopetition successful? What has been your experience and take away?
    2. Was coopetition applied on incremental or radical innovation?
    3. What aspects of innovation and stages of the innovation process were suitable for coopetition?
    4. What did you find specifically important in making working with a competitor successful?
    5. What hindered the coopetition?
    6. Do you see benefits of implementing coopetition? If so, what are they?
    7. What are the challenges of implementing coopetition from your point of view?
    8. Were changes in your company needed to enter a coopetition?
    9. What effect does coopetition have on your present patents and IPRs?

ii. If not,
    1. Why in your opinion has the company avoided coopetition and not engaged with a competitor
    2. What aspects of innovation and stages of the innovation process are problematic for coopetition and may have caused your company not to use this approach?
    3. What are the barriers to overcome before coopetition would be used by your company?

e. How do you draw, or would you draw the limit of cooperation in the coopetition process to preserve the competitive advantage of your company?

Appendix 2: Interview Responses

Appendix 2a: Coding Master

Position and Company

Question	1. Introduction of interviewee and company		Question product	b. What products or services does your company develop and commercialize?
	Responses			
P1 (Participant 1 includes interview interruptions)	P1: I'm the CEO of [name of a company] and the company is based in [name of a city and country]. the company established 2016 one of the founders of the company Four employees. So, we are doing a drug releasing polymer system that should fit on intraocular lenses for post cataract surgery		**P1**	P1 Yeah, that's true. We're not doing it yet
P2	P2 So, I'm (name of the person), the COO, so Chief Operating Officer at (name of the company), a company I co-founded with four other friends; two friends and two others located in (name of the country). So, the company is committed to design a new innovative bone graft for osteoporotic and bone tumor fracture. So, the goal is just to avoid cavity but release locally a drug to manage the bone disorders caused by those pathologies. So, we are located in south of (name of country), (name of town), north of (name of province). So, we can say that we can define (name of the company) as an early-stage company, not a start-up because we are two years. So, (name of the company) is two years old. We raise money, I think, that's around €700,000 for this early-stage phase. So, we should start soon the industrialization phase for the first product in a couple of weeks and regarding our R&D pipeline, normally, the middle term product should be industrialized probably in three years, something like that, on average. Int: So, you are one of the co-founders. That means you are with the company since 2018, P2: Yep, August. You're right, August 2018.		**P2**	I: Right. So, it is still a development company. There is no turnover yet, right, because you don't have product. P2: We have small sales. Meaning that we sign- yes, we sign a development contract with a Brazilian manufacturer, and we have some turnover each month regarding this development contract but as regard to your question if we sell our product to the market and if we generate some sales, no. Not yet, but fingers crossed that we could do that as soon as possible
P3	So, my name is [name of person]. I formed this company [name of company] 10 years ago in 2010 after I left [name of company]. I started this... So, the company I run employees, 24 people, and we covered all of the UK and Ireland selling mainly niche orthopedic products. So, we have our own design and manufactured line of … We distribute the magnetic lengthening now called [name of product] and specialized orthopedics, which is an offshoot of [name of product] spine. And we also distributed the conformance knee, which is a tailor-made for conformance, which is in the medical... a German ... branch and some of the bits and bolts in Orth biologics and anti-microbials.		**P3**	INT: You are a distributing company, but you're also developing your own. P3 So manufacturing is right, yeah, we manufacture via OEMs, not directly ourselves to our spec. I Company was established: December 2010. 10 years now. And employees 24 now. Yeah. The last few years we've grown 25%, 50% year on year to a point now where we turn over... I mean, we started with nothing for the first two years. I thought it was forever going to be nothing, but now we turnover 5 ...And annual turnover, I believe, you said 6 million. Yeah.

Question	1. Introduction of interviewee and company		Question product	b. What products or services does your company develop and commercialize?
	Responses			
P4	I'm the CEO and co-founder of [name of company] and the company is based in [Name of country]. Established in 2010. 10 years ago. August 2010. At that time, we are four people. Actually, we develop the device internally, but we outsource the manufacturing, mainly the manufacturing actually, but we do the sales by ourselves, and we manage quality and regulatory inside ... the annual turnover of the company Oh, very low. Actually, our first device was a disruptive device to do prophylactic fixation. And we have difficulty to introduce it and the product to treat vertebra fracture in the U.S it should be better. We received our first order yesterday, so it's starting.		**P4**	we developed implantable medical devices for the orthopedic surgery, and we have two products, one hip product to address risk of fracture in the proximal femur. So, it's a reinforcement device to avoid the fracture and a second product to treat a vertebral fracture. So, the product for the hip ... is sold in Europe, Brazil, and Turkey and Jordan and the product for the vertebrae's ... just received FDA-510(k). and we are in process of launching it in the US.
P5	The job title, co-founder. The name of the company is [name of company] and locations, [name of city] U.K. we started this in early 2015.We're currently three people, and So, very, very, very lean. We've gone up to about five, six people over that time, but then gone down with other people doing different things. And the large—and the continuous person through that has been me. So, it's me is kind of I say co-founder, but it's really been me who's been the driving force behind that. So, co-founder, there is somebody else who's had a very big role, and So, I say co-founder, but in reality, it's more being me than them, if that makes sense. But somehow there aren't words to describe that. I: Can I ask for the annual turnover? Yeah. I mean it really is varied. We've gone from zero to years of 80,000 or 90,000, back to zero. I mean, we could—I could probably average it. I'm not sure what it would be on average. Not very much. It's really, it's very lean, semi-virtual, spend as little as we can and be as efficient as we can. If we had lots of money, we would spend lots of money. But I think it's partly, though, a question about what you are trying to build and what is your approach. I'm always pretty critical about what we have and what other people have. And I've got to say, I never felt in a position to take a large amount of or even seek large amount of investment … which seems at times very niche. So, my approach is just to focus on building something of value and use, starting small and just keep building. Eventually, at some point, there'll be enough there, and enough things figured out, I hope, that we will be able to seek investment or not need it. But maybe I think, realistically, we'll be seeking investment, but I hope to get to that point where we can put, I can actually put my hand on my heart and say, "This makes sense."		**P5**	our company is in technical development. It's a pre-launch of products for data and analytics which integrates closely in the medical and pharmaceutical research and development sphere. So, what we do is we develop the analytics package, undertake technology validation collaborations, and then we seek to license out that as a package to other companies. It's something that we develop and then look for partners to commercialize. So, we have to pick some—we have to pick problems which are commercially relevant and that we know there will be interest in taking forward. We have a specific focus that we started with and that's—I mean, I can go into more details about the story of how this started because I think that also would tell you that most—many stories are not straight. That they are very, very windy. Non-optimal is probably a short way. And So, we started off intending to do something completely different and ended up doing this for a number of reasons. And some of them maybe we couldn't foresee—you couldn't foresee at the beginning what we could do, if that makes sense. It's only by going forward did we then see new opportunities. And So, very much like walking through a forest or something. You can't see where you're going So, you go forward. You then see another clearing and you go into that and So, forward. But it doesn't—I'm sure from above it doesn't look very straight. There's progress.
P6	My name is ..... I'm the owner, co-owner of a spinal company named ... and we are based in France. We have been in the medical device with .... for ten years. We have a particular business model which is to collaborate		**P6**	We are a very small company, and we did remain small not by choice but by situation and also because

Question	1. Introduction of interviewee and company		Question product	b. What products or services does your company develop and commercialize?
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	with different actors, either customers or even competitors. That's why the new MDR is making this thing a little bit more difficult, but it does not really change the collaboration we have established before. I would say it was even some—a faster track to accomplish duties required by MDR. It remains small because I'm doing a lot of things. I'm doing sales activity, I'm doing some R&D, and I'm doing the whole quality and regulatory file. I have an associate who's taking care of manufacturing and some sales activities, and we have a full-time engineer who is competent, of course, in design and making drawings and making some particular research of our own material or new manufacturing. But at the same time, we work with a lot of outside content. #00:05:02# I: Right. #00:05:04# B: Because of the business model, we don't need to have sales day-to-day by going to visit surgeons. We work within that distribution through the development of the digital communication. It did reduce the impact of having salespeople on the firm. And we are one-million-euro company, and we have some up and down, but what is today's situation is that there are—the financial cost of regulatory has really exploded in the last three years. The CE mark cost has been multiplied by six or seven. So, it changes the life but in order to survive is also to develop new collaboration with competition. And it's also to do some innovation, and I will detail more what is innovation today in the world or in the environment of the MDR or in any kind of environment. Innovation is not only the big invention on raw material or whatsoever. But it can be a day-to-day operation. Because at the end of the day, it can make actors, surgeons or hospitals or customers to gain time. And time is money Three or four employees in the company. Yeah. And annual turnover is a million. I0 years - When we started, we got it funded by our own money, pocket money with my associate. We tried to get some investors in the past, but I guess it's a different job to get financing with business angels ...So, we didn't success despite the long hours of discussion. But we decided to continue and to take the risk of losing everything. But it was nothing. But we succeeded by making more collaboration with partners.			we are totally private funds. We started the company ten years ago by building spinal implants, because I've been in the spinal market for many years so, for me, it was quite easy. But, at that time, the idea was to come up with some new business model and to do kind of a pull strategy rather than doing push. That means that is to provide to a customer the direct final product ~~all through other customers, that could be competitors~~, by providing a CE mark file, technical file in order to grant the product to the company name. Having them they would own the CE mark by themselves based on my technical file. So, that approach was totally new at that time. We have developed cervical and Lumbar products. In total, we had six ~~cervical~~ implants. ~~Not cervical but a CE mark product.~~ And that strategy was really appealing for a lot of our customers. And even today, there are opportunities, a little bit different from ten years ago, but the fact that we had collaboration by offering technical file was a way to move forward and get much more collaboration. #00:04:09#
P7	My name is [name of a person]. I'm the head of global product management at [name of a company], which is based out of [name of a city]. name of a company] was actually founded back in 1988 And then we went public in 2000. Today we have 28 employees in [name of a country] in our headquarters and the [name of a country]. Since we are a public company, the last published turnover from 2018, was at €6.5 million. I have been employed with [name of a company] since May 2016, though, for the past four and a half years.		**P7**	We at [name of a company] develop and manufacture and also market biomaterials and other medical devices mainly for bone and tissue regeneration, as well as pain management and hemostyptics: All of our products are classified as medical devices class three
P8	So, my name is [name of a person]. I'm 47, I have a background in marketing and sales and the company I am currently in is called [name of a company]. It stands for My Personal Life Scope, four letters. And we started this company late in 2017 in Paris, where we have our headquarters there. So, we have a very small desk there. And we operate mostly with partners outside of the company. Yes. I'm one of the founders and one of the associates as well. I'm a chief operating officer, COO. Currently, we have six employees and approximately 30 persons outside of this parameter work who work for our project full-time or part-time to develop code, to develop machine learning algorithms, you know, things like that. Well, we are glad that we have our first turnovers. Our model is partially consulting and mostly comes from fees. When we deploy our solution, we get, I would say, a number of euros according to the number of patients that we are dealing with. So, currently what we are getting as earnings is the first consulting phases and we're doing our first pilots, but the pilots, we finance everything right now.		**P8**	So, first of all, we are in the healthcare business. We develop a software solution, which is deployed in hospitals and private clinics, and that helps deal with what we call critical patients. And we have our customers make critical decisions. So, by critical decisions, we mean, we are confronted with the full stack of information in hospitals, redundant information, information which is difficult to read, difficult to get at. And what we do, we structure data, and we show it in a way that the actors can make decisions quicker and without hopefully making too bad decisions, which can hamper the health of their patients. And our current business is in oncology. So, we are equal device, which is something which stands

Question	1. Introduction of interviewee and company		Question product	b. What products or services does your company develop and commercialize?
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				quite critical against what our competitors are doing, which we'll talk about it afterwards.
P9	My name is (name of the person). I am the CEO of (name of the company). (Name of the company) is in (name of the street) located in (name of the city) The company was established in the beginning of the 2005. It was founded by (name of the person) who was formerly employed at (name of the company) and he was in the development department there and he decided to follow his ideas about bone substitution materials by founding (name of the company) and building up own business. And so, (name of the company) started as a real start-up here in (name of the city) and it was started in (name of the city) because there was a previous collaboration between (name of the company) and the technical university and I think they have also some funding and so on. And so, it was started in an incubator in (name of the city) with a conventional start-up process by collecting money from some private investors and in the first time, focused on pursuing funded development projects with the technical university and other partners. And when after about ten years, the focus or the main ideas were identified and the gap-the product ideas were identified and when it comes to building up and manufacturing, the company decided to go to (name of the city) which is near to (name of the city) because here in a so-called farmer part, there was base for installing a premium area with a manufacturing level and, of course, offices. And we are here since 2014. Yes, we do have 100 square meters screen room, some laboratories for R&D and also all the administrative infrastructures. Currently, we are nine employees. The annual turnover is in the range of €1 million. I was with the company-Well, I was related by when I was employed at the techno university. We have some research projects. This is where I started my contact to (name of the company). It was project-based. After that, I had some time when I was with (name of the company). It was a Swiss company where I was in the management board and then (name of the person) decided to yeah, to retire and he was looking for somebody who could do his job and then he contacted me, and yeah. And facilitated to get me here to (name of the city) and I'm here from 2014. But we started as head for R&D and production, and I'm CEO since the last year.		**P9**	we are working on bone substitution materials. So, we do develop such materials, we manufacture these materials, and we distribute at a low level. Mostly, our distribution is handled by more pick-up partners.
P10	So, my name is [name of a person]. I'm a co-founder and a partner owner of the company. We are located in [name of a country]. Actually, the company was- We started in slightly different form than we are today. We started I think 2001. And then until 2005, we were working under a very basic structure, I would say, and being active on the local market. But since 2005, when we have signed a contract with two global distributors, we've changed the organization structure to current one. And globally, from 2005, we distribute, we sell our products. Initially it was on the OEM basis only. So, under our own brand name, we were selling our products designed here and manufactured here in [name of a country]. We were selling only in [name of a country]. Outside of [name of a country] we used to have two global distributors for the work. It's somewhere between 25, 30. I don't precisely remember. We are between 25 and 30 of full-time employees at the moment. annual turnover It's about €3 million. It is. It's 18 years, 19 years. Actually, I started to work full-time for this company probably in 2004, 2005, I don't remember precisely. Because before, I was still working for some big international corporation. So, it was like I was working a little bit here, a little bit there, and until the moment I decided I have to		**P10**	We develop and manufacture medical devices for optometry/ophthalmology. INT: you are developing, manufacturing, and commercializing? Correct.
P11	I am the Chief Operating Officer of [company name1], a spine company based out to [location1] area, in [location2]. established in 2005. We are around 240 employees globally now. annual turnover. Yes, I can't give you an exact figure, but it is between 70.000$ to 100.000$.		**P11**	We have an almost full range of spinal implants, systems and kyphoplasty systems. So, very little biologics, so far. It is nearly mainly implanting.

Question	1. Introduction of interviewee and company		Question product	b. What products or services does your company develop and commercialize?
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	Well, it is still not one of the big players. At company since November 2019.			
P12	so, my name is [personal name]. I am the monitoring director of the [company name 1], which is the [company name 2] health care solutions in Europe, Middle East, and Africa. And I am located in [location 1]. So, the [company name 1] was established two years ago, 2018, beginning of April. Or when [company name 2] acquire my company, which then transformed into [company name 1]. Before it was acquired by [company name 2], established originally January 2015. INT one of the founders you were there from the beginning? That is 42 employees. Last year the turnover was I think something like-two million was last year		**P12**	[company name 1] is actually only producing or developing only one product at the moment. And that is [product name 1] system. You want me to describe the application? Yes, it is a data monitoring system for … And it is a medical device. It is classified as a medical device. Yes, it is currently class one medical device, but it will be class two quite soon
P13	My name is [Personal name], I am senior manager in [Company name] in [Place name1]. My job title is [senior manager for quality regulatory issues], and I am part of the development team for [ultrasonic based implant placement in bones]. The company is now on the market m, longer than eight years. The development goes on for more than eight years. On the market, there is only product in the [Place name2]. We have [Product name2] market clearance for a (? pedicel) screws in the system using the [Bone welding technology] to fix it, the screws in the (? pedicel) using [bio resolvable polymer]. We are right now eight full time equivalence at that very moment. Right now we have actually no sales. We are developing company, and financed by investors, we have some clinical trials running but there, we do not charge for the implant, so we do not generate any revenues with our [market clear implants] yet. I am employed since half a year and before that, I worked on a freelance bases for more than one and the half a year, so I am with the company for longer than two years now.		**P13**	Company name1] develop [Product name1] which are fixated in the bone with the special fixation technology which is called [Bone welding]. It is an ultrasonic fixation of polymeric implant in bone. Ultrasonic energy is supplied to a polymer, the polymer is liquefied, the liquefied polymer enters the trabecular structure and hardens again. Which gives immediate fixation of for instance metallic implants, but also stand-alone polymer implant is fixated in bones using this technology.
P14	My name is [Personal name1] I am 56 years old, and my job title is [manager for product-, new product and sales], product innovations and I am working for the company [Company name1] in tootling and [Company name1] That means [Company name1] as contract manufacturer has no implants or instrument as well as set configuration under their own [Product name1] mark or [Product name2] registration. We are working only as contract manufacturer. It is a family-owned company. And the company was established in 1954. Now it is set generation. At the moment are around 40 employees and for all positions in the company. The Annual turnover is around [six million euros]. Now three years here at [Company name1], and for about three years I have been working here.		**P14**	Specialist contract manufacturer to provide new and innovative ideas for the customers worldwide to manufacture implant and instrument. Also, complete-, set configurations for surgical instruments, most indication as a spine and orthopedic and trauma. And we are manufacturing all these things about the ideas from the customers, all the instruments are customized.
P15	My name is [name of a person] and I am the CEO and co-founder of the company [name of a company] It's located in [name of a city] Germany. The company was established in 2018. We are five employees with the founders, and we are working also with freelancers … Turnover It's not a secret, we are about- at the moment 300,000 Euros. I: Okay. So still in the start-up phase Yeah. Experience is also from the past, from other companies working as a consultant and we said, we two work well together and let's found a company. And so, we merged everything together.		**P15**	We are a software development company, and we are doing a lot of web application development and also cloud services development and we help with e commerce and a lot of different businesses, retail. And we also have product to support businesses processes in the web … And this is also where we have connection points to the medical business. Int. you are not per se a medical device company, but your software is utilized in medical device? Yeah, it's true. And with some experience in trying to also cooperate with medical device manufacturers by explaining to them what we do. And then I'm also

Question	1. Introduction of interviewee and company		Question product	b. What products or services does your company develop and commercialize?
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				aware where the problems are and where the thinking are and doing things especially when you're going a new direction.

Key Responsibility

Question	How would you describe the main task and responsibilities in your role?
P1	P1: raising legal and we also do like all the IP stuff, and I think I do all the collaborations, so who we need to work with in terms of the regulatory consultants right through to 3D printing people and cell culture experts, everything like that.
P2	I'm in charge of the operation. Meaning that like a project manager, I follow the project or the product at each stage until the launch of the product into the market, but I mainly focus on the development. So, I'm working with our three researchers. I don't practice or I don't perform any testing because again, I prefer to manage and I'm better to manage against performing and testing, but my main role is just to manage the development and the industrialization of all of our projects. So, the first one called MG225 and I'm doing the same for the exploration of our mid-term project of our pipeline. So, operation, so meaning that I'm managing the project and the people from scratch to the end and I'm in charge to manage the exploration of our key project of our pipeline. So, mainly development and marketing. I try just to decrease the link between marketing and the development. INT: Okay, thank you. And you are reporting into- are you reporting into someone? **P2:** Yes, to the CEO. **P2:** So, the co-founders, the CEO and president called (name of the person) and yep, that's it. INT: And as I understand, it is a small company. So, are there any people reporting into you? **P2**: Yes. So, three, four, let me check. No, four people, so three researchers and the regulatory affairs manager is reporting to me and regarding the supply chain, we have decided to cut in two parts: the management and the reporting. So, regarding the logistics, the guy- so (name of the person) is reporting to (name of the person) and regarding the purchasing is reporting to me. So, we try to get in two parts as reporting.
P3	Well, I'm now chief executive, you said my job title, not that there's anything in a job title. My title is chief executive. I was formally the managing director, and I started the company, but we soon joined... we were a two-man outfit. I was sent here by my business director from [name of company]. And he's now the managing director. I've hit the ripe old age of 65, so I've now stepped back, and I did two or three days a week. Mainly see the accountants, but I also tend to deal with the upstream, so the suppliers and the international OEMs tends to be who I deal with while [name of person] is in charge of all internal Salesforce office warehouse administration. I'm face to face with surgeons. I see the old surgeon, who is still alive that remembers me. Otherwise, it's all down to the youngsters to do the selling and the negotiating. INT: So, does that mean there are still people reporting into you or is this now all with the new manager? Mine is purely an executive role. [name of person] is responsible for everyone in the company. And I even stepped back with...if people come to my door, don't speak to me, speak to [name of person]. So, I don't get any hustles
P4	Various. Main tasks raise money. I: So, doing everything. Yes, of course. Everything ... Yeah. Mainly because last year we were 10 people and now we are four, so and we have to do the same work.
P5	Maybe I'll try and rephrase it for my own use. What do I worry about and spend my time worrying about and doing? I spend probably about dominant roles are looking for partners and setting up partnerships. Then second to that, it's technical development and carrying out partnerships: And over time, I know—those two main activities I would say take up about 95% of my effort. So, marketing, zip really. Zip. Five minutes here and there. Just building a website overall over five minutes, really, a day kind of thing. It's really not been much. But focusing on technical development, delivering collaborations, which I would roll those two together because the collaborations are really about validating what we're doing, and it feels like very similar work. There's a lot of software coding there, there's generating reports from data, there's having to figure out a lot of things that we don't know how to do. Whereas obviously building collaborations there's a lot of networking, getting on phone calls with people now, visiting and just trying to follow out where we see a

Question	How would you describe the main task and responsibilities in your role?
	mutual interest. And some of some of that I think has been part of the learning, what works, what doesn't work. I think we—because I think what I've said is we're in technical development but we're at this kind of boundary where we can take fee paying work in some cases, but it depends whether there's just the right match between what we're doing. And again, our focus really is technical development So, if we're doing fee paying work, it's to survive not—it's got to be the right match. So, just be careful on terms of business. Make sure we don't inadvertently create a minefield for us later. That's something that definitely is obviously a concern. I: is there still someone you need to report into? An investor or something? No. You might say we're working with—sometimes it feels like that, right? Because people maybe something's finishing up or something and it feels like you're working directly for somebody. But in official terms, no. It's all—all the equity is owned by us and so, we answer to ourselves.
P6	int: And your personal main task and responsibilities, you said that's quality and regulatory and… Yeah, because today, this is—and ten years ago or 20 years ago, quality was not a part of the strategy. Ten years ago, it started to become, but it was not the number one worries for our top management. But because of my past experience where I did work in the manufacturing business, I knew how to do improvement in the quality process. And just from the raw material selection you can gain a margin. You can improve a lot of things. And if you have a good quality system from the beginning then, when the product is finished, you don't need to provide a lot of control because you have established control all along the process of the manufacturing. So, it's another way to do innovation. Innovation is not what you can see at the end on the table. Innovation is part of what you implement into a manufacturing process. So, regulatory started to be more difficult to assess in the year 2016. And with the application of the MDR in 2017 to 2018, all notified body were already in the state of mind of the MDR but without having all the data, all the elements for them to have a fair and objective evaluation of the clinical data that were presented to them. They were more on the defense approach. So, they were making—doing a lot of non-conformities as beginners and not as expert of medical devices. And those errors or incompetency of those notified bodies do cost a lot of money to companies. Because the cost of non-conformity it takes them 10 minutes to make the invoice at 2,000 euro just to review the technical file, but it takes them three months or six months to review the answers of the non-conformity. So, then you are not making any sales during this time. That's why important strategy has to be implemented around regulatory. And before starting to develop the design of a product, you really have to understand what's going to be asked in the technical file. What can you provide in the technical file?
P7	I'm responsible for the global product marketing and management as well as the business development. I report directly to the head of marketing and sales. There have been people reporting into me, but due to the COVID-19 pandemic situation and an ongoing insolvency proceeding, currently only one assistant marketing manager reports directly to me.
P8	The first task I am working on right now is everything that has to deal with the CTO function, chief technical officer. So, I've been in charge of designing the architecture of our solution. I've been in charge of all, what we call, the back end and front-end development for our software, in parallel dealing with all of our partners, mainly technological partners. So, we have issues in interoperability, in cloud, in well, a lot of technical bricks, which we needed to bring along or to develop internally. So, I've been in charge of this just to get to this phase where we have a pilot product, which works. And one of the first tasks we'll have to do is hire as a full-time CTO in the next coming weeks. So, I'm working as a CTO and also, I'm coordinating everything that has to do with our solution, for the next coming months, deployment, training, getting information feedback from the users, et cetera, et cetera. INT Sounds to me like innovation and development is really your responsibility at the moment. Indeed. Yes. INT: And is it just you do you have other people who support you with this? I'm working a lot with people on mission basis, people who are outside of the company. So, let me talk to you a little bit about this. First of all, we're working with two larger lawyer firms on issues such as intellectual property. So, it's on everything starting from the UX UI and the design, but also a logo image up to the code. But our policy today is not to officialise any code or any machine learning algorithms, because if you do so, people tend to see the way you work. And we try to keep secretive right now. I am also working with a firm, which does some sort of a reverse engineering. You know, we benchmark a lot of our customers and what we do, we have hired a company which looks at what our competitors are doing in terms of intellectual property. It's very helpful because it allows us to understand where they're putting their money, their R&D money. And it's also interesting to see if on some issues that we're working on also ourselves, if there is potentially the possibility to do some intellectual property because sometimes, they find out and we also do that. It's not worth putting the investment because you don't get any protection. So, we do that. And we also are working with the company, the name is [name of a company]. It's a major actor in [name of a country]. I don't know how it works in [name of a country], but we have we have something going on, which allows companies, small, middle, and large companies to get some cash back when you do a lot of R&D or innovation. But you need to do it in a specific way, you need to give a lot of information to the state and say, "Okay, on this specific project, we can say it's R&D because we can prove that nobody else has developed it prior to our work. And also, we can say that there has been this many hours of human power, mainly engineers, working on the subject." So, let's say we have invested 200,000 euros on this project this year, well, the state gives us back 60,000 euros the next year. But you need to do a lot of administrative details.
P9	Okay. I think, what is important for me is to have this really strong relationship to all the development and production processes. Basically, I'm an engineer. So that means I'm familiar with all the processes that I'm shifting from a CEO which was in this role, I was involved in nearly all production processes and development process and handling and

Question	How would you describe the main task and responsibilities in your role?
	managing all of that and I think, for two years, I'm more shifting to from reducing or this operating staff in R&D and production, and going more into all these administrative processes which, yeah, the CEO is responsible before. So, this is also again related to (name of the person) retirement which was not strong cut. It was continuous producing the responsibilities and so, this was the process which was I think over two years. So, now we have the situation that he is completely out since a few months and so I have to realize that it is not possible to pen all these practical staff in the R&D and production. It means at the lower level. Lower level means the first floor because we are in the second floor here. So, yeah. It is something like a shift
P10	Mostly research and development and sale of products. There's two parts. I'm less involved in let's say manufacturing process and some other processes. I'm mostly focusing on R&D and contact with customers, selling the product. I: That's a very interesting combination. Yeah. For this industry it's quite- I think this is, interesting is one thing, but the other, it's important because the end user here, the doctors, they have some very special demands and requirements. So, sometimes you have to speak their language, and this is not common for many people in the industry. And also, for the sales team, they are focused a little bit differently.
P11	I have several heads. One of them is Global Operations, end-to-end. Second one is Commercial Business outside US. Third one is Global Compliance, Global Medical Programs and Global Marketing Operations. Everything from MarCom to communication, to Digital, to events, to market insights and I have also IT, Global IT. I am reporting into the two Co-Founders and CEOs. Reporting to me Roughly, if I am not mistaken, maybe around 80, 90 people. You know, or a bit more
P12	My role is to lead the [company name 1] operations, including sales, development and then deployment. As well as maintenance of software business. So, we produce applications to global deliberate or global distribution. We all sell and delivery only in main region, where we use [company name 2] and other dealers in the actual deployment phase. And also, of course, in the sales phase. So, the core of the operations consists, which is under my direct supervision, of the sales or sales network management and then product development and operations, which is the deployment, maintenance and health task
P13	I am in charge of developing [regulatory path base] to market clear the product in the [Place name2] or in [Place name3] and also in other emerging markets like in [Place name4] and [Place name5], but that is not the main focus. The main focus is first [Place name2] and then [Place name3]. That is my first goal. So, all developments go through my hand in a very early stage, in order to first of all come up with [market clearance strategy], and second of all then be part of the development team in order to guaranty a regulatory compliance, and the feasibility of the development ideas starting from the electronic components to the bio-mechanic components-, the whole rang. Including biocompatibility, clean ability, which sterilization method is the right sterilization method, but the effect does not help, and all that is part of my duty, and I am part of developing this. I report to the CEO directly.
P 14	As the main responsibilities and task that I am in the contact with the customers and I am getting directly the emails and phone calls from the customers when there are searching for new instrument and innovation and, we must develop, present these ideas and must propose some new drawing or draft. So that they can see what we will provide to them. And also, the second point is that [Company name] will develop themselves a little bit more, in this line that we provide directly to the customers complete set configuration or (? deplumate) some proposals from instruments for some special approaches in this (? binary) fields so that the customer can order it and directly this instrument at [Company name]. Report to the company owner. To the CEO [Personal name2]
P15	Right at the moment-and I won't to change this. I would do the usual CEO work and also sales and things like that but also the development. And we have a concept in our company that every day we switch who's responsible for all the others to be contacted. So that me and my co-founder, we have touch points at every part of our company. And so that we don't lose this, especially software development is a skill that is very- that should be maintained because it's very important.: So I do everything but my partner too and then we have people to help us with … and (work).

Organisational Structure

Question	Do you consider the organisational structure of your company as hierarchical or flat?	In Vivo Codes
P1	I'd probably say hierarchical actually. Definitely to some extent because we still have a chairman and a board to report to and then I would say there's now current new employees that we've taken on that report to myself and [name of a person], if that makes sense. So, yeah, there is a slight hierarchy. It's not probably as big as a large corporation, but there is **some sort of tiered system**	1 "some sort of tiered system" (OS)
P2	I would say it is flatter and again because it is **an early-stage company. So, we are only one floor and two guys on top,** but it is quite fla**t**, I would say, and we like to give the opportunity to all people to be **free on their way of thinking** and making decisions	3. early-stage company 3a "we are only one floor and two guys on top "
P3	Well, we don't have to keep it flat. Everybody's got tightness, but this what's in the title. For instance, I was in the office put up hand sanitizers yesterday. Y**ou know, we do everything** with...I've, obviously, when we started off, there was me [name of person] and the secretary. So, we've done everything from put up the shelves within the warehouse, creating the warehouse and all that. But now we have warehouse people and Salesforce, etc. So, **the structure is me**, in my chief exec role, seeing the accountants and seeing the OEM suppliers. Underneath me, **not underneath me, but work alongside me because [name of person], I gave equity and me and him are the only ones who possess equity in the company**. I own 60% and [name of person], 40%. And he then has a sales director plus anything that looks after the Salesforce and an office manager who looks after the office and the warehouse. But we also have a warehouse manager in charge. And so that's the three people internally in the warehouse then there's four or five people in the office and there's 12 in the Salesforce, shortly to be 14 because we've got some vacancies, and somebody just left and then there's the sales director and the managing director. Fairly flat. INT Sometimes it's surprising how hierarchical even small companies can be. We tried to be, you know, because we're from the same background as you did, we tried to be **as little as corporates as possible**.	1 a "not underneath me, but work alongside me" 2 "we do everything" 2b "the structure is me" 1c "as little corporates as possible"
P4	Flat	
P5	Flat. I would—that's driven by experience of companies that I've worked in and been involved with, and particularly if you're aiming to build a company for growth. I don't necessarily mean flat as in everyone—no one's—there's no clear leadership on making decisions, because **I think you always need clear roles, responsibilities and clear person where the buck stops with, who has to make the decision.** But if you're looking to grow a company, to me what's really, really important is to have the "For me, I think it is possible to do it with a hierarchical culture but just So, much harder, because the moment you bring in that rigid hierarchy that there becomes, you're-better-than-me attitude. And you are always fighting that. And the moment you lay it on paper and put an organogram together and say, **"You're at the bottom. You're at the top," you've set into stone a set of representations about value and worth**. To me, that's not about **collective shared responsibility and objective**. That actually starts breaking apart that. And it's not to say that you don't need people—you know, clear lines written, clear areas that people are responsible for, but the idea of putting in hierarchy, strong hierarchy simply if you're in a start-up and small companies I strongly go the other way. I've seen the backroom bitching from people who are kept out of the senior roles and how corrosive it is. It quite honestly brings down companies. I don't—I can't see anything more important than getting the team and culture right. If the technology's junk, you should find that out quickly and find something else and start running with that. But if the culture is junk, you should shut the company down and break it apart and send everybody in their separate ways. #	1b "I think you always need clear roles, responsibilities and clear person where the buck stops with, who has to make the decision" **5a"we like very much to interact with either insiders or outsiders of the company"** **5b "collective shared responsibility and objective"**
P6	Flat	
P7	is definitely organized in a hierarchical structure, in the top-down management structure.	
P8	We share a lot, and we make collective decisions. That's for sure something which I can highlight. And for instance, my associate with the current CEO, who has most of the shares, he speaks with me on all the subjects, and **we like very much to interact with either insiders or outsiders of the company because there's so much at stake.** And it's very, very difficult in our	5. "There's so much at stake" 5a "we like very much to interact with either insiders or outsiders of the company"

Question	Do you consider the organisational structure of your company as hierarchical or flat?	In Vivo Codes
	business to keep in touch with all the evolutions, all the innovation. There's a lot of marketing going on and we need to make our minds clear, you know, because some speak very loudly, but do very little. Or sometimes about technologies, but they don't know how to make it work in the business. For instance, you know, a lot of companies are talking about blockchain. The blockchain, you can see it as a technological brick in healthcare and very large in multiple ways. If you're a pharmaceutical industry, you might want to utilize a blockchain solution for counterfeit reasons, you know. Within [name of a company], within our company, we use blockchain not as a token or you know, financial incentive, but rather to bring about some quality issues. So, there's always a specific perspective, you know, technology itself is nothing, it's mean. And then we'd like to discuss how we do it. So, coming back to your question. We talk about everything, and we make decisions based on facts and what we believe is true. And we stick to it. We've made some bad decisions with my associates, but that's life and we try to make it up afterwards.	
P9	INT: All report to you employees? Yes, indeed. Indeed. And the path we had that something like a department structure, but we moved all of that. I do have installed a small management team. Management team means that I'm with (name of the person) and (name of the person). **We three** do cover all responsibilities or legal responsibilities which are important for a medical device manufacturer. That means (name of the person) is responsible for regulatory affairs and clinical affairs. She is also the safety representative of (name of the company) and on the other hand, there is (name of the person) who is the quality manager which is, of course, a principal position for a company like us and yeah, financial, human resources and so on. And that means, we thre**e together, we consider as a management team which handles and, of course, responsible for all signatures and all our responsibilities covering all which is related to the company.** Flat Yes	2c "we three together, we consider as a management team which handles and, of course, responsible for all signatures and all our responsibilities covering all which is related to the company."
P10	Flat	
P11	I think it is quite flat organization. Relatively flat	
P12	The sales function is about-. Well, it is actually sales and marketing, but we just handed over the marketing part, which was two people to global marketing office. Which means that we have only sales. Which is five people currently. And the product development, which is about three people and in operations, which is 15 people. Roughly. It is quite flat, which is very common in [location 1]. So, **in one room maybe we have monitors, who run the functions and departments. But no other layers in between**.	1c "one room maybe we have monitors, who run the functions and departments. But no other layers in between. "
P13	Yeah, the developing team reports to me, means the bio-medical engineers, the specialist, the clinical specialist, all report directly to me. I think we are a very typical development company in an early stage like a start-up, even so we existed longer, but we have a very flat hierarchy in one way, in another way we have a (? real) u**nstructured collaboration system** still like I said it. It is **comparable to start-up** situation. The regulatory compliance is giving but for existing quality compliance like [Product name2] compliance was ignored, and this is established since now for 7 months, we work with a more structured system. Before that, it was completely unorganized, now we have a little bit more structure in the system, means responsibility but still, we have a flat hierarchy.	"unstructured collaboration system comparable to a start-up"
P14	INT Is there any team member, any employee reporting into you? Yes. There is two people from the development department, and from the product management. They are reporting to me. It is a flat structure Iwe have in the whole company there are short ways, and it is very easy to speak to each people in the company and to organize directly meetings when we have some corrections about a project or some specific question for manufacturing and this is organizing **in a very short steps** and is easy to organize it also.	Id "organize in a very short step"
P15	Yeah, it's- but this is a nice concept I think because I'm tending to do more sales. My partner tends to do more development because he is younger than I am. But every one of us is interested also in the other part. And so, we said, let's do this switch and then the other one can concentrate for the day and do deep work and is not interrupted and this works very well for us.	

Management and Leadership Style

Question	How would you describe the management and leadership style in your company in general?	In Vivo Codes
P1	Oh gosh, that's an interesting one. I think it'd be very **open,** if that's anything. Like, I think we have quite open, honest discussions, debating problems that arise in the company every so many weeks. So, we have operations meetings every three weeks for everyone to attend, which we very much like everyone will send what their issues are, we put them through on an agenda and we work through it all once every three weeks to make sure that we can iron out any of the problems already. So, I'd like to think that we were fairly open, if that makes sense	
P2	It is funny. I think that I spent a lot of time to answer those questions for the last 24 months during my MBA. So, interesting to answer this question now because we have spent more time from the beginning. So, I would say we based our leadership on one value, I would say. **Empathy** and we want to understand exactly why people are saying or answering question or solving their problem by **trusting them**. I mean, it is funny because we have mixed about age, for example. It is completely mixed. We have young people and old people and all of them, they try just to describe during board meeting, for example, their issue by answering the reply they have to solve their issue and what **we try just to give them the opportunity to manage their problem and their solution by themselves.** And if they are stuck with the problem, of course, we can help them but what we want is just to be sure that at the end, they don't need us to solve their own issue and t***ry to set an open innovation philosophy*** because we are sure about one thing, we are specialized in one area and we cannot hire the expert or all of area we cover: biology, physics, chemical and so on. And so, what we want just to be sure that regarding the way we set the leadership at (name of the company) is just to **give the power to the people** and to trust them because at the end, they took a lot of risks to join us and to jump in the (name of the company) boat. So, this is the way we work with them.	6. "Give power to the people" 6a "trusting them" 6b. "give them the opportunity to manage their problem and their solution by themselves" Traits 7a empathy
P3	I'd like to say it's an open, flexible, and very flat. You know, we're all... nobody knows everything and the warehouse guys. And though we've all done the warehouse job, but it's now much bigger than when we started off. And so, you know, we now have Sage systems, and we have all these reports, etc., to do whereby we just go with the warehouse and pick it up by and we start it off. So, everybody has a role and responsibility, and everybody talks to each other. **If you've got a problem, all doors are open**. There's no, go and see him, go and see her him, then get to me or get to [name of person]. You can go to... and you can read this up straight away and say, I've got a problem with this kit being delivered. I've got a problem with this. With the stuff coming in from abroad, can you source it out? Can you get involved, whatever? Otherwise you'd say to them, .ou contact, ... so that you know what the problem is. It's flat and it's **open.**	8 "If you've got a problem, all doors are open" 7
P4	Since the beginning, I have involved the employees in the process of what is building a start-up and what are the difficulties, what are the requirements, etc., what are the needs in terms of fundraising. So, I was program manager before, so I try to manage my company as a project and with a lot of **communication**. INT: Good communication. So, are you open and transparent with your team? Maybe too much.... because people don't care. Some people don't care. I: But you never know upfront? B: No.	7b "communication"
P7	Well, I would say that it's a very classic top-down management structure. We of course do have steering committees and meetings where other, or the lower structures are involved, but the **decision making clearly comes from the board of directors and the CEO**	8a "the decision making clearly comes from the board of directors and the CEO"
P8	I would say, I don't know if the word exists in English, **collegial.** Does that mean something to you? Let try to find a good translation. Just a second. Collegial. Well, yeah, it seems to exist also in English. You know sharing, but for sure, what's interesting is we're very agile and we make very quick decisions indeed. But based on facts. For instance, I spoke about we are working with a lot of partners outside of the company. We do tenders for everything that we-, every decision we make. So, it's based on evidence, it's based on what the partners are giving us in terms of information.	8b "collegial"
P9	Can you give me a hint what you are looking for? Leadership style means, of course, you can imagine we all are quite young people. So, there are no stretched hierarchies and yeah, all to us are **open**. Of course, we have some regular meetings but in principle, yeah, we go to the other office to get things discussed. So, it is really open and really focused on-streamlined. So, it is the same is true for the other employees. So, when there is something to be discussed, okay, they do not have to wait until the next	7. "open" 6c. "Typically, we do have a discussion with a consent which makes everybody happy and which in most cases is the best solution"

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	official meeting or so on. We are close together here and things are handled immediately. I: when you think of decision making, do you think decisions are made bottom up, so it is more coming out of the discussion of all of the people, or it is top down? Yes. I think something in the middle. Of course, for me, it is important to hear all the opinions. I do not decide by goodwill. I do hear all the opinions from all sides in principle. Of course, it depends on the matter and up to that, so far, we every time found a good agreement. So, it is very-in principle, it does not occur that I make a decision over somebody else here**. Typically, we do have a discussion with a consent which makes everybody happy and which in most cases is the best solution**	
P10	I don't know. It's such a small company, and sometimes I perceive the atmosphere inside the company as kind of a team working because we really spend a lot of time working together trying to come with some nice, interesting ideas. Of course, this is mostly related to R&D because when it comes to sales, marketing, and so on, then it's definitely there are people who are focusing on those tasks. The highest number of employees in my company, almost highest, are involved in R&D, because we have probably equal number of people working in R&D as people working in the manufacturing part. So, it's a bit unusual for me. And the management style, I don't know, it's kind of very **cooperative** I would say. It's not that- **Of course, decision making process belongs to me and to my brother, so the** owners. But in general, it's quite free communications with the company. And it's a lot of ideas is coming from the people.	8b, 8a
P 11	I think, you know, it is a company evolving from- I think we are at [company name1] 3.0 now going from initial, which was really a small company start-up, right? Then phase two was, when we got our first private equity. And now phase 3, we become really, with the global footprint, we have our second private equity, that just came in. And we are trying to structure it in a way, that we can definitely drive profitable growth, right? Since there is a lot of organizational readiness that we have been working on. Driving efficiency, more professional level. Being able to attract better talent and (? retained) talent. I think now we need to go from level two to level three, which is becoming much of a structure, the company will delegate to a stronger delegation mindset. And last, concentration of responsibilities and decisions in the few people in the organization	
P12	I would say it is more **mentoring orientated**, rather than hand on management. So, I am **trust**ing very much my managers to run the operations. And of course, then having quite a connection with them	6d"mentoring orientated"; 6a
P13	As I said, we are very developing-, development orientated, meaning there is no-, not much thinking about how we can market the product or how the market should be. How the product should be brought to market which makes it sometimes difficult, because the focus is on the developing of the technology, but part of the implant with new regulatory requirement is packaging, is sterilization, is labeling. Other marketing brochures, the instruction for use, the intended use, that all comes-, came into consideration at a very late stage, which made the way to the market for the developed device very very difficult. In the last six months, we tried to change this, but it is a still ongoing process because the mentality changes not fast. It is a long process. INT way decisions are made, is it more top-down or bottom-up or is it kind like a group discussion or decision … The last six to eight months, it is really a discussion. Meaning the development team comes up with the suggestions, they **discuss it with the C.T.O who is also C.E.O, a**nd then we come to a conclusion together based on inputs from different sides. But before that, it was not like this. It was a very spontaneous decision making by the management which contradicted-, each decision contradicted another one changes where on a weekly basis, because focus changed and that made it very difficult to focus on development pathway. And now we have a **little longer perspective in doing what we are doing.**	6c; 7b
P14	The management style is that the-, How should I describe it? The CEO is asking many questions to all the departments in the company to have the overview you of all the scene and also, the CEO is working directly-, he is not directly managing everything. It is an **open** structure and also the CEO is working directly in the department-, internal department for the product specification and configuration also so that he has the **complete overview of all others** and can see all the manufacturing steps so that he has every time at right, timeline and information when, which project will be ready. I It is, the mostly time it is a group decision. We are discussing every project before we are starting and during manufacturing process, there are also some discussions, and we are deciding every single advice on group decision.	7; 6c
P15	It's very **open** and we are not trying- especially because we are only five people but also our freelancers and so we don't try to have any hierarchy. We know that there is someone who must be responsible, and that sometimes- for example we have also now an intern. Because he couldn't get a job during the corona phase, he did his master's thesis and he is now done with everything and then came corona and he had no	7; 6b; 8; 6;

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	experience and we said, yeah you can work with us. It was a good example because he-we said you can talk to the customer; **you can organize everything,** and he would always be asking us for permission. And this is I think a normal phase in the beginning. But this is also our style, everyone should try things. If **he is not sure, he can ask** but w**e push people to the edge, that they are doing something, to gain more trust in themselves**.	

Leader or Manager?

Question	If you find that an interesting question that maybe this one is even more interesting: do you consider yourself to be a leader or a manager?	In Vivo Codes
Part a		
P1	I would probably say a manager.	
	Yeah. I feel like everything is just an extension on project managing, like my job is **to make sure that everyone comes into deadline on tim**e, and we work it through, really, I'd say. I just think i**t's a big extension on project management**, really.	9. "it's a big extension on project management"; 9a " to make sure that everyone comes into deadline on time"
Part b	INT: So, how then would you describe your personal management style also like you described the general style in the company open or would you describe it differently	
	P1: I'd like to hope it was pretty **open**. Yeah. Personal management style, yeah. I think I ask a lot of people what they're thinking or what their opinion is a lot of the time probably too much, which is a detriment to be perfectly honest because sometimes I probably should just go with what I think and get on with it. But yeah, we do ask quite a lot what people are thinking, especially like	7;
P2	I would say it depends. I'm between because I know for sure that I have some drawback I have to work on. **As a leader, you have to check with people and to give them the opportunity** to report their research and to check with them at a regular time their research and I have to work on that. I give too much and too much, I would say, I give them the **opportunity to be free** and sometimes it is excessive. And for me, a **good leader needs to be close- close, I mean, regarding the frequency at least one time per week, something like that, to be close to the team and just to get a report from them and to just give a way to be reassured about what they are doing and something for me, this is a** way that okay, you have done something you are paid for and please give me a feedback and report following what you have done. And for me, if I have- this is one of my main drawbacks, I cannot check every week what they are doing. I prefer to let them work and one per month, we are doing a meeting dedicated to the reporting, but I know for sure that young person, young people in the team would like to get a meeting per week and it is quite tough for me and that's why I'm considering that I'm not a real leader and **not a leader manager.** I'm more in between crossed by this one	6b; 6a and 4; 10 "not a leader manager" 10a ""good leader needs to be close- close, the frequency at least one time per week, ...close to the team and just to get a report from them…to be reassured about what they are doing "
P3	Yeah, me and [name of person], I'd say, we were always like that at [name of company]. We were always handing on. I was still covering operations up until last year and so was [name of person] because that's where we like to be because our backgrounds are both salesmen in orthopedics. So that's the style and **openness** that we like to have. I: Okay. Okay. Okay. Interesting one here now. Are you a leader or manager? I'd like to think a **leader by example.**	7; 7c "leader by example."
P4	I think **I'm a leader, but I'm a manager also**, but I'm a leader, yes. For a long time, yes. That's what I think	10b "I'm a leader, but I'm a manager also"

Question	If you find that an interesting question that maybe this one is even more interesting: do you consider yourself to be a leader or a manager?	In Vivo Codes
P5	Probably more leader but I don't think—if I'm being honest, things get managed, right? And depending on day to day, I'm having to manage myself, my work, other people, all those loose relationships between people. Management doesn't really—that's not what this is about. This is about moving forward. And if that has to be me doing it, it'll be me. If it's better for somebody else to do it then it'll be then somebody else. But I'm not even sure if I use the word 'leader', to be honest, because **leader to me implies some kind of tribe** or something. I don't know. I can't—maybe I just fear for the word, but I think of it really just as maybe it's just somebody who's willing to t**ry and find a path through this forest**. It's the person who's taking a turn with the machete and hack for a while before they pass it over to somebody else. I don't know whether you call that a leader. I feel like that's—it feels too glamorous to say leader. It's **somebody who is focused on an objective beyond themselves** and is willing to go through some **personal pain to receiv**e—to get there. And with other people as well and help other people through them.	11. "leader implies some kind of tribe .... 11a " try and find a path through this forest..." somebody who is focused on an objective beyond themselves" 11b "go through some personal pain...to receive" 11c " and help other people through them".
P7	Generally speaking, I would say that I am more a **mentor** and a leader, however, in the context of my current position and in the context of the specific current circumstances of the company, more as a manager.... I would say that I'm a leader and a mentor, as I said before. I'm also focused, growth driven, and a strategic executive who has a found history of proven and progressive management success and a vast experience in the medical device industry. I: A bit earlier you said the general leadership or management style in the company is very much top down. So, are you saying yours personally is a bit different? Mine is different. However, I do adapt to the company's situation at the moment. So, I rather manage projects at the moment than having the ability of doing what I do better being a leader and a mentor.	6d;
P9	What came up to my mind are the sketches where there is a distinguishment between leader and boss, but this is not-is that what you are thinking about? NTI: to me, a manager is very much managing the operations of a company leaders are more focused on the vision and the long-term future of something and probably do not have-let us say, the expertise is not so much on the day-to-day business. Okay. In that case, I think I'm **more a manager. So, I am involved in all processes**. So, in principle, nothing happens in the company which I'm not informed about and this is when I-Yeah. So, this is a little bit a background information for you. In the past, when the company developed until, from my point of view, until I started here, there was no management structure. It was like a bundle of people. Everybody did know what he has to do but there was no structure. So, what I did when I started in (name of the company) was really to install such a structure, a robotic structure and what I had-there was the feedback that the people were very happy to have a manager or a-yeah, to have **somebody who is interested in what they are doing** and who is interested to interact and t**o discuss things and really gives feedback about how to do it**, what to do, what other priorities and so on. And this is really what I do. I do encourage people to develop. I think I'm really, let us say, emotional is not the right word but I do have a good feeling for how people behave. Are they happy in their job? And are they doing the right job? Are they in the best position here in the company? And this is what I did in the first years. And yeah. This is how I work is **really hearing the people**, development of people and **encouraging the people to be happy in their job,** to be satisfied in their job in order to disclose their impact. So, I really talk a lot with the employees in the group, in (name of the city), discussions to really give them the feeling, okay what I do is important for the company and to reflect what we do and most important is to develop the people to recognize the priorities because this was really a lack in the past of the company. Everybody was doing something but there was no focus, there are no priorities though things were-yeah, felt to be important but well, not really important for the overall development of the company and this is what I recognized as very valuable for the people. So, what I develop is to for the people to get a feeling for priorities and to develop a feeling for okay, how much time? Is it worth to be invested in the topic?	9c" I am involved in all processes" "somebody who is interested in what they are doing and who is interested to interact and to discuss things and really gives feedback about how to do it, to discuss things and really gives feedback about how to do it"; 9d "really hearing people"; 9e "encouraging the people to be happy in their job"
P10	I would like to be a little bit of one and the other, because a leader is a bit someone who is followed by people. Yes. On the other hand, the company needs some structuring and organization. And then pure leadership in my opinion is not necessarily working here. So, you have to have both, a little bit of both. So, people should work with you, should like working with you, and see that you are leading them in the right direction. But on the other hand, they should know that there is also some kind of a supervisor and someone who will force them to get organized. Leadership to me is this nice thing, but not everybody can work in such an environment. And also, you have to remember, I have many engineers on my team, and each one of the engineers is a leader, at least for himself. So, managing so many leaders is not so easy.	

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P 12	I would say leader. Much closer to leader, because when we display the difference between a manager and a leader, **mindset is always very practical and hands on with all the data operations.** And I am much more on **strategy and vision and target**s and so on. And **trusting t**he next level managers to do the actual hands-on work or elevations	9b; 11a, 6a
P13	I think I am a manager. It depends my role is split. If it comes to the regulatory requirements, I am for sure a leader, but if it comes to managing the development team, it is managing. But the regulatory requirement does not give the possibility to manage. It is something we have to follow. If **you want to bring the product** to the market. IINT: And your personal management style, is this like it describe the company more discussion oriented or what are you personally? Definitely I am a **team player and I like team decisions**, because that brings all the different knowledges into the discussion and makes the decision more valid if you really get the input from all the involved parties.	11a;9c
P14	It is different, it is up to the project. If we are manufacturing-, if we are g**etting an order to manufacture some instrument from a customer, it is very important to have the group decision in this point**. If we have-, in my point, that I should have a look in to the market which in**novating products or instrument or implant or set configuration we can have as [Company name1] project or product and for ourselves. In this case is my decision.** For example, now we created a new line of trace, stainless steel trace and as a complete configuration for this trace, it belongs to me and it comes from this point vibe, I had more experience from the field, from the past as my colleague here in [Place	9c;11a

Organisational Culture

Question 1	how would you describe the culture in your organization?	In Vivo Codes	Question 2	can your company adapt to new situations easily? Is it a flexible company you would say, or is it difficult to adapt to new situations?	In Vivo Codes	Question 3	So, does that include that your company easily learns from you experience? This question is really more on the learning side	In Vivo Codes
P1	I think we're quite a **fun** culture. Like I honestly do. I **don't think we take ourselves too seriously**. I think we do **work very hard**, but we also equally understand that no one dies at the end of the day. If a decision goes wrong, like it's hard and it's horrible, but I think we have quite **good perspective on reality,** if that makes sense. But I do think we're quite fun as a culture. I don't want people to come into work actually dreading going in, if that makes sense. I think we have had previous problems in the past where we have had people,	15b "work hard"; 14b "good perspective on reality"	P1	We're really **good at being flexibl**e **because we're still quite a small team**. We **take to new challenges** that come along **quite quickly**. We **can change direction**. We've got a good group of people now with us that **can swap to writing a grant one minute or they can be doing a 12-hour day in the lab next** like we have that sort of flexibility and that's what's so good about being a small company is we're very much that if people want to work from home one week and labs are quiet, we can do	13a "good at being flexible because we're still quite a small team" 13a" take to new challenges to quite quickly"13b "can change direction" "can swap to writing a grant one minute or they can be	P1	Yeah, we definitely learn because- yeah, I think we do because for instance, we're now as well as doing at the minute, our key product is to make the intraocular lens, but we're also working on some glaucoma shunt technology at the minute and that's been – because it's not in our remit, it's something that **we're all learning** on, but right down to the people who we've brought in for 3D printing work that	15f"we are quite good at learning" P1

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	we've worked with who have made everyone's life and living hell in the process			that. But then equally so if people need to be in and doing something because I've got a deadline or whatever, then **we pull together quite hard**. So, yeah, no, I think we're very flexible still and I think that's a **lot to do with the size of the organization** still. #00:10:23#	doing a 12-hour day in the lab next" 13 **"that's a lot to do with the size of the organization"**		everyone has taken on learning and going away and reading about that kind of missions and what drugs or what type of material the shunt should be made out better and that's actually been something that's really impressed me in the last few weeks is everyone's taking it on themselves to do learning and gaining more knowledge of fields as opposed to just being told like, “Right, you're going to make the shun,” or “You're going to make out of this.” So that's one thing I think has been really good. Yeah, I do you think **we are quite good at learning**	
	And we had to remove that person and I think that's taught me an awful lot about how we deal with the culture of this, particularly because I think even for me personally, it took a knock on our like mental health and seeing other people not want to come into work because of a certain person actually really stressed everyone out. So, I think it's **very important for us that we all get on** and there's not someone just causing everyone's life to be a misery, if that makes sense. I know you can't get on all the time and I think you have to **work hard,** but don't need someone constantly nitpicking. So, yeah	14a 2 very important that we all get on2; 15b		The culture of the company, of this start-up company is more, I would say, innovation, patient oriented. I think that is more standard things you can hear or listen from a lot of people, but it is really the key. So, people-oriented, so, team-oriented, patient and innovation. So, those three, the combo of our culture, I mean.				

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P2			P2	The culture of the company, of this start-up company is more, I would say, innovation, patient oriented. I think that is more standard things you can hear or listen from a lot of people, but it is really the key. So, people-oriented, so, team-oriented, patient and innovation. So, those three, the combo of our culture, I mean. This is clearly the pillar of our culture: But **team first**, **people firs**t, really. It is quite tough to our people and we want to be sure that at the end, **people we hire are in the same cultures as ours and the same values.** It is sometimes difficult, but we try to be sure that at the end, they share the same core values fitting ways our culture. ON FLEXIBILITY P2 answered: **Y**es. I would say yes. Even for older people but I would say yes. I think that we changed our strategy for the last two years one time. At least, it is just one time, but we changed it and for young people to ask them, okay, you have to focus right now on this direction and not this one. You will change a bit the topics of your thesis, **you will have to think differently.** We were, I would say, worried about the way we communicated by this change of strategy and at the end, we had a good result and sensing for all people and I think that **thanks to senior guy, we had this**	12"Thanks to the senior guy"; 4a "You will have to think differently 14 **team first; people first**, 14a " is quite tough to our people and we want to be sure that at the end, people we hire are in the same cultures as ours and the same values";			

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				opportunity to be flexible on the way we think and the way we communicated and the way the people adapt to the strategy but again, we have a small background because only two years' existence; two years for (name of the company) and only one time we changed the strategy, so.				
P3			**P3**	I don't mean it's a difficult question. Given the recent situation, we find ourselves, we all **have to adapt to this different way of doing business** and **nobody knows what the new normal is going to look like**. You still haven't got many reps in theaters. Our reps back now are furlough, but they're all going in sort of two days a week, maybe to look after kits or look at kits to see a ... covering the old operation because, literally, we've gone from four to 500 grand a month to 40 grand a month over the last three months. Now, we're starting to see it slightly turn to 120 grand this month, I think we've taken, which has nowhere...yeah, which is at 25%, 30% of where we would normally ask. And so, yeah, we've had to do social distancing. We've got people working from home still, even though they're all furloughed. So flexible to the situation. We also, and might be raising their head slightly, we also employed last year, our own QnA guy because we needed to with the	16 b “have to adapt to this different way of doing business" ...nobody knows what the new normal is going to look like."	**P3**	Yeah, I think so. I think that's why we went straight to get the QnA guy as soon as the MDR came out with directives and bodies. And the year before that we go in Sage 500, we'd been going with along on Sage 100, but it just became too much for our growth. Right. That **system needs to be changed. So, we need to invest** another 40 grands on getting Sage 500 and get the necessary training and a couple of extra heads to look after that, especially with [name of person] who is now our QnA guy. If I was to rewind 10 years and try and start this company of now under the new guidelines, what we call the new arising. We couldn't do it, not as one-man outfits, we couldn't do. I was just too much.	15a"system needs to be changed. So, we need to invest"

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				reshuffling of the MDR and ... bodies because it was too much for us.				
P4	**Teamwork.**		**P4**	Yes. it's flexible? I: Okay. And your team, does it easily learn from new experience? They learn, but when everything is good...is okay, that's perfect but **when it becomes difficult, some people prefer their own interest**s than the collective interest. This is very disappointing.	15d "when it becomes difficult, some people prefer their own interest…this is very disappointing" P4	**P4**		
P5	**Openness, respect** and—trying to think of one word, but thinking about the other person, which I think comes into being people who will put each other—use empathy. **Empathy**. So, open respect and empathy.	14d "openness" 14d "respect" 14d "empathy"	**P5**		12a “has to be addressed by the top management. P7	**P5**	would say that's true, yeah. I would say I don't know if I've ever learned as much about myself and building a company from the ground up. And I will sometimes joke with people. I say, **“You know, zero to something is the hard step.”** Something to some **multinational** there's hard steps there, but **zero to something** is the really, really hard step. **They're very rarely focused on**, I fear. A lot of focus gets on to post-funded companies where they're taking a lot of resource and it's a bit of a gamble for everyone. So, the founders have put a bit into the game over the years to get to funding. There's a bit of tech maybe from university, a bit of time put in there, obviously, the university. But whether that's been the main objective. And **then you've got the invest** the money side of it and t**here's**	15“You know, **zero to something is the hard step**.” 13f multinational there's hard steps there, but zero to something They're very rarely focused on"; 15e"then you've got the invest the money side of it and there's some personal risk there";13g" a blind alley is explored in a way that I'm not sure it's that feasible to do with the pressure of a big team and big financing";

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							some personal risk there and people care. You start losing money it means a lot, right? So, there's a lot of weight on those once they get going, but it's a very different story and a very different end of things. They start with something and then they try and build from there. Hopefully, they try and build, whatever, 200 or 500 million return minimum. When you start with zero and try and build up to something, **you've got a much longer journey through a lot more forest with much fewer resources and much less help**. In fact, people will quite honestly—you're lucky if you get the meeting. You don't get much help at all. But the reason I say I think it's just So, less focused on because it's just So, not glamorous. It's just not exciting and not glamorous and the day-to-day is very, very dull. Dealt with personal doubt and team doubt or technology doubt and lots of issues like that So, each step is a painful step and it's taking personal sacrifice. But you carry on because of your overall desire and passion to get to that objective goal. But what I would say is that it's also a very, very exciting space because there's a lot of things, a lot of strategic angles which	12b "You've got a much longer journey through a lot more forest with much fewer resources and much less help"

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							can get considered as **a blind alley is explored in a way that I'm not sure it's that feasible to do with the pressure of a big team and big financing** and the net present value of that money or something burning away on you. I think it's a very exciting space for me for people who are trying to go about dialling up what's required to make that a success. Although I think it's helped me learn a lot, actually. I feel like I'm—I think if this one doesn't work and I start again, I feel like I'm going to be in a much, much stronger position to make it a success quicker, because I won't go down blind alleyways, I've already made mistakes with.	
P6	INT: If you are discussing all these ideas together with your colleagues, So, you must have a very open and transparent let's say culture in your company. Yeah, because, for instance, my engineer I gave him a lot of experience to understand what price is. What is the cost of making an error? One month ago, he did an error on the drawing where he forgot to change, reverse the threads, forward functioning. It was his first-time **error** of this kind. So, I told him, “Okay, no problem. We're going t**o redo this thing, okay. But if we redo it, you need also to improve something.**” And that the cost, there's	14c "error of this kind..... “Okay, no problem. We're going to redo this thing" 15c "But if we redo it, you need also to improve something.”;16c not everybody is capable to understand what the cost of errors is!!…	**P6**	we're here to make money P8 very much in phase with quality, making workflows in hospitals improve, bringing quality, bringing transparency. P8	14d ”we talk about everything and very transparently” P8	**P6**	I've always adapted to environment and **try to be a step ahead**. The fact that I built my products with solutions of distributions… step on the model, our business model that nobody was doing by providing OEM and OBL products, today, that's something which is providing a **lot of collaboration**. Second, for instance I have a customer SPINEART wants to have my product. Why? Because **they have no time to develop it in their own R&D and there's**	16b"try to be a step ahead"; 16d"a lot of collaboration; 5c "they have no time to develop it in their own R&D and there's already a CE mark"5c"for them, it is an area of acquisition of product, but

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	always some cost. But everybody has to understand why we're doing this and what is your objective. It's to be really open. But not everybody is capable to understand what the cost of errors is!!…						**already a CE mark**. So, **for them, it is an area of acquisition of product, but acquisition of knowhow.** So, that's one SBU. The other SBU that I've developed is to develop the functional instrumentation, more practical instrumentation dedicated for surgeons. You know, surgeons, when they are in the OR they don't look at you. They look at the patient, but they don't look at what the nurse is putting in his hand. So, we want an instrument to be easy to use. Easy to use but not an R&D instrument. Something simple. Two actions: open, close, up, down. Boom. And get me a new one. So, all this kind of thing have to require adaptation, require innovation. And today, instruments have to become the—as a driver to make sales. Because if you don't have the right instrument, you cannot sell the implants.	acquisition of knowhow"
P7	Well, the culture in our company is very dependent on our overall very difficult economic situation and economic environment. So due to the company's financial situation and due to ongoing internal restructuring processes, that have been ongoing for the past 20 months now, at the moment we are facing an internal culture change. In my opinion, more in a negative context that	12a "has to be addressed by the top management"	**P7**	That is surprising. Nevertheless, the problems that I've just mentioned, I believe that one of [name of a company] strengths is to **always adapt to new situations** and to make the best out of it. I mean, throughout its 30 years history now, the company has been faced with many challenges, both financially and in regard to a very competitive	13a"always adapt to new situations"	**P7**	That always depends which field you refer to. Giving you an example in terms of regulatory affairs, all stakeholders have quickly learned about the new regulatory environment and we have adapted the processes accordingly. However, in other fields like digitalization, automatization, the company is	

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	urgently **has to be addressed by the top management.**			market environment, and always showed great flexibility in adapting or overcoming certain obstacles.			still in a very steep learning curve.	
P8	Well, the fact that we are in the medical sector and especially in oncology, says a lot because we're talking about people who have a lot of pain, suffering. There are a lot of efforts, you know, to improve their lives and that of the people who are around them. So, in terms of culture, I think we are-, there's something which is societal. Of course, we're a business, we're here to make money and a lot of money, but we're not in oncology by chance, you know. We really chose this business because I think everybody knows somebody in oncology who has had cancer and it's usually quite painful. It doesn't end very well usually. So, culturally speaking, we also are very much in phase with quality, making workflows in hospitals improve, bringing quality, bringing **transparency**. And we are expecting from everybody in the team to stick by those rules, you know, and this is why **we talk about everything and very transparently**. And within our company, we're putting a lot of quality. So, we're currently getting this certification to become a medical device. So, you know, you have a lot of [name of an organization]. Well, it's all about quality. When we do something, we do it provided that we stick to some rules and like it	14d"transparency we talk about everything and very transparently"				**P8**	**by agile, I mean that we can make very quick decisions. "we always have alternatives" P8 "We always bear in mind that a contract that we have signed with a company, a third-party company, might end" P8**	16d "by agile, I mean that we can make very quick decisions" (about changing partners JP); 16 "**we always have alternatives"; 17a"** We always bear in mind that a contract that we have signed with a company, a third-party company, might end"

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			P9	I think we are flexible as it is possible. So, I think this is really an advantage for us because, of course, we are **small.** Yeah, we do not have to ask for permission in a typical management or a situation like it is in the big companies and what I really think is that this can be an advantage in the current development in the medical device sector, that we are **flexible.** We can focus, **we can change the focus**. We can easily shift from-yeah, of course, the resources are limited, this is the back draw compared to the big competitors, but we are able to act quite fast. I think we are really flexible.	13a"small, flexible; 13d "we can change the focus"			
P10	I: So, would you say it's an open and transparent culture? I think so, yeah. I think so. This would be a good description. INT are you and your brother speaking openly to all the employees about everything that happens in the company? Yes, we do. We do i**nform them what's going on, what is current status**, and so on. Of course, not about everything, but anyway, look, we're a small company, people on every level, they have access to multiple documents, a lot of information. So, **they can see also what's going on, what's happening in the company.** But yes, we do explain them what's going on and **we share with them information, quite a lot of information.**	inform them what's going on, what is current status P10 they can see also what's going on, what's happening in the company. But yes, we do explain them what's going on and we share with them information, quite a lot of information P10	**P10**	It's easy. **It's easy because it's small**, so also the **decision-making process is easy,** and we have a very flexible team too. And **we quickly check and change anything** on the company. So, we can almost shift from one industry to another if there is such a need. Unfortunately, there is no such a need because the industry is quite good for us. And, yeah, we are very flexible. So changing organization, or even the market where we operate will be easy for us.	13d"It's easy because it's small" decision making process is easy"; 13a"we quickly check and change anything"	**P10**	We are looking what's around. Of course, if the situation gets really tough, then we will be probably looking for some new opportunities. At the moment we feel very well in the industry where we operate, we feel confident. We try to manage company that even if something happens, we still have enough financing to continue over the ... for some time and h**ave a chance to switch the company into other direction, if there is such a need.** And because we have very, as I said, **very talented and very flexible people, so we can easily jump even to another industry,** because- Now, what	13a"have a chance to switch the company into other direction, if there is such a need" 13a "very talented and very flexible people, so we can easily jump even to another industry"

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							is nice also about the industry we are involved in is that we actually are utilizing of all developing markets around because we have a lot of science, like physics. We have a lot of, which is optics, for example, which is- Then we go to electronics, then we go to information technology, and so on. So, we'll have all these people on our team, and we can easily migrate if there is such a need. And it's very, very interesting.	
			P11	I honestly, especially coming from a big, large organization, coming here, it is a lot of flexibility and adaptability. And I was surprised to see **how much people want to learn** and want to **do these things better and different,** so **very agile.**	15f "how much people want to learn... want to do these things better and different"; 16d" very agile".	**P 11**	I think the key aim is. The culture has been- it's a company with people, lots of empathy, right? It has been very close of a family environment, the good and bad. What we are trying now to do, is to **maintain agility**. Actually, to improve agility, because **you want structured agility**. And at the same time, keep a good healthy **environment to minimal politics, where (? insured) there is more transparency and communication, right?** And more as a culture on empowerment. …maybe less, right? To own a smaller company, it is always decision-making is done up. So, we have, you know, you have the (? turn) at the top is clear. And	16d "maintain agility" you want structured agility;12b " environment to minimal politics"; 14d"transparency and communication" ; 16c "a chance to switch the company into other direction, if there is such a need"

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							then you need to work with the people on “What is in it for me?”, right? So, you can be able to drive the change needed, to take the company to a different level: Correct. We are looking what's around. Of course, if the situation gets really tough, then we will be probably looking for some new opportunities. At the moment we feel very well in the industry where we operate, we feel confident. We try to manage company that even if something happens, we still have enough financing to continue over the .... for some time and have **a chance to switch the company into other direction, if there is such a need**. And because we have very, as I said, very talented and very flexible people, so we can easily jump even to another industry, because- Now, what is nice also about the industry we are involved in is that we actually are utilizing of all developing markets around because we have a lot of science, like physics. We have a lot of, which is optics, for example, which is- Then we go to electronics, then we go to information technology, and so on. So, we’ll have all these people on our team, and we	

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							can easily migrate if there is such a need. And it's very, very interesting.	
P12	Well, we have tried and **wanted to keep this Startup Culture**. Because we used to be a Startup, which means that everyone is, how do I put it-. **Everyone feels that they are responsible of their own mini company**. Or the function or responsibility **area, they are running, that they are independently running.** Meaning that they can pause to a certain extent, but at the same time being responsible to deliver what is expected. It means that in the end we are going to be … flexible, efficient, quick and so forth.	13c "wanted to keep this Startup Culture... Everyone feels that they are responsible of their own mini company area" 13c "they are running, that they are independently running"	**P 12**	Well, of course, we are **trying to learn from all the difficulties and experiences** we have on the field. At the same time, as **we are growing** and becoming part of [company name 2] **I can see that we are transforming into much less movable object. Meaning that we have become rather slow and not so quick learning as we used to be**	15f" trying to learn from all the difficulties and experiences"; 13e "we are growing …. can see that we are transforming into much less movable object…..we have become rather slow and not so quick learning as we used to be"			
P13	Start-up. Still, if he does only exist for a much longer time. Not happy with organizational structures yet		**P13**	situation if it comes to new ideas, technology development, very flexible. If it comes to requirements which-. We have to develop in a certain field. We are like the [Formula 1]. We have to develop in the set of rules and regulations. And if we want to bring a product to market with our means of-, with our financial means. Then we have to from the beginning think about a set of rules. If you do not follow those rules, our development will not be brought to market with our financial means. And that is-. There is the company is not very flexible. They do not want to follow those rules because they are right now relatively new, and they have the feeling they	15 e "finances limit you and the rules limit you that is what we have to learn in the company"			

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				limit them but actually not. The **finances limit you and the rules limit you** but that is a natural thing. T**hat is what we have to learn** in the company.				
P14	**The culture is complete mix culture,** we have [Place name3] people, we have people from [Place name4], we have people from [Place name5]. It is also up to the chronification, and you know tootling is a silicon value of medical technique and in this region, and it is very difficult to find very qualified people for machining or engineers, technical engineers to develop this scene while so many companies, also very big companies here in this region who are doing the same as we and that is why, it is a complete mix here in our company **with different qualification**	4c "The culture is complete mix culture... with different qualification"	**P14**	Now it is a flexible organization, and the flexibility comes from this point while we as contract manufacturer we must do every time new scenes. And especially in the machining field, when we shall manufacture new instruments and the requirement for the instrument are getting higher and higher, and that is why we must be the reflex able in this part also.				
			P15	It's- to ask the founder because he always will feel nice thinking about his company, but we built this company to be flexible. Software developers, **we're all in this agile work** and this scrum and Kanban, and especially because we are so less people, we have to concentrate on get the output as high as possible, so **we don't have time to do all these political things** you have in the company. And therefore we- I think we can really adapt to nearly everything that happens. And we also **have to learn every day**. This is a main difference between some other people, information	16d"we're all in this agile work" ; 12b"we don't have time to do all these political things"; 15f "really learn something new every day"; 12b "not doing something for a political reason but because they have a business value"			

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				workers. In software development everything works so fast, and we really learn something new every day, so we have to be flexible. And this is also when we built this company, just maybe to come back to this, we did a lot of consultant work in the past for projects that we didn't want to do but the money was too good. And we said when we built this company, there's only a certain kind- type of customers that we will accept. And these are also the customers that think like that, **not doing something for a political reason** but **because they have a business value** behind it, because they want to achieve something. And yeah, this is has worked well until now for us.				

Innovation

Question 1	If you think about the most critical success factors for your company, what ranking does innovation have?	In Vivo Codes	Process Code	Initial Coding
P1	think it's **really high.** I think if you don't have a product that people are excited about well, why would they invest quite frankly? I think you need to have to have something that gets people excited and things; gosh, that needs to be in the clinic, if that makes sense and I think without that, you really struggle to tell a story about why you do what you do. And it basically pulls in fundraising post that.	17	1 having a product 2 investing in it 3 exciting people 4 needing to be in a clinic 5 pulling in fundraising	qualifying really high; identifying don't have a product that people are excited about. Why would they invest; choosing: that needs to be in a clinic; identifying: Pulls in fundraising

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P2	P2: For me, the key success factor for (name of the company) is mainly the **team first**. For me, we have to have a team A and a team B, and regarding the project and as an example, the project 1 which we plan to launch in one year is an **incremental product.** Meaning, that it is just riser with more, how do we say that? But anyway, it is just an **incremental technology and not disruptive technology**. It is probably, if I have to compare this project again to the other one, it is the project B of C compared to the middle or long-term products which are more project A but the key success factor for (name of the company) to succeed for me is clearly thanks to the team. Mainly, thanks to the team and then the way and then the project. If we can launch on time the first product, it is mainly because we have a great team. I would say **rank 2. to innovation.** The main one is team again. Team first. And it is funny because we discussed with the investor recently and they wanted to check technology, market and so on, and at the end, the team. And I was like, come on, you don't know- you are asking this question at the end of the interview and it is just quite bizarre because you don't want to be sure that we have the right team to proceed and to launch this technology and for me, it was just unbelievable but again, it is just my point of view and for me, again, team is key.	14; 17b"incremental product"; "incremental technology and not disruptive technology". 17 "I would rank 2 to innovation"	1 having a team 2 planning to launch product 3 comparing potential projects 4 succeeding thanks to the team 5 launching on time	qualifying team first; labelling team first; choosing team A and team B; identifying project 1; labelling: incremental; identifying stereotype: incremental technology and not disruptive technology; qualifying: the project B of C compared to the middle or long-term products which are more project A; identifying: the key success factor.... is clearly thanks for the team; criteria for success: launch on time the first product, it is mainly because we have a great team; qualifying: rank 2 innovation; labelling: investor bizarre unbelievable
P3	I would say, and it's **not necessarily hard innovation** because we're distributors, that is **the secret of our success is innovation** .....where you want to define that. When we set out on this quest, we set out with a one product in mind and that was [name of product] because [name of product] and then there's off orientating company, country. I love the UK ...salient come back. So they were old fashioned ..... they call themselves. And we knew there was a... we could provide an alternative from [name of person] because [name of person], at this point, we'll get down to [name of product] get more into broader orthopedics, more specialized locking plates with the new thing to have, etc. So, we thought we'd get into niche, but we'd get into this niche with lightweight aluminum titanium [name of product] especially for pediatrics. And that was the formation of our initial success, but what we also promised ourselves because it was a good return on investments, as well as high profits to be in, by getting your own maze to your own spec, which we did in the lightweight materials. And also adapting some of the things like making the hinges that are hinges, not the like [name of product] , where you sort of Lego everything together and make your own hinge. ... shortcuts but rambling on a bit now. What we decided though, was any of the products we're going to look at, they've got to be high-value and niche and innovative, and we don't want to move...we didn't want to be stuck in hospitals. In fact, we still don't want to be stuck hospital supplies departments. [name of product] being 10 pounds cheaper than their plate and screw. We don't sell plate and screws. We're not going to touch plate and screws. We're not going to touch general hips because the market here has gone. Price has been driven down over the years. So, we're already looking for products that we go, "That's exciting, innovative." And the customer, obviously, doesn't mind what he pays, but will pay a premium price for it. And for that, it has to be innovative. Otherwise, you're selling off the shelf knees, off the shelf hips, off the shelf nails, screws, plates.	17b"not necessarily hard innovation": 17 "**the secret of our success is innovation** "	1.Setting out with project in mind 2 choosing the country 3 providing an alternative 4 having new things 5 getting into a niche 6 returning high profits on investment	Qualifying: not necessarily hard innovation identifying: the secret of our success is innovation; identifying: one product in mind; labelling (partner company; old fashioned; hypothesising: we could provide an alternative in broader orthopaedics; labelling; niche - pediatrics/ lightweight aluminium titanium product; criteria for success: high profit, return on investment

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P4	Okay. **Sales.** I: which rank would innovation have? Two. Rank.	17 "sales"; "two"		Qualifying: rank two innovation
P5	I was about to answer very quickly and say, well, nine or ten out of ten. It's So, important. But I'm going to be a bit more refined, I think, in my answer. I think it's an essential component. It's essential component to be doing something new. But if I'm honest, it's—you only really know if it's an innovation if it's been successful, right? Otherwise, it's just creating something for the sake of it. The test of whether it's **a real innovation** is whether it's successful, and we don't know that yet. I think if I break it down and say doing something new and, certainly, on the face of it it **appears to add value** in and from it, then I think that's **100% essentia**l. I can't see getting going particularly with this kind of company structure is feasible without that. You just—it's hard enough even if you have got a good story about why, So, I mean I can—we were doing this a while and I realized that essentially how I was selling our value add was kind of—I was relying on people to see my passion for why to do this. And I realized it kind of doesn't work. I need to actually refer it back to something that people can see novelty with in a simpler way. So, I gave—I started using an analogy which just helped to break open this, people to see the immediate creativity in what we were doing. Whereas when you're in the deep, you know there's all this stuff going on. But by referring it into a nice little sound bite of where the creativity is coming from, my goodness, did that really help with conversations for other people to very quickly go, "Yeah, okay. I can get you doing something new there. Then I really want that. I want to try that. I want to find out." So, I think there's two parts of that. There's the creativity that comes from going in a completely new—in a really new direction. I think that's really 100% essential if this is going to be—if you're going to have—if you're going to develop something completely from new which is going to stand on its own two feet and be a platform. But there's also a second part about this which is people seeing that what you're doing is creative and unexpected and new. The marketing-slash-public relations, I don't know. The external viewpoint of it. And I don't necessarily mean that in terms of what you put on a website. I mean, in terms of you go into a meeting and start talking about what you're doing, and you say—you get buried in the detail, they're not going to be interested. But if you can refer that back to a creative leap that they understand that you're bringing to the table, then I think that excites people. Whether that thing that you're using to hook people in and get people excited is actually—in our experience, in our case what I would say is that's a small part of the story, the technical development story, because there's lots and lots of innovative things happening. But it's driven by something which—I would say it's driven by an overall kind of vision, technical vision that's actually very hard to neatly get across to people in a short pitch. So, we just don't even bother, quite honestly. Because it's too long-term. It's kind of like if you can go here, you can go to here to here. And people are like, "Okay. I'm lost. It's too complicated." So, we focus on bringing that messaging, the help that people can wrap their heads around in quite a short order initially.	17a "a real innovation …..appears to add value …. that's 100% essential".	1 doing something new 2 adding value 3 selling our value 4 relying on people seeing novelty in a simple way 5	Qualifying: essential component (for success innovation); criteria for innovation: it has been a success; labelling: real innovation as adding value. Quantifying; added value as 100% essential; reflecting: relying on people to see my passion for why to do this. I realized it kind of doesn't work. need to refer it back to something that people can see novelty within a simpler way. criteria for success (innovation): creativity that comes from, completely new, people seeing that .....is creative unexpected ...new.
P6	For me, innovation, as I said before, is not only discovering the new raw material. Innovation is on every sequence of the sales process. So, innovation can be to provide opportunity for the surgeon to go faster in his surgery. It's an opportunity to respond better to regulatory requirements, making the balance between the risk of having something fully cleanable but being at risk if you have to reassemble the instrument, for instance. Innovation is also in the fact that it can be something which has been used before in the industry but not optimized. For instance, raw material provided by		1. discovering the new raw material 2 providing an opportunity to respond to new regulations 3. balancing risks 4. doing an	identifying: innovation in every sequence in sales process; hypothesising innovation as opportunity to better respond to new regulation; qualifying: innovation as risk; identifying:

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	[EVONIK ~~or [name of company].~~ This is the same thing, same thing as implants. To use that, that raw material for instruments it was not possible as of today because the target price was implant price for the raw material. So, if you can use a unique raw material with a tag price which is reasonable for an application of your instrument then that's it. I can tell you—also, of the innovation, it's not only—implant is becoming difficult if you don't have the financial power and the time to do it. Because innovation under the MDR, you're going to have to do an investigation. So, if you have time to select only ten surgeons, have them to use the product and wait for two years of first clinical data, fine. Where between you and me, you can do the same thing by doing the 510k first, having collected clinical data, and then fulfil the MDR with clinical data. But let's come back to innovation. Innovation is on every step. Innovation can be in the manufacturing process. Why continuing to do machining with pedicle screws just—no, for cages with traditional machines? You use 3D printing. It's the same raw material, titanium. It goes much faster for manufacturing. Per piece can be a little bit more expensive but you can reduce your inventory cost. You can reduce your manufacturing time. Instead of having 12 weeks of manufacturing, you can go down to four weeks. So, innovation is not only on implants, and you can see. Whatever—everything I'm telling you, the patient is concerned by that innovation. Not directly but indirectly it will benefit of it. At some time, innovation has to be a driver for making more sales but also, it's really to increase your margin. And innovation is a way for you to have a product of differentiation. Either a tangible product but also can be a process. It can be a different application. That's why innovation. So, that's why [YELLOWSTEPS we are doing R&D for some competitors. We are developing some instruments with a new way of manufacturing by doing 3D, 3D printing for the manufacturing of instruments. And at some time, we have diversified by introducing our network of international distributors to distribute product towards competitors.		investigation 5. waiting 6, collecting clinical data 6. fulfill the MDR	innovation as something used before but not optimised; quantifying that innovation is difficult if you do not have financial power and time; criteria for success: financial power and time to do it; criteria for success; faster. Reduce manufacturing time; criteria for success: increase your margin, differentiation; reflecting patient intactly with benefits;
P7	Well, innovation and the development of new products and services played a crucial role at [name of a company] in the past. However, this critical success pillar has not been addressed properly in the past 10 years. Thus, we find ourselves in a very homogeneous and competitive market environment. And as I said before, digitalization, automatization, and even a closed loop strategy to deliver our message at all touchpoints via omnichannel marketing, for example, becomes evident. So, there has not been a lot of innovation in the past years. We rather sell the products that we have developed a long time ago and try to put the horsepower on the street.		1.finding ourselves in competitive environment 2. delivering our message 3. using multichannel marketing 4. not doing innovation 5. selling products developed long time ago 6 trying to put horsepower on streets	dispelling stereotypes: there has not been a lot of innovation … we rather sell the products we have developed a long time ago
P8	I would say that **it is as critical as hiring the right people**. I've always thought that what makes a company great are the people who make it besides the business in which you are. And innovation definitely in our company, will make it successful. But I would put two things. **There is innovation which can come from laboratories usually state-owned and its very much research rather than development**. And you don't know if there is a market. You create something, but you don't know if you are going to be able to spin it off and make money out of it. **We're rather much more on the development phase because we co-develop our solution with users**. So, [name of a company] today is the fruit of many discussions we've had with oncologists, with surgeons, with pathologists, with radiologists, with hospital leaders who told us, okay, we would like this kind of tool. And so, when we bring you them innovation, **it's innovation that they can put money into**. It's worthwhile for them	17"it is as critical as hiring the right people"; " 17c There is innovation which can come from laboratories usually state-owned and it's very much research rather than development"; "We're rather much more on the development	1 hiring the right people 2 creating something 3 not knowing it will make money 4 users linking it 5 investors putting money into it	qualifying: (innovation) is as critical as hiring the right people; hypothesising: You create something, but you don't know if you are going to…. make money out of it; choosing: We're much more on the development phase ... co-develop our solution with users; qualifying: it's innovation that they can put

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		phase because we co-develop our solution with users"; "it's innovation that they can put money into"		money into (investors); identifying: oncologists, ...surgeons--hospital leaders who would like this kind of tool
P9	I think innovation was more important in the past. What I think is-of course, we are an innovative company as the name (name of the company), you know, standing for innovation. So, we have to be innovative from that point of view,			qualifying innovation was more important in the past
P10	**One of the tops definitely**, because that was something what we wanted to do from the very beginning, to have let's say world class products, and we always wanted to add something extra. And if you look on our products, as an example, the recently introduced slit lamp with this digital system, we see how big impact it is making. You can tell that this is just digital slit lamp, but at the moment, when people are learning how great tool it is, they all love this product. Why? Because it's packed with new technologies, but also is packed with the technologies that are easily accessible by people. So, we really just spend a lot of time and effort to make sure that even the products that are- You can tell that these are obsolete, nothing in on the product. We try always to ask something attractive to the product that puts us a little bit ahead of the competition, at least in certain areas. So, it's very important. It is very important because then you generate a lot of interest from the industry and also from the end user and customers	17"One of the tops definitely"	1 wanting world class products 2 adding something extra 3 making a big impact 4 people learning 5people loving the product 6 putting us ahead of the competition 7 generating interest from industry and end user	quantifying: one of the tops; linking: (innovation)with world class products; labelling: big impact (product); criteria for success: people love the product because it is packed with new technologies; criteria for success: technologies. easily accessible; identifying something attractive that puts us ahead of the competition; criteria for success: generates a lot of interest from industry and end user.
P11	I will give it **number one**.	17"number one"		Qualifying: give it number one innovation ranking)
P12	Considering that the whole [company name 1] is supposed to be the innovation spirit of [company name 2] that needs to be quite high priority and very relevant. I do not know if we succeeded in the innovation part, but we do have many new products coming out this year or next year. **I would rank it high, but at the same time it needs to be implemented** as well. Meaning that those innovations need to be in the answer of organization and people, who then work with the customers. And **not just prototypes, demos and so on.**	17"I would rank it high"; 17c "but at the same time it needs to be implemented ..... not just prototypes, demos and so on"	1 needing to be high priority 2 being very relevant 3 not knowing if innovation has succeeded 4 having new products 5 needing to be implemented 6 not needing to be just prototypes 7 needing to be answers for users	qualifying: I would rank it high (Innovation); critical success factor needs to be implemented as well...not just prototypes, demos and so on; choosing: innovations need to be in the answer of organization …... who ... work with the customer
P13	There are two factors which are limiting our success is, A, the finances for sure and B, the regulatory requirements. Which go together with the finances. Example. If you want to bring a new idea to the market in [Place name2] and you follow the (?5 and k) rules, it is relatively easy to finance, and it is very clear to predict the financial effect. But at the moment we have to go through clinical trials. The financial load is much higher, and it is much harder to predict the success you may or may not have. So, even so I say do not be limited by the regulatory requirements or the finances in your first thinking also (? idea) retention phase, latest when the (? idea) retention phase over, that is the first thing you will have to think. Do you have to finances to bring it to the market and can you do it in the set of rules and regulation which you have to follow? Innovation is number one. I believe so especially because	"the new medical device regulation."	1 bringing a new idea to the market 2 following the rules 3 financing is relatively easy 4 predicting the financial effect 5 going through clinical trials 6 predicting the success much harder	barriers to success: finance ad regulatory requirements; criteria for success: new idea, follow rules and obtain finance; barriers to success: clinical trials, higher finance needed, success not predictable;

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	our focus market is [Place name2]. If we will talk about [place name3], innovation is dead. The first and most important success factor is, can we do what we want to do in the set of rules we have to follow? Meaning **the new medical device regulation.**			
P14	It is two. Okay, can I ask what is first? **Two is about this innovation**, why we are getting-, as I said before, we are getting more and more requirement for instrument, the standard for instrument is getting higher and higher. And [Company name] is a company-, for this point who is very innovated to manufacture these critical scenes for instrument.	17 "Two is about this innovation…instrument critical"		qualifying: (rank) two (innovation) identifying standard for the instrument is getting higher and higher
P15	Yeah. (?A good) question because we split up between, we do client projects and we are also doing our own products, the kind of projects with more money and also experience from other industries and product then because we can apply everything that we want to and also learn from that, so it's working vice versa. But for the product part, innovation is very important, so what was the scale again? I think **it's placed three I think**, in an order, yeah.	17"it's placed three I think"	1 doing client projects and our own products 2 doing the kind of projects with more money 3 having experience from other industries 4 applying that 5 learning	Qualifying: innovation...it's placed three; quantifying: comparing client products and own products; quantifying: innovation against projects with more money, experience from other industries and leaning;

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P1	**I think it is different.** I think it's the **timeline** that is mostly the bit that upsets everyone be it investors or anyone else, what comes in. I think everyone thinks oh, that's really cool, why haven't you made a new shunt or why haven't you made a new stent or why isn't this implant already made or something and then it could be tacked in terms of an app and then the **timeline** is an awful lot different, but if you're doing like an implantable medical device.	18 "I think it is different. "; 18a"timeline"	1. timing id different	Qualifying: its different mainly the time timeline that upsets investor and others
P2	If I **compare with pharmaceutical companies** and usually sorry, for example, **which is more closed innovation**. They try to set a closed innovation strategy with a lot of patents, and it is quite a big different. Regarding our industry, except maybe for the technologies, you know, really well, the BMP, and the pathology they try to solve, for me, in the med tech industry mainly for auto biologics industry, **we are closer to the open innovation**. Meaning that if you launch, for example, a new bone graft and if you have a patent for that, at the end, you have a lot of other substitutes which can compete against your product. The patent is mainly used for or to reassure joint venture and that is it. For me, if I compare again pharmaceutical industry against our industry, we are really close to open and it will be the case more and more. And regarding (name of the company), for example, we are really close to open innovation. We have signed a deal with German company, (name of the company), producing bone grafts and we signed a deal regarding a license, an exclusive license for one of their patents because we think that they have the state of the art. This lab has the state of the art. **We wanted to have a license for this technology, not to have our own technology because as you can imagine, the research you spend probably two, three, four years in research, basic research with a risk to find nothing and in this case**, we found the opportunity to get a product not ready to industrialize but close to be ready to be industrialized, sorry. So, we have decided to sign a deal with them and to work on fine tuning or to fine tune a bit this product by	18a "compare with pharmaceutical companies, which is more closed innovation we are closer to the open innovation"; 18a" license for this technology, not to have our own technology because two, three, four years in research, basic research with a risk to find nothing"	1 trying yo set a closed innovation strategy 2 having lots of substitute products that compete3 using patent for a joint venture; being closer to open innovation (than	identifying: med tech closer to open innovation than pharma which is closed innovation; quantifying: a lot of other substitutes can compete against your product...patent is mainly used...to reassure joint venture; labelling: wanted to have a license for this technology, not to have our own technology (a technology labelled as own but sourced from competitor)

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	researching or by discussing with other specialty like polymer, like drug and so on. So, for us, again, we wanted to subcontract or **to find solution not only in (name of the city), in our R&D lab but outsid**e. So, that's why you think that a lot of companies in the auto biologics are following the same strategy right now. I think, many in the US. P2: (regarding open innovation) Because this is clearly the case, to be honest with you. Again, the minimal phase way subcontract to this (name of the company). And we have only a state of the art on the polymeric side and so we combined both and regarding the drug, we find a key partner in (name of the country) able to give us his knowledge or to give us all his capabilities to design the drug for the pathology we want to solve. So, this is why we try just to find the best outside of our industry to combine both, like to create a Frankenstein, I mean.			
P3	Best way to answer that, I've been in this game since I was 17. So, I don't know any other interesting way, but **medicine is always moving forward.** One of the companies, which I'll get into later, they have a device called a sonic scalpel. And that sounds three really Star-treky to have a sonic scalpel. But these are new and innovative ideas that are coming out. Steel scalpels will be a thing of the past in 10 years. Because when we spoke about cooperation or whatever, coopertition or what you call it, we're just .. and you know how this incestuous to our game is. We're just got to sign a contract with [name of product], our old friends got those, to distribute- they're doing a 5k, 10 K anomalous off system for the States and they're going to sell it. We were up there ... n Florida in March just before lockdown. Yeah. Well, I'm going to, once we've set up this date, I'm going to try and get it off then because they've only got to going through a distributor. And the distributor seems to sell everything from kitchen sinks, ...to whatever in the medical world and for a warehouse, I think such a product needs maybe one or two experts to work in the country.	!7a "medicine is always movring forward"	1 new, innovative idea are coming out 2 speaking about cooperation 3 signing a contract to distribute 4 they're going to sell it	reflecting: medicine is always moving forward new and innovative ideas are coming out; labelling coopetition incestuous (inferring internal to sector)
P4	No, it's different, but there are constraints in any industry. ... constraints, **the constraints are increasing.**	18a "the constraints are always increasing"	1 constraint are increasing	identifying increasing constraints in the industry
P5	I mean, I think—look, I think it's hard to generalize at that level. But if I just generalize, I think that the—I'm going to try and do it by compare and contrast a bit. But if I **compare pharma with medical devices,** med tech, medical, there's some characteristics which help to explain why I think some of it is different. I would say that **in medical as a general, tolerability for failure it's much lower**. It's a general thing that's well known. You rock up to a surgeon and say, "Well, 30% of the time it'll be efficacious work." They would bite your head off and walk out the room screaming at you going, "You're crazy." In the drug pharma world, that's great. 30% of people it's going to work, that's fantastic. So, I think the goal, the tolerability for failure, for it not working it's much harder in medical devices, and that **bar is much higher**. I think to me that actually pervades then right the way down through the culture and how people take on work. I'd say they do have better systems and processes in place than other sectors typically. And I think that can sometimes **be a** break on creativity and trying new things and being willing to take risks **because they are very, very worried about this blowing up in their face.** And once it's inside somebody, you think very differently about it. If it goes wrong you've got to—you've made—we're not just out of business but parent company is gone probably as well. So, bizarrely, I think, even if you look at the drug sector where you'd say you'd expect maybe the risks and approaches to get things right is kind of similar. Actually, I don't think it is.	18a "compare pharma with medical devices…in medical as a general, tolerability for failure it's much lower."; 18 "bar is much higher" 18a "sometimes be a break on creativity and trying new things and being willing to take risks because they are very, very worried about this blowing up in their face."	1 comparing pharam with medical devices 2 tolerating failure is much lower 3 pervading down to how people take on work 4 having better systems and processes 5 hindering innovation and taking risks	quantifying: tolerability for failure - lower in med tech than pharmaceuticals; labelling: the bar is much higher (in med tech); stereotyping: (med tech) how people take on work.....have better systems and processes in place than other sectors typically; choosing: creativity and trying new things.. worried about this blowing up in their face (risk); quantifying: If it goes wrong...we're not just out of business but parent company is gone probably as well;

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	BI think actually—I mean I know pharma better right now, but I think you could look at that as a—you could start to critique pharma as to why they have such high failure rates versus medical devices, and I think it's top-down.			
P6	On decision making - wanders into this It's me and my partner who are taking the decision because we are the ones who are making the checks. We are the ones who are taking the **risk**. And what I share are always choose the pros and cons. It's like when you do product development. What I'm asking people is to think about all the possible risks, all the possible things we should do. But I never said that the answers to all these questions have to be yes, it's fine. There are some questions where we know we should do something, but we are not going to do it now. We are taking some risk if we have some questions from the notified body, but we are taking the risk of having a good, notified body. Because it's also when you grant a regulatory file. It's what I've learned recently. I was too fair in my technical file. I was giving all too many details. And we shouldn't have done this because a technical reviewer they are not at this level of competencies on your product. So, I gave too many details that was for them much easier to ask continuous questions. I'm going to give you an example. I did my mechanical testing on ASTM version 15. And there was a new ASTM version 18. I did explain why we were not redoing the mechanical test, but in details. And those details were by tolerances to the block of the testing, which has nothing to do with the implant itself but for the environmental testing. I could have said just we did not apply because we consider that there were not many changes with consequence on the mechanical test of the implant itself. No. What I did, I gave explanation of all the differences in the changes. I shouldn't have done that because the technical reviewer, she was not even knowledgeable in those details. But she asked many questions, and those questions were non-conformities and that postponed the study file by, say, eight months. You see? So, all those considerations are something where it's very important that we have to consider when we do something, we ask people to consider, to think about all the questions possible, try to put an answer, yes or no, but sometimes do not hesitate not to address those issues on papers if you know that real answers will take for ever .. Maybe that question we will discover later, or maybe that question we would have the answer through the clinical data we're going to collect. This is why MDR for company can be very beneficial because for the sort of time for the first time we're going to have really feedback from the market, from surgeon, from patient about some secondary effects of the device. That's why I can give you example. Full spinal implants, you have implants with some screws into the cage. We have things, you know—do we need the screws to fix the cage? No. Because, in fact, two screws were put. Pretended to be innovation but it was just to make money, just for the purpose of selling more implants, the cage and the screws. But for the patient, it doesn't change because, anyway, after two weeks, the cervical vertebra gets to fuse with screws or without screws. So, that's what clinical data will highlights the excessive sales of implants … INT: But what you're also saying then [name of person] is that innovation and medical device is different from other industries Well, I'm not—**I would not say it is different**. I mean, first, maybe I don't have experience into other industry. But I can tell you, I've recently looked at a company that we may invest or buy out. It's a company which is doing polishing. They're doing polishing for not the medical business but for other industry, like avionics or selling for—to make very good polishing. And polishing it's a job where you need experts. You can do it with robot. You can do it, but to install a robot to do polishing of implants, for instance, you have to put down 200,000 euro just to develop the robot to make the right polishing. What I want you to understand in this kind of thing, we have determined that today	18a "risk"; 18"I would not say it is different...t's a way for you to make product differentiation and to increase your margin".	1 making decisions 2 taking the risks 3 sharing the pros and cons 4 asking people to think about it 5 taking risk if there will be question from the Notified Body 6 Not giving too much detail	choosing; it's me and my partner who are taking the decision... we are the ones who are taking the risk; choosing: 'what I share are always choosing the pros and cons; choosing (time): some questions ..we know we should do something, but we are not going to do it now; choosing: taking the risk of having a good notified body; quantifying: I was too fair in my technical file; barrier to success: giving too many details; barrier to success: I gave explanation of all the differences in the changes. I shouldn't have done that because.... asked many questions … and that postponed the study file by eight months.

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	there may be an opportunity to have another type of industry or company where you can do polishing, finishing. For what purpose? Just to do refurbishing. You know what is refurbishing? Refurbishing is the capability to—there are tons of instruments which are sitting in the hospital or at companies where regulatory people would say, “What? Garbage.” Because the product is having some marks, or it's been used, or we don't have the full traceability of contamination. In fact, you just need a process to give a new life, to do refurbishing. In that case, it's innovation. But you just need to put the knowhow where it's required. But in order to do so, you need to have a knowledge of regulatory requirements and the ability—because subcontractor manufacturing instruments, they will never do this kind of additional work. That's why you have innovation in terms of proposing new type of jobs. So, innovation in other industries, like innovation today in the airline industry is to make a plane with battery, flying with battery. But we know battery are pretty heavy. Or with hydrogen. Or we know that now with the raw material used to construct airplanes, it's done. You know, titanium, aluminium, very light raw materials. This has been done. So, the new type of innovation can be 3D printing application for avionics to make some new parts. Is to use new energy. So, that's why innovation, once again, can be at different areas of a day-to-day activity of a company. Can be through product, it can be through processes, it can be even through human resources management. You see? Today, the innovation in human resources it's 80% of interviews are performed through Skype, Zoom, Meet. But by doing that innovation, you have saved money because you don't need to have expenses to travel. You don't need to have—you are gaining time. So, innovation, whatever the industry, you really—**it's a way for you to make product differentiation and to increase your margin.**			
P7	Well, I think **it definitely is different**. The global medtech industry is maturing and consolidating while serving an increasingly demanding healthcare sector. The share of profits from new products is particularly high in MedTech compared to other industries. And as a result of that, a **high-performance innovation system would generate significant and quantifiable effects, both on profitability and accelerated time to market, or new product development**. I think this viewpoint outlines the future also of the medtech industry and its opportunities as well as how to address those challenges through implementation of a well-designed innovation management system.	18"it definitely is different: "a high-performance innovation system would generate significant and quantifiable effects, both on profitability and accelerated time to market, or new product development"	1 industry is maturing 2 consolidating 3 serving an increasingly demanding healthcare sector4 having high profits from new products 5 high performance innovation systems generating quantifiable effects 6 outlining the future of the med tech industry	labelling: med tech industry is maturing and consolidating; identifying increasingly demanding healthcare sector; quantifying: share of profits from new products is particularly high in MedTech compared to other industries; qualifying: that high performance innovation generates speed to market and profit in NPD; identifying critical success factor: well-designed innovation management system
P8	No. It's, I think, whatever the market you are in, **it is the same thing.** What's maybe a little bit different about healthcare is that the stakeholders with whom you're working are not very keen about making progress or making changes in the way they work. For instance, if you speak with doctors and you tell them, okay-, well, for instance, when you build a plane, you don't want it to crush, obviously. Okay? And you want to bring comfort. You want to make it-, you want to put the noise level very low. You want it to be comfortable. When you are in the business of healthcare and	18"it is the same thing".....but referring to implementation by medic staff 18b "what needs to be very, very clear is that not only do	1 working with stakeholders who do not like changes in their work practices 2 thinking there is no room for innovation 3 needing to	stereotyping: healthcare stakeholders ..not very keen about making progress or making changes in the way they work; barrier to success: healthcare stakeholders .. are

Question 2	Do you think that innovation in medical technologies is different from innovation in other industries and if yes, why so	In Vivo Code	Process Codes	Initial Codes
	you speak with doctors, they tell you, well, you know, people die, we can make errors, it's a human practice. And they think that because it's a human practice, there is no room for innovation the way there is in automobile or airline industries or nuclear industries, which is false, obviously. So, when we speak about innovation in the healthcare business, **what needs to be very, very clear is that not only do you need to bring the product, which is in itself innovative, you also need to bring the mindset, you know, for the change to occur.** So, what we are providing at [name of a company] are *tools* to bring teams to evolve positively, to work differently, to understand what the mistakes they were doing are not any more tolerable. And that they need to work better, which is hard. Because when you speak with professors and you tell them, well, you could do this in a better way, they tell you, "Well, I'm in charge here. I know what I'm doing, and you're not a professor." So, I think that's **maybe one of the differences I see with other markets, is getting people involved in innovation themselves and being able to change their practice**. But of course, the new generations tend to be very much more open-minded towards that	you need to bring the product, which is in itself innovative, you also need to bring the mindset, you know, for the change to occur"; 18b"maybe one of the differences I see with other markets, is getting people involved in innovation themselves and being able to change their practice"	bring new mindset for change to occur 4 we are providing tools to bring teams to evolve positively, to work differently 5 telling you, I know what I'm doing, and you're not a professor 6 seeing differences with other markets are getting people involved in innovation	not very keen ... changes in the way they work; critical success factor: (in med tech business) you need the product which is innovative and you need to bring the mindset of change to occur; critical success factor: providing .. tools to bring teams to evolve positively, to work differently; critical success factor: getting people (users) involved in innovation themselves and being able to change their practice; stereotyping: new generations tend to be very much more open-minded (to change)
P9	but **I think the boundary conditions in the medical device sectors are really toxic for real innovation.** So, there are so many back draws and **so the hurdles are so high** that **I cannot recommend anybody to be innovative** because unfortunately, we have to accept that the most successful companies are the companies working on non-innovative materials or products which are in the market for decades. I think this is a bad situation. We do have quite innovative products and we see how difficult it is to get that into the market and to maintain it in the market when it comes to, for example, re-certifications which are performed under MDD, which is now quite near the MDR level, and it will become much more difficult when we do have that re-certifications under MDR conditions. So, and this is where we talk about the products which are available on the table when it comes to the development of new products, though the situation is worse. I: So, what you are saying is that innovation in medical devices is different from other industries? Exactly. I Okay, and that is because of the regulations you say? Exactly	18a"I think the boundary conditions in the medical device sectors are really toxic for real innovation." 18/18a"so the hurdles are so high I cannot recommend anybody to be innovative"	1 thinking the boundary conditions in the medical devices are really toxic for real innovation 2 making hurdles so high for innovation 3 most successful working on non-innovative products 4 seeing how difficult it is to get into the market (with innovative products) 5 becoming more difficult to iget re-certifications with MDR	labelling: boundary conditions ..really toxic for real innovation; quantifying: the hurdles are so high…I cannot recommend anybody to be innovative; critical success factor: working on non-innovative products on the market for decades; identifying: innovative products….difficult to get into this market; barrier to success: re-certifications, more difficult under MDR conditions I: So what you are saying is that innovation in medical devices is different from other industries? Exactly. I Okay, and that is because of the regulations you say? Exactly

Question 2	Do you think that innovation in medical technologies is different from innovation in other industries and if yes, why so	In Vivo Code	Process Codes	Initial Codes
P10	**It is a little bit because you have to be more responsible**. You have much more- You always have to think about patient and also about the user, because if they don't feel comfortable working with your equipment, or **maybe the device is too advanced for them, they will have problems using i**t. It's like we had a discussion about cars, you remember. When the car is too innovative, people have, especially the older people, they have problem using it. So, it's a little bit the same in the medical field. And as an example, my colleague would love to add a lot of gesture to the product, but then try to explain to doctors what gesture they have to do to get to a certain function that makes no sense. It has to be easy, and push button is quite often better than new gesture, especially when you need two hands of getting this done. At least at the moment. Maybe in the future we'll see..... number five and then the device makes something different. But at the moment, I think still **our industry's a bit conservative,** which is good, which is good. And that's why we should respect this when we build a product	18b "It is a little bit because you have to be more responsible" 18b"maybe the device is too advanced for them, they will have problems using it" 18a "our industry's a bit conservative,"	1 being more responsible 2 thinking about the user 3 thinking maybe the device is too advanced 4 having to make it easy 5 thinking the industry is too conservative 6 respecting this when we build product	critical success factors be more responsible, think about the patient, think about the user, maybe that the device is too advanced; stereotyping: the older people, they have problem using it; critical success factor: has to be easy; labelling: the industry conservative; identifying; should respect (conservative) when we build a product
P11	Listen, **it is,** first of all, if you **compare it**, which I am a bit familiar **with in pharma**. It is the innovation lifecycle, right? That is what I can mention from my experience. The **innovation lifecycle in medical devices is much shorte**r (? than) the innovation in pharmaceuticals. So that is what I can relate to and compare to. Now it is also, the more innovation is not, the way I look at it, it is not the same way I look at it, I looked at it ten years ago. We are talking in countries like Europe, because we have, what I would call, **disruptive innovation** or you have with leap, you know, with **leaps in innovation or you are talking about incremental innovation.** So, the impact is not the same of course, but what I can say, is, that the lifecycle of innovation is much shorter in medical devices. Now what I hear is, you go to the technology and mobile industry, where the innovation lifecycle is much shorter even. So, I bet I am not an expert in that	18" it is"; 18a"If you compare it with in pharma...the **innovation lifecycle in medical devices is much shorte**r "17b" disruptive innovation or you have with leap, you know, with leaps in innovation or you are talking about incremental innovation"	1 comparing it with pharma 2 experiencing that the innovation lifecycle in medical devices is much shorter 3 having disruptive innovation, leaps in innovation	identifying: the innovation lifecycle is shorter; labelling: disruptive innovation as leaps in innovation;
P12	**18 "Definitely** Much, much different with **the regulations and restrictions** and so forth". "the change registrations"-. Especially the doctors. Yes, exactly. So, due to the regulations, **change of registrations** of the medical field. Yes, it is **much more difficult to bring out the new innovation**s. And I have been in Medical IT field for 20 years and especially in the (? Interpersonal) and Startup sector. And I have seen so many great innovations not being able to penetrate the market, because of the regulations and change of registrations. I have seen that to be able to bring out and succeed with an innovation in the medical segment it requires-. It cannot be, how do I put it. It is disruptive in the ways that you do not see in other fields. Of much rarer in the medical field, because they are so much harder to bring out. Why **all the innovations in the medical field are just small things is to data processes and so forth**. Due to that the medical field or the **innovations in the medical field are lagging maybe five years behind from the other software sectors**	18 "Definitely"; 18a "the regulations and restrictions"; 18a "change of registration" 18a "much more difficult to bring out the new innvoations" 18a " It is disruptive in the ways that you do not see in other fields"; 18a"all the innovations in the medical field are just small things is to data processes and so forth...18a innovations in the medical field are lacking maybe five years behind ...other software sectors"	1 changing registrations in the medical field 2 making it much more difficult to bring out new innovations 3 seeing many great innovations not being able to penetrate the market 4 being disruptive in a way you do not see in other fields 5 making all the innovations small 6 innovations lagging five years behind other software	quantifying: (innovation in med tech) much different with the regulations and restrictions; barriers to success: he change registrations quantifying (the barrier) much more difficult to bring out the new innovations…(in med tech for 20 years); qualifying: much more difficult...especially in the start-up sector; quantifying: much more difficult to bring out the new innovations....disruptive in a way you do not see in other fields...harder...so medical innovations are just small things; quantifying innovations in medical field

Question 2	Do you think that innovation in medical technologies is different from innovation in other industries and if yes, why so	In Vivo Code	Process Codes	Initial Codes
				five years behind other software sectors
P 13	As far as I can tell, **yes**. The new medical device regulation which will be implemented in next may because it was postponed for one year by the-, due to the COVID-19 crises. **It is limiting innovation drastically** and I do not see that for instance in aeronautics or in-, even not in the automotive industry. **That kind of brutal regulation make it impossible for small companies to really come up with new innovative products in a financeable way**. Cost a lot of money now in [Place name3]. It is much easier now in the [Place name2]	18 "yes"; 18a "it I am limiting innovation drastically" 18a"That kind of brutal regulation make it impossible for small companies to really come up with new innovative products in a financeable way"	1 limiting innovation 2 do not see than in other industry 3 making it impossible for small companies to innovate 4 costing a lot more now	identifying medical device legislation is limiting innovation; quantifying: I do not see that (regulation limiting) in automotive and aeronautics; labelling: brutal regulation; barrier to affordable innovative products by small companies - brutal regulation
P14	**Yes**. Innovation is a very important point in the medical industry also. Innovation means-, innovation is important why? This innovation or these **instruments are every time in contact directly with the patient.** With the human body. So, and to save the lives of a patients and to make operation time shorter and easily. And it is very important to bring very innovative product to the markets and that why I think, from my point of view, innovation is a very important point for the medical device market. Yeah. And we are doing the tracking also with our QR codes that you can say who was introduced to this device and when were-when was services and so on. So, they told us **there will be a lot of changes,** this is what they maybe need this for- **also for the whole tracking of what happened"** INT: Yeah. Traceability is a big thing in- but it has always been a big thing in medical device regulations but now with the new regulations, it's even more difficult to execute. Because basically as the manufacturer it's your obligation to at any moment, at any time be able to say where's the device and what's been done with the device. Yeah, but this is the problem when you try to innovate in the sector where you say- this is very interesting because the more friction there is, the more opportunity there is usually. But when they don't want really to cooperate with you because we had some questions with it, we came with standard things that you- when a device has- when there's some defect or you need support and you can scan it, the QR code. You can say, this is now going back, the field engineer can do this, you get it to doctors and say this goes back to the manufacturer or wherever, the service partner who repairs it. And then the doctor's staff also can track this from the actual QR code they have in their papers and then see where it is. This is the easier solution. And also, we try to come up with some block chain-based solutions because every other industry where it is important for traceability (? does this now) but it is hard to talk to people about this because then you have another technical thing that most people are not familiar with. So, this is a very hard part to perform. But traceability was something we thought about. INT Do you have an opinion if the new medical device regulations have an impact on innovation? Like medical devices? Yeah. I don't know in detail, but I can see what- how people react when it comes to this and there might be companies that maybe are already cooperating and are open, but we have more to talk to the s. So, it reminds me of all the other companies where these GDPR changes were- they were very frightened and did not know how to apply this. And a lot of people shut their websites	18 "Yes"; 18c"instruments are every time in contact directly with the patient" 18a"there will be a lot of changes……..also for the whole tracking of what happened"	1 instrument contacting human body 2 saving lives of patients 3 making operation time shorter and easier 4 bringing products to market very important 5 they are telling us there will be a lot of changes	quantifying: (context, value and potential issues): instruments in direct contact with human body, save lives, make operations shorter; linking; device the tracking ...a lot of changes (regulatory, ----- maybe need this for...for the whole track; barrier to success: smaller manufacturers u... are very concerned...they are not used to these changes; qualifying: (long term effect of regulation) Europe wide there are regulations that may sound strict but afterwards.. they have common sense about how they reinforce them.

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	completely down because they said we don't want to be punished. But if you had looked into it then you would have known that it's not that bad when you're not multi million or billion company. And so, I think maybe this is still the same, European wide there are regulations that may sound strict but afterwards I think they have common sense about how they reinforce them. I: Your impression is that the medical device companies you are working with are somewhat concerned about innovation? Yeah.			
P15	**I think it's different** because- maybe not from the topic here but because when- in medical areas **you're working more on a patient, on a person**. This is always what I say when you do- when you create a website or if you're programming software for flight control, this is a big difference because what can happen, is there can be much worse in the situation. So maybe this is for the medical part, more important, more critical and then digital. And also, I think from my experience with companies, when I told them what we do, and every time **you talk about medical things and patients then there's also a data policy in their mind,** everything then has to do with- everything has to be secure and has to work and the data has to be- and this spins out a lot of conversations in this direction, this is what we experienced when we presented something. So other companies that were not- did much impact might be on the person are more open to change and to say let's try something	18"I think it's different" 18c "you're working more on a patient, on a person" 18a "you talk about medical things and patients then there's also a data policy in their mind"	1 working more on a patient, on a person 2 what can happen, is there can be much worse in the situation 3 talking about medical things and patients othes always have data policy in their mind 4 everything having to be secure and having to work 5 trying something did not impact on person more open to change	qualifying: different... Working on a person; barrier to success: data policy; criteria for success: everything has to be secure and must work

Innovation Differences in Medical Device Sector

Question 1	In your company now, who's responsible for innovation?	In Vivo Code	Question 2	Does your company, or you have any experience with so-called open innovation?	In Vivo Code	Process Code	Question 3	How about innovation hubs?		Question 4	Meaning of Innovation in your company
P1	Probably **me** and [name of a person]. We're the ones that now come up with the ideas of what we want to do next and then we'd go to the clinicians and say, "Is-?"	me	P1	**Yes**, we do. So, when we started at [name of the company], we were based at [name of a place], which in [name of a city] is. So, our chairman used to be CEO of that [name of a	"Yes"		P1	Innovation hubs. Yeah, we're in a hub at the minute so we're in the [name of a location]. That's where we're based in [name of a city].		P1	

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				person]. our chairman had actually given quite a few lectures on open innovation. He used to be the CEO of [name of a place] and so it is something that we have come across.							
P2	It's (name of the person) B: (Name of the person), she is the- INT: So, (name of the person), is this what you say? P2: Yeah, exactly. So, I work with (name of the person) and with all the researchers, one of them is (name of the person). He is a specialist in polymer and the other one is specialist in biology called (name of the person). INT: Okay. So, the responsibility for innovation is really on the highest level? **It is senior management responsibility**? P2: Yeah, yeah. Exactly. Yes.	P2 "it is a senior management responsibility"	**P2**				**P2**			**P2**	
P3	**Me** and [name of person] was the product manager before he was the business director. He was the product manager for external fixation. And then he was my number two as business director before we left ... But mutually, I think, we are...we both go to Academy. We see something... it depends what you call. We're not sit down	P3m"do we design our own stuff? No, we don't."	**P3**	In fact, I have had... I've touched upon it in some discussions with a guy who I keep in touch with. He's called [name of person]. And he seems to be a bit of a puller of strings. I'll send you his details actually on LinkedIn, but [Name of person] is in a lot of different areas of		1. contact has a man who was working in the nuclear industry 2 has developed a robotic arm 3 he's saying it could be	**P3**			**P3**	

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	and designing our own products all day long. We tinker with the .....and try and improve it. And, well, we have tinkered with it and improved it. But getting hold of new, innovative products is down to both of our ... And also, now more so, we have a young sales director, [name of person], when I say he's young, he's 29. But he has a lot of inputs and indeed, any of the reps who come to us and say, "Look, I've seen this, or this is something we should look at. Yeah. If you mean innovative by, **do we design our own stuff? No, we don't.**			engineering. He's got a guy who was working in the nuclear industry and now the same guy has developed a robotic arm from what I can gather. We're yet to meet up. And he's saying, you know, this could be used in surgery. It could be used in X, Y and Z. So [name of person] seems to form these companies together whereby he'll take innovations and take it out of sorts of nuclear engineering, into medicine, into whatever, into mining, into electronics, and **I'm yet to get into that** as such. I'm supposed to have a discussion with this guy, but then we had the lockdown.		used in surgery 4 contact forms companies and takes innovation out of other industries 5 open innovation					
P4	It's **me and I have an engineer** working with me	P4 "me and... an engineer"	**P4**	**No** (knowledge of open innovation)			**P4**	"I'm yet to get into that"		**P4**	
P5	So, there's different things there. I'm struggling to pick out responsible in terms of a clear kind of this person makes—we make decisions together. But each person brings different viewpoints into that decision. So, we have somebody who's much more aware of the market sector, what is really likely to fly versus go being very	P5 " I'm probably the arbiter saying, "Okay"	**P5**				**P5**			**P5**	

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	negative, and that person has a big role. But also, there's—and then there's somebody, we have somebody who's much stronger in the deep technology in terms of bringing ideas to the table. In a way, I would put those two at one side and then say I**'m probably the arbiter saying, "Okay**, well, I think this is something we can do." I mean that sensible kind of—you're drawing that together. So, we have people putting different viewpoints in and help in, but I'm the person who ultimately makes the decision that we can go this route and do this. And I would be honest that one of those big, big factors is thinking about what we have to do to validate and thinking about whether we can create some shortcuts. Again, that's where a lot of our creativity goes into thinking about instead of reinventing the wheel, can we piggyback on other things and really jump further and faster than we could do otherwise. That is another part which doesn't necessarily come into what people say externally about their story but it's absolutely critical for us. We can't—we really—I've I banged my head against the										

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	wall for two years trying to technically develop one aspect of this and then realized it was crazy. We weren't—even if we had an investment, I don't think we would have got there. But then some things have moved forward So, fast because we've been creative at thinking about how we can close the circle up rather than just could we reinvent it from scratch and build it from scratch. So, that to me has been the things in the way that have been most exciting for the business.										
P6	**With my associate and with the engineer, we evaluate the benefit of the innovation**. Maybe the word is a little bit too strong, innovation. Maybe—because innovation, some people it's something that has to be disruptive. No. At some point innovation can be improvement, yes. But improvement, at the end of the day you are also improving your margin. And that it is a principle. I'm going to give you an example of what is important to have to have a full understanding. When sometimes if you can find a subcontractor, who is capable to manufacture clean	P6 "With my associate and with the engineer, we evaluate the benefit of the innovation"								P6	So, for you, innovation is more on the process and the business model side and less on the product side. Oh, yeah, definitely. Products forget it. Moreover, today, there are some—the field for innovation, customers, direct or indirect customers are really respondent to this kind of approach. Because if you say that you have a product where you are saving the planet, it works. It has to sell. For instance, where **single-use instruments are really becoming fashionable or** important because of the COVID. Because risk of infection.

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	and package your product, it's going to be an improvement for your margin. Why? Because you are reducing the paperwork of traceability between the three steps: manufacturing, cleaning and packaging. Because you don't need to process entry and in and out of paperwork for the traceability. You are increasing your safety in terms of any risk of cross-contamination during the process of the manufacturing. And at the same time, you can really improve your margin because you are giving more knowledge to your subcontractor as well. Because also you have a subcontractor has to make changes, because they have to—and you can transfer your burden, your risk of the manufacturing process to them because you ask them to do some validation that you don't pay. That's why I have established a collaboration with a subcontractor. When I told him I'm ready to have a participation for the cost of the regulatory you have to perform. "Yeah, but it costs a lot of money." I said, "No, no, no, no, no. My part is 1,000. You have 25 customers. If all your customers were paying										But at the same time, it depends the way you present. At the same time, you are using a lot of plastic garbage. But you are using a lot of—you are gaining time in terms of the cleaning process of the instrument, in terms of patient safety. So, there are new areas of development, of innovation, but not on the front line as implants Class IIb or Class III, but on a Class I-Class II where the regulatory file is less difficult. Difficult in terms of what needs to be done and in terms of cost. At the same time, you are generating new areas of revenues, because in the past, it was difficult to sell the instruments.

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	you 1,000 euro, my friend, you would make money out of it. So, I'm paying you but also I'm giving you guarantee that what you're doing is you can sell this activity to your own customers." So, here you will see that innovation is on the product, is on the manufacturing process, is on the regulatory process also. It is important… #00:31:00#										
P7	This is a closed process. Normally innovation is defined **by marketing and product management.** So, we take back the messages from the market, from the key opinion leaders, deliver it to R&D and medical and regulatory affairs. And then depending on the prospective profitability of a project, we adapt our R&D to whether an update of the products, so within the classical product life cycle management, or within the development of new products, depending on market and customer needs. IND: Does a well-structured and organized process like this allow enough creativity? It definitely does allow a certain kind of creativity. However, we have clearly decided that R&D and medical and regulatory affairs are really denominated by pure marketing and sales	P7 "by marketing and product management"	**P7**	No			**P7**	Unfortunately, we neither have the experience with innovation hubs yet.			

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	since our entity, or our company is very sales and turnover focused. So, innovation actually is triggered by marketing and sales.										
P8			P8	What do you mean exactly by open innovation? Just want to make sure- INT: Okay. What I mean by open innovation is sharing your development, sharing your research results. Software industry is a very good example because of a lot of developments it shares so that other people can just pick it up. So, you mean like an open-source model, things like that? #00:28:35# INT: Yes. Exactly. Well, it's very good question, you're asking. What I can tell you is the architecture we have designed is made to integrate, in the future, other algorithms coming from other companies, because what we'll bring to them is the capability to work on various qualitative data and structured data. So, in	"we're not ready to share"	1 innovation, we are more incremental 2 focused on oncology 3 it's very generic 4 we use decision trees from medical societies 5 we don't share our algorithms	P8			P8	**17d "**It's very structured **because we have very scarce resources",** and now we are going to have **investors who are going to ask us**, where do you invest your money? What do you get from your money? Nor from an ROI perspective, but rather, **do you make some intellectual property out of it?** You know, things like that. So, we have we have a roadmap, very clear roadmap for innovation. And given the earnings, we are making and giving the market where it drives us, we'll be picking in this list, exactly what we do

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				this way, we are quite open, but it's only in this way. Today, **we're not ready to share** our own algorithms with other companies, for instance. And if we look at innovation, we are more incremental. You know, we try to be more focused on-, today we're focused on oncology, but it's very generic. If you take breast cancer and you take lung cancer, there are very specific things to say about it. And you may give some-, well, when you look at the data, it tells you other things, when you look at either population. So, what we're doing in the next few years is be more and more specific about every single cancer illness that there is. But today, we don't share. We use a lot of decision trees from medical societies, but in the other way, we don't share. No.							
P9	I think it is a **management team**. So, I think in principle, it is everybody despite the production employees. When it comes to that, we talk about maybe six people. That	P9 "management team"	**P9**				**P9**			**P9**	

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	means these are as a management team where quality, risk management, regulatory affairs is involved and the R&D guys. So, when we talk about innovation, we do that in a group and to, yeah, consider all conditions, what is possible, what is not, what is impossible. That's it										
P10	It's **mostly my part**, but **I'm listening to my team too**. I have a lot of young engineers and sometimes I'm surprised how much forwards the market has moved since I graduated. So, it's continuous learning, learning, and learning. And my guys are very good because they really love to learn new technologies, new things, and use them, test them, and so on. So, it's continuous development. It's mostly my decision to- At a certain stage they're, "Okay, we will use it. We'll deploy this technology. Now at product, we use this technology." And I'm also learning a lot what is happening. I'm trying also to stimulate them to thinking, because when I see that something is working in some industries, and I find this attractive potentially to our user, I'm trying to also to force them to think how we can	"mostly my part listening ones to my team too"	**P10**				**P10**			**P10**	"A **little bit of everything**. Because usually **we plan**, for example, a platform for the group of products, **we build the base** for this platform, then **we test different possibilities** of this platform. And t**hen life brings new ideas,** new- We are **learning some things that were never expected**. We are learning also that's something we expected, and we wanted to use are not necessarily as they are described in the manuals and so on, and so on. So, **it's a lot of learning curve**, but we'll have a plan and then we learn what is possible, and quite often, what's attractive, what interesting is available, we never thought of. And then we are adding to the product, and this is both on the hardware, on software, sometimes even on

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	build something similar. Sometimes it is from the IT world that we add to the product. Sometimes it is purely from the industrial world, as I have also experienced in industrial designs. So, let's say this is how it works. But the team is very, very helpful in developing new technologies, because they also observe, they see a lot of things. Of course, as young engineers, they would love to add everything to the product, but #, first of all, you have no time to do this. And secondly, you sometimes may generate, this is medical industry, you cannot test it. You know, our users, our customers are not the test rabbits. So, we have to make sure that whenever we decided to use whatever technology, we have to make sure that it is safe for the patients and it's also easy to use to the doctors. This is also to the safety. So, I have to be the moderator.									components, on materials we use on our product.
P11	It is **a collective work**. We do have a Chief Product Officer, but then we have- in the end decisions are done at ExCom level on key projects to move forward. Which is the Chief Technology, Chief Operation Officer, me. It is mainly Chief	P11. "a collective work" (senior management)	**P11**	**No**, I think what we do, is, we do have innovation meetings twice a year to drive ideas from field experts. We do have internal innovation platforms to get feedback	"No"		**P11**			**P11**	: I think **it is been evolving**. It was from very semi-structured or not structured process years ago. But one of the Co-CEOs, you know, he is an engineer and lot of things were driven that way. Ideas from customers, his

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	Operation Officer, the Chief Product Officer and the two CEOs and the Head of Strategy.			from the field. And this is mainly from							ideas, right? And now **it's becoming much more of a structured process**. Bu we are still, if I have to rank it on one to ten, I think on level of structure we are 5 (?3).
P12	Yes, exactly. So, due to the regulations, change of registrations of the medical field. Yes, it is much more difficult to bring out the new innovations. And I have been in Medical IT field for 20 years and especially in the (?Interpersonal) and Startup sector. And I have seen so many great innovations not being able to penetrate the market, because of the regulations and change of registrations. I have seen that to be able to bring out and succeed with an innovation in the medical segment it requires-. It cannot be, how do I put it. It is disruptive in the ways that you do not see in other fields. Of much rarer in the medical field, because they are so much harder to bring out. Why all the innovations in the medical field are just small things is to data processes and so forth. Due to that the medical field or the innovations in the medical field are lacking		**P12**	IINT: Do you have any experience with certain specific innovation models like open innovation or participating in innovation hubs? Is that Personally, I have been involved in many of those in the past. But the [company name 1] is **not currently** or has it been part of those innovation networks or hubs. Anything like that. I would say the main reason is the financing bureaus. Because being part of those networks requires that you are part of some kind of a program, which is then financed or requires you to be involved in some kind of a financial scheme. And we are not allowed currently to join those, because	"not currently"		**P12**			**P12**	

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	maybe five years behind from the other software sectors										
P13	It is the CTO, the chief technical officer together with the team of engineers. But actually, everybody can bring in new ideas to the table during our team meeting sessions	P13 "the CTO, the Chief Technical Officer"	**P13**	**Yes.** certainly yes. We are in exchange with automotive-, with **engineers developing automotive applications or aeronautic applications or in the watch industry**. That is by other engineering companies in (Place name1) which also had developing applications in the watch industry, we work together with them partly on a paid basis. Meaning they are our advisers in this field, or they are developing partners in this field. So, **there is knowledge transfer between different applications in different fields.**	"Yes. certainly yes". "with automotive-, with engineers developing automotive applications or aeronautic applications or in the watch industry". "there is knowledge transfer between different applications in different fields".	1 exchanging information with engineers in automotive 2 they are developing partners in this field 3. advising us 4 transferring knowledge between different fields	**P13**	Yeah. If you would-. In a certain way yes. By collaborating with engineering officers in [Place name1] which are known as such hubs but … That is not a That is literally experiencing this yet.		**P13**	Alright. **It is a structured process in a certain way**, **in another way it is also beginners' luck.** But one of the structured ways is, we have-, we had strong exchange with clinical specialist meaning surgeons. We have four groups of surgeons we need on a regular basis. Even during Covid-19 then of course by teleconferencing or emailing or telephone. Another one is the constant monitoring of publications, new findings constantly. **We have I think a very well-organized database of publications in the field of spinal implants** and bio result of the polymers and applications using ultrasonic energy. Then w**e have strong connections into the industry outside of medical devices due to the technology** which is used in automotive and in watch making. Also, **there is influence coming back to us. it is not an accidental process** it is really by observing and researching what is happening in the field and outside of the field of

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											medical devices using our special combination of technology.
P14	As I said before, **it is separated in two parts,** the **innovation sometimes comes from the customer side**, or let us say from the customer side there are coming many ideas. So, the innovation point is that we are checking all these ideas which are coming from the customers, ideas and also the drawings of these ideas and we must check in all these drawings and to revise them also. So that from these ideas the customer is bringing to [Company name1] we are making innovated instruments. Innovation means at this point, for example, the requirement for cleaning process in the [Place name 6] is not so high as here in [Place name 3]. Here in [Place name 3] we have a very high standard for the cleaning process and our experience shows that the ideas from the customers in the [Place name 5] are not so high level as here in [Place name 3] and that is why, we are getting for example, a drawing or an idea, for an instrument like a scroll driver. We are checking all these	P14"it is separated in two parts; the innovation sometimes comes from the customer side" (no mention of who in company side!)					P14	No		P14	INT the request for innovation is ever coming from outside or develop internally, and when it is internally, it is more a group development is not one specific person that is striving it? Alright. Why you need this information from different people here in the company, from sale, from product management and also from manufacturing side. From manufacturing side, it is more and more important. We are working here, we have a very strong cooperation with solid works and all the drawings made by solid works here in the company, and these drawings you can shift directly to the machine at the end. To the drilling or-, and there is also this innovated part at the drilling machine for example, we can use the drilling machine also as a milling machine so that you can make different steps at one machine only about its solid (? cane) and solid drawings. INT I believe I have understood how innovation happens at your company

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	drawings and we make a revision, so that these instruments is at the end, complete this mountable, for cleaning process and stabilization process. So that, the is no risk in the-, these instruments will catch also the normal requirement from the market and from the medical device direction. And this is-, what we are seeing every day, that this is not this requirement for cleaning process in the [Place name5] for example. In the [Place name5] they are developing also good instrument but, all these instruments are not dismountable for cleaning process										
P15	I would say **everyone** in my personal opinion, the CEO's or founders have to go a bit more and so I'm thinking 24/7 about my businesses and it's everyone that's responsible for something. And I think regular employees should also shut down for a part of the day but everyone can also speak up and also say, when I have an idea, this idea is (? original) and no one should have his ego in front and say, no you're just an employee and so on, I think this is important.	P15 everyone									

NPD Models Innovation & Organisational Structure

Question 1	What experience does your company, or you have with a new product development model?	In Vivo Code	Question 2	From your experience, what internal factors are most important for the success of innovation and specifically, to what extent, do you think the organizational structure of your company support or hinders innovation	In Vivo Code	Process Code	Initial Code
P1	Probably **not** as **much**	"not much"	P1	No, that's interesting. So, firstly, I think you need **a good set of cofounders to start**, for sure and I think one thing I realized is **you don't need too many** cofounders, you need like **three maximums** because **too many opinions can kill it** so that's starting point number one. I think in order to get your team together, you **need to have people have** got equal sort of work. They've got to be equally as efficient with work at night, the **same sort of work ethic** as you, because it doesn't work otherwise when you're trying to get an idea off the ground. What was your second question, [name of the interviewer]?	14d "a good set of cofounders to start"; " you don't need too many cofounders; you need like three maximum"; "too many opinions can kill it" 14a " you need to have people equally as efficient ...the same sort of work ethic as you"	1 starting with a good set of cofounders 2 having more than three kills innovation 3 having people with similar work ethic	critical success factors: a good set of cofounders qualifying: three maxima too many opinions can kill it; critical success factor: get your team together...same sort of work ethic as you;
P7	Those kinds of models have **not been implemented in the company** yet. We would describe ourselves more as a natural innovator		P7	Yeah. Well, I can't really reply this question neither to one or to the other side. As within the medical device industry, we're very eager to certain processes and SLPs that are implemented within the company. And even those SLPs are audited by notified bodies. So, there is of course room for innovation. However, this room for innovation needs to be within the process structure of the company.			
		"not been implemented in the company"	P8	INT if I understood you correctly, you said that's **rather flat,** we are one team. Is this helpful for innovation or is it not? I think it helps because-, but it's limited as well. Well, it helps between my associate and I, because these are subjects that we discuss today at this level. And for instance, we don't discuss it very much with our chief financial officer. We discuss it with our chief medical officer because he's a doctor and he's involved with the discussion we have with the end users. But otherwise, it's something that we share today at our level. But not with everybody in the company. I'm making myself clear, please let me know.	14"flat"; "I think it helps because-, but it's limited as well"	qualifying flat organisational structure helps innovation at some level we share at our level--but not with everybody in the company	
P9	INT: There is some-how can you say, some models or strategies out there to drive innovation like open innovation or the creation of innovation hubs or there are some models called new production		P9	think the conditions for innovations are quite good at our company because in principle, we make use of comparably innovative processes. That means, of course, our core business is working with the calcium phosphate cement paste technology which is from the scientific approach which is innovative by itself and we make use of 3D printing which is of	"I think for us the organizational structure is not that important"	qualifying I think for us the organizational structure is not that important	

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	development models. Have you come across any of these? Do you have any experience? To be honest, not really. We do not act really following such, yeah, straight protocols. I think what I have to highlight is that I also implemented a shift in thinking about innovation. Again, in the past and this was the point of view of the former CEO who was, yeah, (name of the company) who had ideas about products which should be useful and should be successful but never turned out to be so and I shifted that point of view and installed a more market-oriented development process. That means, at the end, of course we do hear the feedback from the market, and we have some-of course, we observe what the competitors are doing but finally, my thinking is we do not have a distribution structure. We are not at the end user. So, I will not define what is user for the end user. I do not do that because it is not my principle but for that, we do have strong collaboration partners. For us, it is not a secret. We are strongly related to the company (name of the company), (name of the company) is a very big, worldwide acting company which is based in (name of the city and state) and (name of the city and state) and they do distribute, yeah, about 80, 90 percent of our products. And they do have a very powerful sales structure			course now everybody is doing that but it is still innovative, at least in the medical device community and that means, we make use of innovative processes and of course, out of that, innovative products are generated and that means, on the other hand, **I think for us the organizational structure is not that important** but what I can only talk for us that what we see is with our collaboration partners and we do have several partners with quite big partners where we do have contracts developments where we see on the other side with complicated organizational structures, it is really in doing to drive innovation because we do have-in principle, we are in contact with product management from the other companies and maybe the head of R&D but finally, the decision is taken somewhere in the US by somebody who I have not a clue about what we are doing. So, this is slowing down processes or maybe cutting processes at a certain level with nobody understanding. So, I like our structure because we are able to pursue innovation without management decisions which nobody understands			

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	and product management structure and of course, we participate from each other and we are in contact and we are talking about, okay, what are the new user needs, what is the feedback, what would be a product which will be successful in the market because I do not have any benefit from a product which is nice to have on the table but nobody can sell it and there is no turnover to generate with that. So, I skip that and so, okay, we will never do something. We do not have the resources to do that. We will not do anything which where the risk is too high from the market at the first point. I want to hear from the market there is a demand and where a reliable demand and only when there is somebody who will sell the product and who commits to sell the product and believes in the success of the product, then we start thinking about how to develop the product.						
P10	INT: Have you ever thought about, or discussed, or even applied things like open innovation models or participating in innovation hubs, or kind of new product development models, are they described in the literature? **No.** No, we haven't. Maybe this is my fault then, because as I said, I'm responsible for this part, but this is- Now it's less structured. It's rather learning of technologies. Sometimes it ends up with cooperation with the university on some technologies.	"No"	**P10**	INT organizational structure of your company earlier, and you said it's **kind of flat**. So, do you believe this supports or hinders innovation or doesn't it matter? I think it supports innovation, because there is less- You know, usually the reporting line and alliance are going to the management one level up, and then the decision is taken at this level, eventually forwarded to the higher level. And we work in very flat structure. So **even the employees who are- We have maximum three levels. So, let's say my level is the top. There is one level eventually below. And then we have the lowest level. But because the organization is very small, then communication goes quick.** Of course, they generate some noise too, but if **it comes to innovation, I think this is very good** because if you are able to pull interesting things	13d"Kind of flat" "We have maximum three levels" and because the organization is very small, then communication goes quick". "comes to innovation, I think this is very good "	1 working in a very flat structure 2 communicatio n goes quickly 3 high level of noise does not disturb us 4 pulling interesting things from any noise 5using it for out benefit	Critical success factor: because the organization is very small, then communication goes quick; qualifying; they generate some noise too, but if it comes to innovation, I think this is very good if you are able to pull interesting things from any noise

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	Sometimes it ends up on cooperation with some industry partners and so on, and so on, but usually it's let's say self-learning. It's dependent also on the size of our company. We don't have too much time to build new- How to say? Each one of us is learning his own let's say part, it's observing different part of the industry. And then when people learn of something new and attractive, they share this information. And so, we think eventually about using this. But we don't have any structured way of learning new technologies or-			from any noise, it's very good. So, the level of noise is not disturbing us. It's actually I think we can use it for our benefit rather than as a disturbing part. It's helping. I think it supports innovation, because there is less- You know, usually the reporting line and alliance are going to the management one level up, and then the decision is taken at this level, eventually forwarded to the higher level. And we work in very flat structure. So even the employees who are- We have maximum three levels. So, let's say my level is the top. There is one level eventually below. And then we have the lowest level. But because the organization is very small, then communication goes quick. Of course, they generate some noise too, but if it comes to innovation, I think this is very good because if you are able to pull interesting things from any noise, it's very good. So, the level of noise is not disturbing us. It's actually I think we can use it for our benefit rather than as a disturbing part. It's helping.			
P11			**P11**	Innovation, historically, has been very hierarchical, not from a structured but from the governments, right? And how decisions were made. And this is, where it is becoming much less hierarchical. Now this organization structure is not that, you know, **you don't have many layers between CEO and lowest leve**l. So, it depends what you are looking at, right? Decision-making was very hierarchical, but the structure has not been very hierarchical. Yes, I think **the way are g**oing is by empowering, structuring, and empowering. I think definitely, it will help the innovation process, because it is **not concentrated in the hand of very few. "t is based on much more of a structured innovation methodology"**	13d"you don't have many layers between CEO and lowest level"; 6 "the way are going is by empowering, structuring and empowering. I think definitely, it will help the innovation process, 16d because it is not concentrated in the hand of very few".17d "it is based on much more of a structured innovation methodology"	1 empowering structuring and empowering 2 helping the innovation process 3 not concentrating it in the hands of a few 4 basing it on much more structured innovation methodology	labelling; structure as empowering qualifying: innovation as not concentrate to a few

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P12			P12	I would say it does have impact, because **when you have flat organization**, even the (? grass road) level of **people are encouraged** and they are n**ot afraid to bring out their own opinions and their own ideas**. So that they are not (? boxed) in a certain very small responsibility area. So yes.	"it does have impact, because when you have flat organization people are encouraged not afraid to bring out their own opinions and their own ideas"	1 having a flat organisation 2 encouraging people to bring out own opinions 3 having ideas	
P13	"no"		P 13	IINT, you said the organizational structure is rather **flat**? (B: Yeah.) So, would you say this supports the innovation? **I** would say **it supports the innovation because it invites everybody to bring his-, the ideas to the table openly without any restrictions**. So, oh yeah this makes no sense, this is bad, no such thing. Ideas are open and invited and there is no restriction. And during discussion-, during the discussion of such ideas, there might be restrictions but that is not negative, that is positive. So, I think it is a helpful tool.	6c" flat it supports the innovation because it invites everybody to bring his-, the ideas to the table openly without any restrictions"	1. having flat organisational structure 2 supporting innovation 3 inviting everybody to give ideas openly	quantifying: when you have flat organization...people are encouraged; dispelling stereotypes: this is bad, no such thing. Ideas are open and invited
P14	or participating in innovation hubs together with other companies or applying new product development models? **Yes**, but we have to be very-, to organize these steps very carefully. Why? [Company name] is a contract manufacturer. So, that means 60% of our customers are from the US and this is a critical point. At each order we are getting from our customers from the US is written in this-, when we are getting directly to the market. With own products, they will cancel directly, all the company cooperation with [Company name1]. And that is why **we are developing only instruments and the set configuration so that the end customers can buy these innovative products directly at**	"Yes" "it it is a product of our customers not our product " developing more in this field so that we are getting directly to the market". (currently sold through another company)	P14	That is rather flat." Do you believe that this is supporting innovation? ***it is supporting innovation.*** Why? So, as I said, we-, the innovation point at this field is that we are-, that we can make a revision of the ideas of the customers. So, we can change the style of the instrument. So, that is very innovative only for cleaning process for the handling for data handling and this is the innovative point.	P14 "Yes" "we are developing only instruments and the set configuration so that the end customers can buy these innovative products directly at [Company name1], and can implement these instruments or set configuration to the CE or FDA"	1 make revisions with customer ideas 2 changing the instrument style 3 innovating the data handling process	

Question 1	What experience does your company, or you have with a new product development model?	In Vivo Code	Question 2	From your experience, what internal factors are most important for the success of innovation and specifically, to what extent, do you think the organizational structure of your company support or hinders innovation	In Vivo Code	Process Code	Initial Code
	[Company name1] and can implement these instruments or set configuration to the CE or FDA registration of these companies so that at the end, **it is a product of our customers not our product.** And this is the point why [Company name1] is also-, know developing more in this field so that we are getting directly to the market.						
P15			P15	INT flat, there's not really a hierarchy. In general, do you think this is supporting innovation and development? I think it is important, you have two sides, as I said before. Everything business related and the usual business things you have to do, there's someone who has to be- who has to do it. And these are always the boring stuff but when you say, what's the company really doing, I **think everyone should participate in this. And then a flat hierarchy on this side and its very supporting innovation** because if you say people- and this is not your part, even for a bigger company. You are in sales, you are in marketing, you are in development, you are in research or whatever and you are just the manufacturer and you are just the- I don't know, then one who is cleaning up the desks, whatever. But if you say everyone here is in sales, because everyone here is helping us to do something and everyone should be innovative, everyone should think about it and we are not holding back anyone. I also worked as a consultant for companies who do that, and this was very, very enlightening. Because **then people feel committed to it** and I think then they don't hold back. When they say what do I have from submitting innovation and ideas I have because the company- if it's good the company will say, it is mine, you don't get anything or just maybe more work. Other companies say, why did you waste your time with that? You should do your job and not thinking about other things. INT you said everything is rather open, so open discussions and all this. Do you feel this is good for innovation? why I'm asking the question because I have people here who said, now you know, for us it's- innovation is more a very structure process	6" I think everyone should participate in this then people feel committed to it"; " And then a flat hierarchy on this side and it's very supporting innovation"	1 flat hierarchy supporting innovation very much 2 everyone participates in sales 3 everyone being innovative 4 people feeling committed 5 making shareable innovation with no boundaries	Qualifying: everyone participates then flat hierarchy is very supporting of innovation; labelling: everyone should think about if. Then people feel committed to it

Question 1	What experience does your company, or you have with a new product development model?	In Vivo Code	Question 2	From your experience, what internal factors are most important for the success of innovation and specifically, to what extent, do you think the organizational structure of your company support or hinders innovation	In Vivo Code	Process Code	Initial Code
				and that's what we believe in? Also, big opinion and my experience with it is for example, a company like [name of a company]. I worked as a consultant, big company doing structured innovation, going through it. When they do something, they really get through with it but it's complicated to get to this point. And I also worked with other companies for example [name of a company] is a very flexible company, a very agile company. And when you have there an idea, you can tell it and you can work at it. And maybe- or sometimes that's nonsense what (? they're) working on but you're free to and maybe others can then say this is- the basic idea is good, we can do something else with it, everyone can collaborate, this also helps. For us, for our company we are doing a lot of conversation in written form also. For example, every day we write down what we did, where. It sounds very complicated, but it frees us up to not communicate over the day. We say, push everything on communication to the next day, write it down, put it aside. And then at ten o clock we do our video conference, and we are going through it and you can ask questions, you can say what you have done, you can maybe show what you have done and get questions answered. And especially for the intern that I mentioned before, he said it was so good for him to go back through all his daily status updates, now over three months I think it was. To see how he started and how he gained more confidence and what he asked and what he has wrote down or written down because I always told him to write down his experience as a (? by word) or by product that he then afterwards can say, I write an article about it or it's maybe for some kind of reports I have to put in- and he went over it. And then he said, oh there were some really good ideas in here. So, we had structured approach there because then it's shareable, everyone can read it. And I can send it to someone, I can link to it when someone says, I have a very good mind that can remember when something happened. And I can say, it was there, I sent you a link and then I sent this link to this daily status update and I say, there it was, and this really helps. So, we have both but with the intention to help the shareable creativity and no boundaries. And everyone can read everything. And also, our (? OTR's)			

Question 1	What experience does your company, or you have with a new product development model?	In Vivo Code	Question 2	From your experience, what internal factors are most important for the success of innovation and specifically, to what extent, do you think the organizational structure of your company support or hinders innovation	In Vivo Code	Process Code	Initial Code
				that I plan with my partner for every quarter, and they are also open, you can look into it, what we wanted to achieve, also financial model. And this really helps			

Question 3	I'm interested if you believe that the organizational structure, as you have described it earlier, is supporting or hindering your innovation	In Vivo Code	Process Code	Initial Codes
P1	So at the minute, I think it's supporting it because I think if we didn't have a board and a chairman to speak to, we could very easily go off tangent quite quickly like, think about the product is, how we're going to get its market and what's important and I think you need that chairman and board sometimes to help direct it. They can also hinder it, though. So, you can have the odd board member who doesn't quite understand the research space and will just be like, "Why is this not a product today," and try and derail it. So, it is very useful, but there are also slight drawbacks in the situation. So, yeah, I haven't quite found a way of making that perfect. But it's mostly positive, I'd say.		1 thinking if we did not have a Board to speak to 2 going off at a tangent quickly 3 instead thinking about the product 4 thinking about how we're getting it to market / Board hindering innovation 2 odd Board member not understanding research 3 trying to derail it	quantifying: (org structure) supporting innovation, if we didn't have a board and a chairman to speak to, we could go off tangent quite quickly; critical success factor: chairman and board sometimes to help direct it; barrier to success: you can have the odd board member who doesn't ..understand the research space and will just ..... and try and derail it.
P2	I don't know if I will answer correctly your really interesting question. I would say, for me, for company selling a product and having R&D project, t**he best structure organization would be an ambidextrous organization.** So, give the opportunity for the R&D and innovation department to perform exploration thinking and for the exploitation. So, the operating stuff, another team. For me, this ambidextrous structure leads to get the best one to have innovation, open or closed is not the purpose but again, regarding the structure, ambidextrous is the best one in my point of view. I had the experience at (name of the company) where the R&D pushed a lot, pushed, pushed, pushed, pushed a lot and I was the sales and marketing guy at that time. We were like, okay, come on, you have those technologies but that doesn't fit with what the market needs and we cannot undergo those products and it was clearly focused- the structure was clearly R&D oriented, not sales and marketing and for me, you have to have both and regarding the management, regarding the exchange, regarding the team inside the structure and not the culture but		labelling: best structure organization would be an ambidextrous organization; qualifying innovation department to perform exploration thinking... for the exploitation. So, the operating stuff, another team; qualifying innovation starts from the structure, and you manage the people	

Question 3	I'm interested if you believe that the organizational structure, as you have described it earlier, is supporting or hindering your innovation	In Vivo Code	Process Code	Initial Codes
	the way you innovate starts from the structure and you manage the people. , I don't know if I made it clear but just the way you have exploration and exploitation is the operating system for managing the product you get from exploitation			
P3	I **think it's supporting innovation** in that we will take- we will listening to- **we have a couple of guys within the company who we pay retainers to**. They're not strictly Salesforce, they're not strictly managers. One is a guy called [name of person] who used to be a director with... he used to be a vice president of [name of company] but he's now sort of semi-retired, but we retained [name of person] because **he's got good relationships with surgeons. And he's also a bit of a radical thinker at times.** If they see something in our organization or outside of our organization that they think needs changing, then they come to us and we'll discuss it. [name of person] has got this sort of consultant role with us. And we retained him to, as I say, look after parts of the country to help out the younger reps. But pretty much got a roving mandated to go anywhere suppose we lost track of what it was going to put you there. So [name of person] is out there looking at new products as well and has brought things to us and did the people. But ultimately, the decision rests with me and [name of person]. So, what drives the innovation? It's a, can we see a need for it? You know, and I go back to a thing I've always said, which is you can have the greatest product known to man, these earphones, for instance. Everybody has got them now, ear pods. Where are they? They will never get off the shelf. They will never be a success if someone doesn't go out to sell them. So, the best ideas in the world can be developed but some salesman has got to go out and either find a need or create a need and get people interested. So, I think it's a bit of a two-way street innovation. The product just going to be unique enough but there's also going to be a definite need. And then there's got to be somebody who gets that message out there so that people want to buy it. I could invent but sketchy, I suppose, but, you know, is there a need for an elbow deodorant? No, there isn't, you know, or wrist deodorants, but there's someone probably out there inventing things that are useless and they think that innovating. But you've got identify definitely applications and the need for it. It was a bit like ... I hate to say it was terribly innovative and you, guys, at [name of person]. You know, we thought we need lightweight frames. Everybody had heavy steel frames even in	"think it's supporting innovation" we have a couple of guys within the company who we pay retainers to" " he's got good relationships with surgeons. And he's also a bit of a radical thinker at times."	1 paid adviser see something inside/outside of our organization needs changing 2 coming to us and discussing it 3 sout there looking at new products as well 4 ultimately, I mame decisions 4 thinking can we see need for it 5 somebody who gets that message out there so that people want to buy it.	labelling: consultant...bit of a radical thinker at times; critical success factor: see something in our organization or outside of our organization... they think needs changing, then they come to us and we'll discuss it; quantifying (innovation)L product just going to be unique enough but there's also going to be a definite need; choosing you've got identify definitely applications and the need for it (talks about heavy and lighter metal frames for glasses)

Question 3	I'm interested if you believe that the organizational structure, as you have described it earlier, is supporting or hindering your innovation	In Vivo Code	Process Code	Initial Codes
	pediatrics. So, went on replacing the titanium and then people see, oh, wow, that is a definite advantage, especially when it's only a two-year-old. I don't know if that answers your question. I probably lost it.			
P5	Like 99% or something. I can't—I mean to me, there's a few different components, but the organizational structure. I think I would link culture to that, if I may. The organizational structure and culture are absolutely critical. If the culture of people is to operate in terms of a job specification, you're very unlikely to get the kind of innovation required. If people clock out at a certain time, say 5:00, bang. Down tools. And they say, "That's my job. There's my role. I did da-da-da-da." Trying to get an innovative—to attract innovative people, creative people to that it's very unlikely as a first thing. But also, even if you were innovative and creative and you joined that company, how long would you stay that way? Not very long. So, I think if you want creative—**if you want people to be innovative and take forward new things, you really need to provide a culture and organizational structure** that will first attract them but, secondly and probably more importantly, cultivate them. And some things that I've come across and I would—if I was designing a big organization, I would certainly try and put some of this in there, is I would cite people who stay too long in one division, one area of the company. And I'd say that site, let's just call that siloing. If you spend 40 years doing one—seeing one aspect of the company, that becomes, in your mind, what it's all about. And maybe you just focus on the early-stage R&D. Maybe you focus on manufacturing line. But that world becomes your dominant world. There's nothing wrong with it. It's just human nature that we, our horizons shrink to what we see on mostly a daily basis. But anyway, but that silo thinking really starts to limit the ability to see an integrated solution to something where—and that's really where a lot of the innovation comes from, I think. So, companies like [name of company] where they really do move people, you can't progress through that company without moving around a lot. And they do it deliberately and I never understood why. And they do it partly So, people see—they don't become siloed too much but also that they get a good understanding of how the various parts of the company works, and different products, different product lines what their issues are. I think it really **helps their culture be quite innovative and being willing to accept and go and do new things**. I	17d"if you want people to be innovative and take forward new things, you really need to provide a culture and organizational structure" qualifying: flat hierarchy ... supporting innovation; critical success factor: everyone should think about it--we are not holding back anyone;	1 providing an organisation structure and culture to attract innovative people 2 cultivating them (employees) 3 preventing silo thinking that limit the ability to see an integrated solution to something 4 helping their culture be quite innovative and being willing to do new things	critical success factor: The organizational structure and culture are absolutely critical. Qualifying: If the culture of people is to operate in terms of a job specification, you're very unlikely to get the kind of innovation required; critical success factors: provide a culture and organizational structure that will first attract them...and probably more importantly, cultivate them; labelling: siloing - people who stay too long in one division, one area of the company; barrier to success: silo thinking really starts to limit the ability to see an integrated solution/innovation

Question 3	I'm interested if you believe that the organizational structure, as you have described it earlier, is supporting or hindering your innovation	In Vivo Code	Process Code	Initial Codes
	think that's an example of that. I'm just trying to think of a company where people don't. I'm going to critique pharma here as a whole sector. People don't move around enough. They don't change companies enough and they don't change roles enough. So, you talk to somebody in toxicology and the whole problem is about toxicology. They won't even think about anything else. And you talk to somebody in marketing, it's all about how you get more—you know the story. I look at that whole sector and I just think it's just completely chronically ineffective. And no wonder most drugs fail. The whole sector really, I think they talk about innovation, but they have a very, very, in general, a huge problem in innovation culture. I'm really excited to see some companies, some big biotech companies changing that but also some big pharma companies changing that as well. Another company I would—you know you might—anyway, we'd gone on a knob. There're some things there about not being siloed.			

Leadership for Innovation

Question 1	To what extent does the management and leadership style in your company support or hinder innovation?	In Vivo Code	Process Code	Initial Coding	Question 2	To what extent does the culture in your company support or hinder innovation?	In Vivo Code
P1	*INT asked if openness in leadership was needed not the question as in list* ***P1response:*** *At the minute,* ***I would say it supports*** *it because I think* ***everyone needs to know why you're doing certain tasks*** *to get to a certain point and I think if you keep people in the dark, we don't explain the full backstory of well, we're taking a slightly*	"I would say it supports it"; 11a"everyone needs to know why you're doing certain tasks to get to a certain point"; 13b"because we're such a small company and we do change patterns	1, explain why everything is as important 2 what the end goal is 3 why we are working with these particular people 4why we are working with these particular people 4 in a situation where the management knows what's going on, but the people that work for you at doing	qualifying it supports it; qualifying everyone needs to know why you're doing certain tasks; barriers to success: keeping people in the dark; critical success factor: keep everyone aligned; labelling: because we're such a small company; critical success factors: we do change patterns .... based on market research; critical success factor: need to keep the	P1	It's not bad fun but yeah, we're pretty fun. I think – you've got to have a certain level of trust in the people you work with as well. That's the other thing. INT So, that culture, is this also supporting innovation or not? P1: **I think it supports innovation as in the fact that the people who work on the innovation are happier.** I think. Like I'm glad that we have a more if you come in and get your work done and you've done	9e"I think it supports innovation as in the fact that the people who work on the innovation are happier." 13a "they are more likely to work harder when we need them to work harder because they know we've got that flexibility" 13a"makes better innovation .... some weeks where we have to

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	different direction on XYZ because of this. You need to keep everyone aligned with why, ***because we're such a small company and we do change patterns and we do change based on market research we find*** *and stuff like that. I think* ***you still need to keep the dialogue open.*** *So, for instance, we're talking with a particular strategy and we did some work for them at the minute, and I think a lot of them were like, "Well, why are we doing this bit of work again?" But you have to explain why everything is as important as in what the end goal is and why we are working with these particular people. So, I think open is quite good still, I really do. I think if you're in a situation where the management knows what's going on, but the people that work for you at doing the day to day don't, then that can cause a lot of angst I think having worked in other places and seen that happen. I'd rather have a more open shelf on the situation*	and we do change based on market research we find". . 8b "you still need to keep the dialogue open. "	the day to day don't, then that can cause a lot of angst	dialogue open; critical success factor: you have to explain what the end goal is.		everything for the day and you want to work from home for the rest of the day attitude, then it makes people be a bit more motivated and they don't feel so chained up, if that makes sense because there's no keeping someone there 9 to 5, if they're not as efficient, do you know what I mean? So, but then I think because we have that sort of flexibility and trust with people who we've employed currently, it's worked quite well and **I think they are more likely to work harder when we need them to work harder because they know we've got that flexibility with them, if that makes sense and I think that makes better innovation because we do have some weeks where we have to work incredibly hard. But then the weeks where we don't and we let them have their own time and manage their schedule a bit better, then I think it just makes them more understanding about everything, if** that makes sense. So, yeah, we are quite fun. We do work hard, but also, we do put quite a lot of trust in everyone we've employed. We don't like to micromanage anyone, if that makes sense. But yeah, no, I do think it supports it because no one has told me they hate coming in recently. Well, they haven't really gone in recently, but no one's told me they hate where they work, if that makes sense. They don't, but no one's told me that yet, so they	work incredibly hard...weeks where we don't, and we let them have their own time and manage their schedule a bit better"

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						all seem pretty happy still and quite excited to get back actually. So, yeah	
P2	For me, **it is really important**. Again, it is really important again for a start-up company but regarding the- it is quite difficult to answer your question right now because again, at (name of the company), we don't sell but I think that once you sell a product and you have a research of your exploitation or your operation, you have to be careful at the end that the management- for me, you need a leader. Too many, one for the innovation, another one for the operating and both have to report to a final CEO which has to have an ambidextrous mindset as well. Both have to walk together because it is two different- for me, it is two different jobs, two different tasks, two different philosophies and you cannot- I don't know but for me, it is quite tough to manage both innovation plus exploitation. I don't know it is a good term in English, exploitation. Well, you could give me. Right, example of that is Apple, for example. You have a	" it is really important"	1 you need a leader one for the innovation, another one for the operating 2 both have to report to a final CEO 3.two different teams with an open communication between them 4 to get a product for a client or client needs.	qualifying: really important for a start up company; labelling: start-up company; hypothesising: once you sell a product you need a leader, ons for innovation and the other for operating; choosing (structure); both have to report to CEO; quantifying: for me, it is two different jobs, two different tasks, two different philosophies; barrier to success: quite tough to manage both innovation plus exploitation; critical success factors: two different teams with .. open communication ..to get a product for ... client needs.	**P2**		

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	real manager, a supply chain manager which is a CEO, Tim Cook, on the top and split it in two parts. You have, of course, the innovation and R&D and with clearly some link between the marketing and sales from the exploitation. And for me, this is clearly key success factor. You have to add a mesh. Of course, two different teams with an open communication between both to geta product for a client or client needs.						
P3	(Interviewer asks about openness again as well) It should be. It should be because anybody who sees a good idea should bring it forth to the management of the company and say, okay, what do you think of this? We have had that. We have had guys going over to medical and coming back with a product, but so much medical is the same as everybody else's product. ... And you do see the odd thing there ... ...we've taken them from Medicare in recent years. Only like finding a manufacturer for trays or something similar that you can deal with. There's a lot of innovation coming out of China and, anyway, I think	6c "everybody has an equal say at the table, if you know what I mean. An equal place at the table."	1 anybody who sees a good idea should bring it forth to the management of the company 2 guys going over to medical and coming back with a product, 3 and say, okay, what do you think of this? 4. we've taken them from Medicare in recent years (ideas)	critical success factor: anybody who sees a good idea should bring to the management; hypothesising: what do you think of this (ideal); critical success factor: guys going over to medical ..coming back with a produce,. You do see the odd thing there; quantifying: open and flat management should create innovation, because everyone has an equal say;	P3	INT I believe for the culture in your company, I think you said transparent, right? P3: Yeah. I: Yeah, yeah. So probably, maybe you have to say an answer, but that's also good for innovation then, if everyone knows ... Yeah. You know, **I believe in informing people all the time,** so just to a lesser degree, maybe I'm a bit more secretive to me, but, you know, we have a town hall meeting, I think the Americans call it, occasionally where we all the office staff. And we'll do it on Zoom with the reps as well and go, "Listen, this is what sorts of money we're making. This is, you know, blah, blah, blah, blah, blah. We've got 24 mouths to feed here. If we're not turning over enough, jobs will be lost. The company will be lost, etc." But also, we have the same thing with the product [name of	14" I believe in informing people all the time" 14 "you've got to realize the importance of what they are doing in the warehouse, ultimately can have a devastating effect with a rep and a surgeon "

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	answering the question, a**n open and flat management should create innovation because everybody has an equal say at the table, if you know what I mean. An equal place at the table.**					person] will do response. I will do response. [name of person] do response. [name of person] will do response and just say, you know, this is a land thing there. How does it work? Because the guys in the warehouse don't know, but I think if you get them involved enough, if they're not just opening boxes or packing boxes or whatever. And you've got to realize the importance of what they are doing in the warehouse, ultimately can have a devastating effect with a rep and a surgeon ... #00:29:05#if all the stuff doesn't get there, basic stuff. But we created the .....here, but that's why we have these open forums, town hall meetings. They can be educational. They can be educational about the states of the business. Education about product. Education about the direction you want to go in, where we might need more people. And we ...in case they know anybody. You know, it saves us paying headhunting fees and whatnot.	
P4	INT And thinking about management or leadership style, in terms of innovation now, is it good to discuss all these ideas very openly or is this something where you have to be a bit careful? No. I said we can discuss the innovation, but however, we have to be focused on the objective. So, don't spend too much time to discuss.		1 be focused on the objective 2 don't spend too much time to discuss (ideas)	critical success factor: focused on the objective	**P4**	So small teams that...that **is good if you don't have more than five people reporting to you**. It's linked to the size of the company, not to the... I **think it's important to communicate to anyone in the company when we do something very different.** ... selling arguments of the innovation, so it's important that everybody understand ... In our case, yes, we are flat because we are small. We	14"is good if you don't have more than five people reporting to you" 7b "is good if you don't have more than five people reporting to you"

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						were less flat when we were 10, but...	
P7	Well, within the current management style at [name of a company], there is very little room for innovation, but this is truly depending on the fact that we are going through insolvency proceedings at the moment that will hopefully be over by the end of August. However, our aim and our goal for the future is to achieve a turnaround and to completely set up the company from scratch beginning of September. And obviously by then also implementing a new management style and a new culture. INT From your experience, what type of leadership or management style do you believe it takes to drive and motivate innovation? Well, **in this context, I'm pretty clear. It needs a very agile management and leadership, and you have to give room to the employees for creativity ideas in order to drive innovation.** Well, in this context, I'm pretty clear. It needs a very agile management and leadership, and you have to give room to the employees	12d "It needs a very agile management and leadership", and you have to 9c "give room to the employees for creativity ideas in order to drive innovation".	1 very agile management and leadership 2 give room to the employees for creativity ideas 3 drive innovation	labelling (leadership for innovation): needs agile management and leadership; critical success factors: have to give room to the employees for creativity ideas;	**P7**	INT asked about culture for innovation Definitely. Before we ran into that situation, we had a flatter **hierarchical structure**. We had **direct access to the CEO**. We had direct access to the board. We were **running think tanks**, and all of that of course with a more **agile leadership, w**ith a more **open leadership**. We were **more successful** then.	"flat hierarchical structure... direct access to the CEO…...to the board. ,4 "running think tanks", and a…. 12d "agile leadership, ... open leadership. We were more successful " then."

Question 1	To what extent does the management and leadership style in your company support or hinder innovation?	In Vivo Code	Process Code	Initial Coding	Question 2	To what extent does the culture in your company support or hinder innovation?	In Vivo Code
	for creativity ideas in order to drive innovation.						
P8	INT: thinking about management or leadership style, if I understood you correctly there, then you said that you are sharing a lot? Yes. INT: is this is a good thing for innovation or is it not important or can it even be bad or threat or risk? Well, as long as it's kept within the company borders, it's not a threat I would say. And **it helps also for the people who work in the company to see where we are going, what we're doing. So, I think it's quite positive**. So, I think, well, innovation **can backfire if you don't keep it within the walls of the companies.** So, **I think, well, needs to be secretive in some way. So, it needs to be secretive in some way.**	11c "it helps also for the people who work in the company to see where we are going, what we're doing. So, I think it's quite positive" (referring to leadership openness). "I think, well, 18a "innovation can backfire if you don't keep it within the walls of the companies. So, it needs to be secretive in some way."	1 it helps for people who work in the company to see where we are going 2 keep it within the walls of the companies 3 (then) innovation won't backfire. Needs to be secretive	Qualifying: it helps also for the people who work in the company to see where we are going; quantifying: its quite positive; labelling (innovation): needs to be secretive in some way; barrier to success: (innovation) can backfire if you don't keep it within the walls of the company	P8	"Well, in this context, I'm pretty clear. It needs a very agile management and leadership, and you have to give room to the employees for creativity ideas in order to drive innovation. "	
P9	INT believe you described that as open and transparent. So, what you say this is also something that supports innovation to speak openly about things? **Yes, indeed,** because I only think when you **encourage your people** especially the R&D staff to	9c"I think when you encourage your people to be able to express their ideas, …. open discussion is every time a fruitful basis for getting the best	1 encourage your people to express their ideas 2 brings open discussion 3 basis for getting the best out of people	critical success factor: encourage your people; stereotyping: especially the R&D staff lo be able to express their ideas; hypothesising things and ideas on the table which maybe at the first few-not useful...but finally, of course... fruitful; critical success factor: an open	P9		

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	be able to express their ideas, of course, this brings things and ideas on the table which maybe at the first few-not useful but finally, of course, an **open discussion is every time a fruitful basis for getting the best out of the people.**	out of the people".		discussion is basis for getting the best out of the people.			
P12	Well, **of course it has to have an impact.** I cannot say because I am doing my management style by my style. So, I do not know if the other styles are better for the innovations, but I do trust at least that what I have been doing is somewhat innovative. Because we have had monitors who have been very strict, kind of an army style managers. And from those functions of people we do not usually get innovative ideas	"of course, it has to have an impact"	1 we had very strict army style managers 2 from those functions of people we do not usually get innovative ideas	quantifying: of course, it has to have an impact; barriers to success: very strict, army style managers do not usually get innovative ideas; stereotyping: very strict army style managers, do not usually get innovative ideas (from employees)	**P12**	INT:Culture for innovation. Because always, when you have an **open discussion**, there are a**lways people who will shut down all the new ideas**. So **probably yes**, it **also creates risks** at the same time. But I still believe that the **more discussion you have**, the **more likely** it is to get even some **innovation**, even though some people are bringing them down. Rather than having **less discussion and then less ideas.**	6c"open discussion, ... new ideas …the more discussion ... more likely. Some innovation, rather than less discussion and then less ideas"
P13	INT what you said about the management and leadership style, so does that-, this is very discussion oriented. So, then you would say this also supports the innovation. Yes. A free exchange of ideas without any restrictions to it. There is no bad idea. So, respect that.		1 free exchange of ideas without any restrictions to it 2 there is no bad idea. So, respect that.	critical success factor: free exchange of ideas without any restrictions. Labelling: there is no bad idea. Choosing there is no bad idea... respect that.	**P13**	INT what you told me about the culture, you said: „Yeah, well it is still kind of a start of culture here, a bit chaotic sometimes." If I understood correctly. So, how is this? Is this good for innovation or is this bad for innovation? In the end it is **bad for innovation**. Why? You s**pend a lot of money and time if you do not follow certain requirements which are helpful for the company**. Because you will find	company with "chaotic culture" (P13) "bad for innovation. Why? You spend a lot of money and time if you do not follow certain requirements which are helpful for the company".17d "certain rules and regulations in a chaotic system would help to figure out if you are on the right way, if it is feasible, if it is

Question 1	To what extent does the management and leadership style in your company support or hinder innovation?	In Vivo Code	Process Code	Initial Coding	Question 2	To what extent does the culture in your company support or hinder innovation?	In Vivo Code
						out that you took a wrong turn at a very late stage. Meaning you invested a lot of time and maybe money already. So, **certain rules and regulations in a chaotic system would help to figure ou**t if you are on the right way, **if it is feasible, if it is financeable**. That will help a company even in a start in situation if you follow the cliché, would help the company to focus on what is possible and what is not possible inside the set of limitations, financial regulation, knowledge, whatever. So, free discussion at the beginning of a .. But once there is the decision to look deeper into a project, documentation should start in order to find out when there was a-, when the company took a wrong turn. **Learn from mistakes,** that is the point. I**f you repeat mistake**s over and over and expect the same result, **that is a bad idea.**	financeable" "Learn from mistakes, that is the point. If you repeat mistakes over and over and expect the same result, that is a bad idea"
P14	discussing a lot and we make taking decisions as a group. Is-, would you say this is also good in terms of innovation? Yes. Would not make sense when the management is very strong, would be very strong and when it is not open management, let us say you need all these people here and not all but from each department, you need some people to find the right decision before you		1 people here from each department 2 you need some people to find the right decision before. Starting the manufacturing process 3 management is open to have a complete round table discussion 4 to write down all the information before you start the next step.	critical success factor: you need all these people here and not all but from each department, you need some people to find the right decision; choosing there are so many questions every time and that is why it is very important that the management is open; critical success factor: have a complete round table discussion to write down all the information before you are starting the next step.	**P14**		

Question 1	To what extent does the management and leadership style in your company support or hinder innovation?	In Vivo Code	Process Code	Initial Coding	Question 2	To what extent does the culture in your company support or hinder innovation?	In Vivo Code
	are starting the manufacturing process for each instrument or implant. So that you-, that there are so many questions every time and that is why it is very important that the management is open to have a complete round table discussion to write down all the information before you are starting the next step.						

New EU Medical Device Regulations

Question 1	Do you believe the new regulations? What impact will the new regulations have on innovation in general?	In Vivo Codes	Process Codes	Initial Coding
P1	I honestly, I do think **it's going to make it** harder like, it's already pretty hard **being a small company** and **getting through every regulatory hurdle** and **not running out of cash** as it is and I don't think I've seen anything from what I've read currently that's going to make that particularly easier, if that makes sense. We're quite a tricky drug device combination so we're probably on the hardest spectrum of the devices but we're a device all the same and just like from the chat that we've had with them currently; it has made us very ..... to think even if we did raise a very big series B, we would never have enough cash, I think, to take it right through to market, which **almost makes us think that our only option, really is to partner with one of the key manufacturers**, if that makes sense and I think there needs to be a bit more support and a bit more common sense in the situation, but yeah	19 " it's going to make it harder. being a small company"; 19"getting through every regulatory hurdle and not running out of cash"; 19b "our only option, really is to partner with one of the key manufacturers"	1 we would never have enough cash, I think, to take it right through to market 2 our only option, really is to partner with one of the key manufacturers	quantifying: make it harder; labelling: being a small company; barrier to success: getting through every regulatory hurdle and not running out of cash; qualifying: don't think I've seen anything from what I've read currently that's going to make that particularly easier; labelling: We're quite a tricky drug device combination; quantifying: we're probably on the hardest spectrum of the devices; barrier to success: we would never have enough cash, I think, to take it right through to market; quantifying: only option, really is to partner with one of the key manufacturers; hypothesising: I

Question 1	Do you believe the new regulations? What impact will the new regulations have on innovation in general?	In Vivo Codes	Process Codes	Initial Coding
				think there needs to be a bit more support and a bit more common sense in the situation
P2	EU, you mean the- NT: So, from this year or now from next year because the appoint is for one year, there will be new medical device regulations in EU, P2: Oh, sorry. The new MDR, okay. I think, yes. I think, yes. In my point of view, for the big companies, they will decrease probably their expense or the investment on their innovation departments to save the percentage of margin or net profit margin they currently have because due to this new MDR, of course, you have to pay some clinical trial which is quite costly and at the end, that will increase their R&D cost and something for the post-marketing follow-up. At the end, that will decrease a bit their profit margin. So, in my point of view, for **big companies, they will decrease probably their budget for innovation** but in the other side, I think that we probably see a lot of new start-up company selling their technology before clinical trial to these big companies and we will probably see what we have seen for the last 10 years or maybe 20 years in the pharmaceutical companies, I think, but again, mainly Europe. Regarding the US, it will be probably different because as you know, US, the rule is still the same. So, it is still 510(k). For standard product or medium product and for disruptive product, it is a PMA. So, for me, nothing will change regarding the US but for Europe, if a company wants to sell their- I'm not sure that the first market will be Europe.	19b "we probably see a lot of new start-up company selling their technology before clinical trial to these big companies "	1 big company, they will decrease probably their expense or the investment on their innovation departments 2 big companies, they will decrease probably their expense or the investment on their innovation departments 3 if a company wants to sell their- I'm not sure that the first market will be Europe.	hypothesising new MDR... I think ..big companies.. will decrease investment in their innovation departments; quantifying: to save the .. net profit margin because due to this new MDR.. you have to pay some clinical trial... quite costly... will increase their R&D cost and... the post-marketing follow up;
P3	It seems, and I don't know a great deal about the new regulations as maybe I should have. [name of person] our QA guy here because we deferred everything to him now. Well, you know, yourself that like our former notified body, I think was that our QA in this particular one, there's about half a dozen, maybe 10 in the UK. That's gone down to about two. And why is that? Because the new medical device regulations are so complex that a couple of companies have gone, well, we're not going to do that anymore. So, we've had to go to, I don't know, who's gone to ... # come to me as this interview goes on, it's the guys who do the kite standard mark. They're going to do ours. Anyway, we'll all go through that process at the moment. I was looking for half pins ...where you're on call to go to the States yesterday and I contacted [name of company], probably a company you're familiar with in Shanghai. nd, you know, say that you will use your C Mark and your answer one nine, three, four, five, if that's the right number sequence. And then you see, well, our RSO is okay.. But our CEE is being revaluated at the moment because it seems ... ...body of notification and even those dates where we are on our own eyes, 13485. And that's been on hold, again, because of the new MDR regulations. It's so much tighter and higher. And that's why I say me and [name of person], started this business with my exorbitant pay off from [name of company] and an idea, a couple of mobile phones and an office couldn't do, too many regulations to jumpstart. Yeah. The bar has been lifted so high and we know why it's been the failure of the various things, the metal-on-metal hip, which sold for quite a while and all the things, breast implants ... as well. Rightly so, but you know, you, it has become		1	Quantifying: our QA guy here because we deferred everything to him ...Because the new medical device regulations are so complex; barrier to success: a couple of companies have gone; Quantifying: our CEE is being revaluated at the moment because of the new MDR regulations. It's so much tighter and higher; labelling: the bar has been lifted so high;

Question 1	Do you believe the new regulations? What impact will the new regulations have on innovation in general?	In Vivo Codes	Process Codes	Initial Coding
	so much more difficult to even plus class one devices, which is the bottom ends used to be able to self-certificate virtually yourself.			
P4	**19 It's going to destroy innovation, to avoid innovation to go in the market. ... At least, in orthopedics. It maybe different in other fields, but in orthopaedics ...because it's very difficult to raise money in orthopaedics.** INT:So, what you're saying is you believe it will be very difficult to have new development and innovation with the new regulations. Yes. I had already experimented that ... products.	"It's going to destroy innovation, to avoid innovation to go in the market. ... At least, in orthopedics". "because it's very difficult to raise money in orthopaedics".		quantifying: It's going to destroy innovation; qualifying avoid innovation to go in the market. ... at least, in orthopedics; barrier to success (regs); because it's very difficult to raise money in orthopaedics.
P5	Yeah. I'm just I'm aware of it, but again, as I was saying, my message that we really focus on being components that will be brought into other people's businesses. So, it's not something that I have given a huge amount of worry to. I'm aware that there were changes coming in. If I'm honest, I heard the changes coming through and I thought to myself, "Oh, great. A sector that's already struggling and it's going to get hit with more reporting requirements." But what I would say is because of our focus on being part of other people's businesses, and nobody has said anything to us about have you made sure you've done X, Y, Z. I feel like we're probably too early stage, in a way, to be worrying about it. But I certainly, yeah, I would say too early stage for us to be worrying about it. But I will be honest. It's also entirely possible that we should be worrying about it but just don't or aren't fully aware enough of the implications for us in how or what we should be doing. That could—I know that sounds like not something you put on your website and tell people but it's—the truth is, you don't have enough time to go around, So, we're worrying about doing—sticking everything together and keeping things going			hypothesising: It's also entirely possible that we should be worrying about it but just don't or aren't fully aware enough of the implications for us;
P6	The new impact, first, that you're going to maybe 30% to 40% of small companies that they're going to disappear off the medical market. Yeah. Out of there, you're going to have pretty much 50% of the product portfolio offer it's going to disappear. Look at B. Brawn they have reduced by 25% the product offer on product. Why? Because, finally, it was the hand of stopping—making product just for the sake of a surgeon request. Now, knowing that, especially for big companies like [name of company] and So, on, for them the cost of just maintaining a CE mark on a product, it's for them a 250,000 euro … Hello? It's for them a Maintaining a CE mark it is huge cost of 250,000 euros. So, if they don't make a million euro of sales out of it, forget it. So, rationalization of the product portfolio. And then what now MDR is providing as opportunities, first, you're going to have less competition. Really, you're going to have less competition because when you did use SWOT analysis a long time ago for a product, the barrier of entry is was always regulatory. But in the past, that barrier was not a big jump. Today, this is a huge jump. So, if you are in when the market is closed, the value of your technical file increase suddenly. And the fact that big companies have reduced a product portfolio, you have less competition. There is only one thing that there is little chance that products demand will going to be able to decrease neither increase in the price of implants, except for some areas were, for instance shoulders. Shoulder implants, fracture implants, last year—I mean, no. At the beginning of February, there were only two companies left to		1 new impact, first, that you're going to maybe 30% to 40% of small companies that they're going to disappear off the medical market. 2 big companies like [name of company] and So, on, for them the cost of just maintaining the CE mark 250,000 euros 3. rationalisation of the product portfolio 4 less competition 5 value of technical file will increase 5 little chance that products demand will going to be able to decrease neither	quantifying: 30% to 40% of small companies. Going to disappear; quantifying: 50% of the product portfolio offer it's going to disappear; quantifying: big companies. The cost of just maintain CE mark... 250,000 euro; choosing: if they don't make a million euro of sales out of it, forget it... rationalization the product portfolio; Critical success factor: MDR is providing as opportunities.... you're going to have less competition; quantifying: regulatory…huge jump; critical success factor: if you are in when the market is closes. Value of your technical file increases; hypothesising; there is little change market demand will decrease; critical

Question 1	Do you believe the new regulations? What impact will the new regulations have on innovation in general?	In Vivo Codes	Process Codes	Initial Coding
	provide this kind of implant in France. And I can tell you what the company did. They started to charge instrumentation use. You see, there were opportunities. So, basically, MDR is going to reduce competition. MDR—and this is kind of surprising, but I didn't know it would have that effect So, fast. But today, the new CEO, she has a lot CE mark has some of recognition outside of Europe. I'm not talking about Australia because Australia I've already said two years ago that they will follow the CE regulatory. But I'm talking about Arabic countries. I'm talking South America, Brazil. And whereas those countries were very—were not reluctant to buy a CE mark product ten years ago because it is So, far from the PIP story, So, they were kink on buying Made in Germany. For them 'Made in Germany' was the proof of a quality product. But not the CE, the Made in Germany. Today, you see the distributors down there, they know the difficulty to have a CE. So, they know that the quality is very strict. That's why MDR is a way for improvement.		increase in the price of implants 6 distributors know the difficulty to have a CE... that the quality is very strict … that's why MDR is a way for improvement	success factor (is MDR); distributors (in other countries) ... know the difficulty to have a C... know that the quality is very strict... why MDR is a way for improvement.
P7	: Yeah. Well, I see it every day and for me, it is very clear that there will be **a fundamental impact on the innovation pipeline**. The work required today to get a CE Mark has completely changed. **Smaller companies will need to put heavier emphasis on solid clinical dossier for class three and implantable products. It will also require extra time and investment to put those dossiers together** and to make sure that products meet those new requirements. Furthermore, I believe that the remaining notified bodies will be more competent in the future. So, there will be more pressure on companies to invest more time and effort to make their dossiers user friendly and approachable of course for reviewers, intuitively simple and easy to be followed up. And the assessment process itself is in all likelihood going to take longer in the future. In this context, I believe that the businesses will need to factor the additional time into all of their future development and planning decisions. For example, we understand that only the scrutiny mechanism could add up to 60 days in the process. And the biggest concern about this is that the patients will have to wait longer for the access of the products. However, **there's also an upside. I believe that the new European medical device regulation will lead to longer product life cycles, and thus products can also be cashed out longer, which is definitely beneficial especially for the small and medium size companies.**	19"a fundamental impact on the innovation pipeline" 19b "Smaller companies will need to put heavier emphasis on solid clinical dossier for class three and implantable products. It will also require extra time and investment to put those dossiers together" 19a "there's also an upside.... I believe that the new European medical device regulation will lead to longer product life cycles, ... products can also be cashed out longer.... definitely beneficial especially for the small and medium size companies."	1Smaller companies will need to put heavier emphasis on solid clinical dossier for class three and implantable product 2 will also require extra time and investment 3 the remaining notified bodies will be more competent in the future 4 more pressure on companies to invest more time and effort to make their dossiers user friendly 5 he assessment process itself is in all likelihood going to take longer 6 patients will have to wait longer for the access of the product 7 regulation will lead to longer product life cycles..... products can also be cashed out longer	quantifying: a fundamental impact on the innovation pipeline' qualifying: smaller companies will need ... heavier emphasis on solid clinical dossier for class three and implantable products; critical success factor (for small companies): extra time and investment to put dossiers together...to meet new requirements; labelling: remaining notified bodies will be more competent; hypothesising: assessment process ...likely. To take longer in the future; linking: longer time for assessment process...patients must wait longer; linking; regulations with longer product lifecycle and product profit cycle; qualifying: benefits of longer lifecycle-- especially for small and medium size companies
P8	I might not be specialist as you are, so if you want to give me some insights, please do. I might not be specialist as you are, so if you want to give me some insights, please do. I: you have an opinion if the new regulations have an impact on innovation in the medical industry? Yes, but same as you can be more specific. Are you talking about being able to be			quantifying (the benefits of the regs): quality very much… and because it's building a commercial barrier with other competitors.

Question 1	Do you believe the new regulations? What impact will the new regulations have on innovation in general?	In Vivo Codes	Process Codes	Initial Coding
	considered a medical device or according to classes, is it referring to, INT my understanding of the new regulations is that it will take much more time and much more money to have a product classified as a medical device? And that, of course, has certain implications. Well, I think less and less companies are-, Okay. How can I put it? Can we talk about competitors, for instance? Because yeah, when we look at [name of a company] competitors right now, basically we have three markets which drive innovation and build competition. You have all those major imaging companies like [names of companies], who develop you know, imaging solutions with embarked software algorithms, things like that. And by definition, those companies are making medical devices, but they are making hardware, medical devices. So, it's a specific category of solutions. So, they have the knowledge on how to drive software innovation pretty well, but this software innovation is based on structured data that they are producing themselves. So, for instance, [name of a company] knows very much how to give value to the data that they're producing, but they it's difficult for them to add value to data which has been produced by a competitor like [name of a company] or [name of a company], for instance. But in a sense, if tomorrow they want to do a medical device, they know how to do it. Now, if I'm a pharmaceutical company such as [name of a company], which is one of our competitors, that's another issue because they are developing software's and they don't want to become a medical device. They will do whatever they can not to become a medical device because it has too much impact on their global activities. Because you need to get some [name of an organization] or some certificates, which reach far beyond what they are dealing with looking at only, you know, [name of a company] or competition. So, they try not to go into that segment. And then you have a third type of competitors, you know, companies like [name of a company] and those companies definitely do not want to be medical devices. They want to be [name of a product] company providing software solutions. So, coming back to your question, I think when you look at innovation and should you get a certification as a medical device? First of all, the question is, do we really want to become a medical device? And those companies are asking themselves very loudly this question. Yes or no? And then what impact does it have if the answer is yes on other businesses. INT:That's a very interesting view because most people look at this within the system, but you are taking obviously a step outside and asking the question, do I have to make it part of the system? B: Yeah. And for instance, for [name of a company] we think, first of all, that it's structurally very important for us to become a medical device because it will help us work in a way that we can speak about quality very much because quality is inscribed in our genes. Okay. And also, we want to do it because it's building a commercial barrier with other competitors. Because we will be able to say, okay, we are a medical, they are not. And if they are not it's because the answer to your questions is not the same.			
P9	I think **it cuts off innovation**, **maybe not in total but at a very certain level** because what we do see is that the big players are reducing their portfolio and reducing their portfolio to the really old stuff as a saved staff and **most of the innovative R&D projects are cancelled** because what we could hear what was the most often for the point was that they said, okay, **our regulatory department is completely involved with getting our available**	19 "it cuts off innovation, maybe not in total but at a very certain level " "most of the innovative R&D projects are	1.the big players are reducing their portfolio to the really old stuff 2 regulatory department is completely involved with	quantifying: it cuts off innovation; qualifying: maybe not in total but at a very certain level… the big players...most of the innovative R&D projects are cancelled; critical

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	portfolio on the MDR level that there are no resources for really new developments. So, and I think this status will stay for the next few years at least. So, I think the most important point is that **the companies do not have enough resources to pursue new projects**.	cancelled" 19b"our regulatory department is completely involved with getting our available portfolio on the MDR level" 19 " that there are no resources for really new developments" "the companies do not have enough resources to pursue new projects".	getting our available portfolio on the MDR level 3 most of the innovative R&D projects are cancelled 4 thre are no resources for new developments	success factor (for the big companies): reducing their portfolio to the really old stuff ; choosing getting our available portfolio on the MDR level ...there are no resources for really new developments;
P10	Yes, definitely it **will block small companies from entering the market**. So, I always say to people that we were very lucky in time to start our company when we started, because few years later, the eventual **cost of getting into a medical industry** would be significantly higher. And with the new medical directive, it **will be even higher**. So, there is much more of bureaucracy you have to do before you start working in this industry. So, I suffered in 485, now it actually becomes a doctorate almost. But then how do you want to start it if you are just two people company? You almost have no chance to start this. So again, so it will, definitely it will impact. And you think it will impact in- For the industry, it will be negative from the point of view of innovation. F**or the industry understood as the end users, but because for the suppliers, it will be slightly different. They will have much more time to work on the ideas because less competition means you have definitely more time**. So, we are again fortunate because we are of the size that we can easily participate in this change. And we do not have to be afraid of this change really. But for small companies, as I said, one, two people companies that were come on in this industry in the past, they will go through really huge, huge problems. This is my understanding. That's why on one hand, I understand the importance of implementing more strict rules, more defined processes and so on. But as let's say something that has to bring more safety to the patient, but we have to remember that the latest scandals were not related to the fact that the small company screwed up. The scandals we had a few years ago with the breast implants and so on, you remember. Actually, there was teeth and some big French company who screwed up all the things. So, two big companies created the mess, and the industry has to pay additional restrictions now for this. So, this is, I don't think it's really- The new implementations are to secure patients better. It's just to close the market for the bigger companies and that's it. And also of course, a little bit put some protection on the market too, because this is my observation. This is as I see it. It will work for our benefit of course.	19"it will block small companies from entering the market" 19 "cost of getting into a medical industry would be significantly higher. And with the new medical directive, it will be even higher" 19b "or the industry understood as the end users, but because for the suppliers, it will be slightly different. They will have much more time to work on the ideas because less competition means you have definitely more time"	1 small company blocked from entering the market	Qualifying: will block small companies from entering the market; quantifying: cost of getting into a medical industry ... significantly higher; barrier to success: much more bureaucracy quantifying: cost of getting into a medical industry would be significantly higher; qualifying: e industry, it will be negative from the point of view of innovation; quantifying: for the industry you will have much more time to work on the ideas because less competition;
P11	I think there is general innovation in our company situation, right? If I talk generally, **definitely it is going to slow down innovation**. **It will prioritize more the US market versus the European market, while historically it has been the opposite**, right? I think, there will be an impact on Europe. At the same time, **it does force companies to rethink how they wor**k. And **do you need leverage, or you can do it on your own?** I think small companies- there are two aspects that will have an impact. It will impact from within the	19"definitely it is going to slow down innovation" 19b"It will prioritize more the US market versus the European market, while historically it has	1 innovation will slow 2 focus will move to US market 3 reconsideration of whether a partner Is required 4 drive more	Qualifying: it will slow done innovation; quantifying: it will prioritize more the Us market versus the European; choosing: force companies to rethink how they work; choosing: do you need leverage, or

Question 1	Do you believe the new regulations? What impact will the new regulations have on innovation in general?	In Vivo Codes	Process Codes	Initial Coding
	company. Product-Lifecycle Management do really need to prioritize. Eventually, in my opinion, it will slow but it will drive more valuable innovation through the, you know, through commercialization. The problem **I worry about small companies that are innovative but don't have the resources to do it on their own**. That may, especially if there are lot of American companies with innovation, they may hold back to come to Europe and pursue (?CE) marking, because of the difficulties and because of the attractiveness of the US market"; " it does force companies to rethink how they work. And do you need leverage, or you can do it on your own? I think small companies- there are two aspects that will have an impact. It will impact from within the company. Product-Lifecycle Management do really need to prioritize. Eventually, in my opinion, it will slow but it will drive more valuable innovation through the, you know, through commercialization. The problem I worry about small companies that are innovative but don't have the resources to do it on their own. ..especially if there are lot of American companies with innovation, they may hold back to come to Europe and pursue (?CE) marking, because of the difficulties and because of the attractiveness of the US market"	been the opposite" 19 "it does force companies to **rethink how they work"**....."Do you need leverage or you can do it on your own?" 19a"It will slow but it will drive more valuable innovation through the commercialization" "worry about small companies that are innovative but don't have the resources to do it on their own"	valuable innovation (this company)	you can do it on your own? Hypothesising: Eventually it will drive more valuable innovation through. through commercialization; barriers to success: small companies that are innovative...do not have the resources to do it on their own: stereotyping: small companies that are innovative but don't have the resources to do it on their own;
P12	Honestly, I cannot say yet. To me it looks like it is **raising the barrier of entry**. It **might not decrease innovation, but it might direct innovation more to bigger organization.** Those who have the capability of entering the market.	19"**raising the barrier of entry**" "might not decrease innovation, but it might direct innovation more to bigger organization…. who have the capability of entering the market".		quantifying: raising the barrier of entry. Hypothesising: It might not decrease innovation but might direct innovation more to bigger organization who have the capability of entering the market.
P14	The impact of innovation is for me what we are feeling here in the company, especially when we are talking about instruments and trace and set configuration. Before especially and-, for the class one instruments, it was so that all the companies were looking to buy the instruments and the world market very cheap to provide them to the customer. Now, it is so that also for class one instruments, you need also the documentation. And that is why we are getting the feedback from the market. that we have now contracts to companies which are asking for not only for instruments they are asking for a complete set configuration. So, that they can come to [Company name1] and to make an audit here that we are a critical supplier for them and that I am not buying here an instrument and their instrument, and they are getting not all the important documents at the end. And this is-, for me, it is an innovative point. We can save some market also a little bit from so that **you have at the end only good quality instruments in the market**. For our company, yes. For other companies, smaller companies, like distributors, it is not so good	19a"you have at the end only good quality instruments in the market		qualifying: For other companies, smaller companies, like distributors, it is not so good; quantifying@ at the end only good quality instruments on the market

Question 2	If you think that under the new regulation your company has the financial resources needed	In Vivo Codes	Process Codes	Initial Coding
P1	**No,** I don't think we will. I honestly don't. It's a totally depressing thing to say, but I really don't. It doesn't mean that does worry me	19"NO"	1 establishment of collaboration for collecting clinical data 2	
P2	Interesting, another interesting question. **We will target mainly US, South America or the countries where you don't need to have CE.** For the new one, **we don't plan to get a CE mark**, probably a V2 or a V3 but not for the V1. We don't want to get a CE mark just because at the end, as you know, **the price is quite low and the expense or the budget to get a CE mark or in one year will be so high to have written an investment shortly.** So, that's why we would target mainly the US and South America first probably. We will try Canada in the second time and again- INT: Yeah, that's a very interesting regulatory strategy. **P2**: You know, it is funny because they have launched MDSAP offering, I would say. So, for US, Brazil, Australia, Japan and Brazil, outside Europe. So, you can get an audit for your product and your system for those countries without CE mark. So, due to the fact that we will target FDA and South America are beyond probably that we will follow the or we will ask for an MDSAP audit just to target in a certain time those countries and avoid selling in Europe. Again, because we won't have our own clinical trial. Maybe on the second or third time, once we will have enough clinical studies in Brazil but I'm not sure that the research can be used in Europe but anyway, this is a strategy in short term but for the long-term project, our middle-term project, we requested a PMA for the US, we will probably start first by CE following the US requirement to sell in the US in the second time. We will do the opposite. But again, it is for disruptive technology. It won't be the case for the first technology	19b"We will target mainly US, South America or the countries where you don't need to have CE. For the new one, we don't plan to get a CE mark" 19b"we don't want to get a CE mark just because at the end as you know, the price is quite low and the expense or the budget to get a CE mark or in one year will be so high	choosing we don't plan to get a CE mark ... we will target countries where you don't need a CE mark; quantifying: the price (of VI product) is quite low and the expense to get a CE mark or in one year will be so high;	
P3	Yeah. Well, A, we've had to employ a guy on 30 or 40 grand a year just to look after it. I: Well, do you think your company has the financial resources yourself then anymore? B: Prior to COVID, we had reached the point whereby yes, you know, we would take, you know, [name of person], I don't know what your company makes but we were making, and we make... I'm almost embarrassed to say, but to find out how much of the company, but we're making 13% net, you know, 13% net on our net profits on turnover. And other companies are lucky if they're doing two...other industries are luck if they're doing 2% and 5%. And I thought we were making more money than drug dealers. Well, that was because we had very good innovative products. We were selling screw and plates. I mean, that's the other thing about, you know, utilizing your reps, the bull transport now, or the precise length in there that we sell, they're 12 to anywhere 12 to 18 grands. So, you know, I can have a rep in the theater for one and a half hours watching that, but I can have a rep doing theater for maybe 45 minutes doing a 50-pound screw and plate on somebody's bunion. I mean, that's what I don't want to get into that. So, we all are doing 30 net. And so that move that's 25 net. So, we make good profits. **We have the money ...** **..we will return level and come off ... .with all the restrictions that the new medical directives have placed upon us.**	19b"We have the money ... ..we will return level and come off ... .with all the restrictions that the new medical directives have placed upon us".	quantifying: we've had to employ a guy on 30 or 40 grand a year just to look after it; quantifying: We have the money ..we will return level ..with all the restrictions the new medical directives have placed upon us.	
P4	**NO**	19 "NO"		
P6	No, I don't know. The thing is the fact that you are aware that the application of the new MDR have been postponed by one year. So, what has been done is establishment of collaboration		1.establishment of collaboration for collecting	choosing: establishment of collaboration for collecting

Question 2	If you think that under the new regulation your company has the financial resources needed	In Vivo Codes	Process Codes	Initial Coding
	for collecting clinical data in order to make sure that then the product, when we're going to reach the year 2023, we'll be able to provide good clinical data to sustain the update of the CE mark on basic product. Now, I hope by this time the CE would have kind of make clearer the definition of equivalence for new product, because there have been a lot of—you can do innovation, that you can have new implants, but the outcome is not a big change. It's not a new raw material. It's mostly a new design, much functional, but in a certain way, you can't demonstrate that biologically there's no consequences. ~~Nothing is new. Is not a [name of company], you know, [name of company] new product. We're talking cages, pedicle screws. Your screw can be longer but it doesn't change. It's still titanium anodized. It's still gamma ... #00:49:36# the same~~. So, I hope in the future the competency of notified body will help also to demonstrate much easier evolution of device, so-called innovation. As long as that innovation is not a big eruption. It's not the new raw material. It's not new—what's going to be developing is innovation can be also influenced in conjunction with digital applications. I have some ideas of developing an implant where the implants would incorporate a high Frequency signal in order for the surgeon to determine the level of osteo-integration on it. So, that kind of innovation is very big. So, what we're doing, we're working—tomorrow I have a meeting is to develop the collaboration between—because you know in France there's a lot of funds, public funds, where—and there's a big, huge fund in collaboration between France and a third party which has to be outside of Europe and, in that case, Japan. And it's a fund of over a four million euro. And with that fund, it's fully focusing on innovation. The fact that it's under the two governments, there would be a path for doing innovation. Because sometimes governments can take the lead on some really new innovation because they know that they have to be special. But for this kind of innovation, I'm just participating. I'm not the fool as the main actor. But just to give you there are different areas of innovation. But at the end of it, I just want to say one thing. MDR, for me, it's a good thing. Less competition. Price can be increased again in your own international market. For instance, I've increased my pedicle screws price for Iran by 40%. Because I said, well, it's MDR, because it's a new CE mark and So, on. But also, because Iran took the decision two months ago to ban totally American product. That every American product [name of company] even if it was coming from Switzerland before, the fact it's an American name, no more. Yes, it is still accepted but the reimbursement prices established by the Iran government is less. Now, we see first. So, you see, MDR is what I say always. Whatever the situation, you have to listen, understand the new situation, adapt and surprise at the end of it. When I say surprise is to come up with something which is really benefit to someone in the customer targets. Can be a surprise for surgeon, it can be a surprise for the hospital, it can be a surprise for the people who are participating in the promotion. So, all of this, don't forget, now we are making sales a little bit more with digital application. Yes, but we also are making sale. We never forget. And that's why is never to forget human interaction.		clinical data 2-year 2023, we'll be able to provide good clinical data to sustain the update of the CE mark on basic product	clinical data; critical success factor: able to provide good clinical data to sustain the update of the CE mark on basic product; qualifying (regs impact): you can do innovation, ...but the outcome is not a big change; critical success factor: I hope the competency of the notified body will help also to demonstrate much easier evolution of device, so-called innovation/ quantifying: MDR, for me, it's a good thing. Less competition;
P7	In our context, I believe once we have overcome our current insolvency proceedings, we need to push forward and sell the products that are available today and take those resources back into R&D in order to develop the future products or adjustments of the products within the product life cycle. So, this is definitely an important factor for the future success of our company.			

Question 2	If you think that under the new regulation your company has the financial resources needed	In Vivo Codes	Process Codes	Initial Coding
P8	I would say that the issue is somewhere else. I think it's not a question about today, do we have the resources or not because we have a single product. And if we go through medical device certification, it impacts all of our business. So, since **we have decided that it's important for us, we will do it**. Now the issue we have is about is about algorithms. When you look at the new regulation and when we discussed with lawyers, what they tell us is that you can get a medical device certification, given algorithms that are defined in a specific way. And for machine learning, it's very difficult because machine learning by definition tends to improve over time. And what the regulators tell us is that if our algorithms evolve, the certification we got, let's say, 10 months ago with a specific algorithm is not anymore valid 10 months afterwards because the algorithm itself has improved, but the software is not certified with this new approach	19b"we have decided that it's important for us, we will do it"	choosing we don't plan to get a CE mark ... we will target countries where you don't need a CE mark; quantifying: the price (of VI product) is quite low and the expense....to get a CE mark or in one year will be so high;	choosing we have decided that it's important for us, we will do it; critical success factor: you can get a medical device certification, given algorithms that are defined in a specific way; quantifying: for machine learning, it's very difficult;
P9	**Definitely not.** This is easy question because when we talk about innovative products, **we have to face the requirement to perform clinical studies**. So, I think this is something which in the past was a maybe, but it will be a must and the clinical studies are expensive. I think you know that and **difficult to set up and to organize and in principle, to finance** that. We will not do that on our own and then we come back to how-yeah, we work and what I might think are working then, **we look for a collaborator who is willing to get a product into the market** and then we come to the point where, say, okay, when you believe in the product, feel free to give the resources for setting up all what is needed including the clinical study and then, you will get your product but **we will not do it on our own because the invest is that high though it has to be borne by the company which is willing to make the final turnover**	19"Definitely not" we have to face the requirement to perform clinical studies ….and difficult to set up and to organize and in principle, finance that". 19b"we look for a collaborator who is willing to get a product into the market a... the invest is that high though it has to be borne by the company which is willing to make the final turnover	1 we must face the requirement to perform clinical studies 2 difficult to set up and to organize and in principle, to finance 3 we will not do it on our own because the invest is that high 4 we look for a collaborator who is willing to get a product into the market	quantifying: Definitely not (financial resources); quantifying: we talk about innovative products, we have to face the requirement to perform clinical studies; barriers to success; clinical studies...difficult to set up … and to finance; choosing : we look for a collaborator who is willing to get a product into the market ...we will not do it on our own; quantifying: the invest is that high ....it has to be borne by the company ....willing to make the final turnover
P10	19 Y**es, because for us, it's not a big difference comparing to the previous registration procedure**. So, for us, it's not a big change. It will have some additional bureaucracy, but if it comes to innovation, it won't change anything actually, because we have implemented a lot of let's say processes, reporting in our company, that today already goes in electronic way. And we're not afraid of this. So, we are working with this for years already. So, it's nothing new to us. But as I said, for small companies, it's a big problem. Is a big problem.	"Yes, because for us, it's not a big difference comparing to the previous registration procedure"		qualifying for us, it's not a big difference comparing to the previous registration procedure. Quantifying: will have some additional bureaucracy: qualifying: if it comes to innovation, it won't change anything actually; stereotyping: mall companies, it's a big problem
P11	19bI think this was one of the main reasons I joined the company. You know, before MDR was delayed one year, right? **The company invested a lot to be ready for the post-MDR era.** We had all- every single product was renewed before the deadline. And **we had engaged in big investments in clinical department for collecting data to be used for the new MDR requirements.** So, I think it is quite of competitive advantage that the company tried to invest in.	"the company invested a lot to be ready for the post-MDR era" "we had engaged in big investments in clinical department for collecting	1 company invested a to be ready for the post-MDR era 2 every single product was renewed before the deadline 3 we ... engaged in big investments in clinical	choosing: The company invested a lot to be ready for the post-MDR era; critical success factor: We had every single product renewed before the deadline' quantifying: we had engaged in

Question 2	If you think that under the new regulation your company has the financial resources needed	In Vivo Codes	Process Codes	Initial Coding
		data to be used for the new MDR requirements"	department for collecting data ... for the new MDR requirements 4 it is -- competitive advantage that the company tried to invest in.	big investments in clinical department for collecting data for the new MDR requirements; hypothesising it is .... competitive advantage that the company tried to invest in.
P12	19b "Well, **we have to have".** 19b "when it comes to the regulations, we are not alone…...n Team has its own regulatory persons and the [company name 1] has people for that are as well as the (? THQ). **It should not be an obstacle for us**	"we have to have" "It should not be an obstacle for us"		choosing we must have; critical success factor: Team has its own regulatory persons quantifying should not be an obstacle for us
P13	We changed the focus completely to the [Place name2] because of that.			choosing: We changed the focus completely because of that.
P14	**Expensive** and the documentation is **the main point is documentation. Documentation and investment for audits and quality management. For us, it is okay.** It is okay in this point, by-, we can as men, **we are real manufacturer**. And that is why **we can provide all these internal documents.** And **we can cover also the investment for the audits we** have with the customers. And for us, it is okay	"Expensive" " Documentation and investment for audits and quality management" "for us, it is okay...we are real manufacturer and can provide all these internal documents"		quantifying: expensive: qualifying: documentation and investment for audits and quality management; labelling: we are real manufacturer; critical success factor: we are a real manufacturer and that is why we can provide all these internal documents; critical success factor: we can also cover the investment for the audits
P15	INT asked about cost and knowledge. Il would say more important even that they are not used to innovation in that field. So, because this is not innovation you have because you say, oh this is what the device needs but what this is what someone else says, there's more regulation. So, I think they're more concerned about how to apply this besides everything else that they are currently doing. But then it also becomes easily a question of research also Yeah.			critical success factor: I think they're more concerned about how to apply this beside everything else that they are currently doing.

Question 3	And besides the financial, the new regulations require a certain knowledge to deal with the regulations. How do you see this for your company	In Vivo Codes	Process Codes	Initial Codes	Question 4	Do you see anything in the new regulations that would help your company with innovation efforts?	In Vivo Codes		Initial Code
P1	It's expensive but we take him on because we need him, and he is essential, and I don't think there's a lot of start-up's out there that don't realize how **essential it is to have regulatory guidance early** on because you could be going down something that is **so incredibly hard**. You don't know what was waiting for you and I think we were very naïve when we started; we didn't know how important and these people were and how much we need guidance and I think we just thought we'd go to the regulatory office and someone would tell us what to do and we'd just go, "Okay, here's a file," and it's done. But yeah, there's a heck of a lot more work into building that up than we ever imagined, but we're very lucky to be a start-up that has the money to do that and I don't think everyone does.	19" a lot of start-ups don't realize how essential it is to have regulatory guidance early"… "something that is so incredibly hard"		quantifying: how essential to have regulatory guidance early; quantifying (regs) so incredibly hard; critical success factor: very lucky to be a start up that has the money to do that	P1	**No**, but what I do think i**s good about Europe is they are quite open,** and they do respond to questions, if that makes sense. So, in that respect, I think it's very good because you **can have that open dialogue with them** which I think is really, really useful. But no, I don't think there's anything I particularly thought wow, that is going to make my life a hundred times easier. No, not yet.	"No" 19b."but what I do think is good about Europe is you can have that open dialogue with them"		quantifying: No; qualifying you can have that open dialogue with them (EU)'
P2	I think that we hired our quality manager six months ago just because we wanted to anticipate or to be able to prepare not for the first tech but for the second tech for the full system ready to start in Europe even for the tech- it is only for tech 2 and **we have now a regulatory and**	19b "we have now a regulatory and clinical affair manager"	1 hired a quality manager 6 months ago 2 to prepare not for the first tech but for the second tech	choosing very lucky to be a start up that has the money to do that; critical success factor: we have now a regulatory and clinical affair manager;	P2	I would say one, only one thing. Once mainly for the companies wanted to target- The company which want to target only Europe once we have CE mark. At the end, it is just a **way to increase the barriers at the entrance.** Meaning, that **if you have the CE mark, it is because**	"19b" If you have the CE mark, it is because you have the clinical trial and....evidence based. ..to increase a bit the barrier at the entrance…. for competitor		hypothesising: for the companies which want to target only Europe once we have CE mark- --it is a way to increase the barriers at the entrance; Quantifying: or competitor wanting to target Europe, at the end, the effort for that

Question 3	And besides the financial, the new regulations require a certain knowledge to deal with the regulations. How do you see this for your company	In Vivo Codes	Process Codes	Initial Codes	Question 4	Do you see anything in the new regulations that would help your company with innovation efforts?	In Vivo Codes		Initial Code
	clinical affair manager, it's (name of the person). He is now on board. He was hired, I think, that was in- ah, it was last month. Again, because we want to prepare the very strategy for tech 2.		for the full system			**you have the clinical trial and therefore, you have an evidence-based and thanks to that,** it is just a way to increase a bit the barrier at the entrance. So, for **competitor wanting to target Europe, at the end, the effort for that will be quite huge to compete against us.** So, for the innovation, if you have a project, we clearly key added value for the patient and for the surgeon without answer right now Europe and therefore, their request to get clinical trial is just a way to leverage to have more buyer at the entrance. For me, this is the way I'm thinking regarding this new MDR but again, not for incremental but for disruptive technologies.	wanting to target Europe, at the end, the effort for that will be quite huge to compete against us"		will be quite huge to compete against us; critical success factor: we clearly key added value for the patient and for the surgeon; quantifying: this new MDR not for incremental but for disruptive technologies.
P3	Yeah. Well, **we certainly have the knowledge** because ... .and after **having consultant in, charging us £1,000 a day,** in some cases you know, let's get our own QnA guy. And, and so often, you know, that old adage, you know, you get a consultant in and normally they come in and start telling you what you already know. It like lend your Rolex and I'll tell you the time. I mean, that was.	19b "we certainly have the knowledge after having a consultant charging us £1000 day "		quantifying: having consultant in, charging us £1,000 a day;	**P3**	You're asking the wrong guy. **I don't know enough about the new regulations**. …two days a week. I've left that to [name of person] and the QnA. Maybe you should interview [name of person] as well.			

Question 3	And besides the financial, the new regulations require a certain knowledge to deal with the regulations. How do you see this for your company	In Vivo Codes	Process Codes	Initial Codes	Question 4	Do you see anything in the new regulations that would help your company with innovation efforts?	In Vivo Codes		Initial Code
	They want a bit more knowledge in that.								
P4	Yes, **we have the knowledge**, but **we did not implement yet all the requirements** because we have decided that it cannot be... **strategically, we don't want to go there.**	19 "we have the knowledge, but we did not implement yet all the requirements because ... strategically, we don't want to go there".		quantifying: we have the knowledge; choosing we did not implement yet all the requirements because... strategically, we don't want to go there.	P4	**No**. I can understand that we want to implement more clinical studies, etc., but I cannot understand that it's so heavy and impossible to manage for a small company. Our notified body told us a few years ago that is going to... the consequence is that 40% of the med-tech company will have to stop. ... And if we talk of the number of devices, it should be more.			quantifying: No; barrier to success: cannot understand that it's so heavy and impossible to manage for a small company; quantifying: the consequence is that 40% of the med-tech company will have to stop
P7	**"Definitely, yes"**. 19b "We have **our own medical and regulatory department**. But we are **also working** in addition to that **with external consultants".**	"Definitely, yes"." We have our own medical and regulatory department…we are also working with external consultants".		quantifying: definitely; choosing have our own medical and regulatory department... we are also working…with external consultants"	P7				
P9	**I think so**. We had a number of seminars on that. **We had in-house seminars** regarding the MDR **for the complete company**. That means in principle, everybody is informed at a certain level and of course, we have where we focus a special seminar for the regulatory affairs and clinical affairs employees. So, from my point of view, of course, it is difficult to evaluate at the	19b "think so we had in-house seminars regarding the MDR for the complete company	1. We had in-house seminars regarding the MDR for the whole company 2 everybody is informed at a certain level 3 we must ensure that everybody is	quantifying: I think so; choosing we had in-house seminars regarding the MDR for the complete company; qualifying everybody is informed at a certain level; choosing: focus a special seminar for the regulatory affairs and clinical	P9	What I do hope or what I really think, and this is a message which I transport inside the company at that, okay, I see it as a challenge and at the end, the situation will need that some competitors will fade away, some competitive products will go out of the market and **finally, when we succeed with re-certifications** and of course, in the background **our lean cost structure.** We,	19b" finally, when we succeed with re-certifications and .....the background our lean cost structure....." 19b"We, as a small company, maybe are more able to get innovative products in the market or to		quantifying I see it as a challenge and at the end, the situation will need that some competitors will fade away, some competitive products will go out of the market; hypothesising: as a small company, maybe are more able to get innovative products in the market or to maintain our innovative

Question 3	And besides the financial, the new regulations require a certain knowledge to deal with the regulations. How do you see this for your company	In Vivo Codes	Process Codes	Initial Codes	Question 4	Do you see anything in the new regulations that would help your company with innovation efforts?	In Vivo Codes		Initial Code
	current stage because on the other hand, we are talking, or we have to get along with the reviewers at our notified body and the special situation is that these people also have to be trained on MDR. So, on both sides, people are developing, and we have to ensure that we are on the same level as the guys at the notified body are and I think you do know that the notified bodies are-the workload at the notified bodies is huge. It is incredible. We could fill an additional hour talking about how they work and what are the-how they do not work and yeah. We have to ensure that we are all on the same level. So, and for us, I can say, okay, we are at a good level compared to the people where we have to get along with.		informed at a certain level 4 can say, okay, we are at a good level compared to the people where we have to get along with	affairs employee; hypothesising: it is difficult to evaluate ...because we have to get along with the reviewers at our notified body; quantifying: we are at a good level compared to the people...we have to get along with		as a small company, m**aybe are more able to get innovative products in the market or to maintain our innovative products in the market better than the big players**. So, this is what I really believe and yeah, hopefully, it comes out like that. So, I see the chance. I think there is market share which will, if we in the future because other products will be cancelled perhaps from the competitors, we do know that. We see that companies are going into insolvency because they will not meet the requirements of the MDR or they decided that from financial point of view, it does not make sense to invest money in pursuing, getting the new certificate because the turnover with the product is quite low. So, I think this will be market share which I want to get. So, and this is what I see as a chance for our company	maintain our innovative products in the market better than the big players"		products in the market better than the big players; barrier to success: companies are going into insolvency because they will not meet the requirements of the MDR; choosing: or they decided that from financial point of view, it does not make sense to invest money in .... getting the new certificate because the turnover ..the product is quite low; critical success factor: I think this will be market share which I want to get. So, and this is what I see as a chance for our company
P10	I believe, **yes.** The knowledge at the moment, we have **one person who is focusing on this,** and I trust him a lot because he's very skilled and knowledgeable person. And I'm sure that he will take us through all this quite easily. He's with us for 20 years. He did all the ISO	19b"yes….. we have one person who is focusing on this" 19b"not expecting any troubles, except for the time for introduction product to the market", 19"	1 we have one person who is focusing on this 2 He did all the ISO 9000, ISO 13485, some other certifications	quantifying: Yes we have one person who is focusing on it; qualifying: very skills and knowledgeable person; hypothesising: I'm sure he will take us through this quite	**P10**				

Question 3	And besides the financial, the new regulations require a certain knowledge to deal with the regulations. How do you see this for your company	In Vivo Codes	Process Codes	Initial Codes	Question 4	Do you see anything in the new regulations that would help your company with innovation efforts?	In Vivo Codes		Initial Code
	9000, ISO 13485, some other certifications, a lot of certification with products with us. So, he's the right person on our team and I'm sure we'll do it well. So, I'm **not expecting any troubles, except for the time for introduction product to the market, because as you know, there is very few notified bodies** at the moment who can do the audit. So, you can imagine the queues when it's becomes mandatory	because as you know, there are very few notified bodies"	3 he will take us through this quite easily 4. I'm not expecting any troubles, except for the time for introduction product to the market	easily; quantifying: He did all the ISO 9000, ISO 13485, some other certifications, hypothesising: I'm not expecting any troubles, except for the time for introduction product to the market; barriers to success: very few notified bodies;					
P11					**P11**	Listen, I am not an expert in the new regulation. But one thing what I can tell you on top of my mind, it will help companies to push through the most- the innovation, where they think will have more value, most value, right? So, **it will allow you to push through more valued innovation**. And I think with the clinical requirements you are forced to do and think. Eventually, we are **maybe become more over the year outcome-based innovation-driven than just bringing innovation with some incremental, you know, features**, that do not drive, do not lower costs or improve patient outcome. I think that **will force people to**	19b "it will allow you to push through more valued innovation" 19b "maybe become more over the year outcome-based innovation-driven than just bringing innovation with some incremental, you know, feature" 19b" will force people to prioritize"		hypothesising: it will help companies to push through the most innovation, where they think will have... most value; hypothesising: maybe become more over the year outcome-based innovation-driven than just bringing innovation with some incremental, you know, features, maybe become more over the year outcome-based innovation-driven than just bringing innovation with some incremental, you know, features; choosing: adaptability phase, ..you have a historical product pipeline. what do you

Question 3	And besides the financial, the new regulations require a certain knowledge to deal with the regulations. How do you see this for your company	In Vivo Codes	Process Codes	Initial Codes	Question 4	Do you see anything in the new regulations that would help your company with innovation efforts?	In Vivo Codes		Initial Code
						prioritize and focus on what is most needed. But there is an adaptability phase, because 1) you have a historical product pipeline there, 2) what do you with it? And second, it is a change of mindset and culture, how many companies operated. So there is a phase of adaptability. That comes back to the agility of our company. We are very focused on what to bring and how to bring it.			with it; qualifying; it is a change of mindset and culture, how many companies operated; critical success factor: comes back to the agility, very focused on what to bring and how to bring it.
P12					**P12**	I have not really looked that deep into the new regulation on a practical level, how it affected us. My understanding is there are improvements. Because the old regulation was very much hardware oriented. Which means that with the new regulations **it is easier for the software and applications** over all **to enter and exist in the market. S**o, I do believe that there are benefits also.	19b"it is easier for the software and applications ... to enter and exist in the market"		qualifying new regulations it is easier for the software and applications over all to enter and exist in the market
P13	**Yeah**. That is what **you have to-**. But that is true for every medical device company. If you do not know the requirements in [Place name3] especially, if you do not know them by heart and you look for every loophole and every possibility to find a way to get your product to	19b"Yeah you have to" 19b " It is the number one knowledge you need to have is medical device regulation requirements. not so much the		quantifying: Yeah. you have to; barrier to success If you do not know the requirement ... then you will not be successful; quantifying: it is the number one knowledge … .not	**P13**	In the regulation? (I: Well just a pushback.) It is a pushback. Yeah, it is. The documentation effort has been increased drastically, the clinical investigation part I agree with it partially, we-. The medical device direction-. The directive opened a lot of possibilities to bring medical			quantifying: The documentation effort has been increased drastically, the clinical investigation part I agree with it; qualifying: I agree partially with the clinical requirement; quantifying: The documentation effort

Question 3	And besides the financial, the new regulations require a certain knowledge to deal with the regulations. How do you see this for your company	In Vivo Codes	Process Codes	Initial Codes	Question 4	Do you see anything in the new regulations that would help your company with innovation efforts?	In Vivo Codes		Initial Code
	market in a reasonable way, then you will not be successful at all. **It is the number one knowledge you need to have is medical device regulation requirements**. And **it is not so much the engineering or creativity** or whatever. Because that is so much limited to it by that	engineering or creativity "		so much creativity Engineering		devices to market with little knowledge of it, how it works, how efficiently it is, how safe it is. So, I agree partially with the clinical requirement. But the testing for instance has not changed really not at all, which I personally would have strengthen the less documentation effort but okay. That is engineering. I will rather test more than document a lot. I do not think that if you have the essential requirements or essential performance requirements that makes much of a difference for the safety of the device. Do not think so.			has been increased drastically; quantifying: The documentation effort has been increased drastically; qualifying: I agree partially with the clinical requirement; quantifying: I do not think that if you have the essential requirements or ...performance requirements that makes much of a difference for the safety of the device

Coopetition

Question 1	Are you familiar with that term coopetition and the concept of competitors working together for a specific purpose? do you think that coopetition, so working with a competitor could help to continue delivering innovation given the challenges the new regulation spring?	In Vivo Codes	Process Codes	Initial Coding
P1	didn't know that was the word, but **yeah, I understand the principle** of it. Yes. No, I do. I think it's important because for someone who's like **a little company** like us, you **only have one person working on regs**. **If you're collaborating with the competition who is an awful lot bigger than you, it has an entire team** of it. I think that's going to be more brains are better than one in that situation. I think that's **really useful**. You need that sort of extra lift	"yeah, I understand the principle" 20 " a little company .... have one person working on regs.... If you're collaborating with the competition who is lot bigger ... it has an entire team …. that's really useful"		quantifying: I think it's really important because for a little company like us, you only have one person working on regs'; critical success factor: collaborating with the competition who is a lot bigger than you, it has an

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				entire team...more brains... really useful you need that sort of extra lift
P2	**Yes. Coopetition is just a way that it is a competitor, and you are working with for a specific project**, I imagine or Samsung and Apple, for example. Samsung provides the screen to Apple. At the end, both of them sells phone but one of them is a provider as well, is a supplier. I would say yes because this is our case. INT: Do you think that coopetition could help companies delivering innovation given the challenges of the new regulations P2: **I cannot tell you that it will work because I don't know** yet, but this is our strategy	"Yes. 20 "Coopetition is just a way that it is a competitor, and you are working with for a specific project" "I cannot tell you that it will work because I don't know"		quantifying: Coopetition is just a way that it is a competitor, and you are working with for a specific project;
P3	**No**. I felt was a hybrid, Americanized name that you created yourself when I first read it. In fact, I had to read it twice to make sure I hadn't read cooperation and the eyes weren't playing ... at my old age. Yeah. It's all centralized labs, isn't it? They'll send it off to the university and they'll then develop it. But then don't you use your, sort of, your uniqueness and your innovation. It's all shared knowledge (Int asks if) And then I think also my ... maybe a good example, but it's hardly sharing of, well, it is sharing of knowledge, but we're not in competition with them. They've set out and done a bout on acquisition of various companies. They were [name of person] originally. I mean, has cleverly see a gap, a niche in their market for the treatment of diabetic feet. So, they had the wound. They've got a tissue company. And then last year, is it last year or the year before? He's walking through ... . and, you know, the international meeting, which was funnily enough in [name of place] my hometown. We had a big stand, and he picks the frame of my school. That's what ask me a question about the frames, if we could do it, it's not fast ahead. The next week, I'd invited over to their salesmen in the States and the reps and go, "Wow, this is a clever move by them."	No		qualifying: it's all centralised labs isn't in? It's all shared knowledge;
P4	**Yes, I try since maybe two years ago.** I try to find a partner in order to share what is common to everybody because everybody has to apply the new regulation. So, instead of working alone to implement the new regulations, we should work together **but did not find any partner**	"Yes, I try since maybe two years ago" "but did not find any partner"		quantifying: I try to find a partner to share what is common ...everybody has to apply the new regulation; barrier to success: but did not find any partner
P7	**Yes,** I have been familiar with the word. Well, **I would say that coopetition includes a mixture of cooperation with suppliers, customers, and firms producing complimentary or related products.** So, coopetition finally is the act of a strategic cooperation between competing companies by forming strategic alliances in order to help both companies. I believe so because the medical device market, or let's say the entire life science and healthcare industry, is consolidated, yeah. So, **in this very consolidating and highly regulated and complex market environment, strategic alliances and coopetition models are especially necessary for small and medium sized companies to deliver value** added propositions and innovative solutions to healthcare providers and patients. And of course, to be ahead of the big players.	"Yes" 20" I would say that coopetition includes a mixture of cooperation with suppliers, customers, and firms producing complimentary or related products". 20a"in this very consolidating and highly regulated and complex market environment, strategic alliances and coopetition models are especially	1 very consolidating and highly regulated market 2 strategic alliances are formed 3 deliver value added propositions and innovative solutions 4 to be ahead of the big players	qualifying: I would say that coopetition includes a mixture of cooperation with suppliers, customers, and firms producing complimentary or related products; quantifying: forming strategic alliances in order to help both companies; critical success factor: in this very

Question 1	Are you familiar with that term coopetition and the concept of competitors working together for a specific purpose? do you think that coopetition, so working with a competitor could help to continue delivering innovation given the challenges the new regulation spring?	In Vivo Codes	Process Codes	Initial Coding
		necessary for small and medium sized companies to deliver value"		consolidating and highly regulated and complex market environment, strategic alliances and coopetition models are especially necessary for small and medium sized companies to deliver value added propositions; critical success factor: be ahead of the big players
P8	**Yes**. For me, I would say, it describes **ecosystems where it's very difficult for a single stakeholder to do some innovation in every field**. And this competitor needs to work with others in order to share advances, but for the sake, you know, of the markets. And those competitors between themselves, they utilize resources, intellectual property between themselves. And it's shared contractually between themselves. Yeah, so that's my definition. I don't know if it's the right one, but-, INT: you said that you believe that coopetition can help to deliver innovation in the medical technologies? Yes	"Yes" 20"ecosystems where it's very difficult for a single stakeholder to do some innovation in every field"	1 this competitor needs to work with others in order to share advances 2 they utilize resources, intellectual property between themselves 3 it's shared contractually between themselves.	quantifying: ecosystems where it's very difficult for a single stakeholder to do some innovation in every field; qualifying competitor need to work with others to share advances; critical success factors: utilize resources, intellectual property between them … shared contractually;
P9	**No**. It does mean to me what I read from Google is that the collaboration between what you said that it can be beneficial for both sides when competitors decide to develop new products together. INT do you think that collaboration of competitors can help to deliver innovation? I think, at the moment, it is difficult for me to get a good example to imagine, okay, how such a situation could turn out that-I can imagine that maybe coopetition can help getting products in the market when the competitors are with different notified bodies, maybe? Somebody with the notified body who is accredited with MDR, maybe the other not. So, this can be helpful. Yeah. This is one thing but maybe, you can help me to think into the right direction.....INT I believe your company has been already engaged in collaborating with a competitor? Yes. INT: So, that's also then in innovation? Yes.	"Yes" ""Yes, I would say that coopetition includes a mixture of cooperation with suppliers, customers, and firms producing complimentary or related products". "in this very consolidating and highly regulated and complex market environment, strategic alliances and coopetition models are especially necessary for small and medium sized companies to deliver value" "Yes" (for innovation)		Hypothesising: I can imagine that maybe coopetition can help getting products in the market when the competitors are with different notified bodies, maybe; hypothesising: Somebody with the notified body who is accredited with MDR, maybe the other not.
P10	Coopetition. No, I haven't, honestly speaking, but as I understand, it's something which goes across the competition and cooperation at the same time. Yeah. And it's just from my experience, this is our daily business. The fact that we are speaking together while we are competing on some markets, it's also let's say goes exactly into this description of coopetition.	"No" (in relation to EU regs) "definitely it will enforce such cooperation" 20b "small companies are afraid, ... of		qualifying: we are speaking together while we are competing on some markets; qualifying:

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	(In relation to EU regs). On the one hand, **definitely it will enforce such cooperation** because, of course, always there is a question how the partners will look into this situation, because **small companies are afraid**, especially the start-up's, **are afraid of selling too much to big companies**. So, **they could lose too much on such kind of cooperation**. And on the other hand, **they may not have enough of resources and knowledge to enter those markets without a stronger partner**. So, it will definitely push forward to the cooperation initiatives. But it will be tough I have to say, because we have to understand also the human nature behind the inventors. They love their babies, and you see it is everywhere in the world, even now, even today you see, that each inventor will always fight, will always protect its children, the results of their developments, and they will always find a way to say that "Mine is best. Mine is better," and so on. So, this nature will definitely generate some problems, because when you start working with a big company, you have **sometimes to compromise** certain things. You cannot stick too close to your beliefs and ideas. You have to align. So, this will be the stopping factor. Plus, the financial factor will be stopping one, because each one of the inventors believes that this is huge future for him, huge money for him, because he invented something such great for the market. So, these are two things against. So, I will put it this way. If the bigger partner of such partnership understands the threats and also the position of the smaller one, it will work well. But in other way, so if it is going to be kind of hostile takeover, then it will generate more problems than benefits rather.	selling too much to big companies...they could lose too much on such ..cooperation" 20b but" they may not have enough of resources and knowledge to enter those markets without a stronger partners" "sometimes compromise"		(In relation to EU regs):. quantifying: definitely it (reg) will enforce such cooperation; stereotyping: small companies are afraid; quantifying: especially the start-ups, are afraid of selling too much to big companies; hypothesising: they may not have enough of resources and knowledge to enter those markets without a stronger partner; critical success factors: definitely generate some problems, ...when (small companies) ... working with a big company, you have sometimes to compromise; barrier to success: financial factor--(referring to rewards and conflict of who invented)l hypothesising: if it is going to be kind of hostile takeover, then it will generate more problems than benefits
P11	Honestly, **it is a new term**. **Although when- I know what it means**. It is not new to me, but the term is new. INT Do you think competition can help to continue delivering innovation? Well, let me answer you this way. I think **it will change the business model.** The go-to market business model and some product introduction business- and we are already seeing, right? So, we are seeing it in two ways. Small companies- in three ways, actually, we are seeing it. **One model, where small companies can (? now) with investing in this, putting resources behind regulatory and not being able to invest in go-to market investments, put feet on the ground and these things**. They are **much more open seeking exclusive distribution or licensing rights** and things like this. This is we are seeing more and more and more. I also see it with **companies,** who again **have several innovations, but they need to focus on the few. They are being more open to ……. technology,** completely. But we don't see it with people, who are a hundred percent in spine. You see it more, people, who have a spine innovation, right?	"it is a new term. Although when- I know what it means" "it will change the business model."20b" One model, small companies...investing .... putting resources behind regulatory and not being able to invest in go-to market investments".....20c"much more open seeking exclusive distribution or licensing rights"; 20a"large companies ... are going and acquiring other		quantifying; it will change the... go-to market business model and some product introduction business; quantifying: we are seeing it in small companies- in three ways, one model, where investing in,, resources behind regulatory and not being able to invest in go-to market investments.....they are

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	But they are doing orthopedics. The same innovation applies for trauma heal. And now they are reaching out to us and saying: “We have this ……. technology. Are you interested to take it for, you know, to license it and take it?” We are also seeing it, actually, by us, for example, because we can’t maintain a lot of your product pipeline. We are even selling things to China, telling the innovation to China, right? For the Chinese market, for other companies. What I don’t really see, I don’t see companies of similar size trying to cooperate on regulatory or these things. What I think with ……. which we are always seeing, is lobbying, right? Market development, these things, but they always existed. But definitely I see that two elements. One, **large companies of big size, t**hey are going and **acquiring other companies, who have already some technologies registered** and (? present) **because of the lifecycle is becoming longer. smaller companies are rethinking at what level they try to reach out and try to build cooperation,** but I give you an example. I don’t see much cooperation between us and [company name2] or [company name3] or [company name3] and [company name2]. What people can see is you can be more attractive target at [company name1] to a big company, if you have good innovation that you manage to drive in Europe and you have a leading share. Then you are a potential target for big companies. So, I think focus is going to be key moving forward. And this is going to be crucial on how you. I would love to hear your perspective, but I don’t see companies of similar size cooperating. You know, on driving- unless, you know, but- I saw it in different industries, right? I saw it in industries, where you need to drive significant clinical evidence, right? It is a new therapeutic area. Then companies do team up together to do joint clinical trials, right? Collecting data. I have seen it, but it is the therapeutic segment. Now in spine, to be honest with you, unless if I think of … disc replacements, it is a lot of commoditized, you know, a lot of commoditized techniques. You know more than me.....	companies, who have already some technologies registered because of the lifecycle is becoming longer". 20b"smaller companies are rethinking at what level they try to reach out and try to build cooperation"		much more open seeking exclusive distribution or licensing rights ... I also see companies, that have several innovations, but ...need to focus on the few they are being more open to technology, large companies of are acquiring other companies, who have some technology registered ..because of the lifecycle becoming longer; critical success factors: smaller companies are rethinking at what level they try to reach out and try to build cooperation,;
P12	What was it? Coop-. (I: Coopetition.) Coopetition, **no.** That is a very good question. I**n the past I have been involved with maybe twenty of these EU funded consulted programmes, where we create new innovations**, new innovative products, in collaboration with competitors. 20b "And unfortunately, none of those were successful. 20bE**ither everyone wanted to own the innovation or wanted to have majority of the IPRs", or no one wanted to have them.** So, I do believe, when you can **have clear roles between the companies, it might be possible**. But I have not seen many cases where that has succeeded.	"No” “I have been involved with .. EU funded consulted programmes... 20 "we create new innovations in collaboration with competitors...none of those were successful" 20b"Either everyone wanted to own the innovation or wanted to have majority of the IPRs, or no one wanted to have them" " when you can have clear roles between the companies, it might be possible" "I have not seen many cases where that has succeeded".		barriers to success: IPRs...everyone wanted to own the innovation or wanted to have majority of the IPRs...or no one wanted to have them…hypothesising have clear roles between the companies, it might be possible

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P13	**Actually, not know**, I just read-, and when you send me the guidelines, I Googled it. As I understand it, it is something which we see right now in [Place name6], w**here competitors, small companies** which have to carry the burden of the new [Institution name1] **group together** even so the competitors in order **to fulfill the new requirements in a way they can afford and keep the possibilities open on the market.** Which in an environment where it makes-? But it is getting more difficult for smaller companies to carry the load of regulatory requirement is a must. INT: So, you believe that the collaboration of competitors can help to continue delivering innovation? Yeah. In very many ways. A of all, if you take wrong turns in development, you repeat mistakes other may have made which are cost and time consuming which is the same at the end. The regulatory burden is high. So, if you share it, it is less-, has had impact on your financial structure and on your (? Head count), whatever. It makes it easier. And third, and that is most important. We know a lot about ultrasonic application. We are not interested in let us say bone cutting but we corporate with the new company which is interesting in cutting bones using ultrasonic devices. They are completely independent; they are so these big competitors in the market. Well, if not in the same field but in general they are. Still, we **cooperate together because we benefit from each other's experience, knowledge, findings**."	"Actually not know" 20 " competitors, small companies group together …to fulfill the new requirements in a way they can afford and keep the possibilities open on the market" 20a"cooperate together because we benefit from each other's experience, knowledge, findings."	1 competitor, small companies which have to carry the burden of the new 2 group together 3 benefit from each other's experience, knowledge, findings 4 fulfill the new requirements in a way they can afford 5 keep the possibilities open on the market	quantifying: where competitors, small companies group together…to fulfill new requirement in a way then can afford and keep possibilities open on the market; quantifying: getting more difficult for smaller companies to carry the load of regulatory requirement; quantifying: the regulatory burden is high; critical success factor: if you share it (reg burden), it has less impact on your financial structure and on head count; critical success factors: cooperate...we benefit from each other's experience, knowledge, findings."
P14	It is first time. Yeah, it was explained, but not directly when I must say directly **I did not understand what it means** directly. INT: Very well. It is a combination of cooperation and competition. And when people talk about collaboration of competitors, someone came up with this word coopetition. Okay. Yes, I think it is also **important for the future** that now special in this region of tootling, and there are many **many small very innovative companies, manufacturing companies,** but many of them, they cannot hold the level as now for the future. They h**ave to cooperate with a partner company** for maybe some machining processes or for development processes. They **cannot cover all the steps by themselves.** They have to cooperate with a partner company **to share cost and to grow together**	" I did not understand what it means" 20 "many small very innovative companies, manufacturing companies have to cooperate with a partner company" 20b"cannot cover all the steps by themselves" " have to cooperate ….to share cost and to grow together	1 many small very innovative companies cannot cover all the steps by themselves 2 cooperate with a partner company for maybe some machining processes 3 share cost and to grow together	Qualifying: important for the future; critical success factors: have to cooperate with a partner company for ...some machining ...or for development processes... cannot cover all the steps by themselves... share cost and to grow together
P15	**Yeah**, I saw your post on LinkedIn and I (? immediately) knew what you are looking for and what you're talking of. I was also at this company [name of a company] where I heard that because they are working on a lot of these terms and … a lot of things. So, I knew what it was, and I think also I read it before. INT: do you think that competitors' working together is a way for medical device companies to overcome the hurdles the new regulations bring? I would say this is- would be true for every company in theory maybe they have other hurdles then. But to say, an outside force wants us to do something that we don't want to do so let's	"Yeah" 20b "it is always in the minds and giving up intellectual property, people are looking into what we are doing, …. trying to get over my employees ... now know these ones are really good ones.		barrier to success: always in the minds and giving up intellectual property, people are .. getting familiar .... then maybe they are trying to get….my employees because they

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	join our forces to get it done. And if two or three or four companies together do something the same way, it can't be that wrong and also maybe the regulators can't say you're doing it all wrong. So, from that side, I think it would always be good, but I don't know if this introduces some other things into this, **it is always in the minds and giving up intellectual property, people are looking into what we are doing,** getting familiar with each other and then maybe they are **trying to get over my employees** because they **now know these ones are really good ones**. And so this is **always in the heads of the people.**	…so, this is always in the heads of the people"		know these are good ones (fear stealing resources)

Question 2	Understand about your experience or your view, how you personally being engaged or see collaborating with a competitor	In Vivo Codes	Process Codes	Initial Codes
P1	So just a brief, we are **talking to two key strategics** at the minute and **both have offered us R&D partnership contracts** which is very exciting and something which we could very much need. But they c**ome with such heavy restrictions around the company's IP and what we can and can't do** and who we can and can't work with, posters and the restrictions are so tight even with some great lawyers and we're not finished with this and obviously, we're still in discussions. But we do, for instance, for us, it would really help to have that expertise because for instance, we're a device which is going on one of their devices, essentially. So, we need the technical file from them and that technical expertise on the lens as well as the technical files that we're building on the polymers. So, I really do see the benefit of it, if it comes off and I think they are a bigger force that can help drive the product to market. They have deeper pockets than us. **They have more cash. They've got more expertise in the field.** They probably got ten regs people that have worked purely in the ophthalmology space on their teams. But **the problem is in terms of the IP request they want or some of the legal sides and stuff, it would kill the innovation**, if that makes sense because **we use that technology to do anything else with and we wouldn't be able to go work with another partner or anyone else**, if that makes sense. So, **you're either locked in quite early or you maintain independence, which means you're raising more money to take it through further down the regulatory pathway**. So, I can see why it'd be really beneficial, but from the way we've seen it, it's not going to be particularly nice, if that makes sense	20b"we are talking to two key strategics.. both have offered ..R&D partnership contracts….. 20c" with such heavy restrictions around the company's IP and what we can and can't do" … still in discussions" 20b "really help to have that expertise ..have more cash… probably got ten regs people" 20c" the problem is ..the IP request ….some of the legal sides ….. it would kill the innovation, because we use that technology to do anything else….work with another partner or anyone else" 20b"You're either locked in quite early, or	1 offered us R&D partnership contracts 2 offered us R&D partnership contracts 3 it would really help to have that expertise ... have more cash. 4he problem is in terms of the IP request they want or some of the legal sides and stuff, it would kill the innovation 4 you're either locked in quite early or you maintain independence	qualifying: talking to two (firms),, both have offered us R&D contractors; quantifying: they come with such heavy restrictions around company's IP what we can and can't do; quantifying: it would really help to have that expertise ...., essentially.. we need the technical file from them...f and I think they are a bigger force that can help drive the product to market... have deeper pockets than us; barrier to success:…but the problem is in terms of the IP request they want or some of the legal sides and stuff, it would kill the innovation; barrier to success ;we use that technology to do anything else... and we wouldn't be able to go work with another partner or anyone else'; hypothesising: you're either locked in quite

Question 2	Understand about your experience or your view, how you personally being engaged or see collaborating with a competitor	In Vivo Codes	Process Codes	Initial Codes
		you maintain independence, which means… raising more money….to take it further down the regulatory pathway" " really help to have that expertise ..have more cash… probably got ten regs people" " the problem is ..the IP request ….some of the legal sides ….. it would kill the innovation, because we use that technology to do anything else. Work with another partner or anyone else" "You're either locked in quite early, or you maintain independence, which means… raising more money….to take it further down the regulatory pathway"		early or you maintain independence, which means ..raising more money to take it through ... regulatory pathway.
P2	This is clearly what we have **done and with our partner located in Germany**, it is clearly **a competitor** because t**hey have a product into the market and they sell it and it will compete against our V1** but due to the fact that the V1, **we don't want to sell it in Europe caused by this new regulation**, the V2 and the V3, **this partner won't be a competitor at the end** because we will address new needs for specific indication. So, they help **us**. They sell some products, some mineral phase. We developed, thanks to this phase, a new product for market outside Europe. : And then we will come back to Europe with a new product and they won't be a competitor for this new V2 or V3. So, for me, I would say yes but, in my case, but not directly. If I wouldn't answer your question saying that, okay, you imagine that you have enough money to sell in Europe, at the end, your partner sell mineral phase to build a new bone graft, you started clinical trial to get CE mark and then you sell in Europe, at the end, you will compete against them. In this case, I would say it is a good strategy for us but it is just a way for them to increase a bit their- For me, it is just a way to switch the way you create margin. It is just a question of finance, not only innovation for them, for the partner. From our side, it is just a way to have a jumper and to speed up the research phase. That's it.	20b "done and with our partner located in Germany a competitor because they have a product into the market and they sell it and it will compete against our V1 but don't want to sell it in Europe caused by this new regulation this partner won't be a competitor at the end …so, they help us"		qualifying: partner .is competitor V1, we don't want to sell it in Europes partner won't be a competitor…so they help us'; choosing: . It is just a question of finance, not only innovation for them, for us it is just a way to speed up the research phase.

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P3	Only with [name of company] , I would say, and another company whereby they wanted to sell off their... they wanted to give us a product, basically, they were no longer wishing to distribute. And that's about the only level I've had of cooperation, or coopetition, the word is, whereby, like I say, [name of company] needed a frame but they didn't want to develop it themselves, for the diabetic foot markets. So, when we sat down to discussion with [name of person], he said, you know, we've got the wound, which will treat all the debris on the foot. We've got the tissue, which we can place onto the ganglion cells in the foot. I mean, now we just need a frame to lock it all down. And he said, we can afford to give the frame away. We can afford to give the scalpel away. We can afford to give the tissue away, but we've got to make money on one of those things. And so, they usually wanted two products to leverage the frame and then they'll charge premium to the frame because in the States frames are ridiculous prices. INT: Okay. But I mean, so the area of coopetition, the area of working with your competitor that was then in distribution and not in development. Correct. And the other one was competitive they approached me, a direct competitor approach me with their product, which is very similar to ours i.e., the frame. We accelerate their business, and they want to sell us off the remnants of their business so they could get out and concentrate on the foot and ankle industry, which they are heavily focused on. And the discussions have come to nothing. They want premium price for it, but it's not coopetition, as it were. It's just them wanting to unburden themselves of a now unfocused product area. And if your company, so far, has not collaborated with competitor really in development stages of a product, why not? No need for this or...? The opportunity is not original rarely. Nobody has come to us with an idea. I don't see...Sorry, I'll rephrase that. Are there many shining examples of coopetition in the orthopedic industry? No, not in my humble opinion. I've been in it since I was 17. Maybe a little bit just with two partners in a bit to guarding of all secrets, not as many secrets in hips and knees .and things like that. But things like the nail, you know, things like the [name of product], they're all unique technologies and I'm sure everybody wants to guard their IP. I don't know...are there any other outside of coopetition in our industry outside the ... I: Yeah. One here and there, but it probably really depends on the complexity and resources needed to do something. But let's take this as an example. And now this, of course		1 the company wanted a frame for diabetic foot markets 2 they did not want to develop it themselves 3 we sat down to discussion 4 he said, we can afford to give the frame away...we can afford to give the scalpel away...we can afford to give the tissue away, but we've got to make money on one of those things 5 he said, we can afford to give the frame away. We can afford to give the scalpel away. We can afford to give the tissue away, but we've got to make money on one of those things. 6 area of coopetition was in distribution not development	qualifying (experience): only with… needed a frame but did not want to develop it; barriers to success (coop) I'm sure everybody wants to guard their IP.
P4	Because **everybody wants to work for his own business. It's difficult to find someone** to...because you know this regulation is scaring everybody, and even if some people believe it's a good idea, I didn't find any who were interested to share what...just to have one unique... actually it's ridiculous, the regulation, everything is described and how to implement it and so a lot of people are going to do the same job. It's the same work procedures, etc. So, there are no benefits that everybody does that. It's paperwork, but yeah, I was not able to convince anybody. INT what kind of company is ideal: A midsize company, a company doing €20 million revenues. Not a big one, a midsize in order to be stronger together. So, I did not spend too much time on that because I had a lot to do, but I thought it was a great idea. INT: but let's say, you would find a partner, what would you share with them and where would you draw a	20b "everybody wants to work for his own business. It's difficult to find someone" 20b "I would .... share the quality system and maybe the manufacturing. ... will keep the design and		barrier to success (coop): everybody want to work for ..own business; barrier to success (coop); hypothesising: I would like to share the quality system and maybe the manufacturing... keep the design and development and the follow-up of my product..; critical

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	line and say, "This is something I would share. . I w**ould like to shar**e **the quality system and maybe the manufacturing... keep the design and development and the follow-up of my product and everything linked to a design change, improvement, data collection.** But what it's really... it's easy, the quality system, it's basic. You have to ... you have manufacturing when you have a process in place, it's basic, you have to apply. You should not have any events, new events. INT: What do you think would be important in this relationship? Trust and communication. INT. But trust is sometimes difficult. I mean, how can you protect the important elements of your business in such a relationship? Oh, we have patents. So, we're the owner of our patents and also maybe, yes, you have to find the terms of the agreement. So, it has to be defined from the beginning of a relationship, yes... who owns what, etc., INT: before starting any collaboration, there needs to be a legal framework.? Yes. INT: And the patents are important so that you have protected your idea. Yes INT: How many companies have you talked to? Two or three. I: And they were not interested? Actually. They were interested by the principle, but they had other priorities. I: Oh, it should be also important to them. Everyone has the same problem. And, you know, [name of company] is located in the incubator and the objective of an incubator is to share what is common to everybody. INT: What are the elements in your business that you would never share with someone? Is there something or do you say, if it's protected, I don't care? B: No, no, no, no. It's not because it's protected that I don't care. Because, you know, even if we have patents, if someone wants to copy us, we will not have the money to defend us. It's important to convince investor or buyers, but in practice, you can never be sure …Yes, because of technology....I would not share the sensitive information with them through the regulatory work, they would have access to nearly everything. Yes. No, what I mean what I don't want to share, is that...it's not that I don't want to share, it's that it's our aim. It's our... how can I say that? It's what [name of company] is doing differently	development and the follow up of my product and everything linked to a design change, improvement, data collection"		success factors: trust and communication...terms of (legal) agreement, defined from the beginning
P5	"I didn't" " So, that's the first comment to say. But it doesn't surprise me to think about people in competitive situations working together. ND So, means you have thought about it but you have not practiced it. Ah, that's a good point. **I have not practiced it**.... And the companies that I have been part of, and So, I think this comes a little bit—I've worked in a consultancy for six years doing a lot of med tech, technical development work with people and technical innovation with people, and then worked a little time in university but then mainly in biotech. All of those **companies I've worked for would run a million miles from a competitor.** A million miles I: Why do you think these companies have avoided collaborating with a competitor and not engaged in such a collaboration? What do you think is the reason? Ruthless competition. I	"I have not practiced it" "companies I've worked for would run a million miles from a competitor". "companies I've worked for have been driven by really quite ruthlessly competitive people" "Anti-collaborative,		barrier to (coopetition) success: companies I've worked for have been driven by really quite ruthlessly competitive people; qualifying: . I think they would say happy work in a very early stage

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	think a lot of those **companies I've worked for have been driven by really quite ruthlessly competitive people**. I'm at the heart, kind of the drive behind the company and—I just silenced that for a second. And I think that leads to a sort of sharp elbow approach and keep-away approach and I just don't think it would ever get considered. I just don't think it would be—even the thought process wouldn't get entertained within a business. And I think because you think about to be a successful business, you do need to be somewhat ruthless and competitive just to be the survivor, to be the—it's like a form of evolution. You start off with all these great ambitions but then the people who survive there is, I think by nature, you often drive for an element of kind of ruthlessness there. And that leads—that I think is in its own way somewhat anti-competitive. Sorry, anti-collaborative. **Anti-collaborative, especially with competitors.** I: Let me argue those are very, very good or positive examples. I mean, you are well informed about pharma. So, I believe pharma is a very classical example for collaborating with your competitors because they're doing a lot of basic research together and then share results. But from there it stops and then they go their own ways. I: But still, it's very hard competition in that environment. B: Yeah**. I think they would say they're happy to work with a competitor in very early stage** I: Okay.	especially with competitors" . 20b "I think they would say they're happy to work with a competitor in very early-stage work, So, long as they can each go their own way separately and then compete"		
P6	**Yeah,** because—I'm going to give you an example. Collaboration, as I explained before by the OBL, OEM, okay? It was already in a collaboration because I was providing, giving the full technical file to my partner. So, for me, it was a state of mind. But for companies, competitors were like, "Are you giving away your thing?" I said, "Where?" I mean it's still the machining of a piece of plastic or machining a piece of titanium, So, there's no big innovation. There's no—even and for the things that were big innovation or technical advantage, you have a patent behind, and you have confidential receipt. Anyway, So, this was already a state of mind. **To capture, to adapt to the new MDR, I have proposed to some competitors that we exchange all technical files**. **W**e make a contract where I give them my own technical file So, then they can demonstrate the equivalence, because they have the whole technical file. Then the MDR approaches here is done. Because **you can demonstrate that you have a contract of exchange of information of the whole process. So, that's a second way of collaboration.** That's what I'm doing on the pedicle screw with the company.	Yeah." 20b "To capture, to adapt to the new MDR, I have proposed to some competitors that we exchange all technical files". 20c "you can demonstrate that you have a contract of exchange of information of the whole process".	1 To adapt to the new MDRI have proposed to some competitors that we exchange all technical file 2 We make a contract 3I give them my own technical file so then they can demonstrate the equivalence 4 Then the MDR approaches here is done 5 ou can demonstrate that you have a contract of exchange of information of the whole process	quantifying: was already in a collaboration because I was providing, giving the full technical file to my partner; critical success factors: To adapt to the new MDR, I have proposed to some competitors that we exchange all technical file...make a contract ..the MDR approaches here is done;
P7	**On many occasions, yes**. First of all, we are not only manufacturing and marketing our products on our own, but we are also private label and OEM manufacturers for competitors. INT: so, this is more on the commercialising? Manufacturing- If you talk about- Mm-hmm (affirmative).) Yeah, it's both, it's manufacturing, regulatory, and finally the commercial side. However, we also are in the loop of co-developments. For example, **we have provided our key product**, [name of a product], **to a competitor who has enriched it with biological growth factors and is currently in the process of CE certification**. So **also in terms of R&D, we are looking to strive innovation through coopetition**	20b "On many occasions, yes" "we have provided our key product to a competitor who has enriched it with biological growth factors and is currently in the process of CE certification". 20b"So also in terms of	1 it's manufacturing, regulatory, and finally the commercial side 2 we have provided our key product to a competitor 3 competitor has enriched it 4 it is currently in the process of CE certification	quantifying (done coopetition): on many occasions, yes; qualifying: it's manufacturing, regulatory, and finally the commercial side; critical success factors/choosing: provided our key product to a competitor who has enriched it ..and is currently in the

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		R&D, we are looking to strive innovation through coopetition"		process of CE certification; critical success factor: in terms of R&D, strive to... innovation through coopetition
P8	INT: So, when you talk about coopetition, you are talking about sharing your development results? Yes. INT: So, could you also imagine working with one of these competitors together in development? So, to co-develop something? # **Yes**. Yes. The issue of **co-development** must be also understood not only **with other private companies and** by doing so **with a direct competition,** but it must also, I think, be discussed as co-development with laboratories, public laboratories. And we've been asked quite extensively to co-develop with laboratories. And we are going to have **some projects within the next month and years** with a couple of those laboratories and they will develop for us. And then **we will bring their developments within the** [name of a company] **platform and they will get some incentives out of it**	"Yes" 20b"co-development with other private companies and with a direct competition", "some projects within the next month and years" 20a" then we will bring their developments within the.. platform and they will get some incentives out of it"	1 we've been asked quite extensively to co-develop with laboratories 2 we are going to have projects with a couple of those laboratories 3 they will develop for us 4 we will bring those developments with company platform 5 they will get incentives	quantifying: The issue of co-development must be also understood not only with other private companies and by doing so with a direct competition, but it must also, I think, be discussed as co-development with laboratories, public laboratories; hypothesising: some projects within ...month and years with ... laboratories and they will develop for us... we will bring their developments within the .. company] platform...they will get some incentives out of it
P9	Okay. In principle, **we do have an IP package with several patent families** and so on and we do have a technology portfolio and everything comes out of that but **we are not able to pursue all development son our own** or we have to realize, okay, it doesn't make sense that we want to address all markets and so on or business field and for that reason, I decided to identify some core developments which we will pursue up to the end product and was there the end product and on the other hand, **we do have** some, yeah, packages, **R&D packages which we are willing to make it available to the right partner** and **in that position, we are the contract developer and finally, the contract manufacturer and the legal manufacturer** but with the outcome of the project and of course, **finally a medical device which is exclusively developed for the partner and the partner will sell it and we will receive the transfer price**. And this is the working structure which I implemented since, of course, some years and this works really well because **the motivation on the other side for the partner is high because he invests money in development, and this is how we work with coopetition.** We had and we do have several projects or several contracts which are exactly set up like this. That means, yeah, we do have contact in other company. This can be a small company, this can be a start-up, this can be a quite high, quite big company where we do development according to their needs. They define the product, they define what are, in principle, the development sets. Of course, we make our recommendation how to develop, how to pack it, how to sterilize it and so on and finally, it comes out that we will be the manufacturer of product which might be competitive to our own product at the end.	20"we do have an IP package with several patent families" 20b " we are not able to pursue all developments on our own" 20b"we do have some, yeah, packages, R&D packages which we are willing to make available to the right partner and in that position" 20c "we are the contract developer...finally, the contract manufacturer and the legal manufacturer"	1 I decided to identify some core developments which we will pursue up to the end product 2 we do have some R&D packages which we are willing to make available to the right partner 3 the motivation for the partner is high because he invests money in development 4 we are the contract developer 5 outcome of the project .. a medical device ...exclusively developed for the partner 6 he partners will sell it 7we will receive the transfer price	quantifying: we are not able to pursue all development son our own; choosing I decided to identify some core developments which we will pursue up to the end product; critical success factors: R&D packages... we are willing to make available to the right partner…we are the contract developer and .... the contract .... the legal manufacturer the outcome .... a medical device exclusively developed for the partner.... we will receive the transfer price; critical success factor; partner invests a lot of moneys, motivation to make it work; qualifying (types of

Question 2	Understand about your experience or your view, how you personally being engaged or see collaborating with a competitor	In Vivo Codes	Process Codes	Initial Codes
		20b"The motivation on the other side for the partner is high because he invests money in development and this is how we work with coopetition". 20a"finally a medical device .. exclusively developed for the partner and the partner will sell it...we will receive the transfer price."		coop) can be a small company, this can be a start-up, this can be a quite high, quite big company where we do development; qualifying: it comes out that we will be the manufacturer of product which might be competitive to our own product at the end.
P10	**Many times,** actually **in past five years**. We on one hand, o competitor to us. And **we compete on many markets with the same products**, but **at the same time, we work together,** and we still are working **on new products and we try to partner continuously. So, it can work. It depends on people on both sides.** That's it. I: So, the collaboration is also in the area of innovation and development? Yes.	"Many times actually in past five years" 20"we compete on many markets with the same products, at the same time, we work together and we still are working on new products and...try to partner continuously." 20b"it can work. It depends on people on both sides"	1 we work with Company. for very long time 2 they were just a customer 3 for the past five years they are also a competitor 4 at the same time, we work together on new products.. try to partner continuously 5 it can work... It depends on people on both sides	quantifying; Many times, actually in past five year. Choosing: compete on many markets with the same products, but... work together on new products; qualifying: (on innovation and development, yes); Critical success factor depends on people on both sides,
P13	We develop implants which are fixated using polymers and they develop devices which cuts bone using ultrasonic energy and metal plates. So, we understand metal implants, we understand the ultrasonic device, okay **we do not know much about cutting but that is where we come together.** What they find in the ultrasonic applications for their device helps us to understand our device much better or our ideas we have in mind and the other way round. And **then we can share the packaging, biological testing, sterilization, cleaning which is super expensive** in the end but we can share those things because if we validate our packaging for our device which is worse case for them, they benefit from that and vice versa. So, we can share a certain mandatory cost. INT: Okay. So, that seems it is quite complementary? Yes. I: So, you know things they do not know and vice versa? Yeah. And we can share certain burdens we have to carry as medical device companies in general, as I said, packaging, cleaning and so on. Biological test where we can share our knowledge and I do not have to pay the same test twice so to speak up.	20b "we do not know much about cutting but that is where we come together. "then we can share the packaging, biological testing, sterilization, cleaning which is super expensive"	1 we understand metal implant and... the ultrasonic device 2 we do not know much about cutting 3 What they find in the ultrasonic applications for their device helps us to understand our device much better 4 then we can share the..high costs	qualifying: do not know much about cutting but that is where we come together; critical success factor: what they find in the ultrasonic applications for their device helps us to understand our device much better or our ideas we have in mind and the other way round (mutual benefit??); critical success factors: then we can share the packaging, biological testing, sterilization, cleaning which is super expensive;

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				choosing if we validate our packaging ,,,, which is worse case for them, they benefit from that and vice versa; quantifying: if we share the burdens we don't have to pay the same costs twice
P14	**: Yes. In some points,** yes. Why? **We cannot provide all manufacturing steps** in [Place name2]. For example, specials for face coating processes. This is what we cannot doing in house directly and **that is why we are cooperating very closely with another company**. What we are getting at the end also all the documents for this process **that we can provide to our customers**. INT But then the cooperation is on the manufacturing side" "we are getting at the end also all the documents for this process that we can provide to our customers" Right. I: Not so much on the development side**:** There are some requirements, where we must have also let us say a roundtable discussion before we are starting this process. For example, there is a requirement for a customer where we should provide a special surface coating at only some parts at the instrument. So, and then it is very important that we are discussing before okay, how can [Company name1] of manufacturers his instrument? That at the end, the partner company can make the surface coating directly at this point at the instrument. And that is why sometimes we have to revise the drawing before we are starting the process and that is-. So, that means for us, **we must be very open also to our partner company, with the drawings with all product information.** And we are getting at the end. So complete feedback from them also this document and the process" So, you would say that so far this coopetition, this collaborating with competitors is a successful strategy? I think yes. For us, yes. According to the feedback what we are getting from our customers, I can say, Yes.	20b"Yes. In some points" 20b "We cannot provide all manufacturing steps … that is why we are cooperating very closely with another company" 20c "we must be very open also to our partner company, with the drawings with all product information."	1 We cannot provide all manufacturing steps in a certain location 2 why we are cooperating very closely with another company 3 we are getting at the end also all the documents for this process 4 documents we can provide to our customer 1 There are some requirements, where we must have also let us say a roundtable discussion before we starting this process 2 a requirement for a ..special surface coating at only some parts at the instrument 3 the partner company can make the surface coating directly at this point at the instrument 4 sometimes we have to revise the drawing before we are starting the process 5 we must be very open ... with the drawings with all product information 6 we are getting at the end...complete feedback from them... documents and the process"	quantifying (coopetition): we cannot provide all the manufacturing steps; qualifying: that is why we are cooperating very closely with another company; critical success factor: we are getting ...all the documents for this process...which we can provide to our customers; critical success factors: the are some requirements ...discussed before starting the process; critical success factor: we must be very open….with the drawings... with all product information; quantifying: (success of coopetition) yes, according to the feedback ....getting from our customers,.
P15	**Yeah**. And we also do this, for example for the QR codes, we found two good companies who are doing something similar not like me but close enough. And then we always say get in contact, ask them and some are very open. And the bigger the company gets there is this, I don't know, [name of a company] it's called in [name of a city], they're doing bikes. And they also wanted to do a QR code on a bike that you can scan it and know when to repair or when it gets lost and so on. And we said this is a nice idea, we have a really good, scalable	Yeah		quantifying: we .do this, for example for the QR codes; hypothesising: I think for smaller companies it works because there's no threat on them not working together

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	infrastructure, can we work together? And companies like that don't do that. They said, yes send us everything you have and then I followed up two to three times and no reaction. And so, I think for smaller companies it works because there's no threat on them not working together instead of working with someone. INT So what you're saying is the higher the pressure, the higher the likelihood that competitors collaborate? I think it's always a thing when you- when would you cooperate with your neighbor? When would you cooperate with your whole city? When with your country? And it's always the question if the next one is on the hierarchy up, then you join forces. And I think this is also the same for [name of a company] and [name of a company], they never worked before but when [name of a company] came up they said, now we are German, and we have to-			instead of working with someone;

Question 3	So, you have not practiced coopetition? So, you have not yet worked actively with a competitor in innovation?	In Vivo Codes	Process Code	Initial Codes
P1	Yeah, we have. So, one competitor, we did do some contract work for we're currently doing that for and thankfully, we did get that contract to a position where they didn't have any access to our background or foreground IP. So, one of them we have worked with but to take it to the next level where we do a bit more work again, they're both asking for more, if that makes sense. So, yes. INT:Int So if you have worked with that competitor- so I mean, this was clearly in the area of innovation? P1: Yeah. So, we took one of their lenses and we put our polymers on their lens to show them it worked.		1 one competitor we did some contract work for 2 we did get that contract to a position where they didn't have any access to our...IP 3 so we took one of their lenses and we put our polymers on their lens to show them it worked.	
P3	And if your company, so far, has not collaborated with competitor really in development stages of a product, why not? No need for this or...? The opportunity is not original rarely. Nobody has come to us with an idea. I don't see...Sorry, I'll rephrase that. Are there many shining examples of coopertition in the orthopedic industry? No, not in my humble opinion. I've been in it since I was 17Maybe a little bit just with two partners in a bit to guarding of all secrets, not as many secrets in hips and knees .....and things like that. But things like the nail, you know, things like the [name of product], they're all unique technologies and I'm sure everybody wants to guard their IP. I don't know...are there any other outside of coopertition in our industry outside the .....No, I think we would work with a competitor. The problem is with being an SME, it'd be ... that competitor is, are they going to swallow you up? Are they going to take the best things from you and use it to their advantage? If they're a direct competitor in this country... we have worked with an Italian company at home. ... with a Turkish company on our ...the Italians but they weren't good enough to compete with what was already in our market. So but not with the direct competitor in the ...because a direct competitive, then both of us should go to sell it. And is there enough room in the marketplace with my 12 reps or their 15 reps or whatever to work		1 I think we would work with a competitor 2 The problem is with being an SME, it'd be ... that competitor is...going to swallow you up? 3 Are they going to take the best things from you and use it to their advantage? 4 not with the direct competitor in the ...because a direct competitive, then both of us should go to sell it. And is there enough room in the marketplace	quantifying: Are there many shining examples of coopetition in the orthopedic industry? No; choosing: everybody wants to guard their IP; hypothesising the problem .with being an SME, it'd be ... that competitor is, going to swallow you up? ...take the best things from you and use.to their advantage? quantifying not with the direct competitor....both of us should sell it...enough room in the

Question 3	So, you have not practiced coopetition? So, you have not yet worked actively with a competitor in innovation?	In Vivo Codes	Process Code	Initial Codes
	around the UK. I don't think we would. Maybe, unless you say that the new MDR situation, it's probably going to get more and more driverless into the hands of competitors. I haven't seen the opportunities but if we're presented with those opportunities, I'd say yeah. I: Well, I mean, there's certainly hurdles to overcome with what you mentioned here. But I mean, that's the one side of the coin, the other is, if you...let's say, if you would engage in collaboration with... and you don't think about your company, would you need to overcome hurdles in your own company or what they just do what you tell them? Again, because we're flat and open, we don't have to be convinced that it was the right thing, I suppose, because you know, who maintains, the IP? Whose IP is it in any way blah, blah, blah, blah, blah. Are we just going to used as a Salesforce? And that could be very healthy, which ... for the product that they're going to develop. That's fine and dandy. If they're going to develop it, and they haven't got a sales arm. I mean, that's what we do with anyway. I suppose, one reason the fact that we distribute the precise nail, they could take it away from us at any minute. And if they so wish that we're doing a poor job or that they've got the contacts and the Salesforce are sufficiently trained to sell it, where do you meet in the middle, as it were? I: Okay. So where would you draw the line in terms of working with a competitor where say, so until here, no further? Or is there no such... I don't think there is a line to be drawn if, you know, its people, isn't? It's like, how will I go with you and how well we would get on with your own organization. My son is peeping in the background. I'm trying to give him a hint that it's a bit loud, but always wear earplugs. And so, it depends on how open you could be in discussion, how welcoming the other company were this. Or, again, purely down to personalities. If I, or [name of person] more so is trying to work with another guy, who's a bit more dictatorial, a bit more alpha male, then he'd pushed back on that. I'm sure. And that's ... in life. I			marketplace? hypothesising: there is a line to be drawn if, you know, its people, isn't? It's like, how will I go with you and how well we would get on with your own organization.
P8	We have been asked to do that. Yes. INT: So, you have been asked, but you have not executed so far? No, because it is too early for us at this stage, we believe. But definitely, we've been asked to do that. And we're thinking about it very seriously. Well, we need to gain critical mass; I would say before. Because usually, the way it works is the company who shares their innovation, they get royalties. And on top of those royalties, they ask you to say, okay, this embarked solution is provided by company A. And before doing that, we want people to recognize [name of a company] as a true and strong solution. And then afterwards only can we say [name of a company] already provides you with some great things and we can prove it. But on top of that we are bringing you some innovation from other strong actors who have, for instance, access to databases that we do not have access to. And because of that, they are able to develop algorithms that we don't have yet.		1 we've been asked to do that 2we're thinking about it very seriously 3 Because usually...the company who shares their innovation, they get royalties 4 on top of those royalties, they ask you to say.... this embarked solution is provided by company A 5 Before doing that, we want people to recognize its true and strong solution 6 afterwards only can we say we can prove it. 4 on top of that we are bringing you some innovation from other strong actors who have, for	qualifying: No, because it is too early for us at this stage; choosing: usually the company who shares their innovation, to get royalties... on top of those royalties, they ask you to say... this embarked solution is provided by company A... before doing that, we want people to recognize this company] as a true and strong solution; quantifying afterwards only can we say [name of a company] already provides you with some great things and we can prove it

Question 3	So, you have not practiced coopetition? So, you have not yet worked actively with a competitor in innovation?	In Vivo Codes	Process Code	Initial Codes
			instance, access to databases that we do not have access to. And because of that, they are able to develop algorithms that we don't have yet.	

Question 4	Okay. So, in general, would you say it has been successful or not? So, we were talking about more radical and not incremental innovation, all right? It was something really new	In Vivo Codes	Process codes
P1	Yeah, **it was very successful because some of the technology that they had** for instance, like they have a**ccess to very specialized equipment that we would never have** in terms of measuring optical quality of lenses and -stuff like that. That's all data that we would never have been able to access, but they would, and it was great because it validated our approach completely. So, yeah, **I think both sides really benefited from tha**t, but taking it to the next step has been a harder challenge, if that makes sense.: It was, yeah. It was something really new for their products. Yeah	20b"It was very successful because some of the technology that they had"...."they have access to very specialized equipment that we would never have" 20a "it validated our approach completely.....I think both sides really benefited from that"	1 very successful because some of the technology that they had 2 they have access to very specialized equipment that we would never have 3 That's all data that we would never have been able to access 4 it validated our approach completely 5 both sides really benefited
P2	For the first step, the V1 is incremental. Not the V2 but **the V3, it will be a radical. But for the V1, it is incremental. The V2 is an incremental** as well and for the V3, it will be a radical and we plan to continue to get the product from our partner to **one of our key components in the V3 come from our partner located in Germany** but huge difference between the V1 and V2 compared to the V3, huge different- difference, sorry, about the strategy, about the market, about the client, about the pathology.	17b"the V3, it will be a radical" 17b " for the V1, it is incremental. The V2 is an incremental" 20b "one of the key components in the V3 come from our partner located in Germany"	
P7	I think **it's very useful** to do so. However, **we are, in regard to the R&D projects, at a very early stage**, and we have to see what it brings. In the other context, when it comes to **manufacturing and commercialization, we are pretty far**, and these have been **long lasting relationships which were pretty successful**. In our company, we have **applied incremental innovation** clearly	"it's very useful "20b " in regard to the R&D projects, at a very early stage" In.....manufacturing and commercialization, we are pretty far long	

Question 4	Okay. So, in general, would you say it has been successful or not? So, we were talking about more radical and not incremental innovation, all right? It was something really new	In Vivo Codes	Process codes
		lasting relationships which were pretty successful" 17b"we have applied incremental innovation"	
P9	Of **all the partners at the first stage, it is radical** I think because in principle, when **they come to us to develop an innovative product,** they want **to substitute a product** which they had **in their portfolio** so far **or** they want to **address a new indication.** Though in principle, the first approach is radical and of course, **when it comes to long year or collaboration** over years, of course, there are feedbacks from their product development, product management and of course, their small incremental development steps like when it comes to 3D printing, **adding new shapes to the portfolio though this can be considered as an incremental development, but the first step is maybe radical** when they do install 3D printed product in their portfolio	17b"all the partners at the first stage it is radical" ….20a" they come to us to develop an innovative product" "they want to substitute a product ... in their portfolio or they to address a new indication" "of course, when it comes to... collaboration over years, adding new shapes to the portfolio 17b ".can be considered as an incremental development"	1 they come to us to develop an innovative product 2 they want to substitute a product which they had in their portfolio 3 collaboration over years, of course, there are feedbacks from their product development 4 adding new shapes to the portfolio though this can be considered as an incremental development, but the first step is maybe radical
P14	No, **small steps**	17b" small steps"	

Question 5	From your experience with working with a competitor now, so what aspects or innovation, or let's say, stages in the innovation process were suitable for that collaboration?	In Vivo Codes	Process Codes	Initial Codes
P1	What do you mean? Can I have a bit more clarity? I: So, you worked together in the very early stage? Yes. So yeah, it was **an early stage where we knew that our polymers were releasing drug**, we knew that they could attach, **we didn't know a lot more about how we were going to manufacture them** at that point because it was very rudimentary, but yeah, it was useful for both parties. I'd really say it was.	20a"in early stage where we knew that our polymers were releasing drug, we didn't know how we were going to manufacture them"		qualifying: an early stage...we did not know how we were going to manufacture
P2	would say each stage can be- Let me think about that. It is mainly because the relationship we have with them, it is quite- we know each other on what we are working and what they are working but we are cautious. We avoid seeing a lot of things and the same thing for them, but we try to involve them at each			

Question 5	From your experience with working with a competitor now, so what aspects or innovation, or let's say, stages in the innovation process were suitable for that collaboration?	In Vivo Codes	Process Codes	Initial Codes
	stage. Again, for example, V1, they are involved from scratch to the industrialization step. For the V3, for example, they are only in the first stage. I mean, if I have to rank over 10 grades of innovation, they are only 1 and 2 maximums for the V3 and that is a full stop at 2. Regarding the V1, they are involved until probably 7 or 8, something like that. And again, it depends on the project, I think. From our side, it depends on the project.			
P6	There is collaboration with a competitor in spine. I was talking to him yesterday. We are doing **collaboration** by, **for instance, for validation of instrumentation tray**. You know the cost to do the steam validation.… The cleaning and steam validation costs 50,000. Euros We pretty much have the same suppliers. So, if we established a worst-case scenario with the worst instruments, we could demonstrate that their instrumentation, which are a bit different than ours but pretty much—I mean, they have the same raw materials, the same silicone and or the same supplier. And even if it is different, there are some applications of the ISO 10993 norms where we can demonstrate events. If you—because today, this kind of test, you have to do it in order to demonstrate that your screwdriver, you can do 200 steam cycles. And it's something that costs a lot of money. And the fact **to share those things, you have saved 25,000 euro. But that collaboration is needed because on the report, it's really to have on the report that this report is done for [name of company] Y and Company X because it's a mix.** So, that's a kind of collaboration where you have to do it. And especially small companies, they have to collaborate also in providing for instance example of technical file, of some element of the technical file or to exchange. But it's just another—it is a state of mind. Because myself, I know **very much regulatory** So, I know where I can find areas of collaboration. I know… INT: So, for you [name of person], collaboration with competitors is really on the regulatory side? Yeah, because it's where the cost burden is today. INT: You have a good point because many people, when they talk about collaboration, they think about development and co-development and all this, but you are really focusing on the regulatory aspects. Maybe because it is a cross burden. Cross burden and direct cost and also the cost for the time which is taken by notified body to do your technical file with you. If you can gain three months, three months it's important because three months, what is your fixed cost in your company for three months? I can tell you three months, for me at my size, we're talking three months it's 50,000 euro.	20a"collaboration for instance for validation of instrumentation tray the cleaning and steam validation costs 50,000. Euros share those things; you have saved 25,000 euro" 20a" that collaboration is needed because on the report.....done for [name of company] Y and Company X because it's a mix." 20c "very much regulatory.... cross burden and direct cost. and also, the cost for the time ...taken by notified body to do your technical file with you" 20a" if you can gain three months, three months it's important" 20a "three months, fixed cost i.... for me at my size.... three months it's 50,000 euro. "		qualifying collaboration for validation of instrumentation; quantifying: cost...50,000 euro...to share... saved 25,000 euro; critical success factor: especially small companies,. must collaborate ...providing for instance example of .some element of the technical file; barrier to success: regulatory...that's where the cost burden lies; barrier to success: cost for the time which is taken by notified body to do your technical file; Quantifying (collaboration): If you can gain three months...it's important because... fixed cost in your company during three months 50,000 euro.
P7	Yeah. Well, I would say that **it's very important that the coopetition starts in the very early phase**, even in a phase where you define a market together and bundle forces. Because **otherwise, I believe the risk is pretty high that you are losing important information and resources on the way to success**	20a"it's very important that the coopetition starts in the very early phase" 20c "otherwise, I believe the risk is pretty high that you are losing		qualifying very important that the coopetition starts in the very early phase; quantifying: otherwise…. the risk is high that you are losing important information and resources.

Question 5	From your experience with working with a competitor now, so what aspects or innovation, or let's say, stages in the innovation process were suitable for that collaboration?	In Vivo Codes	Process Codes	Initial Codes
		important information and resources on the way to success"		
P9	Yes. Of course, I try to-I did divide several business fields for us. Maybe it can be there is dental, orthopedics, spine and these business fields can be divided quite easily, and **I can work in all business fields with different partners.** So, **we do have a main partner in dental. We do have another partner in orthopedics and there is no impact to each other**. So, in principle, **you can make use of the same technology of our same IP and innovative processes** and can address on the one hand the dental market and on the other hand, the orthopedics market and can get out the best out of it and the different partners, yeah, there is no-yeah, no negative impact on each other and of course, we are completely transparent though all the partners do know from each other	20a"I can work in all business fields with different partners" 20b".we do have a main partner in dental. ...another partner in orthopaedics and there is no impact to each other".20b "you can make use of the same technology of our same IP and innovative processes" 20b" there is ..no negative impact on each other and ...we are completely transparent though all the partners"	1 I ...divide several business fields for us 2 I can work in all business fields with different partners 3 there is no impact to each other….in principle, you can make use of the same technology of our same IP and innovative processes 4 and can get out the best out of it and the different partners 5 we are completely transparent though all the partners	critical success factor: I can work in all business fields with different partners…make use of same technology our same IP and innovative processes…optimise it
P10	Yeah. **It really depends on the partner**. So, **I don't think that one is more suitable than the other one**. So, you can start from the very early moment, in my opinion, and in my experience, so from the moment where yn the past, we had some devices were- [name of a company] was bringing certain IP to the process. We were packing it together with our technology on electronics and IT side. And then we were doing even the registration because they said we have not much experience in registration.	20b"It really depends on the partner...I don't think that one is more suitable than the other"		Qualifying: it really depends on the partner; critical success factor; start from an early moment; on actually describe what the product is going to be, through whole development process, and then the registration too. I
P11	I think one process we have seen, and we are cooperating with competitors, is- again, it goes back to where you started the product. We have some competitors … where they are weak in Europe and where we do have a gap in our product pipeline. We are reaching out them and, honestly, they are all very open to give us exclusive distribution with our own brand to that market. But I am not sure, how much this is related to MDR versus related to- and I don't think it is related to MDR, for me it is related to focus and presence. And now, if I go back on the chain of- **it depends how you define competitors**, to be honest with you, because f**or me the size matters a lot**. This is, where I don't know what is in your mind, just for me to be specific to be able to answer better your question. Is it everyone, every size doing some type of products in the same field or you are talking more the same size? What is in your mind? How do you see it?	20b"It depends how you define competitors" "for me the size matters a lot"	1 We have some competitors … where they are weak in Europe 2 where we do have a gap in our product pipeline 3 we are reaching out them 4 they are all very open to give us exclusive distribution	qualifying (coopetition): it depends how you define competitors; quantifying (copartner): for me size matters a lot

Question 5	From your experience with working with a competitor now, so what aspects or innovation, or let's say, stages in the innovation process were suitable for that collaboration?	In Vivo Codes	Process Codes	Initial Codes
			5 I don't think it is related to MDR	

Question 6	So, what did you find specifically important in making working with your competitor successful	In Vivo Codes
P1	The legal. Just again, coming back down to **honesty, like what was each side expecting and making sure that the legal agreement that was between us wasn't too complicated** because I think you can spend an awful lot of time wasted just going back and forth with marking up contracts when really it should just be like, this is what I want. This is what you want. We're not going to do this to each other, the end. Do you know what I mean? Like I felt like a **lot of our time was wasted just doing legal, which is a massive hindrance to innovation** when you think you waste so many more months negotiating, if that makes sense. It means that we're ready template for what it is to look like to work with these sorts of organizations. If you're like a small company working with a big company, like there's a couple of templates these legalese departments have, but I don't think anyone's really got anything set and fit for purpose at the minute because we get some long contract and then they're like, "Oh no, we've got a template that looks a bit better and we'd probably seed you more," but then none of them are actually correct and they're supposedly just interested in it. It's an exploratory project to open the innovation outbursts and not entirely sure why there has to be so much jargon around the legalese, if that makes sense.	
P2	I'll try to answer and then just to give a counter argument about my answer. So, let me think. I'm just thinking out loud. I would say the first thing is again, human or team because t**hey are part of our team and we have to trust them, and they have to trust us as well**. Meaning that we have to be fully transparent and honest with them when we are asking some specification or request and so on, and they have to be open as well. For example, in the manufacturing process, the quality request and so on. Not only in the innovation part but I mean, regarding the routine production and it is quite important to have a good relationship and not only relationship between a supplier and a manufacturer. So, I would say trust first even what we try to do probably not enough often but we want to share with them our vision. Meaning that just define exactly what point we want to achieve with their technology and what is- what part of our final product their material will represent. So, we try just to be open and to explain to avoid misunderstanding, to avoid frustration, to avoid- Again, it is a partner. So, the goal for us is just to be sure that at the end, they are involved and sometimes, once we have some issues to solve in our innovation process, they can be part of the solution. So, that's why we want to be open. So, as an example, we plan to submit to fill an improvement patent based on the patent they have and there our name. If for some reason, we have some trouble on specific part and they are involved to help us, to support us to solve the issue, of course, they will co-own the improvement patent and we will let them to co-own the improvement patent. For ours, it is just a question of fair and the same thing for the team, the same thing for the strategy of innovation. The goal is just to be fair with people we are working with at (name of the company) or outside (name of the company). And if we succeed, they will succeed as well: I'm 100 percent sure. INT: So, what I hear is very much about transparency and openness. P2: Exactly. Exactly.	20b"because they are part of our team and we have to trust them, and they have to trust us as well"
P6	It's, first, **it's a state of mind. The will to share benefit.** But in any kind of deal, it's difficult to—it's always the objective to have a 50-50. But you know that's life. Sometimes we would get 70% of benefits out of it. But even if it says, you still have gained something. And what **is important is really to have a contract.** But the contract where it has to be **simple, because in a contract you can never invent every circumstance**. So, that's the most important thing. Then is really to consider that collaboration, **when you establish your collaboration, is what is your final objective? Is this going to be an added value for your company? When?** Now or in three years or in five years? Is this going to be a driver to	20b" it's a state of mind. The will to share benefit." 20c it"s important ...to have a contract... the contract ...has to be simple, because …..you can never invent every circumstance" 20a"when

Question 6	So, what did you find specifically important in making working with your competitor successful	In Vivo Codes
	have an increase of your added value if the company wants to be sold to another competitor? Because if you have contract where you cannot be detached, you are in trouble You see? That's why innovation, collaboration is really a state of mind and it depends where you want to go. How long? But, So, far, I had collaboration with some companies and now things are changing the collaboration. I'm doing some collaboration no more as the manufacturer but I'm doing collaboration on a sales approach. And some of the companies, I was a manufacturer, now I'm doing R&D, because that company they have no experience of the surgical application or the engineers are too young. And the young generation it's not you and me where we spent hours in the OR. So, we know the situation. Even today, things have changed, but we have maybe more common sense. And today, young people in R&D, they are brainstormed by, “Oh, we have to do this. We have to do this kind of test and test and test.” But they don't even have a clue how much does it cost. So, they put this in the risk analysis, So, if you are not knowledgeable in what is it, how much they cost, as a manager, you cannot only sign the check and say ‘yes’ for everything. You have to train your people, “Okay, this is the optimal solution, but can we do something intermediate? Do we have to do it now or can we put it on a program to be done in three years? Is this going to change in the product?” All this kind of thing. So, collaboration with your competitor can address these different steps. And this is a keyword, collaboration between suppliers and customers, collaboration with competitors, as long as it is the same level. As long as there are trust and clear objective in the short-term or mid-term. For instance, I'm doing collaboration with two U.S. companies on my product where I've adapted my product to the U.S. market. See, they didn't like my screwdrivers So, I changed the screwdrivers from the original on to the one they requested. But I had to change the locking device on the implants. So, I do all those changes. I do all—I give more features, but marketing features because, at the end of the day, the surgery is the same. The Americans, they wanted to have the drill, the tapper and the screwdriver to go in the same guide. Okay, fine, because your surgeon is lazy. But the counterpart of this is if you use a guide, you don't see any more.	you establish your collaboration, is what is your final objective? Is this going to be an added value for your company? When?" 20b"collaboration between suppliers and customers, collaboration with competitors, as long as it is the same level...as long as there are trust and clear objective in the short-term or mid-term"
P7	20b "one of the key factors is transparency on the different milestones and development status of the project, ... also to share .. information, mainly the preliminary scientific results"	"one of the key factors is transparency on the different milestones and development status of the project, ... also to share information, mainly the preliminary scientific results"
P8	I think **you need to have a strong legal background** to whatever you are doing because when the issue gets back too many things can get nasty. So, you really need to make to **make everything very clear as to what you're expecting**. And yeah, that's very important. What else can I tell you? Yeah, I think the legal aspect is very important. I also think that **if you co-design, you should co-share the intellectual property.** Yeah	20c"you need to have a strong legal background ...make everything very clear as to what you're expecting." 20a"if you co-design, you should co-share the intellectual property."
P9	I think i**t is very useful when the partner is really familiar with the matte**r and of course, knowing what he talks about **and accepts that sometimes, things are not easy to develop and to get it approved.** I think this is the most important point to accept that all processes as finally to be approved **and to have an agreed feeling on the timeline and resources needed**. This is a very important point I think in the collaboration that it does not make sense to state, okay, let's do it, we will have it on table in six months. It will not happen. So, both sides have to agree and have to accept and although that's quite small changes and small innovative steps require a really large effort to get that approved finally. So, this is something which I experience that maybe some-the old generation does not accept that times change and that it is not easy to get an idea approved as a medical device in one year. So, the more acceptance is available with all people, it makes working easier. It is important to have the understanding that nobody is considered to be- yeah or blame there. Yeah. **It is important to consider all aspects of the innovation process**.	20b "it is very useful when the partner is really familiar with the matter ...and accepts that sometimes, things are not easy to develop and to get it approved" 20b "and to have an agreed feeling on the timeline and resources needed" 20b"It is important to consider all aspects of the innovation process"
P10	Yes. Many times. Yes. Look, in the past, it was easier when we were not directly competing. However, we were supporting, we were supplying the competitors with our products. So, on this way, we were still competing, and we were still involved in development of some products that were- They were coming with certain technologies. We were complimenting these technologies with our technologies, and then we were building together a product for the market they were serving. So it was, even when we were competing, we were collaborating on R&D level too. And we still are. The people on the other side. INT why successful? Because if you **communicate with them easily** and you **trust this cooperation, then everything goes- We**ll, look, we were working together even without special contract. So, the t**rust is I think the basic one and the most**	20b"communicate and trust this cooperation, then everything goes well" 20c" trust is the basic one and the most important one.... no contracts can warranty successful finishing of

Question 6	So, what did you find specifically important in making working with your competitor successful	In Vivo Codes
	important one, because **no contracts can warranty your successful finishing of the project**. And good cooperation and **good communication** with people in my opinion is key factor in bringing the finalizing project.	the project" 20b" good cooperation and good communication...is key factor in bringing the final project".
P12	INT ASKS help and hinder I **look at what is the vision of each company and what do they expect out of this collaboration**. Is it first short-term or it is longer term? Is it more a win-win or more …as a win-lose, because that is what define a lot what type of collaboration and how much investments or priority should be given to this potential collaboration? So, I give you an example. We are working with a competitor, if you define it competitor, because they do have an implant system, that is different than ours. But they are very small, extremely small. They are like five percent our size, seven percent our size. So, I am not sure how much you define competitors, but there is an overlap from product. Now we are collaborating, and we said, we spend time and most importantly see, what is in it for me? And in the end, it is interesting where you see, we ended up collaborating is on complementary technologies, where there is no direct overlap. So, for example, we have implants, but we don't have pre-op systems. So, we collaborate with them on the software and on these things. But it is hard to collaborate on implants, if we have similar ones, because in the end, they are trying to push their innovation, we are trying to push ours. So, for me, either you are collaborating on regions or countries, where there is very little overlap. Or you collaborate on complementary technologies. And one third example I want to give you, when I was actually in my previous company in China, and I collaborated with [company name1]. I helped them register one of their key innovations in China, because my interest was to take the same technology and do local manufacturing under my brand and our brand. So that would be, that is pure innovation. There will be under their brand, the important product. And under my brand, there will be the locally manufactured same product. So that is another way, where we are collaborating and definitely helped them get through registration ……. resources at the time. So, if you look at the cycle …them from the registration process to China. Before we even …. INT asks about importance of contracts etc. **There is nothing called trust,** my friend. **It all starts by MNDAs and clear contracts.** This again**, you need to** have- you need to **build** (? stress coms) **from proper structure,** proper **systems,** proper **processes,** proper **governance in** place. And for me, this is very important. People come and go. It is about having proper things. Plus, to be honest with you, if you talk about **coopetition and competition** then yo**u maybe crossing very fine lines of breaking rules of competitors working together, to maintain prices, limit other competition. So, everything should be very** clear, very well **documented, very transparent.**	20a"I look at what is the vision of each company and what do they expect out of this collaboration" 20c"There is nothing called trust.....It all starts by MNDAs and clear contracts... you need to build from proper structure.... systems, ...processes, governance" 20b"coopetition and competition ... you maybe crossing very fine lines of breaking rules of competitors working together, to maintain prices, limit other competition...so everything should be very documented, very transparent"
P13	Yes, I do think it can be successful. And actually, I have been giving a lot of feedback regarding this. Because there used to be many of these EU financing program interviews, and similar ones, where they wanted to develop it to a better direction. My personal opinion is that **you can have success if you do not have too much of an overlapping in the companies.** So, for example, if you have a very hardware-oriented company and a very software-oriented company and service-oriented company working together, they might end up with a working end product or end solution. But, let us say, three similar software companies, it is almost impossible to have an equal setting in the end. It depends on how you define the competition. Let us say, for example, [company name 3], which is getting this handed camera. They are very much competitor of [company name 2] on a surface level. But at the same time, since they do not have any or bear any software competences, they can be a very good collaboration partner. Well, w**hen you are a small company, it is always a matter of trust. Because you can not take really a legal path anyway. So, you really have to trust. But when it comes to the bigger organizations,** I mean [company name 2] for example is even currently **in coop** with a couple of competitors, so **you do have to have it on paper** INT: So, what you say is, coopetition can work if one partner has something the other does not have and needs. Pretty much. Okay, so kind of complimentary. B: Exactly. Let us assume you have a situation like this. From your experience, what would you do before starting such a collaboration between those competitors? What would be the things to really look at before you enter such a collaboration? Well, I would look at the offering that the company has to the customers. And then compare the offering between the companies. And how much of an overlap there is, in comparison to completing its solutions.	20b"you can have success if you do not have too much of an overlapping in the companies" (means they have something you do not) 20b"when you are a small company, it is always a matter of trust.... because you cannot take really a legal path anyway" 20c"when it comes to the bigger organizations... in coop ...you do have to have it on paper"
P14	I personally would think **it makes sense if the company is in a similar size** as you are. So, in a similar situation obviously. And a similar pressure. I do not know if I will work with one of the big 5s, you know, because they know a lot from their massive portfolio of instruments in implants. For instance, in the field of implant. So, I do not think that makes much sense for implants which are not too far advanced. They change	20a "it makes sense if the company is in a similar size under the same pressure, regulatory wise, timewise,

Question 6	So, what did you find specifically important in making working with your competitor successful	In Vivo Codes
	by the way if it is something really new. Then I will think exactly the opposite. Then I will look for a big player as a partner because of-, I need to get input from so many different sides in order to make it happen. So, I think there is a big partner. It is useful. But for a small medium size company I would look for someone in the same, in the similar field, same size **under the same pressure, regulatory wise, timewise, financially**. Because then I think it is much easier to explain where the benefits are. But can be saved, cost, time, errors. How could I not get input? I think it is much easier than to work with the big one. Actually, that is also the experience we made here in house when we approach different companies with our ideas. **It is much easier to explain what we are doing and why we are doing to smaller entities, than to the big fives, six, sevens**	financially" 20a" It is much easier to explain what we are doing and why we are doing to smaller entities, than to the big fives, six, sevens"
P15	**Both sides must be open to make this cooperation**. And to-. How shall I describe it now? For-. In our field, it is every time when we are in cooperation. For us, it is a very security time as the drawings of-, so and in this moment when we are sharing the drawings of an instrument with the partner, with the competitor and then we are giving know how from our side to them. So, no one can directly say: „Okay, the cooperation partner will give this drawing now tomorrow to another company and can say okay please manufacturer now this instrument for me and I will make the CE mark for this instrument and will bring it directly under my name to the market." This is a point of **trust** to **each other.** When I-, when we are **sharing drawings.** There is a-, we are **signing an NDA before everything is okay, but there is every time a feeling of risk**. INT Okay, so, for you what is more important? Trust or legal documents? Trust. INT can you explain that? Why you believe the trust is more important than doingI can-. If I will, I think I can-, when I look to the quality management of all the documents for the quality management I think when I will do it I can manipulate these documents so as I need. But trust I cannot manipulate direct. INT: Do you have any bad experience Yes. That is why we can speak about this point was many experiences were let us say not with each project, but it was many projects you can start, or you must start every time from begin up. Every project is other than the project before and when you are asking a competitor for some points for documents drawings or if he can make the manufacturing process you must develop this for each project new.	20b"Both sides must be open to make this cooperation" 2oc" trust ..each other….when ... sharing drawings…..signing an NDA before everything is okay, but, ------- every time a feeling of risk
P15	That's a question I never thought about before because whether it works or it doesn't work- usually I would say right on all the things that people are holding back, all the- all this and address it. So, if someone says we are frightened that you will steal our employees, this is also very common in big tech companies. And I think there's **an agreement** for example for [name of a company], [name of a company] and so on, they never try to steal another- from each other an employee and maybe that's that. And maybe this can be addressed from other people higher in management so that they're real productive and together working employees don't have to deal with that, that they're free to work with each other. And but **I think addressing concerns of people is the first step to do something like that.**	20c"an agreement addressing the concerns of people is the first step"

Question 7	5. What hindered the coopetition?	In Vivo Codes	Process Codes
P1	Yeah, I think it was legal and from their side of view, it was y**ou had to wait really long periods of time** for them to go through different levels of management to get signed off essentially. So, I think it was time and legal, really that really kill those to start.	20c "it was legal and from their side of view" 20c"you had to wait really long periods of time or them to go through different levels of management to get signed off" " time and legal, really that really kill those to start"	
P2	The thing is you have to be sure that at the end, you have **to have a lawyer with you to avoid issue at the end**. Meaning that if you work with a competitor for developing a new tech or for whatever, if you are	20c"to have a lawyer .... to avoid issue at the end...they want to	1 have a lawyer with you to avoid issue at the end 2 to sign a contract

Question 7	5. What hindered the coopetition?	In Vivo Codes	Process Codes
	transparent but at the end, in the opposite side, they aren't **and they want to sell the same product you plan to develop**, for me, **the way to avoid issue is just to sign a contract written by a lawyer.** Meaning that sure that you are ready to start legal suit against them if there is some trouble. So, this is exactly what we- and we were open and transparent with them as well with signing a deal or with a contract at the end saying that if we have a trouble, we won't hesitate to pay a lot of fees to our lawyers, not only one but I think that **we have three now to start to fight against them because the risk** and mainly the risk **if we increase our sales** or if we sell or we increase our sale, **they could increase the price or the transfer price of their components** just to have more benefits about what they are selling because we sell more, **they could stop providing us their components just to increase their market share of their own technology**, **they could find a lot of ways to disturb us once we will be in the market**. So, the goal just to be sure that we protect us by contract and to show that, okay, we are open, we are transparent with you but if you do something bad, of course, we will be in a bad shape but at the end, be sure that you will be in a bad shape as well. So, that's why for me, it is just a win-win because at the end, if one of them lose, for me, both will lose at the end.	sell the same product you plan to develop" 20c" the way to avoid issue is just to sign a contract written by a lawyer." 20c"we have three now to start to fight against them because the risk…. if we increase our sales ..they could increase the price or the transfer price of their components... they could stop providing us their components just to increase their market share of their own technology" 20c" they could find a lot of ways to disturb us once we will be in the market"	written by a lawyer 3 you are ready to start legal suit against them if there is some trouble 4mainly the risk if we increase our sales .. they could increase the price or the transfer price of their components 5 could stop providing us their components just to increase their market share
P7	Yes, I can give you an example. One of the drawbacks is of course a **legal aspect**. When you, for example, want to **private label an own product for another company**, you always have to work with external consultants because **otherwise your competitor who simultaneously is your strategic alliance partner would have direct access to the technical documentation of products**. So, it is very important in my opinion that the legal structure within a coopetition model is very clear, clear but not hindering.	20c"legal aspect" " example your private label an own product for another company otherwise your competitor who simultaneously is your strategic alliance partner would have direct access to the technical documentation of products"	1 you want to private label an own product for another company 2 the legal structure within a coopetition model is very clear... but not hindering 3 you have to work with external consultants 4. your competitor. your strategic alliance partner would otherwise have direct access to the technical documentation
P8	Well, I always think that you should be careful as well because **you never know the exact intent your competitor may have.** It might be just to **understand as well, how you're working specifically on the subject or getting access to some of your staff**. And for instance, pinpointing down one or two assets, which they will hire afterwards, you know, you never know. But if you do a coopertition, I think you should play by the rules. And if you do so, you must assess that your competitor is working in the same direction as you are.	20c"you never know the exact intent your competitor may have" 20c "understand as well, how you're working specifically on the subject or getting access to some of your staff and for instance, pinpointing down one or two assets, which they will hire afterwards"	
P9	Yes, I come back to the point which what I mentioned recently. I mean, very important is the **understanding** and the feeling **which steps are important and require attention and resources,** and to distinguish that from the point which are not important **for finally getting a product approval**. This is what I can say from our experience that sometimes, of course, it is difficult when maybe a competition partner is maybe talking about packaging. You can talk about packaging one year, how to make it, how should it look like and so on. Okay, it is easy to lose a year talking about the packaging of a medical device. So, this can waste time and can waste nerves and waste resources, and it is important to get aligned, understanding on	20a"understanding ... which steps are important and require attention and resources, .. to distinguish those…. which are not important for finally getting .. product approval….it is important to have the same	1 understanding which steps are important …for product approval 2

Question 7	5. What hindered the coopetition?	In Vivo Codes	Process Codes
	both sides, okay, which are the essential steps, and which is a correct timeline when do have, which processes implement, when is the correct time to make a design for this, when validations should be initiated? Maybe when it comes to real-time studies. Of course, this has to be started quite early because you are talking about real time when it comes to shelf-life studies and so on and this honest and this is quite difficult to get this project roadmap aligned on both sides. So, the whole thing that complicated, there is no- of course, there is something like a patent or like a route to follow. Yeah. I think this understanding and this continuous understanding because with the-and that's a constellation, you have to make meetings maybe every two weeks and **it is important to have the same working speed and to identify priorities.**	working speed and to identify priorities."	
P10	No. It was nothing. It was, again, something with. I would put it into the basket of human nature, because we started one in device when we were mostly responsible for the mechanical and electronic design of the product. And then **the final software, the application was coming from the patent owner. And the patent owner was not a good programmer**. His programming partner was not good programmer too. And we ended up in the situation that we had also to develop the entire application because we even found the bugs in the software that were making a mistake in the calculation. And finally, we had to tell, we have to explain to our partner, who was [name of a company] at the time, that, "Guys, maybe we'll do this software too, because otherwise we will end up in a never-ending story with new software version and new bugs, and so on, and so on," because we saw that the guys were not good in programming. So, sometimes you have to take the responsibility. You never know what's really on the other end. The patent they assure you that they have wonderful experts and programmers. And in the end, not necessarily this is sure, your point of view is different than their point of view. So, then you have to take action. You have to act. And it works. So, I would say that the most important factor in such cooperation is the trust between people	20a"the final software, the application was coming from the patent owner. And the patent owner was not a good programmer"	
P12	To me it did not seem that the companies were really collaborating. I mean, in those programs, when you started to have something being created, they started to become jealous. Or they wanted to-. The communication started to decrease and whenever some part of the program or some new module being created or product being created, **started to create some value or the companies thought it would have value, they wanted to own it. Especially big vendors.** It seemed to be-. Because in the past, I always used to be with the (? SME) companies in those programs. We had these last enterprises, who were leading the programs, that **they did not want to share the IPRs. So,** in the end **it did not end up as a working product.**	20a"started to create some value or the companies thought it would have value, they wanted to own it". 20a"Especially big vendors" 20c" they did not want to share the IPRs. So, ……. it did not end up as a working product."	1 it did not seem that the companies were really collaborating 2 they started to become 3 communication started to decrease 4 whenever some program…new modules, product being created they wanted to be owned I 5 they did not want to share IPRS
P13	Trust. I: What is trust? Maybe something you can-, while you do your legal framework, you do a contract-. Yeah. Exactly, that is what I mean. You need very clear contract situations. Who gets what? Who tells what? What are the rights? What are the duties?) And you think a good contract can solve the issue of trust? To a certain extent, yes. Because it makes it very clear. I think in this case, there should not be much room for discussion or misunderstandings. It should be very clear. Who gives what? Who gets what? The moment there is something unclear, a lot of human interactions starts. **Misunderstandings, misinterpretations,** and that is **not helpful for a smooth, fast, streamline development process.**	20b"Misunderstandings, misinterpretations, …. not helpful for a smooth, fast, streamline development process."	
P15	.INT when you know about the concerns would you say- what is more important, trust or the legal framework? I **think trust because the legal framework always can be bent to where someone wants to have it**. So, nothing is unbreakable, and I know from experience, from a company, they invested a lot of money for a (? world) patent on a good idea they had. And then they had to recognize or experience that there's some kind of patent breaking law process that someone initiated. So, you never can be sure, but you invest a lot of time into it and afterwards it doesn't help you, you spend time, money. And I always say,	20c"think trust because the legal framework always can be bent to where someone wants to have it" 20c"when every patent thing you see is- you need a lawyer for	

Question 7	5. What hindered the coopetition?	In Vivo Codes	Process Codes
	if it's possible, some legal things are necessary but if it's possible just be faster and maybe even getting your idea out so that someone who is better than you then can succeed on it, you weren't good enough and this is my thinking. But when you ask people for their concerns you exactly know they think, and you meet their concerns. And then you know what kind of people there are- **when every patent thing you see is- you need a lawyer for that and that, then you know it's maybe not the best fit for a competition.** I: Did you personally have bad experience? Yeah, I had, I had bad experience, but I keep it with the story of mine that says only careful (? data, that) you can change, and the rest leave behind and this is experience for you and next time you do it another way. And so, I try to learn from that and overall, I think it helped, learn from experience. INT: what went wrong? When- for example what was it? We worked together with a media agency, I was much younger then, I think I was about 28 or so. And they had a very manual process in every media company, they had their interns or lower paid employees to go through every website, for example (? RTL) where someone booked an advertising. And then they said, we booked this in the category of cars, and then they had to go to cars and refresh the browser until this advertising showed up and then they made a screenshot, they put it into PowerPoint, they wrote where they found it, what the number was and so on. And I did a proof of concept for them and said, I think we can optimize it. And I said, just give me the number and we will find out, we will refresh that often until we find that number, we do a screenshot, we put it into PowerPoint, everything was automated. And yeah, they really liked this idea, liked the proof that it worked and then my company worked on it without any contracts and without any pay. We said when it is on a stage where we can get to the customer then we will split the money and then we will do a real project out of it or a little … whatever the size fits. And they demanded- they always demanded more features, they said we can't go to the customer until this is working, this is working. It was a complete web interface where you can put in all these numbers and then he said, oh I already reached something and- or found something. And later we found out they were already talking to these companies and already showed them how this works. And we were also very open about our source code and then we said we won't continue working with you together and I really didn't want to file a lawsuit, but I said we would. And so, we arranged that they paid us some money and they could keep the source code and get it developed by someone else because then **trust was broken** and even if we now had a contract there was a lot of money on the table, I could have said I couldn't work with you together anymore. This was a real bad experience that I now say the solution is not to have always a contract, the solution is anyway to more create some kind of new and viable product that you invest only so much time to prove that something is working. And after that you have to again regulate how it is continued, this is my approach now.	that and that, then you know it's maybe not the best fit for a competition." "trust... broken "	

Question 8	6. Do you see benefits of implementing coopetition? If so, what are they?	In Vivo Codes
P1	Oh, the benefits for us are we've got more data out there than we could have got previously and I think we had **a lot more interest from investors when they found out we were working with these biggest strategics**, if that makes sense because I think **it meant that you had some sort of industry backing, essentially that they also believed in your concept.**	20a" a lot more interest from investors when they found out we were working with these biggest strategics" (means companies!!) 20a"it meant that you had some sort of industry backing, essentially that they ...believed in your concept."

Question 9	1. What are the challenges of implementing coopetition from your point of view?	
	Not asked	

Question 10	1. Were changes in your company needed to enter into a coopetition?	In Vivo Codes	Process Codes
P1	No, not really. I think we spent more time getting the samples ready for that competitor than doing other stuff and we diverted time for a few weeks when we had to get it all sorted, but in terms of actual **major changes to the company, no**	"major changes to the company, no"	
P2	**Not really** because we started from scratch by thinking by that. So, we had different traction working with R&D, academic (name of the company) having some patent and we knew at that time that we have to sign an exclusive license with them as well. So, after our assessment, technical assessment, we have decided to choose another one, (name of the company), but at the end, we didn't want to start from scratch. **Meaning that to start by our own tech from scratch, spending money and time developing only one part of the technology, no sense from our point of view. So, that's why we cut the corner,** find the best solution for us, took the power, thanks to this exclusive license and doing the same for other components and at the end, to get one product from different side and different partners.	"not really" 20a "Meaning that to start by our own tech from scratch, spending money and time developing only one part of the technology, no sense from our point of view"	1 To start by our own tech from scratch, spending money and time developing only one part of the technology, no sense from our point of view 2 working with R&D, academic (name of the company) having some patent 2 we knew we would have to sign an exclusive licence 3 after our technical assessment 4 we decided to choose another one company
P7	**No. We had to adapt into a couple of new scenarios.** So, in several specific scenarios, we needed to **outsource regulatory affairs** to independent external consultants, who then remain the legal certification holder, but not the distributor. And as I said, this procedure was necessary in order not to share technical file documentation with private label customers or distribution partners, specifically in countries like China, but also in European countries like the Netherlands	No". "We had to adapt into a couple of new scenarios " 19b"outsource regulatory affairs...external consultants, who then remain the legal certification holder, but not the distributor".	1 we did not wish to share technical file documentation with customers or distributors 2 we needed to outsource regulatory affairs to independent external consultants 3 who remain the legal certification holder but not distributor
P10	**No,** because it always- The development process is the same, regardless if we work with competitor or we work on our own product. In the past it was we were a smaller also team, so I was much more involved in all this discussion on the technical side. But I'm trying to get my people as much involved as possible in all the decision making and also on the communication with partners, customers. So, no difference, no difference. **The only thing is that you have to understand that you have to protect the IP of y**our partner, even with higher level than your own. So, you have to explain this to people because-	"No" 20c "The only thing is that you have to understand that you have to protect the IP of your partner, even with higher level than your own"	
P13	Actually, no. **Not in the company**. What we had to do is it of course, **we had to train people** because the competitor has access to our lab and so that is training requirement. There are **certain insurance issues which had to be clarified** in (? totally) yes. I know that, otherwise no	"Not in the company" 20b"we had to train people…competitor access to lab" "certain insurance issues…had to be clarified"	

Question 11	1. What effect does coopetition have on your present patents and IPRs?	In Vivo Codes
P1	No	"No"
P2	Yes. I would say **yes but we base our IP strategy mainly on their IPs**. We have exclusive license and therefore, will base our IP on this licence mainly. And we pay for the licence piece and so on. So, we will the exclusivity so we can do what we want. They cannot stop giving us license because again, it is under law, so-. Oh, yeah. All of **licence, IP and manufacturing, all stuff is managed under law**, yeah, **and contract and so on.**	20b" yes but we base our IP strategy mainly on their IPs." 20c "licence, IP and manufacturing, all stuff is managed under law, ..and contract and so on. "
P7	Not so much. I believe **thanks to the implementation of those third party independent and non-commercial consultants** in the above-mentioned scenarios, **we haven't seen any side effects on our patterns or intellectual property**"	20a"thanks to the implementation of those third party independent and non-commercial consultants"…. we haven't seen any side effects on our patterns or intellectual property"
P9	In principle, **we make use of our patents and this is part of the contract**	20a"we make use of our patents …this is part of the contract"
P10	Actually, there was- **No, we were using the IP and the patent they acquired the rights to use. So, we were building product based on this patent, and then the functionality of the product** and so on, and so on, **was designed together**. So, they had much more information from the market so to say. We were bringing what is available in the technology side today to implement these requirements in the product. And the **final product was going out to the market, as their product, but manufactured and also registered by us.**	"No" 20b "we were using the IP and the patent they acquired the rights to use" 20b"So we were building product based on this patent, and then the functionality of the product was designed together final product was going out to the market, as their product, but manufactured and registered by us. "
P13	**On our patents, I will say no**. **On our development cost, it does**. As I said before, **we share cost for certain development co**st which are part of the development nowadays which is packaging, cleaning and so on, and that yes **if you can share that laboratory cost.** We can share that. We do actually right now. We have a nice little laboratory that is fine. They cost a lot. Now we share it with our competitor, **we reduce cost which open up possibilities in development because we have resources free for doing something with it**	20d"On our patents, I will say no" 20a"On our development cost, it does.... we share cost for certain development ...if you can share that laboratory cost.... Now we share it with our competitor, we reduce cost which open up possibilities in development because we have resources free for doing something with it"
P14	No. INT: So, and because you are securing your own IP and patents Right. There were for example, a big problem was in the past, we are buying for our instruments, also silicone handles from another manufacturer. Since these silicone handles are patented under the name of these other manufacturer. So, and these other manufacturers had also a contract with another company and to sell only these sellers to these company. But we were getting the order to manufacturer instruments (? disease) enters directly from the other company. So, now it was a big discussion, who is responsible now for this patent? And who made a failure to use this pattern from the silicone handles?	NO

Second Coopetition

Question 1	And you were mentioning a second coopetition but if I understood correctly, that was just a plan or is still in planning?		Question 2	So, the first success story working with a competitor makes you positive about doing this again?		Question 3	So maybe different cultures, different mentality, different style. How was that? Did that impact or influence the collaboration?		Question 4	Okay and was culture aspect just an observation or would you say this had a, I don't know, positive or negative impact on the collaboration
P1	It's still in planning at the minute. So, we are actually, after all that nonsense I've just said about legal, we are now discussing the legal again in the next part of the project, essentially. So, because they're obviously putting in more money into this one because it's a bigger project and we're going further down the line; they also want a more stringent contract. So, that's why we're currently sat up with it, which is quite hard work, but it is good because it means that the first project was useful, everyone benefited from it and we want to carry on. So, it's a good thing to have. It's not a bad problem.		**P1**	Yeah. I think we are. If we get the right contract in place and everyone's comfortable, then yeah, we're happy to do it again and we're also looking at two other – we're looking at taking some drugs from [name of a company] at the minute as well in a screening process because they might have these antifibrotic drugs for their PCO, which is one of the endpoints we're trying to prevent as well after cataract surgery and yeah, it's been really positive; our first interaction with the first strategic. We wanted to go do stuff again with bigger ones so it's not a problem.		**P1**	Yeah, I think the amount of how many different people you have to speak to you to get to the answer really did frighten – not frighten us, but it shocked us how long it took, if that makes sense. From one person saying yes to getting to the final yes and just the time because obviously, we're not priority in the bigger company. It's just the time it takes to get to that point, and I think they've got to be a bit quicker because they're working with a smaller company who are like, "We can change our mind two weeks later," if that makes sense. Do you know what I mean? If you wanted to, not that we are going to, but I think there needs to be a bit more understanding from the other side about our agency as well as their culture. Yeah, I think the culture is very different.		**P1**	I think it's negative because yeah, I think we got felt quite frustrated because we've waited for a month to hear back from- we did an awful lot of work, got all these proposal plan set up and everything and then it was like a month until we got a response back from them and it's like, that's an awfully long time in a small company's lifestyle. If that makes sense. Like we're raising rounds, we are doing all sorts of other stuff. If they can take that long, we can't always make sure that our team are blocked off to do stuff for them. No, like we obviously do make allowances and we did because of who they are. But if, for instance, we had had something very big planned, they might have taken a stupid amount longer, but then it meant that when we were – because we were currently talking to another strategic two who were very similar in the space who were very much trying to make sure we didn't sign that one's deal when we were talking to the other. That very long period of time that everyone takes to make a decision conflicts us quite badly, if that makes sense because you just turn one of them away when you know that the other one's still debating and the other one gets impatient. So, yeah, they could do is speeding up quite frankly.

Limiting Coopetition (last question)

Question	a. How do you draw, or would you draw the limit of cooperation in the coopetition process to preserve the competitive advantage of your company?	In Vivo Codes	Process Codes	Initial Coding
P1	I think **if the cooperation agreement affects our IP or our ability to have someone else have access to it in a not worthwhile** way to us, then we happily walk away from situations like that. If that makes sense. Because I think at these early cooperation standpoints when you're just trying to work on the innovation and find more out about it, I don't see why they have to have access to your IP forever and you have to have access to their IP forever. Like it needs to be you both maintain your own situation until more money is on the table from both sides if that makes sense. So, yeah, I think that is the biggest hindrance ready for this sort of stuff is some people just trying to do a land grab unnecessarily, essentially	20d" if the cooperation agreement affects our IP or our ability to have someone else have access to it in a not worthwhile"	1 if the cooperation agreement affects our IP or our ability to have someone else have access to it 2 we happily walk away	quantifying: if the cooperation agreement affects our IP or our ability to have someone else have access to it in a not worthwhile; hypothesising at these early cooperation standpoints .... you're just trying to work on the innovation and find more out about it., I don't see why they have to have access your IP forever; barriers to success: biggest hindrance ready is some people just trying to... grab
P2	For me, like Apple with Samsung and this is exactly the same thing for me, for us. **Your provider or your partner asked to provide only one component of your full tech if we provide the full technology or the full-on 80 percent of the technology, for me, there is a huge risk**. Not only the risk but the competitive advantage is you cannot say that I have huge competitive advantages on the way that I'm the link between different type of expertise and I'm doing only one product, only one expertise, thanks to that several expertise. For me, you cannot have competitive advantages with this fact. So, competitive advantages is just a way- in my point of view, it is just to get your own expertise and you can subcontract or sign a deal with a competitor for only one component, one small part of your technology and you develop, you expertise, your competitive advantages on the other one. Logistic or supply chain in our industry cannot be competitive advantages. Now, our stage is quite for me to say, oh, I have the best supply chain strategy or team or whatever. You know, I don't have instrumentation. So, that's why maybe I'm saying that but for me	20c" Your provider or your partner asked to provide only one component of your full tech if we provide the full technology or the full-on 80 percent of the technology, for me, there is a huge risk"	1we provide the full technology or the full-on 80 percent of the technology 2 there is a huge risk 3 cannot say that I have huge competitive advantage 4 you can subcontract or sign a deal with a competitor for only one component, one small part of your technology and you develop, your expertise, your competitive advantage	quantifying: our partner asked …you to provide the full technology or the full-on 80 percent of the technology, for me, there is a huge risk; barrier to success: you cannot say that I have huge competitive advantage; hypothesising: you can subcontract or sign a deal with a competitor for only one component, one small part of your technology and you develop, you expertise, your competitive advantage;
P5	COMPANIES GENERALLY: Yeah. I think they would say they're **happy to work with a competitor in very early stage** work, S**o, long as they can each go their own way separately and then compete**. And So, in early stage, very early stage work, I think it just speaks to the fact that in that sector, at those very early stages, they haven't got a clue what's going to work and what's not going to work, whether it's going to be a hot air or not. So, there's such a big area to explore. There's a huge mutual incentive if	20a"happy to work with a competitor in very early stage…so long as they can each go their own way separately and then	1 in early stage. Work. they haven't got a clue what's going to work 2 such a big area to	qualifying: happy to work with a competitor in very early stage work... So, long as they can each go their own way separately and then

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	you can share results, such as what doesn't work. I always draw, sometimes draw an analogy between people who—oil companies drilling for oil and pharma companies. They all have to sink a huge amount in before you know whether you're going to get something back out, whether you're an oil company drilling or whether you're a pharma company doing R&D and development on a drug target, say. They haven't got it. But the trouble is oil company knows they've got a very limited space/globe to look in. Oil companies they all have a mutual incentive to share, at least an understanding saying, "Just don't go and look over here. I tried that. There's nothing there." There's a huge mutual incentive actually across the sector to do that. And that is working with a competitor. But it's only really recently, there's a few examples of organizations trying to help that and them coming together to do that. So, I'm thinking people like the Structural Genomics Consortium in this box from [name of city], So, that's [name of person], ex- [name of company] where he is a model. He's got quite decent funding in for lots and lots of different pharma companies to work together, but it's really based on that mutual benefit there of knowing what doesn't work. Or what does work is actually probably the more—is probably the way he probably has to speak about it, that is what doesn't work. I: What you're saying is you believe that can work out in a very early stage. B: I think early stage that can work out. I think **later stage I struggle a little bit more to see cooperation between competitors**. And if there was, I think there might be something illegal about it. I think if you had two people selling a product in a specific indicator, So, first do medical issue, and they were the rivals and then they started working together, I think more likely or not it's going to be bad for patients and/or consumers, I would think. Because they're—the brutal commercial end of it, innovation is driven by the competition in wanting to be ahead of each other. So, if you could make just as much money by sitting on your hands, you would. You see that in sectors plenty. The idea that commercial world is some great driver of innovation I think it's the competitive part which drives out of fear. Fear that they're going to be out of business. And fear and opportunity about getting a new one though. **OWN COMPANY** It's a really good question. I think it would need to be—the simplest, let's put it this way. I think the simplest way to make that move forward would be an area that we couldn't do it alone. We really needed to work together, and I could really foresee that. That could be a geography or a particular product line that you each knew but didn't know each other's but working together you could do a third one. So, it would be something obviously that you couldn't do alone. But in terms of doing that, I think it would be to have a very, very clear framework for the proposed collaboration. And I think that the part which gets difficult would be about really—I would think I'd really want to, as much as possible, be looking at bringing together very different parts. For example, I think if you're bringing together someone's market, marketing …you do a different product development off your basis. Then that would make sense to me because you could do that. You own the product development bit there in the market but there would never be that much confusion. But if you said, "Oh, we'll do a lot of technical product development and you do your technical product development. We'll work really closely together to bring those in together." I would be scratching my head and thinking how do we get clear boundaries in place for information flow? How the heck are we going to do that? And I'd spend probably a lot, So, much time worrying about that that I'm not sure it would ever get off the ground. But it might be possible. Say, well, you build that box, we'll build this box and they'll interface like this, but we'll never tell too much about each of the boxes. Or I know you could never do that because we've tooled up or something and you're never going to do that. There'd be some reason, but I **think you'd be**	compete" 20b" later stage I struggle a little bit more to see cooperation between competitors" 20d"think you'd be continuously having to think .....that they've become exposed to and become knowledgeable about through you, is it an area that they can easily move into or is it difficult .....as long as it's difficult, and vice versa, then I think you can make it work"	explore... a huge mutual incentive if you can share results 3 ater stage I struggle a little bit more to see cooperation between competitors 4 the simplest way to ...move forward would be an area that we couldn't do it alone... but working together you could, maybe a geography or a particular product line	compete.; hypothesising: at those early stages they haven't got a clue what's going to work and what's not going to work….big area to explore; critical success factor: huge mutual incentive if you can share results; critical success factor: funding in for lots and lots of different pharma companies to work together; hypothesising: simplest way to make that move forward would be an area that we couldn't do it alone; choosing: could be a geography or a particular product line that you each knew but didn't know each other's, but working together you could do a third one; critical success factor: have a very, very clear framework for the proposed collaboration; hypothesising: think if you're bringing together someone's market, marketing …you do a different product development off your basis.. that would make sense to me because you could do that; barrier to success: technical product development... closely together ...you'd be continuously having to think is this—the bit that they've become knowledgeable about through you, is it an area that they can easily move into.

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	continuously having to think is this—the bit that they've become exposed to and become knowledgeable about through you, is it an area that they can easily move into or is it difficult for them to move into? I think as long as it's difficult, and vice versa, then I think you can make it work. It's a bit like, I guess it's sort of, ultimately, if there was good trust you wouldn't worry about that because you just have an agreement, sign something and say you won't do this. But I think trust is really helped if you also know it's really difficult for someone; barrier to success: think is this—the bit that they've become exposed to and become knowledgeable about through you,			
P6	: If this is not—if I don't have an added value of the collaboration either in my balance sheet now, I always consider the added value in the balance sheet when it is now, not for the future. Because the future COVID can happen again. So, the financial application is for now on the balance sheet. In the mid-term, is to have the possibility to have access to a new market and, thirdly, is if I can have in return a cross-version, for instance. So, that's why the draw line is when do I get the added value? Now? This is for the benefit. Mid-term is for sales opportunities and time, because I give time for preparation. But overall, everything has to be state of mind, but not everybody is open at this. Because also there are a lot of top managers, maybe it's a weaker thinking but I consider a lot of top management they have not considered yet the burden of the regulatory. I have some return because we have [name of company] which is in …. I had a couple of people that had worked there as consultant but, for instance, the top management didn't know enough. He never participated to a risk analysis So, he was not able to ask the right questions. Guess what? They did a validation of the cleaning process of an implant, but they forgot in the validation of the cleaning of the packaging that some of the implants are outsourced. So, in the cleaning process, they didn't consider outsourced implants. And there are no data, clinical data for this device. They must have sold about a million for years. So, MDR was published the draft three years ago. They should have a minimum, established a minimum of clinical data. No. Zero. Nothing. So, you see, that in those big companies, for them, again, 'when' is no big deal. They have a huge budget over—out of Sweden over 30 million euro to finance validation. But it's a waste of money. Total. They don't even use the people. They use consultant, junior consultant. For European companies, for the top management who understand what the challenges are of regulatory, it's an opportunity to do innovation also in the long term because you're going to have clinical data that will show what needs to be improved for the comfort of the surgeon or what needs to be improved for the patient's safety or effectiveness. So, that shows that today, up to now, we were selling just a piece of titanium and piece of plastic. And we were making innovation but not optimized innovation. In fact, look at—so today, innovation is everywhere in the day-to-day operation of the company. But it's driven by the financial costs. Because in that game, you cannot—you really have to be careful when you take the decision, we're going to develop this product. But when you start, you cannot stop in between. It's a minimum of three years. It's a minimum of 250,000-euro investment.			quantifying: f I don't have an added value of the collaboration in my balance sheet… possibility to have access to a new market ..if I can have in return a cross-version; barrier to success: a lot of top management not considered the burden of the regulation....cannot ask the right questions;; hypothesising: for European companies, for the top management who understand what are the challenges of regulatory, it's an opportunity to do innovation also in the long term; barrier to success: on innovation time and cost of innovation/
P7	To be honest with you. I always think from a very commercial and sales-oriented perspective. So, neither me nor the company has drawn any line yet in regard to a strategic alliance. We are always open for all discussions. However, **the only limit that we have is really sharing our intellectual property and our technical files in order to avoid copies on the market, which we unfortunately have also seen in the past.**	20d "the only limit that we have is really sharing our intellectual property and our technical files in order to avoid copies on the market, which we	1 the company has drawn any line yet regarding a strategic alliance 2 We are always open for all discussions. 3 only limit that we have is	barrier to success (coopetition): sharing our intellectual property and our technical files

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		unfortunately have also seen in the past"	really sharing our intellectual property and our technical files 4 n order to avoid copies on the market	
P8	I think **I would never work with a competitor with my own customers.** Because as I told you, we co-develop solutions with medical staff and **it takes a lot of time, really, a lot of time to get access to those people and to have the relationship work. So, I would definitely not access to my end users. That's a secret.** I think it's also **interesting to think about coopetition with companies who are not at all in the same market field, not the same market. And for instance, when you think about machine learning** and engineers who are working on those subjects, you think about aeronautical business, you think about finance, quite an extensive number of markets, where you might find the expertise, available resources, a way of dealing with specific data, which is interesting to you. But you know, without the risk of seeing [name of a company] company [name of a company] company or [name of a company] company working on the same issues as you are. So, I think **coopetition should be also-, well, it could make a lot of sense to work with not direct competitors, but companies who have expertise,** that will definitely not come into your business. coopetition should be also-,	20d"I would never work with a competitor with my own customers". 20d" it takes a lot of time, really, a lot of time to get access to those people and to have the relationship work. So, I would definitely not access to my end users. 20d "That's a secret." (lumper code!!)20a"interesting to think about coopetition with companies who are not at all in the same market field, not the same market. for instance, when you think about machine learning...coopetition ..... could make a lot of sense to work with not direct competitors, but companies who have expertise"	1 we codevelop solutions with medical staff 2 it takes a lot of time to get access to those people 3 customer knowledge that's a secret	barrier to success (coopetition): never work with a competitor with my own customers; qualifying access to my end users. That's a secret; hypothesising it could make a lot of sense to work with not direct competitors, but companies who have expertise
P9	I try to link it to our most recent coopetition relationship with a company in France and I think, of course, most important is the first step when it comes to the product idea. So, in principle, yeah, this is something from our point of view which is initiated by the partner. Of course, we do look, okay, what do we have available in our portfolio which can be suitable to be used for their product idea and then when it comes-I think, this really depends on the partner and the experience of the partner. On one hand, you can have somebody who only has the idea and on the other hand, when you do have a coopetition partner who is really familiar with the business, he will give more impact and more input on the product development process. I think it is strong at the beginning. I think all the regulatory stuff nobody wants to have anything to do with the regulatory stuff because everybody is happy when somebody else is doing that. So, this is a part which we do quite on our own. Finally, one side has to be the legal manufacturer.	20c"There is only one legal manufacturer in such a coopetition situation, and this has to be defined... is important because the quality and risk management systems of that partners has to be used for the innovation process"	1 I think... most important is the first step to the product idea 2 from our point of view ...is initiated by the partner 3 we look...what we have available in our portfolio suitable for their product idea 4	choosing: what do we have available in our portfolio ... can be suitable to be used for their product idea' critical success factor: really depends on the partner and the experience of the partner; choosing: nobody wants to have anything to do with the regulatory stuff

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	So, **there is only one legal manufacturer in such a coopetition situation, and this has to be defined**. And th**is is important because the quality and risk management systems of that partners has to be used for the innovation process,** and this is something which is I think now very important. You cannot start with something in the R&D department and like, okay, let's do innovation. I think it is very important to involve the regulatory department in the very beginning because when you develop something or make use of processes which will never be able to be satisfied, it does not make sense. So, I think you have to keep in mind that from the very beginning and this is what we do to have a look on that, okay, how can we make this sure and safe for the technical documentation. From my point of view, I'm completely open when special constellation makes sense of both sides. There is no principal limitation. Of course, I think all these points are-it is only a question of the agreement, how the agreement looks like, when it makes sense for both sides finally and everybody is doing what he is best in, then everything is fine. So, when it makes sense to take our core technology to get it into another market with a competitor where the product is more suitable or can make more-can reach more patients and help patients, it is fine with me. So, you have to consider that from the very beginning, and this is something which can only be done by one of the partners. I think you can divide on-the project idea can be done by one partner and marketing but all between I think should be done by one partner. That means **all the setting up the technical file and implementing that into the management system, this is nothing which can be done by coopetition because the management systems are that different and the way of working in these documents and organizations is different. I do not think that this is something where which can be aligned.**	20b "all the setting up the technical file and implementing that into the management system, this is nothing which can be done by coopetition because the management systems are that different and the way of working in these documents and organizations is different. I do not think that this is something where which can be aligned"	really depends on the partner and the experience of the partner 5 when you have a coopetition partner who is really familiar with the business, ...will give more impact 6 one side has to be the legal manufacturer 7 one side has to be the legal manufacturer 8 no principal limitation.....all these points only a question of the agreement, how agreement looks 9 when it makes sense for both sides ..... everything is fine	because everybody is happy when somebody else is doing that....so, this is a part which we do quite on our own; critical success factor: only one legal manufacturer in such a coopetition and this has to be defined; critical success factor: very important to involve the regulatory department in the very beginning because maybe you develop something or make use of processes which will never be able to be satisfied, it does not make sense; critical success factor: the agreement...makes sense for both sides ;
P10	I would say **I'm open in cooperation in all areas**. Of course, **if I see that this has absolutely no sense for my company**, then I will draw the line and **I'll say, "I'm sorry, it's not interesting to us." It has to be beneficial for both sides**. And then it's fine because each partner has its own goal in going for the project. In the past for us, it was important to grow the revenue, to grow also the knowledge we have in our company, because each project is learning. Now we will look more carefully if it aligns with our development strategy, with our development process, because we have our own plans on the development. So, now we'll probably more often say, "No, thank you, but no." But in the past, it was very exciting for us and still is. We really do share a lot of information with many partners.	20d "I'm open in cooperation in all areas". 20a"if I see that this has absolutely no sense for my company...I'll say, "I'm sorry, it's not interesting to us." 20a"It has to be beneficial for both sides."	1 I'm open in cooperation in all areas 2 if I see that this has absolutely no sense for my company, I'll say, "I'm sorry, it's not interesting to us." 3 has to be beneficial for both side.because each partner has its own goal...for the project	choosing I'm open in cooperation in all areas...It has to be beneficial for both sides;
P11	Again, I want to define competitor. This for me, if I look at our company, we are- there are, in my opinion, if you look at the spine market, there are three categories of buckets of companies. You have the big six American companies. And then you have the other few five companies, five, six companies, that come in with the revenue of 50.000 to 250.000, 300.000. And then you have all the rest. So, for me, companies, who are below the 20.000, 50.000, I don't really see them as a key competitor,	20a"I see much more cooperation with the smaller sized companies and definitely I see a lot of cooperation there, but not	1 MDR allowed us, is to reflect on what can we do in-house 2 significantly changed the	choosing: much more cooperation with the smaller sized companies …but not companies more our size or bigger; critical success

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	because they are competing on a certain type of the portfolio. And they have a lot of- yes, there is overlap, but they have complementary technology. For me, the key competitors are the one, which are either in the same size or the big ones, of course, who they see us more as competitors (? as) us. So, this is important how to define it and how to see it. So, **I see much more cooperation with the smaller sized companies and definitely I see a lot of cooperation there, but not companies more our size or bigger**. And then, sharing info yes, like I told you. **There is this company with very small size, we have a NDA, we share about pipeline, they share about pipeline. It is not much of holding back significantly**. IND: Because you feel secure by- No, **first of all you have the MNDAs in place**, you have these things, but wherever, **of course you don't share know-how**. The most thing you share is what is in your pipeline coming. This is what you mainly focus on. When you are sharing. And you need to be transparent. You can't come and cooperate with a company on a certain product (? but) you don't tell them you are developing your own that is coming in two, three years. Especially at the time, to maybe this helps you on a earlier question, where you see the most focus. I think what MDR allowed us, is to reflect on what can we do in-house and significantly change the mindset to be open to inorganic acquisition or strategic partnership. I am in a lot of favor of strategic partnership, but it also allowed us to look internally and even the way we innovate what products can you bring to market that you can develop clinical evidence and can allow you to register. So that again goes to the point I mentioned to you. There is an internal prioritization, an internal change of mindset what innovation means. Is it quantity or quality? How much value add? How much robust? And how much evidence you can bring toward it? Or, how much you can generate revenue out of it, because now the investments are much bigger to bring a product to market with the	companies more our size or bigger" 20b"sharing info yes……there is this company with very small size, we have a NDA, we share about pipeline, they share about pipeline. It is not much of holding back" 20d"you have the MNDAs in place…..but wherever…you don't share know-how"	mindset to be open to inorganic acquisition or strategic partnership 3 allowed us to look internally and even the way we innovate what products can you bring to market 4 an internal prioritization, an internal change of mindset what innovation means 5 because now the investments are much bigger to bring a product to market	factor: have a NDA, ...share about pipeline, t... not much of holding back; quantifying: you don't share know-how; critical success factor: strategic partnership, .. allowed us to look internally and even the way we innovate what products can you bring to market that you can develop clinical evidence and can allow you to register; barrier to success: investments are much bigger to bring a product to market
P12	Typically, **in software sector there is not that much**. Because it is more about implementation. I mean it is very open. You can see what the other company has done on a very deep technical level. Even still, it is too much work to do it yourself. So, **unless you have a patent, which is not possible in Europe for software, then you can share pretty much everything, besides the source codes of the applications**.	20d " in software sector there is not that much unless you have a patent, which is not possible in Europe for software, then you can share pretty much everything, besides the source codes of the applications"		quantifying: in the software sector there is not that much it is more about implementation
P13	**I would be open to discuss everything because it depends on very many factors. Are we interested in the same market? Have-, do we have strategic similarities, and it may be useful to work with the competitor very open because it is beneficial for both**. Let us say your goal is to develop, to bring it to market and then find-, sell it. extra strategy and you share that with your competitor. (? And you reach it) with your competitor together, it maybe very beneficial for both in the end. Or if you are interested in different markets, we have a-, you have a competitor who is interested in the aging market and you are focused on the [Place name2] market, because you want to really bring it to market. Why not? Depending on your strategy actually.	20a"I would be open to discuss everything because it depends on very many factors. ARE we interested in the same market.... do we have strategic similarities, and it may be useful to work with the competitor very open because it is beneficial for both"	1 open to discuss everything 2 do we have strategic similarities 3 your goal is to develop, to bring it to market that with your competitor.4 maybe very beneficial for both in the end	qualifying open to discuss anything…but beneficial to both; qualifying: Depending on your strategy

Question	a. How do you draw, or would you draw the limit of cooperation in the coopetition process to preserve the competitive advantage of your company?	In Vivo Codes	Process Codes	Initial Coding
P14	I think, I would stop this part when they said: „Okay, I will invest also in your company to share maybe a machining cost." To buy a machine together. So, I think at this point, I would stop. No one knows how long-. This is cooperation with was the other partner and **can I work for a long time together with them or is it only a short time**? And, w**hen the point is a discussion for the investment for these points, I will stop**	20a "can I work for a long time together with them or is it only a short time and when the point is a discussion for the investment for these points, I will stop"	1 they said: „Okay, I will invest also in your company to share maybe a machining cost 2I would stop	barrier to success: when they said: .. I will invest also in your company to share maybe a machining cost; choosing can I work for a long time together ...or is it only a short time.
P 15	I guess **there would be some areas, but I don't know where they are currently** because you- (? really) as I said before **I would really share everything because** if I couldn't share it then I think something is wrong. And I never have seen something good coming out of not being willing to share something, I have- I had four corner regular meet up in [name of a city] and [name of a city] where we- where always it was called brain trust because the idea is that you have others doing the same thing that I do, tell them what you are doing and then giving your feedback and then maybe you can apply it to your company or your … idea whatever. And then the next one is (? insist on) the other ones I have given you feedback. And there were sometimes very little ideas but the people there were making a fuss out of it, that they can talk about this and that. And then I always said the feedback you can get from us would really- I think that it's that way, outweigh the thing that someone could steal your idea. Because what idea is really so original that if you can hear it and you can steal it without being so much ahead as the other one who is thinking for it for months, for years and has everything planned. And I never heard from these ideas and people again. So, it was not that they kept everything and then went really successful, they vanished over time. And the ones who did something were always the ones that shared everything with each other.	20d"there would be some areas, but I don't know where they are currently" 20a" I would really share everything because if I couldn't share it then I think something is wrong"	1 I never have seen something good coming out of not being willing to share something 2 I never have seen something good coming out of not being willing to share something	barrier to success: if I could not share everything

Other Comments

Question	Is there anything that came to your mind which you believe will be worthwhile mentioning in that context
P1	No. I think it's a really good, exciting thing and you're doing a really cool topic because more small start-ups are going to need to collaborate with bigger, more mature ones to get through this medical device situation and I don't think the big corporations are doing probably as much R&D and out there, innovation is probably some of the little random start-ups coming through for them. But I think what would be really useful is like a template of—I know it's probably very unlikely and it's very idealistic, but I think a template of well, this is how you work, how a small series A company works with a big, massive multinational cooperation, if that makes sense. I think there needs to be more of a this is what relationship looks like and this is how you know
P2	No, only one thing. This would maybe the conclusion of my short description regarding innovation, the way I'm thinking about innovation, what I like on innovation. For me, closed innovation is the path for the last century and I think that if we want to innovate mainly with these new rules, we have to be open not only fully open but close to a mix and an open innovation mindset at each company, start-up or a big one but this is clearly my philosophy and the way of thinking at (name of the company).
P5	INT: is competition is driving innovation. Is that what you said? It's part of what I say, yeah. I mean it's not because—if you think about why, even if there's a new market to explore, if there was no—if nobody was worried, if you were the only

Question	Is there anything that came to your mind which you believe will be worthwhile mentioning in that context
	person that could go into that market it’s going to be like it’ll take 10 years, 20 years, 100 years, doesn't matter. I'll get there eventually. But nobody else is going there. But if you think, “Ah, my rival is going to jump there and be first in,” bah, you go quickly. And that drives innovation into new markets, new emerging areas. But if you're in a very stagnant area that's existed for a long time, if you know them, if you know it's just two of you and you've carved up the market—diabetes would be a good area to look at. Diabetes, there's So, few—it's a well-established phenomenon. You have too few players and you end up with a non-functioning market. That happens all over the place in medical and in pharma and these other sectors and it's driven by things—which is basically driven by sufficiently few players that the competitive side becomes mutually destroyed. They mutually destroy competition.

Appendix 2b: Code Book

Major Codes (Key Themes, Framework)

Name of Major Codes	Description of Code	Inclusion	Exclusion	Exemplar
Organisational Structure	The management span of control, type of hierarchy and extent of bureaucracy; structuring or the polices and processes comprising degree of specialisation, formalisation, and centralisation characteristic of the company			
Organisational Culture	a society's distinctive ideas, beliefs, values, and knowledge. It exhibits the ways humans interpret their environments	Organisational context	Individual perspective	
Strategy	Strategy as choice is matter of opportunity cost, choosing one move over another, with no idea of the value of either outcome or which is correct. - based uncertainty and laws of probability. It about intuition, exploiting the best opportunities in uncertain situations, experimenting with different ideas, testing them for a short time and if they are not successful in creating value and competitive advantage, replacing them with new strategies-	Simple 21st century focused	Complex and rigid	Aligns with strategy for innovation, which includes consideration of formation of alliances or mergers and acquisitions
Leadership	Leadership relates to influencing employees/followers to accomplish a vision of the future shape of the organisation that the leader creates. Leadership is responsible for creating the appropriate new culture	Forms of shared leadership and effective followership		
Follower	Employee	Effective followers who are a critical thinker, who expresses own thoughts and ideas, questions those of the leader in a positive manner, is proactive and self-motivated	followers classed as sheep, alienated, yes person, survivor all who are unfocused on achieving organisational goals for firm not for self interest	

Name of Major Codes	Description of Code	Inclusion	Exclusion	Exemplar
Innovation	doing of new things or the doing of things that are already done, in a new way	new or highly improved product; process to enhancing the quality of activities to better meet strategic goals; marketing including involving customers' input into marketing communications or transactions; organisational, relating to devising or creating new behaviours or ideas. All four contexts are relevant to medical devices innovation in the contemporary context, and innovation must be managed so that all value chain activities are accomplished as efficiently as possible, allowing fast to market process, in order to retain competitive advantage		
Coopetition	a contextual coopetition network comprising of two (or more) competitive firms in which also at least one or more actor, such as own or foreign government, customers or other stakeholders of the firms are involved	Two or more firms cooperating generate an outcome, which is valuable to other stakeholders within the value chain. One of the main reasons for competing firms to cooperate is to eliminate threats that impact on both parties by combining resources	the same firms compete rather than collaborate, with another outcome.	
New EU Medical Regulations	European Union (EU) regulations on Small and Medium Size (SME) enterprises operating in the Medical Devices sector of the healthcare market	Relating to EU Directive 2017/745 and 5EU Directive 2017/746	EU regulations not relevant to the new classes of medical devices. Other national regulations	

In Vivo Codes

In Vivo Codes		
1	**"some sort of tiered system" (OS)**	framework/status
1a	"not underneath me, but work alongside me"	
1b	"organize in a very short step"	
1c	"as little corporates as possible"	
Id	"You're at the bottom. You're at the top," you've set into stone a set of representations about value and worth	
2	**" we do everything"**	roles
2a	"I think you always need clear roles, responsibilities and clear person where the buck stops with, who has to make the decision"	
2b	"the structure is me"	

In Vivo Codes		
2c	"we three together, we consider as a management team which handles and, of course, responsible for all signatures and all our responsibilities covering all which is related to the company."	
3	**"an early-stage company".**	about stage and size
3a	"we are only one floor and two guys on top"	
3b	"unstructured collaboration system comparable to a start-up"	
4	**"free on their way of thinking"**	**Culture -mindset**
4a	"You will have to think differently"	
4b	"good perspective on reality"	
4c	"the culture is complete mix culture... with different qualification"	
4d	a blind alley is explored in a way that I'm not sure it's that feasible to do with the pressure of a big team and big financing"	
5	**"There's so much at stake"**	**purpose of culture**
5a	"we like very much to interact with either insiders or outsiders of the company"	
5b	"collective shared responsibility and objective"	
5c	"they have no time to develop it in their own R&D and there's already a CE mark	
6	**"Give power to the people"**	Leadership
6a	"trusting them"	
6b	"give them the opportunity to manage their problem and their solution by themselves"	
6c	" Typically, we do have a discussion with a consent which makes everybody happy and which in most cases is the best solution"	
6d	"mentoring orientated"	
6e		
7	**"Open"**	**Traits**
7a	"Empathy"	
7b	"communication"	
7c	"leader by example."	
8	**"If you've got a problem, all doors are open"**	Style
8a	"decision making clearly comes from the board of directors and the CEO"	
8b	"collegial"	
9	**"it's a big extension on project management"**	Manager
9a	to make sure that everyone comes into deadline on time	
9b	" I am involved in all processes to discuss things and really gives feedback about how to do it"	
9c	"somebody who is interested in what they are doing and who is interested to interact and to discuss things and really gives feedback about how to do it "	
9d	really hearing people	
9e	"encouraging the people to be happy in their job"	
10	**"Leader manager not a leader"**	Leader's work
10a	"good leader needs to be close- close, the frequency at least one time per week, ...close to the team and just to get a report from them…to be reassured about what they are doing "	
10b	"I'm a leader, but I'm a manager also"	
11	**"Leaded. Implies a tribe"**	Feelings of being a leader/vision targets
11a	" trying to find a path through this forest, focused on an objective beyond themselves"	
11b	"going through personal pain"	

In Vivo Codes		
11c	"and help other people through them".	
12	**"Thanks to the senior guy"(P2)**	Leadership for innovation/ creates organisational culture
12a	"has to be addressed by top management"	
12b	"not doing something for a political reason but because they have a business value"	
12c	“you've got a much longer journey through a lot more forest with much fewer resources and much less help”	
12d	"it has to be agile leadership and management"	
13	**"that's a lot to do with the size of the organization"**	cultural context for innovation
13a	"good at being flexible because we're still quite a small team"	
13b	"can swap to writing a grant one minute or they can be doing a 12-hour day in the lab next"	
13c	“wanted to keep this Startup Culture" ... everyone feels that they are responsible of their own mini company area"	
13d	"it's easy because it's small…decision making is easy"	
13e	we are growing …. can see that we are transforming into much less movable object…...we have become rather slow and not so quick learning as we used to be"	
13f	multinational there's hard steps there, but zero to something ……..... they're very rarely focused on"	
13g	"a blind alley is explored in a way that I'm not sure it's that feasible to do with the pressure of a big team and big financing”	
14	"**team first; people first”** P2	culture people resources for innovation
14a	“It is quite tough to our people and we want to be sure that at the end, people we hire are in the same cultures as ours and the same values"	
14b	error of this kind..... “Okay, no problem. We're going to redo this thing"	
14c	"inform them what's going on, what is current status”	
14d	"you need good cofounders…not too many-- too much opinion kills it"	
15	"**zero to something is the hard step**”	culture of painful learning
15a	"system needs to be changed. So, we need to invest"	
15b	work hard	
15c	"But if we redo it, you need also to improve something.”	
15d	when it becomes difficult, some people prefer their own interest…this is very disappointing P4	
15e	"finances limit you and the rules limit you. That is what we have to learn in the company"	
15f	" trying to learn from all the difficulties and experiences"	
16	“**we always have alternatives”**	culture of uncertainty
16a	We always bear in mind that a contract that we have signed with a company, a third-party company, might end”	
16b	"a lot of collaboration"	
16c	"have to adapt to this different way of doing business. Nobody knows what the new normal is going to look like."	
16d	"agile	
17	**secret of our success is innovation**	
17a	"a real innovation appears to add value"	
17b	"incremental technology and not disruptive technology "	
17c	"innovation from laboratories. very much research rather than development... we co-develop our solution with users...it's innovation "	
17d	"structured. with scarce resources learning internal/externally"	

In Vivo Codes		
18	**"bar is much higher"** "	Innovation in Med Tech is Different
18a	boundary conditions for innovation are toxic in medical devices	
18b	getting people involved in innovation…..... being able to change their practice"	
18c	"instruments…. in contact directly with the patient"	
19	**"raising the barrier of entry"**	EU **Regulations**
19a	" more valuable innovation"	
19b	"rethink how you work"	
20	**"ecosystems for innovation"**	**Coopetition**
20a	"deliver value"	
20b	"resource sharing and compromise"	
20c	"legal side kills the innovation"	
20d	"that's a secret"	

Process Codes

Revised process code															
Innovation EU regs															
	P1	**P2**	**P3**	**P4**	**P5**	**P6**	**P7**	**P8**	**P9**	**P10**	**P11**	**P12**	**P13**	**P14**	**P15**
	1 having a product	1 having a team	1.Setting out with project in mind		1 doing something new	1 discovering the new raw material	1 finding ourselves in competitive environment	1 hiring the right people		1 wanting world class products		1 needing to be high priority	1 bringing a new idea to the market		1 doing client projects and our own products
	2 investing in it	2 planning to launch product	2 choosing the country		2 adding value	2 providing an opportunity to respond to new regulations	2.delivering our message	2 creating something		2 adding somethin g extra		2 being very relevant	2 following the rules		2 doing the kind of projects with more money
choosing and learning	3 exciting people	3 comparing potential projects	3 providing an alternative		3 selling our value	3 balancing risks	3 using multichanne l marketing	3 not knowing it will make money		3 making a big impact		3 not knowing if innovation has succeeded	3 financing is relatively easy		3 having experience from other industries

	4 needing to be in a clinic	4 succeeding thanks to the team	4 having new things		4 relying on people seeing novelty in a simple way	4 Doing an investigation	4.not doing innovation	4 users linking it		4 people learning		4 having new products	4 predicting the financial effect		4 applying that
	5 pulling in fundraising	5 launching on time	5getting into a niche			5 waiting	5.selling products developed long time ago	5 investors putting money into it		5 people loving the product		5 needing to be implemented	5 going through clinical trials		5 learning
			6 returning high profits on investment			6 collecting clinical data	6 trying to put horsepower on streets			6 putting us ahead of the competition		6 not needing to be just prototypes	6 predicting the success much harder		
						7 fulfill the MDR						7 needing to be answers for users			

Innovation differences in medical device sector															
	P1	**P2**	**P3**	**P4**	**P5**	**P6**	**P7**	**P8**	**P9**	**P10**	**P11**	**P12**	**P13**	**P14**	**P15**
	1. timing is different	1 trying to set a closed innovation strategy	1 new, innovative idea are coming out	1 constraint are increasing	1 comparing pharma with medical devices	1 making decisions	1 industry is maturing	1 working with stakeholders who do not like changes in their work practices	1 thinking the boundary conditions in the medical devices are toxic for real innovation	1 being more responsible	1 comparing it with pharma	1 changing registrations in the medical field	1 limiting innovation	1 instrument contacting human body	1 working more on a patient, on a person
what's at stake?		2 having lots of substitute products that compete	2 speaking about cooperation		2 tolerating failure is much lower	2 taking the risks	2 consolidating	2 thinking there is no room for innovation	2 making hurdles so high for innovation	2 thinking about the user	2 experiencing that the innovation lifecycle in medical devices is much shorter	2 making it much more difficult to bring out new innovations	2 not seeing that in other industry	2 saving lives of patients	2 what can happen, is there can be much worse in the situation

Innovation differences in medical device sector															
	P1	**P2**	**P3**	**P4**	**P5**	**P6**	**P7**	**P8**	**P9**	**P10**	**P11**	**P12**	**P13**	**P14**	**P15**
		3 using patent for a joint venture	3 signing a contract to distribute		3 pervading down to how people take on work	3 sharing the pros and cons	3 serving an increase-ingly demand-ding healthcare sector	3 needing to bring new mindset for change to occur	3 most successful working on non-innovative products	3 thinking maybe the device is too advanced	3 having disruptive innovation, leaps in innovation	3 seeing many great innovations not being able to penetrate the market	3 making it impossible for small companies to innovate	3 making operation time shorter and easier	3 talking about medical things and patients' others always have data policy in their mind
		4 being closer to open innovation	4 they're going to sell it		4 having better systems and processes	4 asking people to think about it	4 having high profits from new products	4 we are providing tools to bring teams to evolve positively, to work differently	4 seeing how difficult it is to get into the market (with innovative products)	4 having to make it easy		4 being disruptive in a way you do not see in other fields	4 costing a lot more now	4 bringing products to market very important	4 everything having to be secure and having to work
					5 hindering innovation and taking risks	5 taking risk if there will be question from the Notified Body	5 high performance innovation systems generating quantifiable effects	5 telling you, I know what I'm doing, and you're not a professor	5 becoming more difficult to get re-certifications with MDR	5 thinking the industry is too conservative		5 making all the innovations small		5 they are telling us there will be a lot of changes	5 trying something did not impact on person more open to change
						6 Not giving too much detail	6 outlining the future of the med tech industry	6 seeing differences with other markets is getting people involved in innovation		6 respecting this when we build product		6 innovations lagging five years behind other software			

Responsibility for innovation															
	P1	**P2**	**P3**	**P4**	**P5**	**P6**	**P7**	**P8**	**P9**	**P10**	**P11**	**P12**	**P13**	**P14**	**P15**

	1 Participant CEO	1 Senior Management group	1 No internal design	Cofounder and an engineer	Cofounder	Co Founder, associate, and the engineer	Marketing and product management		Management Team		Cofounder but involves team	Senior Manage-ment	1 Chief Technical Officer	1 sometimes comes from customers no mention of who in company side	Every-one

Innovation in your company															
			P3			**P6**		**P8**		**P10**			**P13**		**P15**
			1 contact has a man who was working in the nuclear industry			1 having a product where you are saving the planet		1 innovation, we are more incremental		1 planning			1 exchanging information with engineers in automotive		1 needing information from different people in the company
choosing and learning			2 has developed a robotic arm			2.customers responding to this approach		2 focused on oncology		2 building the base			2 they are developing partners in this field		2 having strong cooperation with design department
			3 he's saying it could be used in surgery			3 using single use instruments is becoming fashionable		3 it's very generic		3 testing possibilities			3 advising us		3 shifting directly to manufacturing
			4 contact forms company and takes innovation out of other industries			4 lowering risk of infection		4 we use decision trees from medical societies		4 bringing new ideas			4 transferring knowledge between different fields		4 making something
			5 open innovation			5 gaining time related to instrument cleaning		5 we don't share our algorithms		5 learning things never expected					

Innovation in your company														
			P3			P6		P8		P10			P13		P15
						6 having regulatory file that is less difficult				6 learning things we expected are not as described					
													1 having a strong exchange with a clinical specialist		
								1 having very scarce resources					2 monitoring publications constantly		
								2 investors asking what you get from your money					3 having strong connections outside of the medical industry		
								3 making some intellectual property					4 observing and researching what is happing outside		
								4 picking exactly what we do					5 being influenced is not an accidental process		
								5 having a road map for innovation							
								6 making earnings							

What supports or hinders innovation															
	P1		P3		P5				P9	P10	P11	P12	P13	P14	P15
	1 starting with a good set of cofounders		1 paid adviser see something inside/outside of our organization needs changing		1 providing an organisation structure and culture to attract innovative people				1 making use of comparably innovative processes ...3D printing		1 empowering structuring and empowering	1 having a flat organisation	1 having flat organisational structure	1 make revisions with customer ideas	1 flat hierarchy supporting innovation very much
	2 having more than three kills innovation		2 coming to us and discussing it		2 cultivating them (employees)				2 making innovative products	1 working in a very flat structure	2 helping the innovation process	2 encouraging people to bring out own opinions	2 supporting innovation	2 changing the instrument style	2 everyone participates in sales
	3 having people with similar work ethic		3 out there looking at new products as well		3 preventing silo thinking that limit the ability to see an integrated solution to something					2 communication goes quickly	3 not concentrating it in the hands of a few	3 having ideas	3 inviting everybody to give ideas openly	3 innovating the data handling process (presumably because not all customers want the new style)	3 everyone being innovative
			4 ultimately, I make decisions		4 helping their culture be quite innovative and being willing to do new things					3 high level of noise does not disturb us	4 basing it on much more structured innovation methodology				4 people feeling committed
	P1		5 thinking can we see need for it						1 thinking organisational structure is not important for us	4 pulling interesting things from any noise					5 making shareable innovation with no boundaries

What supports or hinders innovation														
	P1		P3		P5				P9	P10	P11	P12	P13	P14	P15
Behaviours?	1 thinking if we did not have a Board to speak to		6 somebody who gets that message out there so that people want to buy it.						2 seeing that organisational structure is complicated for our collaboration partners	5 using it for out benefit					
	2 going off at a tangent quickly								3 knowing decisions are taken somewhere in the US						
	3 instead thinking about the product								4 slowing down and cutting processes						
	4 thinking about how we're getting it to market								5 no one understanding why						
									6 understanding we can pursue innovation without management decisions no one understands						
	1 Board hindering innovation														
	2 odd Board members not understanding research														
	3 trying to derail it														

Leadership for innovation															
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
Behaviours	1 explain why everything is as important	1 you need a leader one for the innovation, another one for the operating	1 anybody who sees a good idea should bring it forth to the managem ent of the company	1 be focused on the objective	1 very agile management and leadership		1 very agile management and leadership	1 it helps for people who work in the company to see where we are going	1 encourage your people to express their ideas			1 we had very strict army style managers	1 free exchange of ideas without any restrictions to it	1 people here from each department	
	2 what the end goal is	2 both have to report to a final CEO	2 guys going over to medical and coming back with a product	2 don't spend too much time to discuss (ideas)	2 give room to the employees for creativity ideas		2 give room to the employees for creativity ideas	2 keep it within the walls of the companies	2 brings open discussion			2 from those functions of people we do not usually get innovative ideas	2 there is no bad idea. So, respect that	2 you need some people to find the right decision before ..starting the manufacturi ng process	
	3 why we are working with these particular people	3.two different teams with an open communicat ion between	3 and say, okay, what do you think of this?		3 drive innovation		3 drive innovation	3 (then) innovation won't backfire. Needs to be secretive	3 bases for getting the best out of people					3 manageme nt is open to have a complete round table discussion	

Leadership for innovation															
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
	4 in a situation where the management knows what's going on, but the people that work for you at doing the day to day don't, then that can cause a lot of angst	4 to get a product for a client or client needs	4 we've taken them from Medicare in recent years (ideas)											4 to write down all the information before you start the next step.	

New EU Regs impact on innovation, financial and knowledge resources															
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
minimising barriers/create agility	1 we would never have enough cash, I think, to take it right through to market	1 big companies they will decrease probably their expense or the investment on their innovation department s				1 30% to 40% of small companies that they're going to disappear off the medical market.	1smaller companies will need to put heavier emphasis on solid clinical dossier for class three and implantable product		1 the big players are reducing their portfolio to the really old stuff		1 innovation will slow				

New EU Regs impact on innovation, financial and knowledge resources															
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
	2 our only option, really is to partner with one of the key manufacturers	2 big companies, they will decrease probably their expense or the investment on their innovation departments				2 big companies the cost of just maintaining the CE mark 250,000 euros	2 will also require extra time and investment		2 regulatory department is completely involved with getting our available portfolio on the MDR level		2 focus will move to US market				
		3 if a company wants to sell their- I'm not sure that the first market will be Europe.				3. rationalisation of the product portfolio	3 the remaining notified bodies will be more competent in the future		3 most of the innovative R&D projects are cancelled		3 reconsideration of whether a partner Is required				
						4 less competition	4 more pressure on companies to invest more time and effort to make their dossiers user friendly		4 there are no resources for new developments		4 drive more valuable innovation (this company)				
						5 value of technical file will increase	5 the assessment process itself is in all likelihood going to take longer								

New EU Regs impact on innovation, financial and knowledge resources															
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
						6 little chance that products demand will decrease… neither increase in the price of implants	6 patients will have to wait longer for the access of the product								
						7 distributors. know the difficulty to have a CE... that the quality is very strict. that's why MDR is a way for improvement	7 regulation will lead to longer product life cycles products can also be cashed out longer								

Financial															
	P1								P9		P11				
minimising barriers	1 we don't plan to get a CE mark								1 we have to face the requirement to perform clinical studies		1 company invested a… to be ready for the post-MDR era				
	2 we will target countries where you don't need a CE mark								2 difficult to set up and to organize and in principle, to finance		2 every single product was renewed before the deadline				

Financial															
	P1								P9		P11				
									3 we will not do it on our own because the invest is that high		3 we ... engaged in big investments in clinical department for collecting data ... for the new MDR requirements				
									4 we look for a collaborator who is willing to get a product into the market		4 it is ---- competitive advantage that the company tried to invest in.				

Knowledge															
		P2							P9	P10					
									1. We had in-house seminars regarding the MDR for the whole company	1 we have one person who is focusing on this					
Minimising barriers		1 hired a quality manager 6 months ago							2 everybody is informed at a certain level	2 He did all the ISO 9000, ISO 13485, some other certifications					

Knowledge															
		P2							P9	P10					
		2 prepare not for the first tech but for the second tech for the full system							3 we have to ensure that everybody is informed at a certain level	3 he will take us through this quite easily					
									4 can say, okay, we are at a good level compared to the people where we have to get along with						

Meaning of Coopetition

	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
							1 very consolidating and highly regulated market	1 this competitor needs to work with others in order to share advances					1 competitor, small companies which have to carry the burden of the new	1 many small very innovative companies cannot cover all the steps by themselves	
							2 strategic alliances are formed	2 they utilize resources, intellectual property between themselves					2 group together	2 cooperate with a partner company for maybe some machining processes	
outcomes/what's at stake?							3 deliver value added propositions and innovative solutions	3 it's shared contractually between themselves.					3 benefit from each other's experience, knowledge, findings	3 share cost and to grow together	
							4 to be ahead of the big players						4 fulfill the new requirements in a way they can afford		

												5 keep the possibilities open on the market			

Experience of perception of collaborating with competitor														
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
choosing and learning?	1 offered us R&D partnership contracts	1 partner….is clearly a competitor	1 the company wanted a frame for diabetic foot markets			1 To adapt to the new MDRI have proposed to some competitors that we exchange all technical file	1 it's manufacturing, regulatory, and finally the commercial side	1 we've been asked quite extensively to co-develop with laboratories	1 I decided to identify some core developments which we will pursue up to the end product	1 we work with. Company . for very long time					
	2 it would really help to have that expertise ... have more cash.	2 V1, we don't want to sell it in Europe caused by this new regulation	2 they didn't want to develop it themselves			2 We make a contract	2 we have provided our key product to a competitor	2 we are going to have projects with a couple of those laboratories	2 we do have some R&D packages which we are willing to make available to the right partner	2 they were just a customer			1 we understand metal implant and the ultrasonic device	1 We cannot provide all manufacturing steps in a certain location	
	3 the problem is in terms of the IP request they want or some of the legal sides and stuff, it would kill	3 the V2 and the V3, this partner won't be a competitor	3 we sat down to discussion			3 I give them my own technical file so then they can demonstrate the	3 competitors have enriched it	3 they will develop for us	3 the motivation for the partner is high because he invests money in development 4 we are the contract developer	3 for the past five years they are also a competitor			2 we do not know much about cutting	2 why we are cooperating very closely with another company	

Experience of perception of collaborating with competitor															
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
	the innovation					equivalence									
	4 you're either locked in quite early or you maintain independence	4 So, they help us	4 he said, we can afford to give the frame away we can afford to give the scalpel away we can afford to give the tissue away, but we've got to make money on one of those things			4 Then the MDR approaches here is done	4 it is currently in the process of CE certification	4 we will bring those developments with company platform	5 outcome of the project .. a medical device ...exclusively developed for the partner	4 at the same time, we work together ..on new products.. try to partner continuously 5 it can work... It depends on people on both sides			3 What they find in the ultrasonic applications for their device helps us to understand our device much better	3 we are getting at the end also all the documents for this process	
		5 they sell some products, some mineral phase, we developed, a new product for market outside Europe thanks to this phase	5 area of coopetition was in distribution not development			5 You can demonstrate that you have a contract of exchange of information of the whole process		5 they will get incentives	6 the partner will sell it				4 then we can share the mandatory high costs	4 documents we can provide to our customer	
	1 one competitor we did some contract work for								7 we will receive the transfer price						

Experience of perception of collaborating with competitor															
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
what's at stake??	2 we did get that contract to a position where they didn't have any access to our...IP		1 I think we would work with a competitor					1 we've been asked to do that						1 There are some requirements, where we must have also let us say a roundtable discussion before we are starting this process	
	3 so we took one of their lenses and we put our polymers on their lens to show them it worked		2 The problem is with being an SME, it'd be ... that competitor is going to swallow you up?					2we're thinking about it very seriously						2 a requirement for a special surface coating at only some parts at the instrument	
			3 Are they going to take the best things from you and use it to their advantage?					3 Because usually...the company who shares their innovation, they get royalties						3 the partner company can make the surface coating directly at this point at the instrument	
			4 not with the direct competitor in the ...because a direct competitive, then both of us should go to sell it. And is there enough room in the marketplace					4 on top of those royalties, they ask you to say.... this embarked solution is provided by company A						4 sometimes we must revise the drawing before we are starting the process	
								5 Before doing that, we want people to recognize it as true and strong solution						5 we must be very open ... with the drawings with all product information	

Experience of perception of collaborating with competitor															
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
								6 afterwards only can we say we can prove it						6 we are getting at the end complete feedback from them... documents and the process"	

Success factors for coopetition															
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
	1 very successful because some of the technology that they had								1they come to us to develop an innovative product		**1** We have some competitors … where they are weak in Europe				
minimising barriers	2 they have access to very specialized equipment that we would never have								2 they want to substitute a product which they had in their portfolio		2 where we do have a gap in our product pipeline				
	3 That's all data that we would never have been able to access								3 collaboration over years, of course, there are feedbacks from their product development		3 We are reaching out them				
	4 it validated our approach completely								4 adding new shapes to the portfolio though this can be considered as an incremental development, but the first step is maybe radical		4 they are all very open to give us exclusive distribution				
	5 both sides really benefited										5 I don't think it is related to MDR				
									1 I ...divide several business fields for us						
									2 I can work in all business fields with different partners						
									3 there is no impact to each other. In principle, you can make use of the same technology of our same IP and innovative processes						
									4 and can get out the best out of it and the different partners						
									5 we are completely transparent though all the partners						

Hindrances to coopetition															
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
		1 have a lawyer with you to avoid issue at the end					1 you want to private label an own product for another company					1 it did not seem that the companies were really collaborating			
minimising barriers?		2 to sign a contract written by a lawyer					2 the legal structure within a coopetition model is very clear... but not hindering					2 they started to become			
or what is at stake??		3 you are ready to start legal suit against them if there is some trouble					3 you have to work with external consultants					3 communication started to decrease			
		4 mainly the risk if we increase our sales, they could increase the price or the transfer price of their components					4 your competitor... your strategic alliance partner would otherwise have direct access to the technical documentation					4 whenever some program…new modules, product being created they wanted to own it			
		5 could stop providing us their components just to increase their market share										5 they did not want to share IPRS			

Changes to company for coopetition															
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
		1 To start by our own tech from scratch, spending money and time developing only one part of the technology, no sense from our point of view					1 we did not wish to share technical file documentation with customers or distributors								
		2 working with R&D, academic (name of the company) having some patent					2 we needed to outsource regulatory affairs to independent external consultants								
minimising barriers?		3 we knew we would have to sign an exclusive licence					3 who remain the legal certification holder but not distributor								
		4 after our technical assessment													

Limitations of coopetition/sharing															
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
	1 if the cooperation agreement affects our IP or our ability to have someone else have access to it				1 in early stages when they haven't got a clue what's going to work		1 the company has drawn any line yet regarding a strategic alliance	1 we codevelop solutions with medical staff	1 I think... most important is the first step to the product idea	1 I'm open in cooperation in all areas	1 MDR allowed us, is to reflect on what can we do in-house		1 open to discuss everything	1 they said: „Okay, I will invest also in your company to share maybe a machining cost	1 I never have seen something good coming out of not being willing to share something

Limitations of coopetition/sharing															
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
choosing and learning	2 we happily walk away	1 if we provide the full technology or the full-on 80 percent of the technology			2 such a big area to explore... a huge mutual incentive if you can share results		2 We are always open for all discussions.	2 it takes a lot of time to get access to those people	2 from our point of view ...is initiated by the partner	2 if I see that this has absolutely no sense for my company, I'll say, "I'm sorry, it's not interesting to us."	2 significantly changed the mindset to be open to inorganic acquisition or strategic partnership		2 do we have strategic similarities	2 I would stop	2 I never have seen something good coming out of not being willing to share something
		2 there is a huge risk			3 later stage I struggle a little bit more to see cooperation between competitors		3 only limit that we have is really sharing our intellectual property and our technical files	3 customer knowledge that's a secret	3 we look...what we have available in our portfolio suitable for their product idea	3 has to be beneficial for both sides	3 allowed us to look internally and even the way we innovate what products can you bring to market		3 your goal is to develop, to bring it to market that with your competitor.		
		3 I cannot say that I have huge competitive advantage			4 the simplest way to ...move forward would be an area that we couldn't do it alone... but working together you could, maybe a geography or a particular product line		4 in order to avoid copies on the market		4 really depends on the partner and the experience of the partner	4.because each partner has its own goal...for the project	4 an internal prioritization, an internal change of mindset what innovation means		4 maybe very beneficial for both in the end		

Limitations of coopetition/sharing															
	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14	P15
		4 you can subcontract or sign a deal with a competitor for only one component, one small part of your technology							5 when you have a coopetition partner who is really familiar with the business, ...will give more impact		5 because now the investments are much bigger to bring a product to market				
		5 and you develop, your expertise, your competitive advantage							6 one side must be the legal manufactu rer						
									7 no principal limitation all these points only a question of the agreement , how agreement looks						
									8 when it makes sense for both sides ..... everything is fine						

INITIAL CODING			
These are the first codes used which may change. All items cited by participants are recorded in the coding diary			
Innovation		revised codes	revision again
Qualifying/			
ranking innovation	merge with quantifying		
Identifying	merge with CSF or barriers to success	qualifying	qualifying
Identifying critical success factor		Identifying critical success factor	Identifying critical success factor
Barriers to success		Barriers to success	Barriers to success
Criteria for innovation	merge with quantifying	Choosing	Choosing
Choosing		Labelling	Labelling
Labelling		Quantifying	Quantifying
Quantifying	merge ranking in here	Hypothesising	merge linking into hypotheisising
Reflecting	Merge as hyothesising	Linking	
Hypothesising		stereotyping	stereotyping
Dispelling stereotypes		Dispelling stereotypes	Dispelling stereotypes
Linking			
stereotyping			

Internal factors helping/hindering innovation	
qualifying	P1 three maximums too many opinions can kill it; P8: flat organisational structure helps innovation at some levels. We share.at our level--but not with everybody in the company P9 I think for us the organizational structure is not that important P10 they generate some noise too, but if it comes to innovation, I think this is very good .. if you are able to pull interesting things from any noise P11: innovation as not concentrated to a few P15 everyone participates then flat hierarchy is very supporting of innovation; P2 innovation department to perform exploration thinking... for the exploitation. So, the operating stuff, another team; qualifying innovation starts from the structure and you manage the people P5 If the culture of people is to operate in terms of a job specification, you're very unlikely to get the kind of innovation required;
critical success factors	P1 a good set of cofounders; get your team together...same sort of work ethic as you; P10 because the organization is very small, then communication goes quick; P1 a good set of cofounders P1 critical success factor: chairman and board sometimes to help direct it; barrier to success: you can have the odd board member who doesn't ..understand the research space and will just ..... and try and derail it. P5 The organizational structure and culture are absolutely critical.; provide a culture and organizational structure that will first attract them...and probably more importantly, cultivate them;
Barriers to success	P5 silo thinking really starts to limit the ability to see an integrated solution/innovation
Choosing	P3 you've got identify definitely applications and the need for it (talks about heavy and lighter metal frames for glasses)
Labelling	P11 structure as empowering P15 everyone should think about it then people feel committed to it P2 best structure organization would be an ambidextrous organization; P3consultant...bit of a radical thinker at times; critical success factor: see something in our organization or outside of our organization... they think needs changing, then they come to us and we'll discuss it P5 soloing - people who stay too long in one division, one area of the company;
Quantifying	P13: when you have flat organization...people are encouraged; P1 quantifying: (org structure) supporting innovation, if didn't have a board and a chairman to speak to, we could go off tangent quite quickly; P3 (innovation)L product just going to be unique enough but there's also going to be a definite need;
merge linking into hypothesising	
stereotyping	
Dispelling stereotypes	P13: this is bad (idea), no such thing. Ideas are open and invited
qualifying	P1 it supports it; qualifying everyone needs to know why you're doing certain tasks; P2 really important for a start up company P8(leadership for inn): it helps also for the people who work in the company to see where we are going;
critical success factors	P1 keep everyone aligned; critical success factors: we do change patterns .... based on market research; need to keep the dialogue open : you have to explain what the end goal is. P2: two different teams with open communication .to geta product for ... client needs. P3: anybody who sees a good idea should bring to the management; guys going over to medical ...coming back with a product you do see the odd thing there. P4 critical success factor: focused on the objective. P7 have to give room to the employees for creativity ideas. P9 encourage your people; an open discussion is. basis for getting the best out of the people.

Internal factors helping/hindering innovation	
	13 free exchange of ideas without any restrictions; P14: you need all these people here and not all but from each department, you need some people to find the right decision. P15 have a complete round table discussion to write down all the information before …starting the next step.
Barriers to success	P1: keeping people in the dark; P2 quite tough to manage both innovation plus exploitation; P8 (innovation) can backfire if you don't keep it within the walls of the company; P12 very strict managers…. do not usually get innovative ideas;
Choosing	P2 (structure); both have to report to CEO; P13 there is no bad idea... respect that'; P14 there are so many questions every time and that is why it is very important that the management is open;
Labelling	P1: we're such a small company; P2 start-up company P7 (leadership for innovation): needs agile management and leadership; P8 (innovation): needs to be secretive in some way; P13: there is no bad idea.
Quantifying	P2 it is two different jobs, two different tasks, two different philosophies; P3 open and flat management should create innovation because everyone has an equal say; P8 its quite positive; P12 of course it has to have an impact
merge linking into hypothesising	P2 once you sell a product you need a leader, one for innovation and the other for operating; P3 what do you think of this(idea); P9: things and ideas on the table which maybe at the first few-not useful. But finally, of course. fruitful;
	P1 I think there needs to be a bit more support and a bit more common sense in the situation; P2: new MDR... I think big companies... will decrease investment in their innovation departments; P5 It's also entirely possible that we should be worrying about it but just don't or aren't fully aware enough of the implications for us; P6 there is little chance market demand will decrease; P7 assessment process ...likely .to take longer in the future; longer time for assessment process...patients must wait longer; regulations with longer product lifecycle and product profit cycle; P11 eventually... it will drive more valuable innovation through. through commercialization, P12 it might not decrease innovation, but might direct innovation more to bigger organizations. Who have the capability of entering the market?
stereotyping	P9 especially the R&D staff lo be able to express their ideas; P12 very strict, …. army style managers-.. do not usually get innovative ideas (from employees);
Dispelling stereotypes	

Regulation	
Qualifying	P1 don't think I've seen anything from what I've read currently that's going to make that particularly easier. P4: avoid innovation to go in the market. ... at least, in orthopaedics; P7 Smaller companies will need ... heavier emphasis on solid clinical dossier for class three and implantable products; benefits of longer product lifecycle-- especially for small and medium size companies. P10 will block small companies from entering the market; for the industry, it will be negative from the point of view of innovation. P11 it will slow down innovation;
Critical success factors	P2 (for start-up) we probably see a lot of new start-up company selling their technology before clinical trial to these big companies; P6 MDR is providing as opportunities.... you're going to have less competition; quantifying: regulatory…huge jump; P6 if you are in when the market is closes. Value of your technical file increases; P7 (for small companies): extra time and investment to put dossiers together...to meet new requirements; P9 (for the big companies): reducing their portfolio to the really old stuff P6 the CE mark would be recognised by distributors in other countries as representing high quality
Barriers to success	P1: getting through every regulatory hurdle and not running out of cash; we would never have enough cash, I think, to take it right through to market; P3 a couple of companies have gone; P4 (regs); because it's very difficult to raise money in orthopaedics; P10 much more bureaucracy; P11 small companies that are innovative...do not have the resources to do it on their own:

Regulation	
Choosing	P2 (markets) nothing will change regarding the US but for Europe, if a company wants to sell. I'm not sure that the first market will be Europe; P6 if they don't make a million euro of sales out of it, forget it... rationalization the product portfolio; getting our available portfolio on the MDR level ...there are no resources for really new developments; P11 force companies to rethink how they work: do you need leverage or you can do it on your own?
Labelling	P1 being a small company; labelling: We're quite a tricky drug device combination; P3 the bar has been lifted so high; P7 remaining notified bodies will be more competent;
Quantifying	P1 make it harder; we're probably on the hardest spectrum of the devices; only option, really is to partner with one of the key manufacturers; P2 to save the. net profit margin because due to this new MDR.. you have to pay some clinical trial... quite costly. will increase their R&D cost and... the post-marketing follow up; P3 our QA guy here because we deferred everything to him ...Because the new medical device regulations are so complex; our CEE is being revaluated at the moment … because of the new MDR regulations…so much tighter and higher; P4 quantifying: It's going to destroy innovation; P6 regulatory…huge jump; 30% to 40% of small companies. Going to disappear; 50% of the product portfolio offer it's going to disappear; big companies. The cost of just maintaining CE mark. 250,000 euro; P7 a fundamental impact on the innovation pipeline' P8 (the benefits of the regs): quality very much… and because it's building a commercial barrier with other competitors' P9 quantifying: it cuts off innovation; qualifying: maybe not in total but at a very certain level… the big players...most of the innovative R&D projects are cancelled; P10 cost of getting into a medical industry ... significantly higher; cost of getting into a medical industry would be significantly higher;: for the industry you...will have much more time to work on the ideas because less competition; it will prioritize more the US market versus the European;P12 quantifying: raising the barrier of entry; P14: the end only good quality instruments on the market
Merge linking into hypothesising	P1 I think there needs to be a bit more support and a bit more common sense in the situation; P2 new MDR... I think .big companies. will decrease investment in their innovation departments; P5 It's also entirely possible that we should be worrying about it but just don't or aren't fully aware enough of the implications for us; P6 there is little chance market demand will decrease; P6 critical success factor (is MDR); distributors (in other countries) ... know the difficulty to have a CE mark... know that the quality is very strict... why MDR is a way for improvement; P7 assessment process ...likely to take longer in the future; longer time for assessment process...patients must wait longer; regulations with longer product lifecycle and product profit cycle; P11 eventually... it will drive more valuable innovation through. through commercialization, P12 It might not decrease innovation, but might direct innovation more to bigger organization who have the capability of entering the market.
stereotyping	P11 small companies that are innovative but don't have the resources to do it on their own;
Dispelling stereotypes	

Impact on financial resources	
qualifying	P6 (regs impact): you can do innovation, but the outcome is not a big change; P10 for us, it's not a big difference comparing to the previous registration procedure; if it comes to innovation, it won't change anything actually; P14 documentation and investment for audits and quality management;
critical success factors	P6 able to provide good clinical data to sustain the update of the CE mark on basic product; I hope the competency of the notified body will help also to demonstrate much easier evolution of device, so-called innovation; P8 you can get a medical device certification, given algorithms that are defined in a specific way; P11 factor: We had every single product renewed before the deadline; P12 team has its own regulatory persons; P14 we are a real manufacturer and that is why we can provide all these internal documents; we can cover also the investment for the audits; P15 I think they're more concerned about how to apply this beside everything else that they are currently doing.
Barriers to success	P9 clinical studies. difficult to set up … and to finance;

Impact on financial resources	
Choosing	P2 we don't plan to get a CE mark … we will target countries where you don't need a CE mark; P6: establishment of collaboration for collecting clinical data; P 8 we have decided that it's important for us, we will do it; P9 we look for a collaborator who is willing to get a product into the market ...we will not do it on our own; P11 The company invested a lot to be ready for the post-MDR era; P12 we have to have P 13 We changed the focus completely ..,because of that.
Labelling	P14 we are real manufacturer;
Quantifying	P2 the price (of V I product) is quite low and the expense ..to get a CE mark or in one year will be so high; P3 we've had to employ a guy on 30 or 40 grand a year just to look after it; we have the money ... ..we will return level ..with all the restrictions the new medical directives have placed upon us. P9 we talk about innovative products, we have to face the requirement to perform clinical studies; the invest is that high ....it has to be borne by the company willing to make the final turnover; P6 MDR, for me, it's a good thing. Less competition; P8 or machine learning, it's very difficult; P10 will have some additional bureaucracy; P11 we had engaged in big investments in clinical department for collecting data for the new MDR requirements; P 12 should not be an obstacle for us
Hypothesising	P 11: it is .... competitive advantage that the company tried to invest in.
stereotyping	P10 small companies, it's a big problem
Dispelling stereotypes	

Knowledge resources and regs	
qualifying	P9 everybody is informed at a certain level;
critical success factors	P1 very lucky to be a start-up that has the money to do that P2 we have now a regulatory and clinical affair manager;
Barriers to success	P10 very few notified bodies; P 13 If you do not know the requirements then you will not be successful;
Choosing	P2 very lucky to be a start-up that has the money to do that; P4 we did not implement yet all the requirements …because... strategically, we don't want to go there; P7 have our own medical and regulatory department... we are also working…with external consultants; P9 we had in-house seminars regarding the MDR for the complete company; focus a special seminar for the regulatory affairs and clinical affairs employee
Labelling	
Quantifying	P1 (regs) so incredibly hard; P3 having consultant in, charging us £1,000 a day, P4 we have the knowledge; P7 definitely; P9 I think so; we are at a good level compared to the people .we have to get along with; P10 yes we have one person who is focusing on it; qualifying: very skills and knowledgeable person; he did all the ISO 9000, ISO 13485, some other certifications; P13: yeah .you have to..; it is the number one knowledge .not so much creativity .engineering
Hypothesising	
	P9: it is difficult to evaluate ...because we have to get along with the reviewers at our notified body; P10 I'm sure he will take us through this quite easily; P10 I'm not expecting any troubles, except for the time for introduction product to the market;
stereotyping	

New regs aid innovation?	
qualifying	P1: you can have that open dialogue with them (EU; P11 it is a change of mindset and culture, how many companies operated; P12 new regulations it is easier for the software and applications over all to enter and exist in the market. P13 I agree partially with the clinical requirement;
critical success factors	P2 well clearly key added value for the patient and for the surgeon; P9 I think this will be market share which I want to get….and this is what I see as a chance for our company; P11 maybe become more over the year outcome-based innovation-driven than just bringing innovation with some incremental, you know, features; comes back to the agility…. very focused on what to bring and how to bring it.
Barriers to success	P4 cannot understand that it's so heavy and impossible to manage for a small company; P9 companies are going into insolvency because they will not meet the requirements of the MDR;
Choosing	P9 or they decided that from financial point of view, it does not make sense to invest money in .... getting the new certificate because the turnover ..the product is quite low; P11 adaptability phase, ..you have a historical product pipeline. what do you with it;
Labelling	
Quantifying	P1 No; P2 competitor wanting to target Europe, at the end, the effort for that; this new MDR not for incremental but for disruptive technologies. will be quite huge to compete against us; P4 No; the consequence is that 40% of the med-tech company will have to stop; P9 I see it as a challenge and at the end, the situation will need that some competitors will fade away, some competitive products will go out of the market; P 13 The documentation effort has been increased drastically; P13 I do not think that if you have the essential requirements or ...performance requirements that makes much of a difference for the safety of the device
Hypothesising	P2 for the companies which want to target only Europe ..once we have CE mark---it is ..a way to increase the barriers at the entrance;.P9 as a small company, maybe are more able to get innovative products in the market or to maintain our innovative products in the market better than the big players; P11: it will help companies to push through the most innovation, where they think will have.. most value: maybe become more over the year outcome-based innovation-driven than just bringing innovation with some incremental, you know, features,
stereotyping	

COOPETITION	
Meaning applicability to med dev	
qualifying	P3 it's all centralised labs isn't if? It's all shared knowledge; P7 I would say that coopetition includes a mixture of cooperation with suppliers, customers, and firms producing complimentary or related products; P8 competitor need to work with others to share advances; P 19 we are speaking together while we are competing on some markets; qualifying: (In relation to EU regs).
critical success factors	P1 collaborating with the competition who is a lot bigger than you, it has an entire team...more brains... really useful....you need that sort of extra lift: P7 in this very consolidating and highly regulated and complex market environment, strategic alliances and coopetition models are especially necessary for small and medium sized companies to deliver value added propositions; be ahead of the big players; P8 utilize resources, intellectual property between them...shared contractually; P10 definitely generate some problems, ...when (small companies) ... working with a big company, you have sometimes to compromise; P 11 smaller companies are rethinking at what level they try to reach out and try to build cooperation; P13: if you share it (reg burden), it has less impact on your financial structure and on head count;P13 cooperate...we benefit from each other's experience, knowledge, findings; P14 have to cooperate with a partner company for ...some machining ...or for development processes.. cannot cover all the steps by themselves. Share cost and to grow together
Barriers to success	

COOPETITION	
Choosing	P 15 always in the minds and giving up intellectual property, people are getting familiar .... then maybe they are trying to get.my employees because they know these are really good ones (fear stealing resources)
Labelling	
Quantifying	P1 I think it's really important because for a little company like us, you only have one person working on regs; P2 coopetition is just a way that it is a competitor and you are working with for a specific project;P4 I try to find a partner in order to share what is common ...everybody has to apply the new regulation; P7 forming strategic alliances in order to help both companies; P8 ecosystems where it's very difficult for a single stakeholder to do some innovation in every field;P10 definitely it (reg) will enforce such cooperation; P11: it will change the.. go-to market business model and some product introduction business; P11 we are seeing it in small companies- in three ways, one model, where investing in… resources behind regulatory and not being able to invest in go-to market investments.....they are much more open seeking exclusive distribution or licensing rights ... I also see companies, that have several innovations, but ...need to focus on the few, they are being more open to ……. technology large companies of are ..acquiring other companies, who have some technology registered ..because of the lifecycle becoming longer; P13 where competitors, small companies group together .to fulfill new requirement in a way then can afford and keep possibilities open on the market; getting more difficult for smaller companies to carry the load of regulatory requirement; quantifying: the regulatory burden is high; P 14 important for the future
Hypothesising	P9 I can imagine that maybe coopetition can help getting products in the market when the competitors are with different notified bodies, maybe; somebody with the notified body who is accredited with MDR, maybe the other not; P10 they may not have enough of resources and knowledge to enter those markets without a stronger partner; P12 have clear roles between the companies, it might be possible
stereotyping	P10 small companies are afraid; quantifying: especially the start-ups, are afraid of selling too much to big companies;

Experience or view of coopetition	
qualifying	P1 talking to two (firms), both have offered us R&D contracts; P2 partner…. Is a competitor V1, we don't want to sell it in Europe partner won't be a competitor…so they help us: P3 (experience): only with… needed a frame but did not want to develop it; P5 I think they would say happy work in a very early stage (in coopetition);
critical success factors	P4 trust and communication...terms of (legal) agreement, defined from the beginning; P6 To adapt to the new MDR, I have proposed to some competitors that we exchange all technical file...make a contract ..the MDR approaches here is done; P7 provided our key product to a competitor who has enriched it ..and is currently in the process of CE certification; P7 in terms of R&D, strive to... innovation through coopetition; P9 R&D packages... we are willing to make available to the right partner...we are the contract developer and ..... the contract ... the legal manufacturer the outcome .... a medical device exclusively developed for the partner.... we will receive the transfer price; P9 partner invests a lot of moneys, motivation to make it work; P10 depends on people on both sides; P13 what they find in the ultrasonic applications for their device helps us to understand our device much better or our ideas we have in mind and the other way round (mutual benefit??); P13 then we can share the packaging, biological testing, sterilization, cleaning which is super expensive; choosing if we validate our packaging ,,,, which is worse case for them, they benefit from that and vice versa; P14 we are getting ...all the documents for this process...which we can provide to our customers; the are some requirements ...discussed before starting the process; we must be very open with the drawings... with all product information; quantifying: (success of coopetition) yes, according to the feedback ....getting from our customers,.
Barriers to success	P1 we can't use that technology to do anything else... and we wouldn't be able to go work with another partner or anyone else; the problem is in terms of the IP request they want or some of the legal sides and stuff, it would kill the innovation; P3 (coop) I'm sure everybody wants to guard their IP; P4 (coop): everybody want to work for ..own business; P5 companies I've worked for have been driven by really quite ruthlessly competitive people;
Choosing	P2 It is just a question of finance, not only innovation for them, for us it is just a way to speed up the research phase P9 I decided to identify some core developments which we will pursue up to the end product; P10 compete on many markets with the same products, but... work together on new products

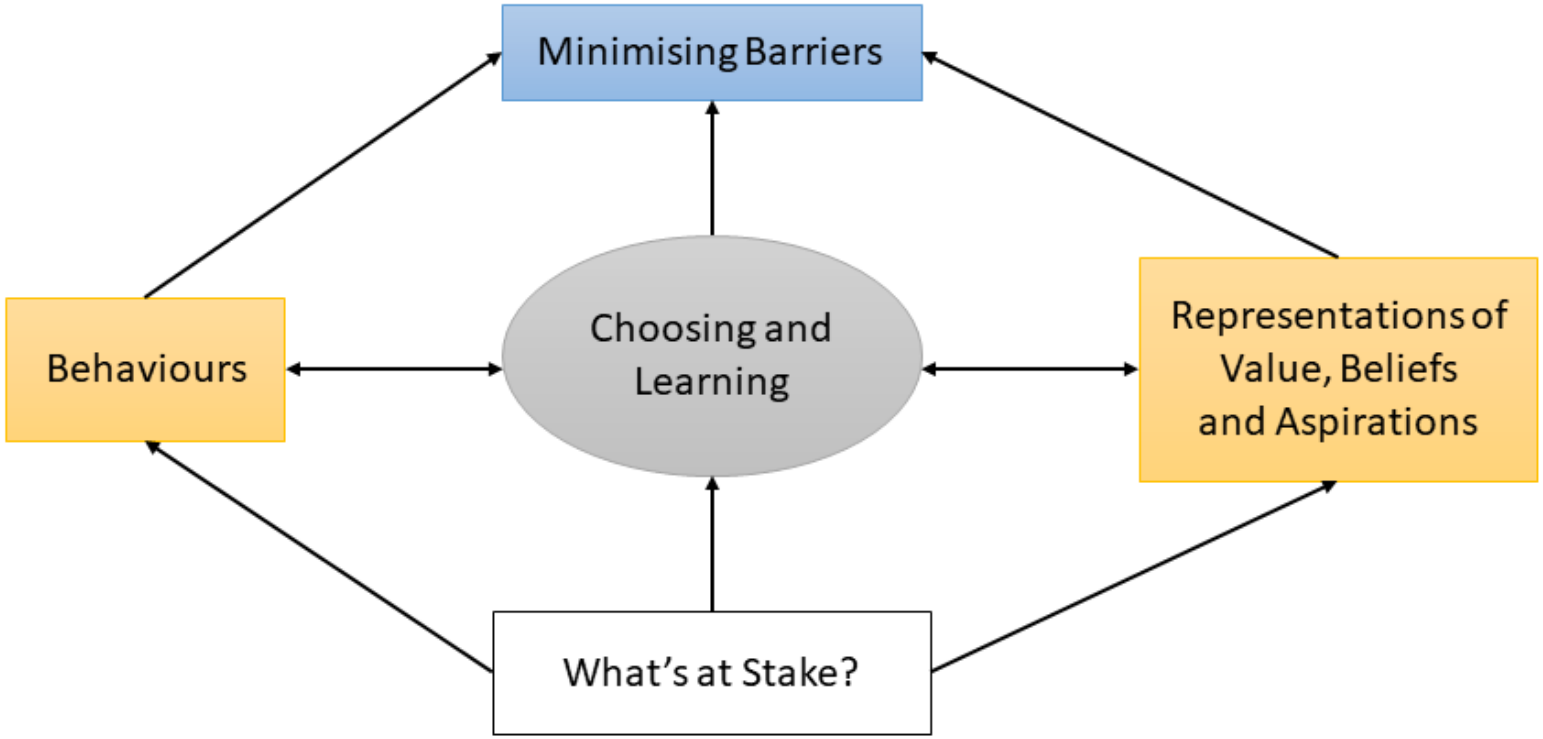
Experience or view of coopetition	
Labelling	
Quantifying	P1 they come with such heavy restrictions around company's IP, what we can and can't do; it would really help to have that expertise essentially we need the technical file from them...and I think they are a bigger force that can help drive the product to market have deeper pockets than us; P6 was already in a collaboration because I was providing, giving the full technical file to my partner; P8 The issue of co-development must be also understood not only with other private companies and by doing so with a direct competition, but it must also, I think, be discussed as co-development with laboratories, public laboratories; P9 we are not able to pursue all developments on our own; P7 (done coopetition): on many occasions, yes; P10 many times actually in past five year; (coopetition on innovation and development, yes); P13 quantifying: if we share the burdens we don't have to pay the same costs twice
Hypothesising	P4 I would like to share the quality system and maybe the manufacturing... keep the design and development and the follow-up of my product; P1 you're either locked in quite early or you maintain independence, which means raising more money to take it through regulatory pathway'; P8 some projects within ...month and years with ... laboratories and they will develop for us... we will bring their developments within the .. company] platform...they will get some incentives out of it; P15 I think for smaller companies it works because there's no threat on them not working together instead of working with someone;
stereotyping	

Experience or view of coopetition	
qualifying	P8 No, because it is too early for us at this stage; choosing usually the company who shares their innovation, to get royalties... on top of those royalties, they ask you to say... this embarked solution is provided by company A... before doing that, we want people to recognize this company] as a true and strong solution.
critical success factors	
Barriers to success	
Choosing	P3 choosing everybody wants to guard their IP;
Labelling	
Quantifying	P3 Are there many shining examples of coopertition in the orthopedic industry? No; not with the direct competitor.... ..both of us should .. sell it...enough room in the marketplace? P8 afterwards only can we say [name of a company] already provides you with some great things and we can prove it
Hypothesising	P3 hypothesising: there is a line to be drawn if, you know, its people, isn't? It's like, how will I go with you and how well we would get on with your own organization. P3 hypothesising: he problem with being an SME, it'd be ... that competitor is, going to swallow you up? ...take the best things from you and use.to their advantage?
Stereotyping	

Suitable context and limits of coopetition	
qualifying	"Suitable stages: P1 an early stage we did not know how we were going to manufacture; P6: collaboration for validation of instrumentation; P7: very important that the coopetition starts in the very early phase; P10 it really depends on the partner; P11 (coopetition): it depends how you define competitors; LIMITS P5 qualifying: happy to work with a competitor in very early-stage work. So, long as they can each go their own way separately and then compete.; P8 qualifying access to my end users. That's a secret. no LIMITS -P 13 qualifying: open to discuss anything…but beneficial to both; qualifying: Depending on your strategy."
critical success factors	P6: especially small companies, have to collaborate ...providing for instance example of ..some element of the technical file; P9 I can work in all business fields with different partners…make use of same technology our same IP and innovative processes…optimise it; P10; start from an early moment; you actually describe what the product is going to be, through whole development process, and then the registration too; P9 very important to involve the regulatory department in the very beginning because maybe you develop something or make use of processes which will never be able to be satisfied, it does not make sense; P9 the agreement...makes sense for both sides; P5: have a very, very clear framework for the proposed collaboration; P6: really depends on the partner and the experience of the partner; P11: have a NDA, ...share about pipeline, t... not much of holding back; strategic partnership, .. allowed us to look internally and even the way we innovate what products can you bring to market that you can develop clinical evidence and can allow you to register;
Barriers to success	P6 regulatory...that's where the cost burden lies; barrier to success: cost for the time which is taken by notified body to do your technical file; P1 biggest hindrance ready ..is some people just trying to... grab[P2: you cannot say that I have huge competitive advantage; P5 technical product development.. closely together ...you'd be continuously having to think is this—the bit that they've become knowledgeable about through you, is it an area that they can easily move into; P6: long innovation time and cost of innovation; P6: a lot of top management not considered the burden of the regulation cannot ask the right questions; P7 (coopetition): sharing our intellectual property and our technical files; P8 (coopetition): never work with a competitor with my own customers; P11: investments are much bigger to bring a product to market
Choosing	P6 what do we have available in our portfolio ... can be suitable to be used for their product idea; P9 nobody wants to have anything to do with the regulatory stuff because everybody is happy when somebody else is doing that....so, this is a part which we do quite on our own; choosing: I'm open in cooperation in all areas...It has to be beneficial for both sides; P11 much more cooperation with the smaller sized companies …but not companies more our size or bigger;
Labelling	
Quantifying	Suitable stages for collaboration quantified: P6 cost...50,000 euro...to share... saved 25,000 euro; (collaboration): If you can gain three months...it's important because... fixed cost in your company for three months. 50,000 euro; otherwise…. the risk is pretty high that you are losing important information and resources; P11 (coop partner): for me size matters a lot
Hypothesising	P1 at these early cooperation standpoints ....you're just trying to work on the innovation and find more out about it.., I don't see why they have to have access your IP forever; P2 you can subcontract or sign a deal with a competitor for only one component, one small part of your technology and you develop, you expertise, your competitive advantage; P 5 hypothesising: at those early stages they haven't got a clue what's going to work and what's not going to work...big area to explore; P5 simplest way to make that move forward would be an area that we couldn't do it alone; choosing: could be a geography or a particular product line that you each knew but didn't know each other's, but working together you could do a third one; P6 for European companies, for the top management who understand what are the challenges of regulatory, it's an opportunity to do innovation also in the long term; P8 hypothesising: it could make a lot of sense to work with not direct competitors, but companies who have expertise
stereotyping	

Axial Codes	Spokes with examples
Representations of values beliefs and aspirations	Culture for innovation – team first
	Structure small, start-up agile v large dominant
	Aspirations – competitive advantage/stay in market v independence
Behaviours	Failure – control of certain resources, stealing assets
	Success -openness, trust, empowerment
	Compromise - flexibility
Choosing and Learning	Which partners? Size of company, competitor or non competitor
	Which mindsets? Open/closed innovation, degree of legislations
	Which strategy? Type of alliance, business model
	Which aspects of coopetition? Technology, regulations, innovations, stages from initial development to market launch
What's at stake/outcomes	Time
	Competitive Advantage
	Financial costs, profits, transfer pricing, registrations
	Markets
	Secrets – fear of sharing
	Uncertainty
Minimising Barriers	Regulation – in house shared
	Eco-system – getting resources
	Legal rights agreed
	Get to market - compromise markets/product lines

Theoretical Code



Coding Diary

7th December

Opened a new Excel workbook.

The prework is to separate the interviews question be question so that the 15 responses to each type of question are in the same excel folio.

Whilst doing the initial organisation also setting sheets for the apparent key themes, **initial rough codes**

The task is difficult because I have asked too many closed questions instead of a broad open question and let the participant talk. I have also interrupted with other questions which makes trying to keep a set of key questions difficult!

I decided to put the added minor questions into participant answer pane to reduce confusion.

Once at end of first participant script can rearrange as necessary by copying and pasting from one Excel sheet to another or from one position to another.

8th December

I started this diary now and worked backwards. First job is to read my original notes on the overall coding technique which involved 6 coding sessions. The reread first parts of Saldana (2016) to add styles to the text indicating important words, for example and regarding initial themes. Then continue with initial recording in Excel of all of the interviews by question.

I have added a whole series of unplanned questions about a second coopetition for Participant 1 – made new basic coding category.

10th December

Finally finished transferring questions to Excel spreadsheets by question. Very difficult because I have ignored some questions, combined others and jumped about with the order. Sometimes it was difficult to assign these new questions to the defined categories in the original interview plan. Not sure how this will impact on the coding at this moment.

Now going to Saldana to decide how to start off cycle one so we do all the coding methods in systematic way.

Memo writing is reflecting on the coding and more important than coding – may be done after a session of coding initial codes?? **They help to make hypotheses about the connection between categories and integrate the connections with clusters of other categories to generate the theory.**

Research Question: What are the critical success factors for coopetition that will provide benefits to medical device SME given the impact of the new European medical device regulations on time and cost to market?

Sub questions

SQ1: What are the critical success factors involved in adopting the new legislation in relation to innovation management?

SQ2: How will established success factors need to be adapted and into what form?

SQ3: What does coopetition mean for these SMEs?

SQ4: How has coopetition been approached/considered in the context of innovation management, if at all?

SQ5: What aspects of innovation management or stages of the innovation process are suitable for coopetition, based on the experience of these SMEs?

SQ6: What are the challenges of implementing coopetition from the SME point of view?

SQ7: What strategic changes are needed for coopetition?

SQ 8: What organisational structure/changes are required for coopetition?

SQ 9: What role does corporate culture play?

SQ 10: Which management and leadership characteristics support the application of coopetition?

SQ11: What other critical success factors for coopetition have been identified?

Clarifying the meaning of the initial coding types of code before starting anything and then listing the initial codes from the Excel SS already completed and adding any others that are highly relevant concepts in the Lit Review Chapters.

In vivo coding – live words or phrases **used by the participants** not the researcher

Adopt the lumper rather than splitter method since the latter will produce too many codes

Put these words and phrases in “XX”

In vivo codes reveal to the analyst behaviours or processes for how the actors problems are resolved

Use **bold text**

List of key themes relevant to RQs (not to the participant profile)

- Organisational Structure
- Organisational Culture
- Strategy
- Leadership
- Innovation
- Coopetition
- New EU Medical Regulations
- Knowledge
- Memo Note on In Vivo Codes
- Organisational Structure (OS)

This initial coding of the interview question on precisely this was quite interesting and had unexpected elements. It is likely to change somewhat as all the questions are analysed, since OS is mentioned in later questions. I was able to identify some lumper codes that provided insight into the participant's thinking and then to split them down with later comments. Hence for instance OS as **"**some sort of tiered system" (P1) was ideal to summarise the various expressions made about it. Interesting was that a hierarchy was perceived as value placed on the individual (P5). Organised in short steps and works alongside me not under me was indicative of many of the firm (P3) and reflects the short/non-existent chain of command depending on the individual firm. Also "as little corporates as possible" (P3) reflected the idea of the large firm being abhorrent to the type of work that the company performed,

A second lumper code concerned what the roles of individuals are which ranged from "the structure is me" meaning that the CEO (P3) did or had done everything as had many of the employees and another where three people had designated themselves a management team that shared all the key tasks. In other cases, a more defined roles and responsibilities scenario was considered important inferred a sole final decision maker who would take the consequences if something went wrong. The third OS concept focused on the size of the company and its relationship to its stage of development, the lumper code for this was "an early-stage company" (P2) and descriptions provided a graphic account to clarify the point "we are only one floor and two guys on top" (P2)

"unstructured collaboration system…..comparable to a start-up" (P13)

Organisational Culture

The initial coding on culture is sparse as not many participants provided useful feedback and not all were asked the question, but two initial lumper codes emerged a conceptual intangible idea of individuals' context in the firm for which no splitter codes are aet identified

"free on their way of thinking" (P2)

12th December

Splitter codes were identified in later questions related to culture as associated with mindset for instance P2 stated “you will have to think differently” and P2 as “a good perspective on reality”. P14 splitter codes about the “culture is a complete mix culture” referring to individuals with different disciplines and backgrounds. Free thinking culture was also associated with “a blind alley is explored in a way that I'm not sure it's that feasible to do with the pressure of a big team and big financing” (P5) and the purpose of culture indicated by "There's so much at stake" (P8); two splitter codes were identified which described processes to gather information "we like very much to interact with either insiders or outsiders of the company" (P8) and the idea of shared values of "collective shared responsibility and objective" (P5). The idea of collaboration as an opportunity to achieve goals is another splitter code; a response to the need to be successful by P6, "they have no time to develop it in their own R&D and there's already a CE mark”

Leadership and Management

These codes emerged initially from the questions on management and leadership and whether the participant considered him/herself as a leader of a manager. The first lumper code in this initial section on leaderships was **"**give power to the people" (P2) and four splitter codes were established as to how this was exemplified in the firms: "trusting them” (P2) “give them the opportunity to manage their problem and their solution by themselves" (P2), " Typically, we do have a discussion with a consent which makes everybody happy and which in most cases is the best solution" (P9) "mentoring orientated" (P12). next category that emerged was leadership perceived as traits with the code Open and three splitter codes “empathy" (P2) "communication" (p4) "leader by example." (P3)/ The third leadership lumper code referred to leadership style **"If you've got a problem, all doors are open" (P3) and two splitter codes demonstrated contrasting style** "decision making clearly comes from the board of directors and the CEO" (P7) and “collegial: (P8).

13th December

The first lumper code on manager was **"it's a big extension on project management"(P1),** which reflects the everyday duties of a leaders (Kotter, 20120, ensuring that the short-term project objectives are accomplished and was reflected in the additional comments: “to make sure that everyone comes into deadline on time” (P1); " I am involved in all processes to discuss things and really gives feedback about how to do it" (P9). The leader also as communicator, interacting with employees, motivating and mentoring (Mintzberg, 2009)

"somebody who is interested in what they are doing and who is interested to interact and to discuss things and really gives feedback about how to do it "(P9)

“really hearing people” (P9)

"encouraging the people to be happy in their job" (P9)

Leaders' responsibilities were identified in the lumper code **"Leader manager not a leader"** (P2) with other descriptions that enunciated the two aspects being combined.

"good leader needs to be close- close, ...the frequency at least one time per week, ...close to the team and just to get a report from them…to be reassured about what they are doing " (P2)

This first splitter code reflects the more day to day approach of the leadership part of the role whilst needing to get a report on how the employees are progressing more reflects the anxiety of leadership described by Stacey (2010) of totally empowering employees and orchestrating the whole strategy from a distance. The second splitter code focusing on these two duties

"I'm a leader, but I'm a manager also" (P4)

The last of these leadership lumper codes focused on the leader's perception of hiher role **"Leader..implies a tribe" (P5).**

The leader feeling responsible for developing the strategy for the future, an unknowable future as reflected in the words beyond themselves (Stacey, 2010).

" trying to find a path through this forest, focused on an objective beyond themselves" (P5)

and that the task was not easy personally

"going through personal pain" (P5)

as well as being responsible for encouraging followers to help accomplish the goal (Kotter, 2012) "and help other people through them". (P5)

13th December later – now restarted on responses on the rest of organisational culture and finding it difficult to get on track again after two days on something else. It is very slow because I have to try to find the most important words and phrases, log them at the time, transfer to a sheet to identify the lumper codes and then assign splitter codes. After that all codes must be entered in the code logbook and I must go back to the master coding document and enter the logbook codes!

Some additional splitter codes were added to those previously entered in the code logbook and 5 new ones established from additional culture questions. I had substantial difficulty in reducing these to a few words since the context would have been lost and hope it is possible to reduce them somewhat as other recoding proceeds.

Code 12 reflects the perceived importance of leadership for influencing a culture of innovation, although a later question on this may add to and/or modify splitter

codes. The lumper code "Thanks to the senior guy"(P2) reflects the theme but the first splitter code captures the person responsible "has to be addressed by top management" (P7). The influence of top management (Schein, 1985) is also inferred in seeking to create value rather than satisfying political motives by "not doing something for a political reason but because they have a business value" (P15) and the leadership allocating rare resources (Barney, 1991) whilst understanding the uncertainty of outcomes (Eisenhardt, 2002) characterises by P5 in “you've got a much longer journey through a lot more forest with much fewer resources and much less help”

The capabilities that resulted from the size of the organisation were referred to frequently as a fundamental reason for possessing an innovation culture. The lumper code for this is **"that's a lot to do with the size of the organization" (P1)** and splitter codes referring to the highly flexible approach possible because the team was small and could swop tasks from a vital administrative role such as applying for funding to working a long day in the laboratory.

“good at being flexible because we're still quite a small team”

“can swap to writing a grant one minute or they can be doing a 12-hour day in the lab next"

The perception of individuals in the small team that they were developing and managing the own business, inferred that start-up culture must be maintained (P1); small made decision making easy in contrast to growing in size when inertia started to slow learning considerably.

“wanted to keep this Startup Culture" ... everyone feels that they are responsible of their own mini company area" (P12).

"it's easy because it's small…decision making is easy" (P10)

“we are growing …. can see that we are transforming into much less movable object…...we have become rather slow and not so quick learning as we used to be" (P12).

Two remarks were made by P5 which emphasised the relative lack of speed and capacity to experiment associated with multinational companies aligning with Zaradis and Mousiolis (2014):

“multinational there's hard steps there, but zero to something ……..... they're very rarely focused on”

“a blind alley is explored in a way that I'm not sure it's that feasible to do with the pressure of a big team and big financing”

These remarks tend to match those of Tidd and Bessant (2018) that firms in the early business life cycle stages are more adept at innovation than more mature organisations.

The lumper code 14 **“team first; people first”** captured the culture of the people resources required for innovation and four initial splitter codes were also identified “It is quite tough to our people and we want to be sure that at the end, people we

hire are in the same cultures as ours and the same values" (P2) was emphasised in different ways by several participants, and seems to be contrary to the theoretical idea of diversity of mindset being necessary for innovation. This was not explained further so it is difficult to ascertain whether this merely referred to similar values and beliefs about the type and mode of working required for innovation. P10 implied that making errors was acceptable so long as team members learnt from them to improve performance

“error of this kind..... “Okay, no problem. We're going to redo this thing” (P10)

People first was also associated with sharing full information relating to firm’s progress and status with all team members (P10).

Success for these firms was based on acceptance that creating a new idea or product was challenging so that lumper code 15 is "**zero to something is the hard step**” (P3) a painful learning process that the team must endure. Therefore “hard work” was considered necessary attribute by P1,P2 and a major characteristic was the "system needs to be changed….so we need to invest” (P3), so that "finances limit you and the rules limit you…..that is what we have to learn in the company" (P13), to which P5 added that potential of personal risk, and P10 that the cost of errors needed to be understood and "if we redo it, you need also to improve something.” Hence, other hard steps included " trying to learn from all the difficulties and experiences” (P12) and realising that “when it becomes difficult, some people prefer their own interest…this is very disappointing” (P4). Organising these remarks from three similar questions but with a slightly different focus is interesting and demonstrates how variations of the same theme enable the researcher to capture connected themes that provide a most holistic perspective. Innovation as zero to something with personal and team hardship along the route, is perhaps a new theme emerging from this study or one that has not been much emphasised in the Med Tech sector.

The last of these main themes on organisational culture relates to a culture of acknowledging and managing uncertainty, in which theme of collaboration with other companies, which is the focus of this research, also emerges within the lumper code 16**“we always have alternatives”** (P8)

16a is “We always bear in mind that a contract that we have signed with a company, a third-party company, might end”

16b "a lot of collaboration" (P8)

16c "have to adapt to this different way of doing business…. nobody knows what the new normal is going to look like." (P6)

The uncertainty about the future was directed post Covid 19 pandemic (P3) but is also relevant to the companies’ regarding the new EU regulations

The term agile was expressed by several respondents:

"by agile, I mean that we can make very quick decisions" (P8)

"we’re all in this agile work" (P15)

“maintain agility” (P11)

The comments on always having alternatives and being agile somewhat reflect Aghina et al., (2015) and Rigby, Sutherland and Takeuch (2016) but provide good context for medical devices rather than generalist features.

14th December

I am realising that not controlling the interviews effectively enough means I have over 200 pages of notes to code and this is feeling highly excessive. Trying not to miss key information but with 5 more codes to do I must try to be more focused on the question and not pick up everything that is interesting to the topic and not in the question! It is a very tedious process!!

Innovation

started today 14/12

The first of the questions was to determine if innovation was the critical success factor for businesses and the responses were interesting because only P11 stated it as being number one; p2, p4,p14 rated it two and p15 third. Two participants stated “really high” but were non-committal and P8 suggested recruiting the right people was equally important. Sales (P4), team first (P2) and the new regulation were rated first (P13). Whilst not answering the question directly two interesting concepts of innovation emerged, qualifying innovation as being either incremental or disruptive and distinguishing innovation from creativity

“Incremental technology and not disruptive technology” (P2)

This was captured by P3 stating “not necessarily hard innovation” so it could be either of these.

The difference between creativity and commercialised ideas referred to as innovation was expressed by P12 and P8

"I would rank it high…but at the same time it needs to be implemented ... not just prototypes, demos and so on* (p12)

“innovation which can come from laboratories usually state-owned and it's very much research rather than development"; "We're rather much more on the development phase because we co-develop our solution with users"; "it's innovation that they can put money into"* (P8)

Innovation was further qualified as representative of ideas that added value:

”a real innovation …..appears to add value …. that's 100% essential” (P5).

Hence the lumper code 17 emerged as **“secret of our success is innovation”** (P3) and splitter codes:

17a “area I innovation ….appears to add value"

17b “incremental technology and not disruptive technology

17c “innovation ... from laboratories. very much research rather than development... we co-develop our solution with users...it's innovation "

These responses about the incremental and disruptive innovation align with existing theory (Christensen, Raynor & Anthony, 2003), and that innovation is the stage of product/service development that creative ideas are commercialised (Amabile et al., 1996; Hunter & Cushenbery 2011). Innovation is generally regarded as the source of competitive advantage and must add value (Tidd & Bessant, 2018) and possibly the most vital CSF for sustainable organisations, whilst this research suggests this is not always the case and people, sales and following regulations may take precedence.

Innovation in Medical Devices

The focus of the question was whether innovation in medical devices was different, but sub questions emerged of how it was different, which provided a range of responses. Thirteen responses were that innovation in this sector was different but P6 and P8 disagreed, P6 perceived that it was the means to higher profit margin through product differentiation. However, when P8 focused not on the product implementation by medical staff rather than the innovation, a difference from other sectors was considered present, the mindset of the user

"what needs to be very, very clear is that not only do you need to bring the product, which is in itself innovative, you also need to bring the mindset, you know, for the change to occur"

"maybe one of the differences I see with other markets, is getting people involved in innovation themselves and being able to change their practice"

The implication was that success or failure depended more on the user than the innovator.

Bringing this important aspect into the lumper codes is therefore quite challenging. The responses regarding medical devices innovation are represented the lumper code 18 **“bar is much higher”** because generally respondents felt it was more difficult to innovate in this sector owing to boundary conditions being referred to as “toxic” (P5), the difficulty of implementation of the innovation, which required change of mindset by users (P9, P8, P10) and medical device instruments being in contact with patients (P14. P15). These remarks reflect the definition of innovation and creative destruction in which new ways of doing old things are discover, making previous skills and mindsets redundant (Schumpeter, 1947). The implication of the human bar being higher was that firms needed to be more responsible (P10), subject to higher hurdles (P9). Regulations, restrictions and changes in medical registration (P12) were some other hurdles as was the tracking capacity of devices owing to data privacy issues (P12. P15). The regulation being referred to as

“that kind of brutal regulation make it impossible for small companies to really come up with new innovative products in a financeable way" (P13)

The range of boundary conditions that hindered innovation, “limiting innovation drastically” (P13), particularly disruptive innovation, were highly diverse; these made the industry rather “conservative” (p10) and software innovation by five years compared with other sectors (P12). An interesting comment from P2 was that Med-Tech companies were generally more associated with open innovation, as stated by Guerra Bretaña and Flórez-Rendón (2018) because it was too high risk to spend up to 4 years research and produce nothing; P5 also mentioned risk added that tolerability for failure was also much lower than in pharmaceuticals. According to P4 the constraints were increasing. However, when innovation was successful this sector it held potential for higher profits and quick time to market for new products (P7).

The responses are important to this research because they have externalised many of the fears and frustrations within senior management of medical devices companies, which cannot be easily expressed by quantitative research methods; they are therefore relatively rare example of the multiple emotional issues that the sector is currently experiencing. They add new insight to the huge gaps in knowledge about the effect of new regulations identified by Pelkmans and Renda (2014)

Several additional questions on innovation were posed to some or all the participants, the first being which person in the organisation was in charge of innovation: five responded that it was senior management team or specific members (P2,P7,P9,P11,P13,P15); P1,P5, P10 had sole responsibility and P4 and P6 share it with an engineer; P3 did no inhouse design; P14 customers and company; P8,P12 no answer. The implication of these responses is that innovation is the responsibility of senior managers alone or with other senior managers rather than a whole organisation decision; this tends confirm the theory that innovation is orchestrated by leadership (Stacey, 2010), but no evidence that it is optimised by whole firm involvement from these responses.

Seven participants were asked directly in their firms practised open innovation (p1,p3,P7,P8, p11, p12, p13) but only P1 and P13 currently did so, P13 describing partnerships and knowledge transfer (Chesbrough, Vanhaverbeke & West, 2006):

"with automotive-, with engineers developing automotive applications or aeronautic applications or in the watch industry".

"there is knowledge transfer between different applications in different fields".

Three participants were asked if they were involved in an innovation hub, only P1 confirmed; P7,P13 did not at this point of the interview at least. These responses tend to reinforce the lack of open innovation in these participant companies expressed previously; contrary to other industries (Arkhipova & Arkhipov, 2016).

There also was agreement about innovation being a structured process from the four participants who were directly asked another question about how innovation occurred in their company. This motivated another splitter code was added to

innovation lumper code 17 **secret of our success is innovation;** 17d structured with scarce resources and learning internal/externally

The details of structured innovation varied somewhat but one theme was scarce resources and being asked to demonstrate how value was added by investors for instance:

"It's very structured because we have very scarce resources" (P8)

"We are going to have investors who are going to ask us: where do you invest your money? What do you get from your money? "do you make some intellectual property out of it?" (P8)

Structure described by P10 was about the learning from the creative idea until the point of commercialisation

"A little bit of everything…..we plan...we build the base.....we test different possibilities.....then life brings new idea...we are learning some things that were never expected.....we are learning also that's something we expected.....So it's a lot of learning curve."

There was "beginners' luck" associated with the structure process (P11) but structure also involved learning but using a different resource pool:

"strong exchange with clinical specialists... constant monitoring of publications.....a very well-organized database of publications strong connections into the industry outside of medical device..... there is influence coming back to us"

Hence innovation was "not an accidental process, it is really by observing and researching what is happening in the field and outside of the field of medical devices"

Therefore, the structured process mirrors both the learning by experimenting to find a commercial solution (Hunter & Cushenbery, 2011; Jill, 2014) and open innovation (Chesbrough, 2006).

15th December

The **last of the direct questions on leadership for innovation and culture,** which really have little to add but must be scrutinised because these were focused on the participant's own company structure, culture and leadership. Trying to select words or phrases proving very difficult as there is so much noise in the responses, these participants do not answer the question but tell irrelevant stories many times. It is also becoming more difficult to apply splitter codes within those existing in the code book in some cases such as P5, P8, P10 in the organisational structure question. However, I am aware of trying not to develop too many new codes as there is still so much more content to analyse and some of these statements lie within the original coding themes. Hence coding is not always ideal of easy and many aspects are repeated at this stage.

The participants were asked about the experience they had of NPD models, and four of the five participants to whom the question was posed, stated that they had very little or no experience of them; P14 tried to explain that currently it had a partner that sold its product and required certain specification, but it was developing its own version to sell direct to the market. Hence P14 was exiting a collaborative relationship and employing NPD to do so, rather than the reverse and often the reason for coopetition according to Bouncken et al., 2018).

There were three questions on internal factors in participants' organisations that led to successful innovation or hindered it; the first two were based around organisational structure and culture, although leadership also became a large element of those responses, which was interesting as it reinforces theory of leaders being responsible for culture and change (Schein, 1983; Kotter, 2012). The third question was about leadership for innovation and generally triangulated the features of leaders and leadership for innovation in early questions so that codes could be assigned to these ideas.

Q: From your experience, what internal factors are most important for the success of innovation and specifically, to what extent, do you think the organisational structure of your company support or hinders innovation

Q: I'm interested if you believe that the organisational structure, as you have described it earlier, is supporting or hindering your innovation

The small size of the participant organisation and a flat structure, were both repeated as providing an excellent context for innovation (P3, P5,P8,P10,P12,P13,P14,P15) and P11 reemphasised that innovation was more likely with fewer organisational layers as well as empowering people, linking leadership culture (Kotter, 2012; Stacey,2010) which increased their commitment to it (Kotter, 2012).

However, P1 suggested that too many founders could destroy innovation and that choosing co-founders with a similar work ethic was important to support innovation, reflecting the lumper code 14 of people and team first

"a good set of cofounders to start"; " you don't need too many cofounders; you need like three maximum"; "too many opinions can kill it" (P1)

" you need to have people ..equally as efficient ...the same sort of work ethic as you" (P1)

The emphasis from P5 was that appropriate organisational structure and culture were vital to facilitate innovation, strong agreement with theory (Dalton et al.,1980). Contrary to theory, P9 suggest it was not that important to that organisation.

All responses confirmed that leadership was important to supporting innovation in their organisations (Hunter & Cushenbery, 2011), a variety of reasons were expressed for instance: everyone needed understand why they were being asked to do certain tasks and why there were changes in patterns (P1,P8); leaders needed to encourage constant two-way dialogue(P1) and facilitate equal participation in innovation by all employees (P3,P7,P9). The comment by P7 that

innovation “needs very agile management and leadership to “give room to the employees for creativity ideas in order to drive innovation " created a new splitter code 12d of lumper code “**thanks to the senior guy”,** where leadership was not necessarily specifically restricted to any one person or group. The tribe concept of leadership, lumper code 11 also re-emerged regarding leadership openness, but this should be restricted (P8)

"I think, well, innovation can backfire if you don't keep it within the walls of the companies. So, it needs to be secretive in some way."

This is a particularly important observation in the context of coopetition which this thesis is most interested in and reinforces existing empirical research (McCarthy et al., 2018).

These extracts demonstrate that it was important to scrutinise these later direct questions on leadership for innovation and culture, which really have little to add because a few new perspectives emerged. However, trying to select words or phrases that were relevant proved very difficult because there was so much noise in the responses, these participants do not answer the question but tell irrelevant stories many times.

Reflective note

After spending half the day coding the notes from the master text, providing them with a lumper/splitter code, I continued onto the last sets of questions on coopetition. This is also going to be very lengthy and maybe I am not doing this appropriately. I look in Saldana (2016) again about the purpose of these critical memos. Whilst I understand the in vivo codes, I am also aware of needing to expand beyond them for the findings and discussions chapter, so that vital information is expressed in the thesis to increase current knowledge of how the medical device companies are approaching the issue of the new regulations, reflecting their beliefs and uncertainties. I believe this cannot be done from the two cycles of coding to get to the new theory, merely doing that would not capture the live circumstance, the in-depth perceptions, actions and anxieties. Hence, I am taking a dual approach during this coding cycle of relating the fuller remarks to the existing theory wherever possible and in some cases qualifying it.

Q To what extent does the culture in your company support or hinder innovation?

P1 9e"I think it supports innovation as in the fact that the people who work on the innovation are happier." (Referring to leadership as being responsible for culture”

13a "they are more likely to work harder when we need them to work harder because they know we've got that flexibility" 13a"makes better innovation .... some weeks where we have to work incredibly hard...weeks where we don’t, and we let them have their own time and manage their schedule a bit better"

P3. 14 " I believe in informing people all the time" 14"you've got to realize the importance of what they are doing in the warehouse, ultimately can have a devastating effect with a rep and a surgeon .."

P4 14“is good if you don't have more than five people reporting to you” 7b “I think it's important to communicate to anyone in the company when we do something very different”

P7 "flat hierarchical structure... direct access to the CEO…...to the board. ,,,,4”running think tanks”, and a…. 12d “agile leadership, ... open leadership..we were more successful then."

P12 "open discussion, ... new ideas….the more discussion ... more likely ....some innovation, ….Rather than ….less discussion and then less ideas"

P13 company with "chaotic culture" (P13) "bad for innovation. Why? You spend a lot of money and time if you do not follow certain requirements which are helpful for the company". 17d"certain rules and regulations in a chaotic system would help to figure out if you are on the right way, if it is feasible, if it is financeable" "Learn from mistakes, that is the point. If you repeat mistakes over and over and expect the same result, that is a bad idea"

16th December

I continue with the coopetition section, identifying key words and phrases until that is completed now. I can then identify appropriate lumper and associated splitter codes.

17th December

I finally finished putting all the key remarks in the original transcripts into the coding master but now have to find the lumper and splitter codes for all those final questions and write the reflections in this diary before the first code run, in vivo coding is complete, and we can continue with the first cycle. This proving to be very onerous but hope to complete by end of 19 December and go on to next code!

New EU Regulations

The first question in the interviews, which related directly to the two new EU directives was their effect on innovation in the perception of the participants. The lumper code was "**raising the barrier of entry**" (P12), which captures a range of diverse inferences for the EU medical devices companies and reflects studies such as Maresova et al. (2020). The most often cited effect, which is embraced by the lumper code is that small companies will find it much more difficult to

continue to participate in the sector, many will not survive (P1,P4,P10,P11,P12). Several reasons were associated with this concern”

"getting through every regulatory hurdle and not running out of cash" (P1)

“no resources for really new developments … companies do not have enough resources to pursue new projects” (P9)

“It's going to destroy innovation, to avoid innovation to go in the market. ... At least, in orthopaedics. It may be different in other fields, but in orthopaedics ...because it's very difficult to raise money in orthopaedics.” (P4)

“it cuts off innovation, maybe not in total but at a very certain level " (P9)

The last comment reiterated by P7 who proposed that new regulation would have a “fundamental impact on the innovation pipeline. The concerns about resources confirm earlier studies (Ikram, 2015). However, P12 felt that the quantity of innovation might not be decreased but rather redirected, so that bigger organisations with greater market power would be the main sources of innovation,

Three participants, P7,P11,P14, proposed that the value of innovation would be enhanced as it would have both a higher potential for commercialisation and only good quality instruments would enter the market; reinforcing the findings of Mattke, Liu and Orr (2016). These indicated splitter code 19a “more valuable innovation” (P11).

"there's also an upside.... I believe that the new European medical device regulation will lead to longer product life cycles, ... products can also be cashed out longer.... definitely beneficial especially for the small and medium size companies." (P7)

There was considerable evidence that firms would need to “rethink how you work”, splitter code 19b (P11); comprising aspects such as partnerships, changing the length of the small company innovation cycle by developing the idea to a shorter extent and then selling it on, and focusing on the regulatory aspects for some products.

"our only option, really is to partner with one of the key manufacturers" (P1)

"we probably see a lot of new start-up company selling their technology before clinical trial to these big companies " (P2)

"Smaller companies will need to put heavier emphasis on solid clinical dossier for class three and implantable products. It will also require extra time and investment to put those dossiers together" (P7)

The most innovative R&D projects would also be cancelled according to P9 and focus would move to ensuring that the existing product portfolio would be suitable for aligning with the new regulation (Maresova et al., 2020). The cost of entering the sector would increase as a consequence of the tighter regulation (P10), inferring that potential new entrants would consider their options in new ways; one option was to examine the options, was the firm able to continue alone or did

it need to consider searching for funding (P11). These challenges reflect the findings of Gast et al. (2015).

In addition, companies would need to rethink how to compete with advantages the US market might have rather than trading in the EU.

"It will prioritize more the US market versus the European market, while historically it has been the opposite" (P11)

These remarks illustrate the complexity has been invoked by the new directives, multiple potential issues and solutions and considerably increased bureaucracy (Guerra Bretaña & Flórez-Rendón, 2018).

The participants were asked specifically whether their companies had the financial and knowledge resources to implement the new EU regulations, the responses were mixed as indicated by direct quotations. Some were finding the required resources difficult to generate but were rethinking their position (P1,P2,P9) whilst others had resources or intended to divert resources to ensuring compliance (P3,P8, P10,P11,P12,P4) but some did not (P4,P6). In terms of financial resources, for instance:

"Definitely not" we have to face the requirement to perform clinical studies ….and difficult to set up and to organize and in principle, finance that….we look for a collaborator who is willing to get a product into the market " (P9)

"We will target mainly US, South America or the countries where you don't need to have CE…for the new one, we don't plan to get a CE mark… we don't want to get a CE mark just because at the end..... as you know, the price is quite low and the expense or the budget to get a CE mark or in one year will be so high" (P2)

In this case, the company would exit EU markets and trade in other export markets only and the implied intention was that all new innovations would also be excluded from EU markets.

In contrast

"We have the money ... ..we will return level and come off ... .with all the restrictions that the new medical directives have placed upon us." (P3)

"Yes, because for us, it's not a big difference comparing to the previous registration procedure" (P10)

The majority of the group recognised that need to obtain knowledge regarding the regulation by seeking guidance (P1,P3,P7,P9,P10,P13) or appointing internal regulatory responsibility to employee(s) (P2,P7); this could also be a high cost factor

"we certainly have the knowledge after having a consultant ... charging us £1000 day" (P3)

"Definitely, yes…we have our own medical and regulatory department…we are also working with external consultants" (p7)

However, P4 made a conscious decision to delay full implementation:

“we have the knowledge, but we did not implement yet all the requirements because ... strategically, we don't want to go there".

A concern expressed by P10 was the additional time the regulatory procedures added to the product to market timescale especially

“there are very few notified bodies" (Jeandupeux**,** 2019**;** Peter et al., 2020).

The comments indicate very different financial readiness/capacity also be a consequence of specialism, size and business lifecycle. The diverse contexts of these companies in respect to DMR is evolving with approximately half changing their previous approaches to ensure they can comply but other finding the financial challenges too great. It is evident that firms regard possessing the required regulatory knowledge was of high importance, with P13 suggesting it took precedence over engineering knowledge or creativity.

The new regulations were regarded as assisting the companies to innovate by although P1,P2,P9,P11,P12, who expressed some advantages. However, responses throughout the entire interviews did not align with the EU proposition that innovation will be enhanced (Jeandupeux**,** 2019**;** Peter et al., 2020).

It was evident that medical device companies were rethinking their approach as a consequence of the impending implementation of the legislations, for instance P2 stated that the regulatory authorities engaged in open dialogue regarding changes.

There were also being proactive in identifying positive outcomes on a personal business basis:

“ as a small company, maybe are more able to get innovative products in the market or to maintain our innovative products in the market better than the big players" (P9)

"it will allow you to push through more valued innovation" (P11)

"maybe become more ... outcome-based innovation-driven than just bringing innovation with some incremental, you know, feature" (P11)

1" it will force people to prioritize"

A particularly positive response from P2 was that the regulatory requirements would reduce external competitors from trading in EU markets

“If you have the CE mark, it is because you have the clinical trial and....evidence-based...to increase a bit the barrier at the entrance…. for competitor wanting to target Europe, at the end, the effort for that will be quite huge to compete against us"

Most responses to this question were long but did not give any insight into this question!

Coopetition

Q: So, are you familiar with that term coopetition and the concept of competitors working together for a specific purpose? do you think that coopetition, so working with a competitor could help to continue delivering innovation given the challenges the new regulation spring?

The majority had an understanding of the term coopetition even if they had no personal experience and whilst working in such an arrangement had its advantages there were acknowledged compromises and pitfalls. Hence the lumper code 20 emerged as **"ecosystems for innovation**" (P7) which provided a framework for a range of interpretations of the terms. The splitter codes that fulfilled a similar purpose but represented specific aspects of the ecosystem were: "deliver value" (P7); "resource sharing and compromise" (P1) which embraced both human and physical asset exchange and behaviours; legal side kills the innovation (P10).

Coopetition was described as collaborating with the competition (P1,P2), which was likely to be a much bigger firm with more resources (P1) and for a specific project (P2); the coopetition might include

"suppliers, customers, and firms producing complimentary or related products".(P7)

However, P4 identified the challenge of finding a suitable partner, which it has not been able to achieve so far because no one wanted to release control of own business.

A major purpose of coopetition was help small and medium sized companies to deliver value in the complex medical devices market, which was characterised by high consolidation and regulation, according to P7, and where a single stakeholder would find it difficult to innovate in all the required aspects (P1). Hence, P10 suggested coopetition was an enforced collaboration.

The need for resources was accompanied by the requirement to compromise to obtain them (P10) but this could be disadvantageous for small companies who might ultimately experience much less proportionately from the arrangement than large company partner (P10).

The particular resource need for Intellectual Property (IP) or associated licences might be a limiting factor (P11) as would fear of the competitor poaching talented employees (P15) so that if companies were unable to compromise and agree a contract, the legal side "kills the innovation" (P11). Small companies would therefore be cautious about how much they were willing to compromise to form a coopetitive relationship (P12,P13,p15)

Whilst many of these perspectives, may have been derived from personal experience, the participants were asked to relate actual experiences, which provide some additional insight into perceptions of coopetition as a solution to the complex challenges of the new regulation, the main focus of this research.

A few of the participant firms were able to provide examples of when coopetition has been successful, for instance P7 had employed the model many times. Its experience had been that by providing its partner with its major product had

facilitated its enrichment and accelerated the CE certification process. P7 also intended to find a coopetitive R^D arrangement to enhance its innovation.

Partner behaviours in both firms were the key aspect of successful coopetition in the perspective of P10, who had participated in several arrangement in the past five years. The partners produce with the same products in the same market. Different skills sets had been the basis of success for P13, whose company knew little about cutting and relied on the partner, whilst the companies were able to share but was able to share the costs of packaging, biological testing, sterilization and cleaning which was extremely expensive. Similarly, P14 shared expertise, some manufacturing activities were beyond its competence, but the arrangement worked by mutual transparency of design and product information.

A unique approach in this research was revealed by P2, which had a German partner, a direct competitor producing the same level 1 product; their development partnership worked because ultimately, they would sell the product in different markets; P2 outside of Europe and without the CE mark.

Although perceiving coopetition as a positive strategy to overcome the innovation challenges, P1 found that the IP issue was the most difficult aspect of the agreement because of the restrictions it would place on future use of this valuable asset, such that ultimately inability to reach legal agreement prevented the coopetition proceeding. According to P6 exchange of technical information required to adapt to the new regulation in a coopetitive arrangement could be protected be protected by a contract relevant to the whole process.

The alternative to coopetition was to maintain independence by identifying a funding source so that it could meet the new regulatory requirement (P1).

Although P5 has no experience of coopetition to recount, he felt the most companies would not agree to work in collaboration with a competitor because of their own “ruthless competitiveness”. They were:

"anti-collaborative, especially with competitors" .(P5)

If they were to collaborate with a competitor, it would be at very early-stage work only and on condition they could compete in the same market afterwards (P5).

A similar restriction in agreeing any arrangement was promoted by P4, who suggested the deadlock might be overcome by limiting its input assets to manufacturing and the quality system but retaining design change, improvement, and critical data; this may also account for the inability to find a suitable partner.

The mutual exchange of resources, even if limited could form the basis of successful coopetition according to P9, which had assets such as an IP package with several patent families, R&D packages that would be willing to share with the appropriate partner who was interested in investing in development. The firm would retain its status as the contract developer, and the legal contract manufacturer and the legal manufacturer. The resulting medical device would be exclusively available to the partner who would be responsible for its sales and distribution, whilst P9 received the transfer price. Whilst these intentions are

useful in principle, since no coopetition has yet occurred, it is not possible to forecast how well this would work,

Note to self: Reflection here and in other parts needs some different approaches, for instance some comparison table to make it easier to identify different strategies

18th December

The initial stage today is to in vivo codes the notes taken from the master document and then to reflect on them here.

Reflection on the final four questions regarding coopetition, which revisited what aspect made is successful or unsuccessful, the elements of the business operations that they would not share and the benefits of coopetition. A new splitter code 20d for lumper code 20, arose from a remark by P8.

Incremental and radical innovation had characterised coopetition between participants and their partners, p2 and P9 had experienced both whereas P7 and P14 had coopetitve partnership for incremental innovate projects.

There was some repetition of the remarks made in earlier questions, so that this reflection focuses on comparison of the main success and failure factors for coopetition and which aspects of the business, participants would not share in a coopetition with the rationale for that decision; the summary is provided in table X.

Table X: Perspectives on Competition

Success factors	Failure Factors	It's a secret
• Specialist equipment or knowledge possessed by partner (P1,P2,P9P12) • Potential to work with different partners in diverse business fields (P9) ➢ companies not in the same market field, which have expertise for instance in machine learning (P8)	• Skills of partner were not as described (P10) ➢ Programming issue (P10) ➢ Different working speed and priorities regarding regulatory approval (P12) ➢ Refusal to share IPR so no working product evolved (P12)	• Work with a competitor limited to early stage and each partner then further develops and competes separately (P5) • There can only be one legal manufacturer, and this has to be defined. (P9) • Never share know-how (P11) • Never share software/source codes as it cannot be patented in EU (P12)
• Added value for both partners (P1P9P6) b) Examples ➢ manufacturing ➢ partner wants to – substitute a new product in existing portfolio) ➢ product validation (P6) ➢ sharing cost (P6) ➢ sharing regulator (P6) ➢ shared technology and IP (P9) ➢ will to share benefits (P6P13P14)	• Partner without honest intent (P8**)** ➢ Access to employee talent (P8) ➢ Documentation ➢ Software c)	• Never work with a competitor in any aspect involving company's clients (P8)

Success factors	Failure Factors	It's a secret
➢ share information (P6) particularly preliminary scientific results (P6)		
• Collaboration in the early stages (P1,) of R&D projects (P7) • Collaboration at the same level, defined short- and medium-term objectives (P6P7) • Compromise that accepts some processes take longer than expected (P9)	• Collaboration in later stages (P7) ➢ Lose important information/ resources for success(P7) • Partner wanted to own product (P12) • Misunderstanding, misinterpretations (P13)	• When the partner wants to invest in company (P14)

Success factors	Failure Factors	It's a secret
• Complete transparency in all matters (P9P1P11P14) ➢ Expectations of both parties recorded (P11P15) ➢ Legal agreement quickly made (P1P8) ➢ Simple contract as every potential issue cannot be determined (P6)	• Lack of transparency ➢ Legal agreement takes too long (P1) ➢ No legal agreement (P2), partner makes new demands as success is identified (P2)	• When the potential partner does not agree to share everything (P15)

➢ Mutual trust (P1, P10 P13) ➢ Communication (P10)	➢ Partner gains access to technical product documentation -lack of legal contract (P7) ➢ Partner does not adhere to legal contract (P15) • Lack of trust everything must be in contract (P15)	
• Size of partner (P11) ➢ Similar size (P11P13) same pressure, regulatory wise, timewise, financially *P13) ➢ Small size trust not legal contracts		• No coopetition with bigger companies (P11)
• Co-design means sharing IP (P8)		
• No major changes to the company needed (P1P2P7P10P13) ➢ Outsource regulatory affairs but not distribution (P7) ➢ Must protect partner's IP even more than own (P10) ➢ Train partner employees, insurance adjustments (P13)		
• Impact on IP ➢ None (P1) ➢ Based IP strategy mainly on partner IPs all managed legally (P2,P10)		• Use of our patents (P13,P1,P2,P7) ➢ Including capacity for someone else to use it (P1)

➢ Liaison with independent consultant eliminated any IP effects (P7) ➢ Contract specified use of own IP (P9)		➢ Patents and technical files (P7)

Amongst the different success factors for coopetition, a very dominant one and very much stressed by the participants is ‘trust’. The companies must handle uncertainty and fear with a new business context and work with a partner whose motives may not be sincere, whilst adopting a collegial approach which enables a collective shared responsibility.

Whilst stressing the need for trust, most participants in this research describe a more conditional type of trust instead of just believing the other party, linked to legal agreements, balance of power and mutual guarantees. This description of trust adds new theory since literature so far does specify the requisite type of trust necessary in a coopetitive relationship.

19th December

Commenced with writing notes on the Coding Categories and Notes file about my reactions on completing the In Vivo coding and how this would influence continuing with the other coding runs. The In Vivo coding has given a broad understanding of the participants and their specific contexts and allowed me to gain a good understanding of the data and what it reveals about coopetition, as well as beginning the discussion of the findings and identifying the major outcomes.

The final In Vivo lumper and splitter codes are transferred to the code book.

For process coding the initial interview questions are no longer so relevant so that the interview questions relating directly to the main research question and the 11 sub questions are the focus of the rest of the coding methods.

Hence the process coding began with the questions on innovation and moved onto EU regulation as the first stage, since the initial question in the latter section was about innovation and EU regulation. The notes from In Vivo questions were copied onto a new file for process coding so that additions/subtractions could be made as needed to identify doing.

Innovation

The analysis of processes is documented in the coding master file and appendix XX where the sequences are documented.

Innovation generally

Innovation in relation to EU regulations

Although the first question about innovation in the group of questions relating to the new ER directives asked participants the ranking of innovation as one of the most critical success factors for their company most did not answer the question directly instead providing instead a description of the innovation process relating to it. This produced a variety of step wise processes, which revealed different experiences and tensions. The steps could be summarised as definite patterns of between five and seven steps of: first step; second step, turning point; continue; don't continue, outcome. The participants' starting points varied from having a team to having a project idea, a new material or clients, to identifying a high priority or world class product need, to realisation that they were in a competitive market. These remarks reflect the breadth of interests of the companies involved in the medical devices industry. The second stages were equally varying from planning to launch or to create a product and investing in it, to adding value, making sure it is relevant in once case as a response to the new regulations, following the rules and having experiences from other industries and

The decision to continue or to discontinue usually occurs soon after this stage, which could be considered the turning point. Motivations to continue included exciting people about the product, knowing it will make money, attracting funding, implementing the prototype/idea, doing an investigation, the team's effort. Reasons to discontinue varied from not knowing/predicting if innovation has succeeded, reaching the prototype stage only. Hence examples of key outcomes getting funding, returning high profit on investment, competitive advantage, obtaining the required clinical data and fulfilling the MDR. The response reflects the pride and satisfaction when desired outcomes are reached but the huge uncertainty and tensions from innovative intention to success are apparent.

Q Do you think that innovation in medical technologies is different from innovation in other industries and if yes, why so

The responses to this question affirm that mainly processes are different in medical devices than in most industries with some comparisons with pharmaceuticals and the required processes mostly have consequences that inhibit innovation. Several themes emerge to explain the difference: **safety and security issues** - working on **devices in contact with patients** means being more responsible but also issues with data collection policies; **inertia to change by users**, medical staff and patients means that the industry is conservative and **slows innovation** and change; innovation in medical devices is **too fast for the market** mindset, disruptive innovation (Christensen, Raynor & Anthony, 2003); **legal issues including regulation and notified body processes** *slow* time to market and **prevent** some **very good innovations reaching the market; toleration of failure** is much higher and riskier, which **reduces motivation to innovate; market structure is changing,** consolidation **meaning higher profits; higher costs limit** small companies innovating.

Meaning of Innovation is taken from the responses from three questions on innovation in the interviews, which were not asked to all individuals, and combined to one process here, owing to the interrelationship. The process coding technique revealed details of innovation in the industry not specifically identified

by the in vivo codes, and in two cases P8 and P3 two different perspectives. The initiation of the innovation owing to interaction with others is emphasised by P3, P13 and P15 direct exchange of information initiating and open innovation approach.

Innovation in medical devices by transferring knowledge from other sectors is emphasised by P3 and P13 and is an interesting prospect for other manufacturers, therefore a valuable finding. This is not mentioned in the empirical studies appraised in this thesis and warrants more investigation in further research to identify the areas of shared interest exactly, and how and where the practices could be applied throughout the sector.

In contrast P6 gains ideas from the responses of users to sustainable practices “saving the planet” which drives the innovation in single use instruments made from plastic waste, saving users time cleaning instruments whilst providing company with a new source of highly profitable and less effort because the regulation class is lowered, and the certification made easier. These are very new important findings that may have implications for many medical device manufacturers.

Choosing innovation projects very carefully is a strategy adopted by P8 owing to possessing scarce resources and being asked by investors to justify how the company uses funds. Being able to generate intellectual property appears to be a vital decision as to whether the project proceeds or not. It also seems that P8 use closed innovation but gain information on algorithms from medical institutions, in other words access outside knowledge without needing to form formal partnerships. This tactic may also be useful in other contexts where small companies attempt to avoid risks of information sharing.

In contrast P10 and P15 appear to adopt a more closed innovation approach than P10, which are very reliant on internal information exchange and the classic innovation approach of idea generation leading to prototype, experimenting, gaining new ideas and modified approaches to old ideas, and testing (Hunter & Cushenbery, 2011; Jill,2004)

The internal factors, particularly organisational structure and culture that supported and hindered innovation were also discussed, and the process coding examined these two aspects from the responses that were generated in the interviews.

The flat organisational structure generates a process of innovation comprising fast communication, empowerment, generation of multiple ideas that can be applied to engender employee commitment beneficial outcomes (P10,P11,P12,p14,P15). However, P14 focused on customer ideas as the means to initiate this process suggesting similarities in open and closed innovation processes.

In terms of organisational structure P1 perceived three factors: needing a limited number of cofounders, so as not to kill innovation and having a similar work ethic supported innovation. Similarly having the Board to refer to prevented innovation

being misdirected, initiated thinking about the product that should be innovated and about how to get it into the market. However, Board members could hinder innovation if they did not understand the research process and tried to prevent the progress of innovative product,

The process of innovation related to company structure described by P3 is useful to this thesis in reflecting the huge uncertainty associated with it. In this company advisers were retained and initiated the process of innovation, either by observation of something inside or outside the company that needed changing or identifying new products externally. This would be followed by the advisers discussing the matter with founder who made the decision, based agreement there was a need for it but, in order to get consumers to buy it, the final stage was to ensure the message reached the potential customers. In this case the outside-in model of open innovation (Gassmann & Enkel, 2004) appears to be employed and deliberately controlled by the owners with individuals they know and trust. This has not been mentioned in the empirical part of the thesis neither did it emerge in the in vivo coding process.

In contrast, the requirement for successful innovation in P5, which seems to prefer closed innovation, was a process of first creating a culture and structure to attract innovative employees, cultivating and moving them around the company to prevent silo thinking that would be a hindrance to developing innovative solutions. Instead ensuring that employees integrated generated their ability to try new things.

In P9's case, innovation could also be hindered by the internal structure but in this case it was the internal structure of the collaborating company, which was large and hierarchical. Whereas P9 made use of the innovative process to produce innovative products, this could be hindered by waiting for the partner to complete the process of getting the project approved by a series of managers in that company. The issue was that no one understood what caused the delay, a phenomenon that did not happen in P9. The inference is that collaborative partners' organisational structure and culture is an additional potential source of uncertainty for medical device companies to manage, a phenomenon not so apparent from the previous coding run.

These examples are interesting since they reveal diverse innovation processes, multiple scenarios of open innovation, closed innovation, characterised by structural and/or cultural support or prevention, and collaborative open innovation hindered by partner organisational structure and culture. Risk is also implied by the uncertainty of these contexts.

27th December 2020

After a few days without continuing any coding work it was difficult to decide exactly where I was starting but the extensive cross-referenced notes were of immense support with this. Although coopetition seemed to be the starting point,

leadership for innovation and the EU regulations had not been process coded so these needed to be checked first for key processes that many have been missed.

The specific question on leadership for innovation did not generate very informative responses. The main themes were providing information to create awareness of objectives throughout the company and ensuring it stayed with the company to prevent ideas being implemented by others; appropriate leadership style and structure so that both innovation, operations, and open communication were optimised, and focus was on delivering products aligned with client needs which might also be revealed by observing products in complementary sectors. These themes align with indirect leadership for innovation, creating the climate, and direct actions, such as leadership vision and strategy which combine to develop individual and team creativity leading to organisational innovation (Hunter & Cushenberry, 2011).

Explaining the importance of the entire process and the end goal including why specific partners had been chosen (P1P6P8) because failing to be open caused employee anxiety (P1) rather than getting the best out of people (P9) but keeping information within the company was vital to ensure that sharing did not backfire on company (P8) inferring the danger of the idea being implemented by competitors.

The type of leader, for instance P2 suggested at least two leaders were important one for leading innovation and the other to head operations and both reporting directly to CEO. In addition open communication between the teams was vital to developing a product that clients needed (P2,P3,P9,P14). Leaders should also encourage (P9,P3) anyone who observes a good idea in a related part of the sector to discuss it with management and this had produced new products in recent years (P3); in other words, very agile leadership and management was vital to drive innovation (P5) free exchange of ideas without restriction (P13) and respect for all ideas as there is no bad idea (P13). The importance of focusing on objectives and not spending too long discussing ideas was important to P4. These remarks capture the importance of exchanging ideas emphasised by Stacey (1996) but hardly reflect any complexity of the process or conflicting views and questioning of ideas expressed that might improve the final innovative output (Stacey, 1996). The inappropriate leadership for innovation was highlighted by P12 as strict formal management “army style managers” that suppressed innovative ideas; this aligns with too much structure being damaging to innovation (Auletta, 2009).

Therefore, in these companies, the range of leadership qualities expressed is very limited and may be a factor that hinders optimising the innovation that could be accomplished.

Integrating the idea of process codes to gain insight into the ideas of participants about new regulations and innovation appears quite difficult so that it is likely that the process codes against the group of questions may be reflected on as a group, the information the group responses identify rather than question by question. This will not emerge as a valuable or not so valuable approach until after the

coding is complete. I anticipate that process coding many responses will be difficult or inappropriate so there will be significant gaps in P1 to P15. However, responses should indicate if there are perceptions of critical processes involved that will support/limit adoption of the legislation (**SQ1).**

Impact on Innovation

The reflections from this set of codes are that a unique and critical factor was associated with the new regulations by P1P9, namely the cost of implementing them, which would prevent commercialisation owing to lack of funds, so that the process was completed by partnering with a major manufacturer as the sole option for P1 also selected by P9 the ensure commercialisation. This is also inferring that for P1 at least collaboration will be vital in the EU new medical device contact. The change represent a new strategic direction and new business model, and a similar response is also cited byP6,P7,P9, for a number of reasons. A range of new processes occurring within firms evolved

Strategic change in the form of new business models, product portfolios, distribution markets and process are also proposed as critical success factor responses to the new EU regulations. Some big companies were likely to abandon new innovation in favour of ensuring that their current products were prepared to meet the new market regulation (P2), financial and other resources needing to be focused on accomplishing that objective (P2,P6,P9); rationalisation of product portfolios also being cited by P6 and focus on the most profitable items by big companies at the expense of new innovation (P9). Generally, innovation would slow and be more valuable innovation (P11). In P2's case its distribution market would be outside Europe in order to avoid obtaining CE certification and optimise financial resources, and P11 proposed that some EU based companies would focus on the US rather than the EU market.

A decline in market participation by 30% to 40% of small companies as forecast by P6 whilst the other changes in business models and markets would mean less competition and therefore increase the value of the technological abilities of companies remaining in the market (P6). Since it was unlikely that consumer demand for products or their prices would decline (P6), the result of the process would be longer product lifecycle and cash returns (P7,P6) particularly as distributors would interpret the CE mark as representing high quality.

The whole post creative phase process would change, especially for smaller companies, who would need to devote more time and financial investment to the clinical dossier required to gain the CE mark, which would need to be more user friendly and acceptance of it made more difficult because the remaining notified bodies will be more competent in the future. The process would also take longer with the impact that the period of time that patient would wait for the product would be extended (P7). The requirement to perform clinical studies that were difficult to initiate and to finance motivated P9 to change business model to collaborative practice, whereas P10P11 invested heavily internally, P10 with a dedicated employee experienced in ISO standards and P11 in its clinical department, which would review all its products prior to the deadline with the purpose of obtaining

competitive advantage; in house training programme and seminars were the solution for P9, a tactic to be able work effectively with the notified bodies. The acquisition of knowledge to gain CE was acquired by creating a new internal role by P2, and also to be prepared for the implementation of the regulations well in advance

These findings demonstrate the application of diverse solutions by participant companies all representing strategic change and implementation of it by the application of new business models (Casadesus-Masanell, R., & Ricart, J. (2010). with two participants stressing the vital need for collaboration with competitors, which is of particular value to this research. The number of responses to these questions was limited so that the degree of financial and knowledge acquisition that companies anticipated necessary in not fully evident and, consequently, an accurate indication of the pressure for coopetition as a response to the challenges of implementing the legislation successfully.

Coopetition Process Coding

Revision of process coding for my focus tomorrow

- *Actual and conceptual doing*
- *Conflicts for the participants*
- *What evoked, slowed, changed, accelerated or stopped the action from evolving*
- *After completing these the Analytical Memos record what I realised as a result of this coding: the sequences, conflicts, tensions etc.*

Process coding very slow today 28 December as finding the actions in so much irrelevant conversation is difficult again reflecting how poorly I have constructed the questions and too many sub questions. Also, whilst trying to follow Saldana (2016) about using a few words for each action, this becomes difficult in the context on the thesis and having to explain complex operations with technical subject matter when we get to writing up. Hence the process coding is rather more very short extracts, from which I can later pick out key contexts/outcomes to discuss.

I finished the process coding of the rest of the questions regarding coopetition in which I search for conceptual and actual processes, there was a lot of overlap and I tried to identify the major conflicts and what impacted on the speed of the action that evolved in each case.

In the first specific question on coopetition, interviewees were asked if they had heard of coopetition, a few provided their understanding of coopetition be describing it as a process. The reasons for it were expressed by P7 as resulting from changing market forces:

“very consolidating and highly regulated market”

Which had encouraged strategic alliances with the rational for delivering higher value-added propositions and innovative solutions so as to be able to gain

competitive advantage of the big companies. The inference was, therefore, speed that could be accomplished by smaller companies initiating collaboration

In contrast P8 P13 P14 described the concept in relation to the need to share knowledge and resources including IP to innovate, as well as steps in the manufacturing process, on a contractual basis in an affordable manner, in other words a micro rather than macro sense of the term; P14 added the macro aspect of keeping market opportunities open. Capacity for the coopetition to allow companies to grow together was added by P14.

Hence all of these processes have a similar structure: a context is provided; action(s) to taken, a rationale for the action described and the desired outcome from coopetiton, which was perceived as being achieved more quickly by small companies than their large competitors, size was a factor.

When participants were asked to relate their actual experience of coopetition or how they envisaged it might happen, more detail of tensions surrounding it and how specific factors affected the speed of outcomes. Having analysed each comment separately as a process, as shown in the code book, several dilemmas occurred in the process, usually concerned with IP rights, P1P2, or other legal rights P1

The consequence of a partner wanting the IP rights eliminated the possibility of a coopetitive relationship for P1, unless it could be agreed in legal terms that it did not insist on those rights, P2.

Another dilemma was that the partner would try to acquire the company, P3 especially for an SME, P3 or had the motive of identifying know-how P3. It the potential partner was a direct competitor, there was concern that there might not be enough market demand for both partners to sell sufficient volumes of the product to make coopetition worthwhile financially, P3. In addition, P8 would be cautious of any partner wishing to be publicly endorsed by it as a result of a successful coopetition that had been proven by customer feedback, in other words its reputation could be damaged by the coopetition,

Hence legal agreement was either agreed early, P1P6 or the firm decided to remain independent of any coopetitve arrangement P1

The type of reasons for adopting coopetition were to gain resources such as R&D partnership contracts, P1P9, other expertise P1P2P7P13P14, for instance a stage in the process that could not be accomplished in-house, P2P7 and/or partner did not wish to develop this step, P2, cash P1P9P13, investment in the development stage P9. To be able to comply with new regulations was a motivator for coopetition, P6P7P4 and to provide these to their customer< P14, or for the partner to gain exclusive rights to the product, P8.

Partners were usually identified by being previous customers, P2, long term customers, P10, or as a competitor but one which would sell the product co-developed in other markets. Coopetition was speeded up when there had been a long-term relationship, P10 and a continuous partnership P10, the qualities of

the partners were the basis for success P10, openness and sharing of documents and feedback from partner P14.

Sometimes the coopetition was agreed based on demonstrating how one partner's expertise could achieve the solution the other partner sought, P2P7P8, for instance by showing equivalence via examination of the technical file, P6 and/or was not a competitor in regulated devices at other levels, P2, part of the total to market process generally for instance on distribution, P3, and specified financial outcomes P3P8P9 such as sales revenues P9 transfer price P9.

No process dilemma – illustrates importance of retaining IP to do the coopetition

The major success factors and possible reasons for proceeding with coopetition of not were investigated in complementary questions.

Added value from coopeititive relationship, P1 examples:

Partner could substitute a current product in its portfolio with innovative product. P9 and P11 could exploit gaps in its product portfolio by coopetition with a partner that has weak market presence in Europe and exclusive distribution.

Company could divide its business into a variety of non-competing medical device customers and used its technology for each one, P9.

The degree of success was a consequence of the quality and appropriateness of the partner's technology, P1P9, specialist equipment that facilitated data capture that would otherwise been unavailable to P1. A partner who is familiar with the business has more impact for P9 so greater potential for success.

The technology was valuable because it validated P1's approach

Both sides benefitted from the coopetition and reflected its success P1P9P10P13, companies should have strategic similarities P13

Long term collaboration, P9 transparency, P9P11

Feedback was provided to P9 on the success of its development

The major obstacles to coopetition were also further investigated in other questions

The main issues are f**ear of competitor in coopetition, pre-empting risk slows or prohibits coopetition**

Inability to agree a legal contract, written by a lawyer that avoids issues at the end of the agreement, P2P7

Need to employ external consultants to ensure that partner does not have direct access to

The potential to be forced to instigate legal proceeding if there were issues during the coopetition period, P2

Increased risk to sales volumes if the competitor was potential able to increase the price or the transfer price of their components or cease providing them, P2

Partner does not appear to be collaborating, communication levels decrease P12

Partner wants to own the IPR, P12

Changes to company for coopetition generally few indicating that this speed up the process

Not having to develop own technology, which reduces costs and time, P2

Signing an exclusive licence but this was known P2

Outsourcing regulatory affairs to independent external consultants P7 so that no sharing of technical file with customer or distributors P7. Separation of certification and production/distribution ownership

Competitive relationship more likely if only a small part of technology shared, P2 this enables company to develop own expertise by learning what competitor does with it and enhance competitive advantage P2

29th December

Q Limitations of coopetition practice/sharing – key factor is IP rights

Frequently no coopetition proceeds if all or the majority of the company's IP must be accessed by partner(s), P1P2P7, or partner prevents company from sharing it with others, P1. Loss of competitive advantage P2 including risk of copies being marketed by competitive partner, P7. One partner must also be the legal manufacturer, P9. The terms of the legal agreement generally are also a potential limitation or motivator for coopetition in P9.

Each partner must be able to accomplish own objectives from the coopetition, P10

The coopetition should be restricted to the early stages of development when knowledge is weak and both parties are incentivised to share results, at a certain knowledge stage the parties should separate unless they do not have the resources/knowledge to continue alone or agree to split sales/distribution geographically or by product line (P5). A partner wishing to invest in P14 or share certain costs such as machining would prevent coopetition proceeding.

A partner requiring access to P8'scustomers who are also co-developers, valuable contacts gathered over a long period of time, would result in coopetition being impossible.

Unwillingness to share everything would deter P15 from coopetitive relationship.

A general perspective on the context of the new regulation by P11 was that it had forced the company to identify what operations it was possible to accomplish

internally, to questions it assumptions about acquisitions, strategic partnership and internal practices such as how it innovates, and which products are marketable. This prioritisation was primarily driven by the higher investments required to progress idea to commercial product. Hence the limitations to coopetition could be interpreted as dependent on type of innovation considered in the perspective of investment cost and market changes.

The companies are in a range of medical device subsectors and yet core trends have been revealed as to their interpretation of coopetition, success factors and reasons why these companies would not enter into coopetitive relationships, these are summarised:

Overall rationale for coopetition – market changes and consolidation/alliances

Macroeconomic reasons to keep market opportunities open

Microeconomic reasons: make innovation/manufacture more affordable for each partner, provide added value, enable company growth

Speed/success enabled by:

Long term collaboration between partners

Partners know the business well and have more impact

Both/all partner's benefit

Company able to use its technology with several non-competing partners withing medical device sector

Complete transparency

Quality of partner technology

Only small parts of company technology are shared

Sharing expertise and company learning from expertise

Company has a stage of development/manufacture unavailable in-house

Cash or investment in development

Resource gain generally

Help with regulatory issues

Partners agree to or already operate in different markets and or product lines/regulatory classes

Competition slowed or eliminated by:

Partner wants to share or buy company's IP

Other legal issues such as licensing

Reputation risk if partner's technology/contribution not optimum

Partner wants to invest in company or buy it

Partner wants to increase transfer price when it observes high sales or threatens to stop supplying components

Partner wants exclusive rights to products or markets

Potential partners operate in same markets

Type of partner for success: long term relationships, customers, those characterised by openness and sharing

The evidence suggests that there are more reasons for coopetitive partnerships to be successful and to develop quickly than hindrances but that intellectual property rights and fear of the partner stealing ideas/technology/products is the most likely to prevent or destroy coopetition.

Initial Coding

I began by ensuring that I had understood that this was also referred to as open coding:

- *breaks the work into discrete parts closely*
- *examines them for similarities and differences*
- *open to all theoretical possibilities suggested by my interpretation of the data*
- *line by line suitable for interview transcripts*

It very much seems that I have already taken this approach to both of the other codes. The interview transcripts are already broken down by subject and question so the objective will be to revisit them a third time to identify additional words, processes, qualifying, labelling, choosing etc. This is restricted to the same questions as in the process coding. This coding is proving difficult when trying to follow Saldana (2016, pp 116-117 coding categories, but since CSFs and CFFS plus ranking are relevant to this research they are some of the initial codes selected. For these sections, tables showing similarities and differences may be useful to obtain strength of opinion.

Code	Critical Success Factors for your company, what ranking does innovation have?
Qualifying/ ranking innovation	First P11 Second P4 P2 P14 Third P15 Really high P1P10P12 essential component for success P5 the project B or C compared to the middle or long-term products which are more project A P2 Team first P2 is as critical as hiring the right people P8 Hard innovation not necessarily first P3 Innovation as a risk P6 innovation is difficult if you do not have financial power and time P6 it's innovation that they can put money into (investors) P8 innovation was more important in the past P9
Identifying	Must have product that excites people to motivate them to invest in P1 innovation that pulls in funding P1 Project one P2 One project in mind P3 incremental technology and not disruptive technology P2 innovation in every sequence in sales process P6 innovation as something used before but not optimised P6 oncologists, ...surgeons--hospital leaders who .....would like this kind of tool P8 something attractive than. Puts us ahead of the competition P10 standard for the instrument is getting higher and higher P14
Identifying critical success factor	launch the first product on timeP2 mainly because we have a great teamP2 the secret of our success is innovation P3P5 high profit P3 P7, return on investment P3

	(innovation) creativity that comes from.. completely new, people seeing that .....is creative unexpected ...new.P5 financial power and time to do it P7 faster..reduce manufacturing time P7 differentiation P7 technologies..easily accessible P10 people love the product because it is packed with new technologies P10 generates a lot of interest from industry. And end user P10 needs to be implemented as well...not just prototypes, demos and so on P12 new idea, follow rules and obtain finance P13
Barriers to success	finance ad regulatory requirements P13 clinical trials, higher finance needed, success not predictable P13
Criteria for innovation	It has been a success P5
Choosing	(product) that needs to be in a clinic P1: innovations need to be in the answer of organization …... who ... work with the customer P12 Team A and team B (key but different skills/knowledge P2) We're .. much more on the development phase ... co-develop our solution with users P8
Labelling	Team first P2 Incremental (innovation) P2 bizarre unbelievable (investor) P2 (partner company) old fashioned P3 Niche (product) P3 Real innovation as added value P5 big impact (product) P10
Quantifying	Added value of 100% essential P5 innovation is difficult if you do not have financial power and time P6 one of the top (ranks for innovation) P10;

	comparing client products and own products P15 innovation against projects with more money, experience from other industries and leaning P15
Reflecting	relying on people to see my passion for why .. do this,,I realized it kind of doesn't work.. need to .. refer it back to something that people can see novelty within a simpler way P5 patient indirectly associates (innovation) with benefits
Hypothesising	innovation as opportunity to better respond to new regulationP6
Dispelling stereotypes	there has not been a lot of innovation … we rather sell the products ...we have developed a long time ago P7 You create something, but you don't know if you are going to…make money out of it P8
Linking	(innovation)with world class products P10

This coding analysis has been interesting since it has identified that innovation is not the most critical success factor for these companies, only in a few cases is ranked in the first three, although rated high by others. The verbose responses to the question had the effect of reducing capacity to identify where innovation factored in overall company success. It has generally emerged as important, but people are a key factor as are the factors identified such as establishing the product and attracting finance, making the right choices. Critical success factors focus considerably on new product, quickly produced but in contrast others stress finance, getting past the prototype stage and profit indicating the highly different contexts in which the companies perceive their future business success. Quantifying aspects of operations such as novelty/simplicity, adding value, and the most profitable projects are also processes undertaken by a few firms. In other words, there is considerable diversity in the position innovation holds in company success and which other elements must be combined to optimise it. The inference is very different perceptions of reasons for or against coopetitive relationships.

Q do you think that innovation in medical technologies is different from innovation in other industries and if yes, why so (30/12/2020)

The responses to this question generally quantified the difference between innovation in medical technologies or qualified it in some way, but some critical success factors and barriers to success emerged. Additionally, emotion including expression of high risk involved in this industry was evident from some

responses, which seemed to be more apparent than found when using the in vivo and process codes.

Quantifying remarks generally compared the difference between innovation in med tech devices with pharmaceutical companies or was a general remark, although P14 remarked that regulation did not limit the automotive and aeronautics sectors as greatly.

The med tech industry was characterised by continuous new products on the market because medicine was “always moving forward”, P3, and new regulation meant that industry constraints were always increasing, P4, and had made it more difficult to innovate over the past 20 years, P12; regulations and restrictions were very different from other sectors,.P12. The increasing regulation meant that the software sector in med teach was five years behind software sectors of other industries

Innovation in medical devices was open innovation, P2, in comparison to closed innovation, which was characteristic of pharmaceutical industry, P2, tolerability for failure was lower than in pharmaceuticals, P5. The risk was higher than in pharmaceuticals because if the innovation does not succeed

“we're not just out of business but parent company is gone probably as well” (P5)

This was reinforced by P6 who considered the hurdles in the medical devices industry were “so high…I cannot recommend anybody to be innovative”.

In contrast P6 remarked that the share of profits from new products was particularly high in medtech compared to other industries.

A major difference with innovation in med tech and other industries was the context, the value added and the potential issues, exemplified by devices being instruments in direct contact with human body, which saved lives, and made operations shorter, P14. This meant that regulation could be linked to the device in some cases, device. which tracked patient health were subject to a lot of regulatory change with implications for the “whole track” (P14)

Another unique issue with innovation in MedTech was passing the regulations, a bigger challenge for P6, who had found that providing too much information the notified body slowed the process down by up to eight months

There were a lot of substitute med tech products, P2, patents were often used but for joint venture purposes than to protect he innovation, P2

The degree of difference between med tech and other industries was captured by qualifying remarks, for instance:

“working on a person” (P15)

“much more difficult...especially in the start-up sector” P12 referring to the effect of regulation

“brutal regulation”, which was a barrier to affordable innovative products by small companies, P13

However, P1 considered that the effect of new regulation was different mainly because the timeline upset investors and others (P1) and P14 further qualified the relative impact of the regulation in the long-term reflecting that there were regulations throughout Europe that initially sound strict

“but afterwards. they have common sense about how they reinforce them.”

The extent of difference in med tech was also qualified positively by P7 in terms of that high performance innovation generating higher speed to market and profit.

Labelling and stereotyping provided emotional and cultural perceptions of how innovation in the sector differed from that of other sectors.

Labelling

“coopetition is incestuous” P3

“wanted to have a license for this technology, not to have our own technology” P2

“ the bar is much higher” (in med tech) P5

“boundary conditions ..really toxic for real innovation” P9

“ the industry is conservative” P10

“med tech industry is maturing and consolidating; P7

Whilst P11 was of the opinion that innovation was disruptive innovation, leaps in innovation;

Stereotyping remarks were focused on the user and the industry:

In comparison with the pharmaceutical industry, in med tech people take on work in a different way, “have better systems and processes in place than other sectors typically” (P5)

This is reinforced by P8 “healthcare stakeholders ..not very keen about making progress or making changes in the way they work”.

These two remarks contrast with P10 who suggested that the med tech industry was conservative

Age stereotyping was exemplified by

“new generations tend to be very much more open-minded” (to change) P8

“ the older people, they have problem using it” (P10)

The remaining differences between innovation in med tech and other industries could be classified in terms of critical success factors, barriers to success, making choices and identifying major changes

Critical Success Factors	well-designed innovation management system P7 Having both a product which is innovative and being able to generate the mindset of change P8 Providing... tools to bring teams to evolve positively, to work differently. P8 getting people (users) involved in innovation .. and being able to change their practice P8 be more responsible, think about the patient, think about the user, maybe that the device is too advanced; device use must be easy, P10

	everything has to be secure and must work p15; implying link to human health associations with med tech devices
Barriers to Success	giving too many details to notified body slows process “I gave explanation of all the differences in the changes. I shouldn't have done that because... asked many questions... and that postponed the study file by… eight months” P6 “healthcare stakeholders ... are not very keen … changes in the way they work;” P8 re-certifications… more difficult under MDR conditions, P9 change in product registrations P10 smaller manufacturers are very concerned...they are not used to these changes P14 Data policy P15 in reference to tracking devices
Making choices **/dilemmas**	creativity and trying new things but worried about this blowing up in their face (risk) P5 it's me and my partner who are taking the decision... we are the ones who are taking the risk P6' what I share… always choosing the pros and cons P6 some questions... we know we should do something, but we are not going to do it now P6 Taking the risk of having a good, notified body P6
Identifying	increasingly demanding healthcare sector P7 innovative products… difficult to get into this market P9 should respect (conservative) when we build a product P10 identifying: medical device legislation is limiting innovation P13

Whilst some of these CSFs were responses regarding the difference between innovation in the medical devices sector and in other industries, some are evidently more general, such as providing tools to get people to work differently. Which would be a relatively generic change management approach (Kotter, 2012) not merely in this context. However, the CSF focus on changing user mindset is likely to be very relevant owing to the huge advances in healthcare technologies. These differences also indicate the potential aspects for coopetitive relationships.

The identifying remarks indicate that this code should be abandoned going forward since these could be including in CSFs or barriers to success.

Two sub questions mentioned organisational structure and responses are taken together

Q from your experience, what internal factors are most important for the success of innovation and specifically, to what extent, do you think **the organisational structure of your company support or hinders innovation**

Q I'm interested if you believe that the organisational structure, as you have described it earlier, is supporting or hindering your innovation

Qualifying, in this case specifying internal factors considered important for successful innovation, were expressed by six participants. The number of people involved in innovation was emphasised by: P1 as no more than three, as too many individuals “kill it” owing to too many opinions being voiced, and P8 that not all ideas were shared with all employees; P10, P11, P15 preferred most employees to be involved.

However, P2 took a different approach qualifying innovation as being most successful when two separate divisions were created in the organisation: an innovation department to explore ideas and suggest the best ones, and then an operating team which developed the idea. P5 qualifying innovation as unlikely If the internal organisational culture was that employees strictly adhered to a job specification.

P8, P15 cited flat structure as supporting innovation but P9 expressed organisational structure was not important for the company, and P2 qualifying structure for innovation as starting from its purpose of managing people, no ideal structure being specified.

The rationale for a flat structure was quantified by P13 as

“people are encouraged”

Organisational structure for innovation was also somewhat quantified by P1 as requiring a board and a chairman to ensure it stayed on track. Innovation within the organisation quantified in terms of product being unique enough but there's also going to be a definite need (P3)

The CSFs for structure to support innovation were expressed as

a good set of cofounders P1

get your team together...same sort of work ethic as you P1

communication goes quick when organisation is small P10

Structure supporting an appropriate culture was implied by P3 and P5: observing aspects inside and outside the firm that needed to be changed, thinking about them and discussing them (P3); P5 directly stating the structure and culture were critical factors for innovation and extending to

“provide a culture and organisational structure that will first attract them...and probably more importantly, cultivate them” P5

The inference was making the appropriate choice of organisational structure and culture, characteristics of employee and how to develop their skills to enhance innovation. This aligns with P1's remark that the Board help to direct innovation.

Organisational structure was labelled as empowering (P11), and innovation labelled as influencing people to be committed to it (P15). The best structure for innovation was labelled ambidextrous by P2 although this was not defined but implied as having thinkers and doers. Similarly, P3 labelled consultants as radical thinkers. An inappropriate organisational structure was labelled as enabling siloing generated when employees stayed too long in one organisational division; P5 stating that silo thinking was a CFF because it limited the capacity for developing integrated solutions required for innovation. Board members not familiar with innovation and research were additional organisational factor that could "derail" innovation as they opposed approving some options (P3). This is an interesting remark, conflicts between Board rarely being evident in this research and potentially a greater failure factor than is admitted.

The stereotypical remark that there were bad ideas was dispelled by P13 who stressed that all ideas were invited and there was no bad idea.

Making choices is evident from other codes applied to these responses but very evident in remarks such as

"you've got identify definitely applications and the need for ..them"

P3 was referring to organisational decision making as a factor for successful innovation, choosing appropriate materials for the innovation.

The perspectives on organisational structure for innovation were limited by the question not being posed to all. There was little agreement on the internal factors that influenced innovation, for instance opinion was divided about the number of people in the organisation that should involved. Most responses implied that flat structure aided innovation, especially in a small company because communication was fast, but a few good founder members and team with similar work ethic were also important were critical for some firms. The link between organisational structure and its culture was evident and interestingly in regard to the company Board which either enabled it or restricted it. This also reflects the ideas of thinkers and doers within the structure in order to enable innovation to be achieved; conflict represented by silos in the structure or Board member thinking is another important outcome from these remarks.

Leadership for innovation

This question evoked diverse responses and the term leadership was qualified by several participants as supporting innovation because it allowed everyone to be aware of why the company was engaged in certain tasks (P1) and what the company's aspirations were (P8), really important for start-ups (P2)

The specific aspects of leadership were quantified by P2 as being characterised by two different jobs and philosophies although these were not further explained. Leadership was linked to innovation by the type of management structure it

comprised, open, flat management in which everyone has an equal say, P3; it was positive, P4, and it must be impactful, P12

The major barriers to innovation represented by inappropriate leadership: were failing to keep employees informed, P1;, attempting to manage both the innovation and commercialisation phases, P2; failing to confine the details of the innovation inside the firm,P8; “strict management” military style which would inhibit expression of ideas,P12.

In contrast critical success factors for leadership, according to P1 included ensuring dialogue was always open, also P2,P9,explaining the end goal, making sure everyone’s activities were aligned and focused on the objective, P1,P4 and that activity patterns changed based on market research, P1. The separation of leadership roles to two divisions of innovation and commercialisation reemphasised by P2. Leadership should encourage anyone observing a good idea to freely discuss it, P3,P9,P13,P14,P15, internal and external observations including other sectors which were sources of new ideas, P3. Leaders also needed to appoint a decision-making team, not everyone should be involved P14.

Labelling occurred in a few cases describing the company as being “such a small company or a start-up company, P1 and P2 respectively but for leadership P7 proposed that leadership for innovation should be agile management and leadership, and P8 somewhat secretive. Ideas were labelled by “there is no bad ideas by P13. These labels reflected some of the previous ideas of leadership for innovation but emphasis on the small company size, need for agility in leadership and management were important for revealing what behaviours and context a participant associated.

The leadership behaviours of hypothesising and choosing were also revealed for instance hypothesising on the division of the leadership’s roles by P2

“once you sell a product you need a leader, one for innovation and the other for operating”

Hypothesising was considering an idea (P3), reinforced by P9 stating that ideas may not always seem useful at first “but finally, of course. fruitful”.

Making leadership choices embraced decisions regarding reporting lines for P2, choosing to respect all ideas, P13, and

“there are so many questions every time and that is why it is very important that the management is open” (P14)

The R&D staff were stereotyped by P9 as idea generators that leaders should allow to express their ideas, the inference being that other organisational functions were much less important to leaders in this respect. Leaders with directive style were also stereotyped, associated with suppressing ideas by P12

The importance of leadership to accomplishing successful innovation, to guide and involve employees is evidence from these responses. Handling uncertainty is revealed here as a leadership attribute reflecting Stacey (2010) and leadership

for innovation as characterised by agility (Aghina et al., 2015). by hypothesising on different ideas, as making choices and changing patterns as a consequence of market research (Eisenhardt, 2002).

Questions on regulation (3/1/2021)

Do you believe the new regulations will- what impact will the new regulations have on innovation in general?

The impact of regulation was qualified in terms of its potential impact on innovation as generally negative, making innovation more difficult, P1, P2, P10, P4, and slower, P11 in orthopaedics to discourage anyone from innovating, P4. In respect to small companies, P10 proposed that they would be blocked from market entry and P7 that small companies currently operating in the market would need to focus on their clinic dossiers much more. The only somewhat beneficial impact was a longer product lifecycle for small and medium size companies, according to P7.

The degree of impact was quantified by remarks that generally reinforced the negative initial comments that qualified what it meant for the firms.

Innovation would become more difficult for all, but the impact would be greater on some devices, P1; costs would be higher and consequently net profit reduced, owing to the added expense of clinic trials and post purchase follow up, according to P2; the additional costs of just maintaining the CE mark were quoted as euro 250.000 for P6. The cost of implementing the regulatory requirements was also stressed by P4, who described them as much tighter and stricter, P4, P6, such that a quality assurance specialist had been appointed in the company, P6.

The regulatory impact would force new working practices and business models, for instance P1 stated the only option was to partner with a big company

The effect of the regulations was to destroy innovation, P4, or impact negatively on the innovation pipeline, although P9 specified that only R&D type innovation would be ceased and by the big companies; P7 and P6 stated that 30% to $0% small companies would disappear and 50% of the content of product portfolios. The new regulations were a high barrier to entry for new companies to enter the sector owing to the high cost, P10, P12, so that the US market would be prioritised over EU market, P11.

In contrast P8 P14 proposed the benefits of the regulations; quality would be very much higher, and this would provide a commercial barrier to competitors, P8. This positive effect was stressed by P10 suggesting that firms would have a long period of time to develop ideas because there would be less competition in the market.

The most serious barriers to success in the new regulatory regimes were the amount of regulation, bureaucracy P1, P10; insufficient financial resources to fully implement the new rules in order to market the product, P1, as already indicated

by observing companies close, P3. Small companies especially would suffer from the lack of resources to implement the regulations without external assistance, P11; the regulations would make it more difficult to raise finance in especially difficult activities, for instance orthopaedics, P4.

However, participants were able to suggest a range of success criteria, the positive factors of the regulation being: less competition, P6; if your company was already in the market, the value of its technical file would increase, P6; large companies reducing their product portfolio to really old products. In order for new start-up companies to succeed they should sell their technology to big companies before the clinical trial stage but if small companies chose to go beyond the initial product stage they would have more time and to prepare their clinical dossiers if they had the financial resources to do so; P6 the CE mark would be recognised by distributors in other countries as representing high quality.

Labelling associated with the introduction of the EU regulations were a tricky drug device combination, P1; the bar has been lifted so high, P3; remaining notified bodies will be more competent, P7; ramifications of being a small company, P1.

The perceived consequences of the regulation, the hypotheses, were many, for instance that big companies would decrease investment in their innovation departments, P2. The leaders of firms may not have understood the regulations, and appeared to be insufficiently worried, P5 and more support was needed, and common sense adopted regarding them, P1. Positively, there was little chance market demand would decrease, P6; implementation of the regulations implied a longer product life cycle and cash-in period; P11 more valuable innovation through commercialisation would result over time. However P12 perceived two conflicting consequences, innovation might not decrease overall but it might be concentrated in big companies, implying consolidation or small business failure, as suggested by Fernández, Triguero and Alfaro-Cortés (2019).

The choices to be made by leaders were also varied: uncertain decisions on markets in which to participate based on regulations in US remaining unchanged and EU market regulation being stricter, P2; selecting products to eliminate from the current portfolio based on minimum sales revenues, for example of I million euro minimum, P6; focusing solely on current product portfolio since there are no resources for new development. Therefore, companies had to decide on how they would work in the future including considering whether or not they could continue without forming some type of alliance, P11. There ws also stereotyping regarding innovative small companies as lacking the resources to adhere to the regulations without getting resources from outside

This question appears to have been on significant interest to the participants who responded with highly detailed information, particularly quantifying by the effects of the regulations on business models, working practices and barrier to entry as well as considerable reduction in innovation, breadth of product portfolios and the exit of big companies from radical innovations. The negative effects of the EU regulations were cited more often and in greater detail than potential success factors. There was also considerably hypothesising regarding the regulation,

reflecting the uncertainties that companies considered it represented to their businesses.

These responses provided indications of medical devices companies having to make choices about future strategies/products etc)

Q And besides the financial, the new regulations require a certain knowledge to deal with the regulations. How do you see this for your company

The general impact of the new regulations on participant firms were qualified again by some participants; they would have little effect on the outcomes from innovation, P6, P10; little difference from previous registration, P10; added investment and documentation for audits and quality managing was the main change for P14

The financial consequences of the new regulations and the capacity of the companies to fund them were varied, for instance P4,P9, said they were not able to do so and the financial resources considered high by P2,P9,P14,P11. The difference implementation had on net profit was significant for a level 1 product since the selling price was so log, P2. The increase in expenditure was generally a consequence of: employing someone to do the extra work, for instance P3 stated euro 30,000 to 40000 per year, but that it would be able to recoup the expenditure; cost of clinical trials, P9,P11. Other burdens not directly related to finance by the participants, were additional bureaucracy, and difficulty of using machine learning, P8. There was no issue with financing the additional work for P12 and P9 suggested it would be paid for by companies which would make profit from the innovation.

The only barriers to successfully implementing the new regulations were financial and the difficulty of implementing the clinical studies, highlighted by P9. However, there were a number of CSFs associated with regulations, knowing how to apply them effectively, P15 ensuring that the clinical data is sufficiently accurate so as to retain the CE mark, that the notified body is competent to support the firm with easy evolution of the device to comply with the rules (P6) or that the firm had its own regulatory experts, P12. In some devices the defining the algorithms in the appropriate was vital for certification (P8). The timing of completion of all regulation related to products before the deadline was the major factor for P11. Finance was mentioned CSF only by P14.

There were choices regarding the implementation of regulations, for instance P2 chose not to implement them but to export to countries that did not demand it, whereas P8 decided to implement the rules as did P11 who had already made substantial investment to accomplish the goal. Instead, P6P9 chose collaboration as a means to collect clinical data and getting their products to market, whilst P12 has made changes to strategy as a consequence of the regulations. The inference for this research is that some companies may choose coopetition solely for implementing the regulations, but it is not the only option to either obtain the

financial or knowledge resources. There was also a stereotypical remark that small companies would have the biggest problem, P10 and the hypothesis that companies applying the regulations are investing competitive advantage.

The adequacy of the companies' knowledge resource was also considered by the participants who qualified and quantified the current situation as generally having been assessed and accomplished, although the regulations were considered difficult, P1 and the implementation cost high, P3 quoting the initial use of a consultant at £1000 per day. In one case the certification expertise required was illustrated by allocating the role to an employee with existing expertise in ISO certifications, P10.

Two issues were identified as hindering implementation, the few notified bodies available to support certification, P10, and lack of organisational knowledge regarding them, P13. Possession of the finance or a regulatory/clinical affairs manager were critical to start-ups wishing to gain certification, according to P1 and P2 respectively. Choices were necessary to ensure that the firm possessed the knowledge; allocating the finance, P2, choosing the mode of implementation either an in house department, external consultants or both, P7, organising seminars, P9. The alternative was making the decision not to implement the regulation, P4.

P9 expressed uncertainty about capacity to implement the regulations because the company would need to reach accord with the notified body and P10 surmised that the notified body would help the firm to get through the certification easily; similarly, P11 hypothesised that time to market would be the only major difference from prior situation.

Q Do you see anything in the new regulations that would help your company with innovation efforts?

The regulations were not generally considered to help the company with innovation although P13 expressed some agreement with the clinical trials and P12 perceived that they would make market entry for software and applications-based devices somewhat easier. The regulations were qualitatively a means to changing organisational mindset a culture, but P11 did not state how that supported innovation directly. Quantification of the positive effect of regulations on innovation varied from none, P2P4 to little effect on device safety, P13, to huge in terms of disruptive technologies because it would make it more difficult for others to compete. The negative effect was quantified at loss of 40% medical device companies, P4, fewer competitive product would exist, P9, and documentation effort was "drastically" increased, P14

Whilst two CFFs and four CSFs were regulation to support/hinder innovation, there was substantial hypothesising on the linkage. The main barriers to regulation supporting success were the burden for a small company, P4, which would force companies which could not comply to become insolvent, P9. Conversely, regulations could drive innovation that represented added value for

patient and surgeon, P2, and generate corporate agility and higher levels of innovation than incremental improvements, P11, and facilitate market share growth, P9.

Hypothesising focused on the impact of the regulation on market entry barriers, P2, on small companies being potentially more able to bring innovative products to market and/or maintain them on the market than big companies, P9, and on innovation value added, P11.

Therefore, choosing responses to the regulation that might enhance innovation was considered by some participants; hypothesising resulting in realising that lack of net profit would result if regulation was implemented for low profit products, P9, and choosing decisions regarding the historic product pipeline to optimise outcomes, P11

A great deal of uncertainty and hypothesising existed about the positive impact new regulation would have on innovation; firms being forced to quantify the options and to make choices but the overwhelming perspective that small firms would not generally gain innovation related benefit from the regulations

Coopetition

So, are you familiar with that term coopetition and the concept of competitors working together for a specific purpose? do you think that coopetition, so working with a competitor could help to continue delivering innovation given the challenges the new regulation spring?

Coopetiton is the main focus of this thesis, so that obtaining the participant perspectives on what the term meant and how the concept might be useful to them for positively exploiting the change and enhancing/supporting innovation was a major objective of the first question**.** Although many of the participants had not been familiar with the term, they were aware of the concept by another name and some initially qualified its meaning to ensure their intuition was correct. Whilst all qualifying statements showed some knowledge they varied from describing coopetition as represented by centralised laboratories for sharing knowledge, P3, to a combination of competition and cooperation of diverse activities or strategies, P7,P8, P10. The remarks that attempted to quantify competition were more positive and informative, suggesting that the companies could benefit from the concept as a means to implement the regulations more effectively in a customised manner. The responses revealed that several firms had already used this strategy and business model, P11.

Coopetition was considered important, P1,P10,P14 and quantified further:

“because for a little company like us, you only have one person working on regs' P1

“it (regulation) will enforce such cooperation” P10

“ important for the future” P14

“getting more difficult for smaller companies to carry the load of regulatory requirement; quantifying: the regulatory burden is high” P13

It was also quantified as being temporary, a relationship for a specific project by P2 and for sharing resources, P4, beneficial to both companies, P7. The description by P8 of coopetition as an eco-system was also interesting because this was explained as needed in situations when a single stakeholder finds it difficult to do innovation in every field, suggesting that innovation was not merely happening in one process but in multiple terms, which is a new description.

Three models of coopetition were described by P11:

“we are seeing it in small companies in three ways, one model, where investing in… resources behind regulatory, and not being able to invest in go-to market investments.....they are much more open seeking exclusive distribution or licensing rights ...

I also see . companies, that have several innovations, but ...need to focus on the few, they are being more open to ……. technology,

large companies of are ..acquiring other companies, who have some technology registered ..because of the lifecycle becoming longer”

A single growth strategy of coopetition but three different business models, which is also a relatively unique way of expressing the concept and not evident in previous research in one study in this way: getting to market associated with acquiring licences, acquiring technology to develop innovations and big company acquisitions of technology companies to enhance lifecycles.

These are major findings that were not so evident from the other two types of coding implemented in this research.

However, coopetition success was hindered if a suitable partner could not be identified, P4, if the competitor appeared to wish to take over the company, P10, or their IP, P12,P15 and acquire their most talented employees, P15.

The factors that were critical to successful coopetition could be summarised as

CSF	Participant
Collaborating with a much larger competitor	P1
Forming strategic alliances especially for small and medium size firms	P7

Share resources particularly IP but contractually, knowledge, experience and for accessing necessary procedures/processes to fill gaps in own operations to go to market	P8 P13 P14
Compromise especially small company when coopetitive with big company	P10
Small business must rethink the level at which they need to be coopetitive	P11

The remarks made also reveal the underlying rationale and emotions being experienced by the firms as they make such decisions:

“competition who is a lot bigger than you, it has an entire team...more brains... really useful....you need that sort of extra lift” P1

The formation of strategic alliances is required to gain competitive advantage over the big companies, to get to market faster according to P7 but P10 highlights the potential for conflict between small and very large coopetitive partners such that the small company may have to compromise on some of its beliefs and values. The small company must also carefully consider to what extent it is willing to collaborate with a partner, P11. The emotional experience is that the new regulations are a “burden” to be shared between the partners, and that coopetition

“has less impact on your financial structure and on head count;…....we benefit from each other’s experience, knowledge, findings." P13

Coopetition was vital to success in the context of “cannot cover all steps by themselves” and of being able to “grow together” P14

This remark by P14 implies that coopetition is critical to survival of both organisations and to their future growth, which appears rather strange in the context that coopetition is usually considered in the context of a specific project or projects at a given time. This remark represents a somewhat different mindset. The remarks do align with Simmons (1996) of coopetition being an option that is dependent on the situation, in the case considered owing to new regulation and to eliminate its threat (Doz& Hamel, 1998).

The emotional response to considering a coopetitive relationship were captured in the hypothesising by three of the participants, for instance anxiety: that it might help when the partners have different notified bodies or one partner already has an accredited notified body which is accredited whilst it is not, P9; conscious of lacking resources and knowledge to enter the market “without a stronger partner”, P1O. However, P12’s anxiety is ensuring that there are specific criteria for each company’s contribution to the collaboration. As in other aspects of these interviews, small companies, particularly start-up companies, are again stereotyped, as being afraid of coopetition, in this case that they give away too much the bigger companies, P10; high anxiety state.

Q understand about your experience or your view, how you personally being engaged or see collaborating with a competitor

The next sub-question was in many ways an overlap of the previous one where participants provided their concept of the term coopetition but several also related their experiences of it. The responses recorded in this section therefore tend to demonstrate triangulation of data but have attempted to mostly capture additional perceptions.

Five participants, who had experience of coopetition qualified its meaning in terms of specific activities: the partner had offered R&D contracts to P1, whilst P3's partner need a frame but did not want to develop it internally, P9 was to be the manufacturer of a product, P13 lacked experience in cutting. In contrast P2 and partner developed a V1 product, which they would both sell in different geographical locations. The remaining remarks were more qualifying the personal meaning or commitment to coopetition for instance P5 would only consider it in the early stages of development and P7 that it concerned regulation, manufacturing and commercialisation.

However, competition was quantified in terms of its perceived scope or restrictions in the specific firm context. Coopetition put restrictions on what P1 could use its IP for, and that full access to IP or technical files was necessary, P6. Its scope and rational was to gain expertise not possessed by the company, for instance the technical file and financial support for P1; codevelopment with public laboratories, P8; to share cost burden, P13; to access manufacturing, P14. Two companies, P7 and P10 stated that they had already pursued coopetitve relationships several times.

Many factors were cited as critical to success in coopetition, revealing the perceived objectives for the relationship and the specific criteria that were considered as beneficial for the participant companies.

Behaviours: trust and communication, P4; openness, P14; motivation of partner to make it work owing to investment made, P9; joint commitment to making the coopetition successful, P10; learning, P13,

Legal context: terms of agreement defined from the beginning, P4P8P6P9; P9 would receive transfer price whilst partner sells the product

Gaining required expertise: technical file, P6; innovation, P7; enriching the product, P7; required documents for customer, P14

Outcome: sharing costs, reducing overall fixed costs, P14

Success in coopetitive relationship was hindered by not being able to use the same technology in any other context/relationship by P1, which meant that the opportunity for innovation was eliminated. IP rights were also an issue for P3, whilst no longer having full control of the business was the concern for P4, also implied by P5 who foresaw individuals being too competitive to collaborate.

These CSFs and CFFS provide the key aspects for successful coopetition as limited to four distinct categories. IP is vitally important as is feeling in control. Whilst Pullen et al (2012) also found trust and fairness to be CSF in the empirical study it conducted in medical devices companies, in agreement with this research, and gaining expertise (McCarthy et al., 2018). The other success factors were not revealed and represent new findings in the medtech context, specifically other behaviours, legal agreements and outcomes, although these have been found in other competition contexts ( ).,

The potential limitations of coopetition to manufacturing and quality systems were a hypothesis that could make the arrangement work for P4

Making suitable choices for success is inferred as being vital to success and some choices are implied by participant remarks: how to speed up the research phases, identifying and selecting resources such as finance and access to innovation, P2, core developments, P9 and markets, P10.

The process of identifying whether coopetition was a suitable strategy for the firm also involved hypothesising about the benefit of an early agreement of being independent and raising funds to complete the regulatory process instead, P1 There was also a practice of assessing the outcomes and associated incentives, P8, including the threat of small companies working together as maybe lower than when there was big size difference, P15.

Experience of coopetition and certainty of its applicability to drive innovation in medical devices companies, whilst also implementing the regulation was a conundrum for many of the companies. The logic of sharing resources was agreed but the implications of doing so caused much uncertainty owing to potential unacceptable behaviours, lack of any legal agreement and uncertainty of outcomes, despite companies understanding what resources they lacked and/or were willing to share.

Q So, you have not practiced coopetition? So, you have not yet worked actively with a competitor in innovation?

P8 had not worked in coopetition, this reluctance was qualified by explaining that was too early for the company to consider it as building its reputation was a higher priority.

The companies quantified that non active involvement in competition in terms of there being no suitably impressive examples of it in the orthopaedic sub sector, and P4 wanted to build the company’s reputation first. P3 who also stated that there might not be sufficient market demand for two direct competitors and that choices had to be made as all companies wished to protect their IP. Therefore, P3 hypothesised that about the firms needed to identify how they could work together especially when a competitor could potentially acquire the SME and would focus on its key resources and competences for its own advantage.

These two participants were evidently hostile to coopetition for loss of identity and the danger of disappearing from the market.

The responses to the next two questions are merged since there is considerable overlap in the context:

Q – from your experience with working with a competitor now, so what aspects or innovation, or let's say, stages in the innovation process were suitable for that collaboration?

Q a. - How do you draw, or would you draw the limit of cooperation in the coopetition process to preserve the competitive advantage of your company?

The potential willingness of organisations to adopt coopetition was qualified in terms of some potential positive aspects, limits of cooperation and an openness to the idea.

The potential aspects of the innovation process that were suitable for collaboration were qualified as being manufacturing, P1, validation of the instrument, P6, a very early stage of development, P7. However, P10P11 were vaguer stating it was dependent on the partner and how competitors were defined

The limits of coopetition: P5 not after the early-stage work was complete; the company would need to continue on its own; the partner wanting access to the company's end users was definitely off limits.

However, P13 was open to considering any situation as long as it was mutually beneficial and in line with its strategy.

Suitable aspects for coopetition quantified: Cost sharing was an aspect of coopetition that quantified its value, P6 stating that collaboration on certain aspects saved the company €25,000 compared with completing them alone and that the end product was ready for market three months earlier so that it saved €50,000 on its fixed costs. The risk of losing important information and resources made these a motive for coopetition for P7, whilst the size of the partner was a key factor for P11. The limits were quantified as: IP rights and sharing them in other contexts affected no collaboration, P1, sharing all the company's technology was too high risk for P2, no added value from the relationship P6 and sharing know-how, P11.

The barriers to success of coopetition were gathered in both sub-questions, most in the limitations to coopetition and related to:

Regulatory burden which was the main cost factor and included much larger investment to bring product to market, P6,P11 and the time taken for the notified body to pass the technical files, P6.

Partner behaviour for instance partner acquiring the company's resources, including knowledge, P2, in the technical product development context P5; lack of top management awareness of the regulation and capacity to ask right questions, P6; partner wishing to invest in/acquire the company, P14

Resource sharing: access to IP, P8; access to the company's customers, P8;

Outcomes: limitation of no recognisable competitive advantage, P2; length of innovation time and associate cost, P6

These closely parallel the four CSFs for coopetition generally, which were expressed earlier by the participants, strengthening their impact and validating them owing to the degree of triangulation (Ritchie & Lewis, 2010).

The CSFs for successful collaboration were asked for directly in both sub questions

Behaviours: willing to share important information such as elements of the technical file, P6; mutual willingness to agree from the earlies stage the exact details of the collaboration from initiation to registration, P10P5; involving regulatory personnel from the outset to ensure the plans align with the rules, P9;

Legal aspects: defining the legal manufacturer, P10; agreement make sense for both parties, P9l non-disclosure agreement, P11;

Resource sharing: the company's technology can be shared with a range of partners in different non-competing industry sectors, P9; strategic agreement with no limits on sharing information, P11.

The same factors are evident again, emphasising clarity of thought on the important factors in coopetition generally and for the medical devices sector.

The sub question on the limitations to collaboration envisaged by the participants, very much revealed that these were based on choosing and hypothesising

""what do we have available in our portfolio ... can be suitable to be used for their product idea' P6

Coopetition was limited if there was no mutual benefit, P10 so that it would occur in circumstances limited to that and for companies of similar size or smaller not bigger, P11.

A remark made by P9 implies that coopetition based on one partner managing the regulatory aspects was unlikely and a limitation to coopetition:

"Nobody wants to have anything to do with the regulatory stuff because everybody is happy when somebody else is doing that....so, this is a part which we do quite on our own.

The hypotheses were focused on P1 wondering why a partner would want to have permanent access to its IP when the coopetition was only at its early stages and the longer-term possibilities remained unknown. P2 also considered the possibility that one aspect of its technology could be used contractually with the competitor and that the company could develop its expertise with that element of its technology. In contrast P5 considered the simplest way to look at the possibilities of coopetition was to identify aspects of the whole process to market that it could not do alone; The issue was the top management of companies not understanding the regulatory challenges and/or the innovation opportunities they

could represent, according to P6, whilst P8 perceived that identifying companies with specific expertise might be a better approach to coopetition that focusing on competitors

The major reflections on the question of coopetition are:

Coopetition is not a new phenomenon in the medical devices sector, only the term.

It was a viable option to consider for managing the challenges of adhering to the EU regulations and gaining certification

It was often considered a temporary arrangement and the idea of it being an ecosystem seemed to align with participant perspectives on applying it successfully in their companies

- It could be interesting even given the expressions of fear and uncertainty expressed including loss of identity.
- All had a need for certain defined resources
- Small companies could gain speed to market and competitive advantage compared with large companies
- Survival was important for both partners and an incentive for collaboration

Variety of reasons for and benefits from coopetition and business models and activities to implement it – these make coopetition a viable strategic alliance for med devices organisations

The participants descriptions fit the definition of coopetition as depended on a specific situation (as Simmons)

These aspects demonstrate that coopetition in MedTech sector is likely to be a strategy of choices (Child) and that minimise fear and uncertainty but offer the potential of future survival and prosperity,

The four major aspects are:

Behaviours

Legal- EU regulations and contracts between firms

Resources – gaining/sharing specified resources/expertise

Outcomes

THE INFERENCE IS THAT THESE SHOULD BE THE MAJOR CODES USED TO BUILD THE THEORY.

Preparing for Second Cycle Coding

Revising codes in all three first cycle coding and rationalising them – looking for Axial codes that I can then add the relevant categories to both in the original theoretical base of the work culture, organisational structure, leadership and innovation but more importantly seeing if they can be applied to the coopetition aspects for which the theory needs to be realised.

In Vivo Codes	1	New code
1	**"some sort of tiered system" (OS)**	**These are organisational context codes**
1a	"not underneath me, but work alongside me"	Representation of values, beliefs, and aspirations
1b	"organize in a very short step"	
1c	"as little corporates as possible"	
Id	"You're at the bottom. You're at the top," you've set into stone a set of representations about value and worth	
2	**" we do everything"**	
2a	"I think you always need clear roles, responsibilities and clear person where the buck stops with, who has to make the decision"	Behaviours
2b	"the structure is me"	
2c	"we three together, we consider as a management team which handles and, of course, responsible for all signatures and all our responsibilities covering all which is related to the company."	
3	**"an early-stage company".**	
3a	"we are only one floor and two guys on top"	Representation of values, beliefs and aspirations
3b	"unstructured collaboration system…..comparable to a start-up"	

4	**"free on their way of thinking"**	
4a	"You will have to think differently"	Choosing and learning
4b	"good perspective on reality"	
4c	"the culture is complete mix culture... with different qualification"	
4d	a blind alley is explored in a way that I'm not sure it's that feasible to do with the pressure of a big team and big financing"	
5	**"There's so much at stake"**	
5a	"we like very much to interact with either insiders or outsiders of the company"	What's at stake/Outcomes
5b	"collective shared responsibility and objective"	
5c	"they have no time to develop it in their own R&D and there's already a CE mark	
6	**"Give power to the people"**	
6a	"trusting them"	Behaviours
6b	"give them the opportunity to manage their problem and their solution by themselves"	
6c	" Typically, we do have a discussion with a consent which makes everybody happy and which in most cases is the best solution"	
6d	"mentoring orientated"	
6e		
7	**"Open"**	**Behaviours**
7a	"Empathy"	

7b	"communication"	
7c	"leader by example."	
8	**"If you've got a problem, all doors are open"**	
8a	"decision making clearly comes from the board of directors and the CEO"	
8b	"collegial"	
9	**"it's a big extension on project management"**	Representations of values, beliefs and Aspirations
9a	to make sure that everyone comes into deadline on time	
9b	" I am involved in all processes to discuss things and really gives feedback about how to do it"	
9c	"somebody who is interested in what they are doing and who is interested to interact and to discuss things and really gives feedback about how to do it "	
9d	really hearing people	
9e	"encouraging the people to be happy in their job"	
10	**"Leader manager not a leader"**	
10a	"good leader needs to be close- close, ...the frequency at least one time per week, ...close to the team and just to get a report from them…to be reassured about what they are doing "	**Behaviours**
10b	"I'm a leader, but I'm a manager also"	
11	**"Leader..implies a tribe"**	

11a	" trying to find a path through this forest,,focused on an objective beyond themselves"	Choosing and learning
11b	"going through personal pain"	
11c	"and help other people through them".	
12	**"Thanks to the senior guy"(P2)**	
12a	"has to be addressed by top management"	Representations of values, beliefs and aspirations
12b	"not doing something for a political reason but because they have a business value"	
12c	“you've got a much longer journey through a lot more forest with much fewer resources and much less help”	
12d	"it has to be agile leadership and management"	
13	**"that's a lot to do with the size of the organization"**	**Behaviours**
13a	"good at being flexible because we're still quite a small team"	
13b	"can swap to writing a grant one minute or they can be doing a 12-hour day in the lab next"	
13c	“wanted to keep this Start-up Culture" ... everyone feels that they are responsible of their own mini company area"	
13d	"it's easy because it's small…decision making is easy"	

13e	we are growing …. can see that we are transforming into much less movable object…...we have become rather slow and not so quick learning as we used to be"	
13f	multinational there's hard steps there, but zero to something ……..... they're very rarely focused on"	
13g	"a blind alley is explored in a way that I'm not sure it's that feasible to do with the pressure of a big team and big financing"	
14	"**team first; people first"** P2	
14a	"It is quite tough to our people and we want to be sure that at the end, people we hire are in the same cultures as ours and the same values"	Representations of values, beliefs and aspirations
14b	error of this kind..... "Okay, no problem. We're going to redo this thing"	
14c	"inform them what's going on, what is current status"	
14d	"you need good cofounders…not too many-- too much opinion kills it"	
15	"**zero to something is the hard step**"	
15a	"system needs to be changed. So, we need to invest"	Choosing and learning
15b	work hard	
15c	"But if we redo it, you need also to improve something."	
15d	when it becomes difficult, some people prefer their own interest…this is very disappointing P4	

15e	"finances limit you and the rules limit you…..that is what we have to learn in the company"	
15f	" trying to learn from all the difficulties and experiences"	
16	"**we always have alternatives"**	
16a	We always bear in mind that a contract that we have signed with a company, a third-party company, might end"	Choosing and learning
16b	"a lot of collaboration"	
16c	"have to adapt to this different way of doing business. Nobody knows what the new normal is going to look like."	
16d	"agile	
17	**secret of our success is innovation**	
17a	"a real innovation …appears to add value"	Choosing and learning
17b	"incremental technology and not disruptive technology "	
17c	"innovation ....from laboratories. very much research rather than development... we co-develop our solution with users...it's innovation "	
17d	"structured... with scarce resources ...learning internal/externally"	
18	**"bar is much higher"** "	

18a	boundary conditions for innovation are toxic in medical devices	Minimising barriers/ creating Agility
18b	getting people involved in innovation…being able to change their practice"	
18c	"instruments…. in contact directly with the patient"	
19	**"raising the barrier of entry"**	
19a	" more valuable innovation"	Choosing and learning
19b	"rethink how you work"	
20	**"ecosystems for innovation"**	
20a	"deliver value"	Creating agility/minimising barriers
20b	"resource sharing and compromise"	
20c	"legal side kills the innovation"	
20d	"that's a secret"	

These five category codes appear to be applicable to each of the in vivo codes and reflect the CSFs and CFFs discovered in the initial coding so basically using those 4 items and other ideas that emerged as important in the initial coding such as choosing/hypothesising reflecting uncertainty and fear. Not sure yet where outcomes/what's at stake fits as it has replaced what's at stake and none of the other in vivo codes reflect this idea whilst it is the only code with just one application. Now I remember Saldana (2016, p. 244) stating that Axial codes are derived from initial codes I feel more confident that I have selected an appropriate method of transitioning into the second coding cycle.

Process codes – examining these original process codes with the same five potential axial codes and assessing the fit. These are recorded under each of the process codes in the code book in red as they are too cumbersome to transfer to these analytical memos,

Initial interview question coding should be included since it provides ideas of how well the companies modes of thinking and doing align with what they state is needed for coopetition to be successful.

Interesting to compare in vivo and process codes overlaps tomorrow – brain too tired now concentration on this tedious activity drains you.

Initial Codes	Final Initial Coding
Qualifying/	Qualifying/Quantifying
~~ranking innovation~~	
~~Identifying~~	
Identifying critical success factor	critical success factor
Barriers to success	barriers to success
Criteria for innovation	
Choosing	Choosing
Labelling	Labelling
~~Quantifying~~	
~~Reflecting~~	
~~Hypothesising~~	
~~Dispelling stereotypes~~	
~~Linking~~	
~~stereotyping~~	

Not so easy now to replace these initial codes with potential axial codes chosen, may have to revisit the initial coding and revamp into these axial codes.

Behaviours were noticed and emotions, how do I fit these n. Read Saldana on Axial coding

I need to revisit this on 4/1

Trying to revise the initial coding difficult and to keep within the five codes develop initially with the outcomes of the initial coding as the first guide. In order to do so the main outcomes from the initial coding that appeared to focus on four or five main outcomes needed to be considered. For instance, CSFs and CFFs generally were a combination of behaviours, reducing barriers to coopetition/innovation/regulation, making choices, and adopting certain structures/business models, values, and beliefs. Hence the initial codes were revamped to actual codes as in the table to keep with the five mains themes.

Qualifying	Quantifying/qualifying merge to -what's at stake?? Some hypothesising
critical success factors	Minimising barriers Behaviours Representations Choosing and learning
Barriers to success	(merge in stereotyping) Minimising barriers Behaviours Representations Choosing and learning
Choosing	Merge in some hypothesising Choosing and learning
Labelling	representations
~~Quantifying~~	
~~Hypothesising~~	

Moving to the Meaning of the Axial Codes

Attempting to place the categories on each of the axial codes proved difficult and after several attempts these were shaped as in table below, rather than diagrams which will move in a Word document. However, at this stage it was necessary to know exactly what I was trying to achieve by further analysis of these codes, so that understanding the final objective more accurately was required before proceeding with a type of code charting exploring the dimensions of each of the codes and subcodes by revisiting the data analysed and extensively reported in this coding diary. The notes on theoretical codes were completed.

These criteria are now used to develop the analyses of the Axial Codes, which can then be summarised to the central or core code. I have already noticed that the five axial codes had overlap of data categories and found the categories difficult to define.

Focused / Axial Codes

Axial Code	Categories with examples
Representations of values beliefs and aspirations	Culture for innovation – team first
	Structure small, start-up agile v large dominant
	Aspirations – competitive advantage/stay in market v independence
Behaviours	Failure – control of certain resources, stealing assets
	Success -openness, trust, empowerment
	Compromise - flexibility
Choosing and Learning	Which partners? Size of company, competitor or non-competitor
	Which mindsets? Open/closed innovation, degree of legislations
	Which strategy? Type of alliance, business model
	Which aspects of coopetition? Technology, regulations, innovations, stages from initial development to market launch
What's at stake/outcomes	Time
	Competitive Advantage
	Financial costs, profits, transfer pricing, registrations
	Markets
	Secrets – fear of sharing
	Uncertainty
Minimising Barriers	Regulation – in house shared
	Eco-system – getting resources

	Legal rights agreed
	Get to market - compromise markets/product lines

Representations Of Values Beliefs and Aspirations

	Supportive of coopetition/innovation	**Hindrances to coopetition innovation**
culture	I do everything Formal leader takes responsibility when things go wrong Understanding why Unstructured collaboration internal Free thinking – blind alley innovation Thinking differently Certain rules for guidance Cope with uncertainty	Blame Insufficient information available Too much structure Certainty Repeating the same mistakes Chaotic Need for certainty
structure	Small, start-up Works alongside Small steps Flat Fast communication through flat organisation As little corporate as possible Similar size for coopetition Partner has similar organisational structure and culture Board to refer to helps avoid misdirection Consultants and other external links as part of informal structure – advice/collaboration	Large Hierarchical approach Longer chains of command hierarchy Slow communication Big team, big finance Much bigger partner Partners have highly dissimilar structures and cultures No Board may increase tendency for misdirection Internal focus
aspiration	Mutual survival/prosperity Independence -each partner able to achieve own objectives	Acquisition Fear of being swallowed up

	Seeking to create value/innovation adds value for user Stay flexible and agile Innovation as finding new ways of doing old things	Focus only on business value/Innovation does not focus on user Inertia sets in Failing to observe what is happening externally in own and other fields

Behaviours

In this case the continuum is between the two categories of success and failure so third column in not needed

	Supportive of coopetition/innovation	**Hindrances**
Failure	Partner's objective to control of certain resources such as IP or to acquire the company Partner stealing assets such as employees and know how Silo thinking and lack of cooperation employees and teams strictly adhere to own job description Insufficient talent Healthcare stakeholders unwilling to change -includes developing innovations that are too advanced for user and add no value Top management fail to understand the implications of new regulations	
Success	openness, listening, trust with employees and partners, innovation controlled to coopetition with trusted long-term partners empowerment of employees, full involvement in decision making recruit and nurture talented employees with similar work ethic employees include thinkers and doers being more responsible for instance -think of end user needs and competences Keeping secrets such as know how Gathering and discussing internal and externally generated ideas Leaders able to handle uncertainty Agile, flexible approach to leadership and management	

	Capacity to share critical resources as necessary Consider regulation needs from the beginning of the coopetition Small companies concentrate resources on improving dossiers	
Compromise For Success	Some degree of flexibility in how company should act Agree with competitors to operate in separate geographical markets and/or product lines so that coopetition is possible Identify a range of non-competitive partners in different industry subsectors with which company can share same technology	

Choosing and Learning - do I need this??? NO rather it could be subsumed into behaviours – go back no forward

Choosing and Learning	
Which partners?	Size of company, competitor or non-competitor
Which mindsets?	Open/closed innovation, degree of legislations
Which strategy?	Type of alliance, business model
Which aspects of coopetition?	Technology, regulations, innovations, stages from initial development to market launch

Behaviours Updated

In this case the continuum is between the two categories of success and failure so third column in not needed

	Supportive of coopetition/innovation	**Hindrances**
Failure	Partner's objective to control of certain resources such as IP or to acquire the company Partner stealing assets such as employees and know how Losing control of the business General lack of transparency and trust, including everything must be contracted Silo thinking and lack of cooperation	

	Supportive of coopetition/innovation	Hindrances
	Skills of partner are not as described Employees and teams strictly adhere to own job description hinders innovation Management is formal, strict and hinders innovation Insufficient talent Healthcare stakeholders unwilling to change -includes developing innovations that are too advanced for user and add no value Top management fail to understand the implications of new regulations	
Success	openness, listening, trust with employees and partners, innovation controlled to coopetition with trusted long-term partners empowerment of employees, full involvement in decision making recruit and nurture talented employees with similar work ethic employees include thinkers and doers being more responsible for instance -think of end user needs and competences Keeping secrets such as know-how, customers/client data Gathering and discussing internal and externally generated ideas Leaders able to handle uncertainty Agile, flexible approach to leadership and management Decide which types of innovation, open or closed, incremental or radical Develop strategic objectives for the coopetition/innovation with teams Consider regulation needs from the beginning of the coopetition Selecting which aspects of coopetition to contribute – stages of the process, for instance regulation/clinical trials Decide which coopetition business model allows all partners to benefit/added value Select the resources the company is willing to share and under what conditions, technology, finance, know how/validation	
Compromise For Success	Some degree of flexibility in how company should act Agree with competitors to operate in separate geographical markets and/or product lines so that coopetition is possible	

	Supportive of coopetition/innovation	Hindrances
	Identify a range of non-competitive partners in different industry subsectors with which company can share same technology	

What's At Stake/Outcome

	Success Innovation/Coopetition	Failure Innovation/Coopetition
Time	Coopetition reduces time to market Competent notified body and/or regulatory expertise	Conflicts, poor collaboration/resource use add time to market
Competitive Advantage	Added value for both partners Real innovation adds value Better products, less competition, higher profits Redirecting innovation to existing selected products in portfolio- especially big companies Assess low profit products consider exiting owing to higher cost factor	One partner has most/all of the benefits Products do not meet the new requirements Insufficient resources because attempt made to retain full existing portfolio and/or continue R&D activities
Finance	Sharing of resources generates cost savings and/or increases profits	Partner changes agreed rules for instance withholds components/transfer price in order to increase financial outcome Issues with new registration rules
Markets	Competitors in coopetition, markets and product lines agreed where/what to compete and not to compete	
Secrets – fear of sharing	Transparency and trust	Partner has hidden agendas
Uncertainty	Leaderships managing uncertainty orchestrate relationship	Lack of appetite for uncertainty, too many restrictions

Minimising Barriers

Key Barrier to Innovation/Coopetition	Positive Outcome	Negative Outcome
Regulation	In house expertise developed External expertise accessed Part or all processes shared with coopetition partner Competent notified body aids companies Able to access one of the limited numbers of notified bodies Exit the EU Market operate only outside Europe Understanding the implications of changing global healthcare policies and constantly updating knowledge	Insufficient financial and/or knowledge resources, leave market or product to market too late to compete Failure to understand new value focus on healthcare policies No/little access to competent notified body
Accessing resources	Understanding limitation of company resources Acknowledging zero to something is hard Mindset change – openness to other ideas Eco-system concept of sharing to access process/technology/knowledge gaps to fulfil new regulatory requirements. non-contractual or limited time contract Observing practice in other sectors and applying it Using outside consultants to fill gaps in expertise/new ideas	Failure to understand the complexity of the issues Partner acquires resources such as employees or technologies by means of the coopetition
Legal rights agreed	Limits of technology rights agreed contractually	Partner demands full rights and/or ongoing after coopetition completed or acquires them illegally
Get to market	Coopetition objectives to get to market quickly fulfilled by shared responsibility for accomplishing them After agreed stage of coopetition ends, all parties able to proceed with own further development	Neither partner or just one accomplishes market entry with relevant products/services

Theoretical Coding central or core category of the research

In order to ensure the code is determined in alignment with answering the research question, it was revisited

Research Question: What are the critical success factors for coopetition that will provide benefits to medical device SME given the impact of the new European medical device regulations on time and cost to market?

Therefore, the **Theoretical Code**, the central or core category (Saldana, 2016, p. 250) must be **Critical Success Factors for Coopetition**, the code

- Combines all the products of analysis
- in a few words it explains what this research is all about
- the main themes of the study
- key words or key phrases that that trigger discussion of the theory
- elements are applicable for and have relevance to all cases in the study, details included in all categories and subcategories of the study
- needs to answer **how** the phenomenon of **coopetition** works and **why** it **works,** in other words **under what conditions** and **why**

When determined use a category code diagram for the Theoretical Code

The category code of theoretical code for this research is Minimising Barriers and represented by the category code diagram that integrates the main themes that underlying it.