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Advancing a Framework for the Adoption of Outbound Open Innovation Practices

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Advancing a Framework for the Adoption of Outbound Open Innovation Practices

Fiona M. Oster

A thesis submitted in partial fulfilment of the requirements of
Sheffield Hallam University
for the degree of Doctor of Business Administration

August 2025

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.
3. I certify that this thesis is my own work. The use of all published or other sources of material consulted have been properly and fully acknowledged.
4. The work undertaken towards the thesis has been conducted in accordance with the Sheffield Hallam University (SHU) Principles of Integrity in Research and the SHU Research Ethics Policy, and ethics approval has been granted for all research studies in the thesis.
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Abstract

Healthcare provision faces mounting pressures, including constrained public finances, workforce shortages, emergent diseases, climate change, as well as digital and geopolitical disruptions. The COVID-19 pandemic prompted a reduction in healthcare expenditure, underscoring the urgency of building resilience through integrated strategies that bolster research, knowledge transfer and technological capacity, to meet 2030 health objectives. Early-stage medical technology (MedTech) innovation is essential for widening patient access and requires novel organizational capabilities alongside sustained leadership commitment.

This thesis presents a cross-country study of MedTech innovation in small and medium-sized enterprises (SMEs) in Germany, the United Kingdom and Ireland. Germany, due to its patent output, and its research and development (R&D) investment, which exceeds European Union targets, is used as a benchmark.

Underpinned by the resource-based view and dynamic capabilities theories, the study examines how MedTech SMEs leverage internal assets to transfer knowledge via outbound modes of open innovation. In addition, the barriers to commercializing new technologies and forming collaborative partnerships are explored. The knowledge, skills and organizational capacities SMEs must develop to strengthen their ability to address challenges are identified.

Guided by Braun and Clarke's six-phase thematic analysis, the research draws on semi-structured interviews with senior managers, R&D leads and regulatory experts in each market as well as specialist investor. Six core themes developed relating to: 1) industry structure; 2) markets; 3) finance; 4) collaboration for new product development; 5) distribution; and 6) skills.

Respondents consistently reported heavy regulatory burdens and delayed market approvals as major issues resulting in increased development costs. While the United States market attracts many European firms due to its scale and level of healthcare spending, domestic European markets posed challenges for SMEs surrounding regulatory heterogeneity, BREXIT-related barriers, and economic uncertainty. Financial constraints loomed large as SMEs navigated volatile valuations, concerns over equity dilution, and limited awareness of government support mechanisms.

The thesis concludes that policy reforms to streamline regulation, enhanced funding opportunities and targeted training, especially in medical device regulations, could significantly improve SME survival rates and increase competitiveness. These reforms could be expected to yield improved health and economic outcomes, while promoting more equitable and improved access for all.

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I also owe sincere thanks to my second supervisor, Dr Michael Benson, for his invaluable advice and encouragement throughout this project.

To my husband, Hans; my daughter, Serena; my son, John; and my mother, Mary, whose steadfast patience and belief in me sustained every stage of this journey.

I extend my heartfelt appreciation to colleagues and friends, too numerous to mention individually, whose camaraderie, encouragement and advice enriched both my research and my experience.

Dedication

This thesis is dedicated to my inspirational father, Arthur O'Loan, whom I lost before its completion. Discovering early drafts amongst his papers reminded me how passionately he wanted this work to come to fruition.

I also remember my father-in-law, Gisbert Oster, who spurred me on with his emphatic "Tue es einfach!" ("Just do it!").

I like to imagine both of them celebrating with two large beers in heaven!

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Abbreviations

ANVISA	Brazilian Health Regulatory Agency
APHT	Air Pollution and Health Training
CDMO	Contract Development and Manufacturing Organisation
CDRH	Center for Devices and Radiological Health
CE	Conformité Européenne
CSO	Central Statistics Office
EASAC	European Academies Science Advisory Council
EC	European Commission
ECCP	European Cluster Collaboration Platform
EESC	European Economic and Social Committee
EIU	Economist Intelligence Unit
EMA	European Medicines Agency
EPO	European Patent Office
EU	European Union
Eudamed	European database for medical devices
FDA	Food and Drug Administration
FEAM	Federation of European Academies of Medicine
GDP	Gross Domestic Product
GT&I	Germany Trade & Invest
GVA	Gross Value Added
HMRC	His Majesty's Revenue & Customs
IBEC	Irish Business and Employers' Confederation
IDA	Irish Industrial Development Authority
ILO	International Labour Organization
IP	Intellectual Property
ISO	International Organization for Standardization
M&A	Mergers & Acquisitions
MDRs	Medical Device Regulations
MedTech	Medical Technology
MHRA	Medicines and Healthcare Products Regulatory Agency
OECD	Organisation for Economic Cooperation and Development
ONS	Office for National Statistics
OR	Operation Room
PESTEL	Political, Economic, Social, Technological, Ecological and Legal
PIP	Poly Implant Prothèse
PMS	Post-Market Surveillance
QMS	Quality Management Systems
R&D	Research and Development
RWE	Real World Evidence
SMEs	Small and Medium-Sized Enterprises
TRL	Technology Readiness Level
UHC	Universal Health Coverage
UK	United Kingdom

UKRI	UK Research and Innovation
UN HLM	United Nations High-Level Meeting
US	United States
VC	Venture Capital
WEF	World Economic Forum
WHO	World Health Organization

Interview Codes

D1	First German SME interviewed
D2	Second German SME interviewed
D3	Third German SME interviewed
UK1	First British SME interviewed
UK2	Second British SME interviewed
UK3	Third British company interviewed (large)
UK4	Fourth British SME interviewed
IRL1	First Irish SME interviewed
IRL2	Second Irish company interviewed (large)
IRL3	Third Irish SME interviewed
E1	Medical Device Regulation Expert (UK & Ireland)
E2	Medical Device Regulation Expert (Germany)
E3	Medical Device Regulation Expert (UK & Ireland)
FM1	Fund Manager for Medical Technology (EU based)

Chapter 1: Introduction

1.1 Outline

This cross-national study examines outbound open innovation practices amongst small and medium-sized enterprises (SMEs) in the medical technology sector, focusing on Germany, the United Kingdom (UK) and Ireland. It has been undertaken with a view to advancing a framework for the adoption of outbound open innovation practices. The purpose of this chapter is threefold: first, to introduce the Health Services sector and identify the important role played by medical technology in meeting global health challenges; second, to present the key features of the medical technology or MedTech sectors in Germany, the United Kingdom and Ireland, with a particular focus on innovation and relevant current developments; and third, to provide a provisional rationale for the approach taken in this study, namely to use Germany as a benchmark and to connect this approach to an initial statement of the research aims and questions. An overview of the contents of the thesis and the remaining chapters is provided at the end.

1.2 Sectoral Overview

Health services are critical both to society and to the economy. Equitable access to quality healthcare has positive effects for personal and public health, for economic growth and development, and for employment and job creation (International Labour Organization (ILO), 2025). However, the challenges to future healthcare provision are significant and complex, and for these there is no universal or simple solution.

In 2025, global health stands at a crossroads. While innovations and broader access offer hope, rising costs, staffing challenges, and new disease threats present serious obstacles to improved health, and they do so in ways that are shaped by climate, technology, and geopolitical shifts (Economist Impact, 2025). The Economist Intelligence Unit (EIU) (2023) reported an increase in global spending on health during the COVID-19 pandemic, but disposable funding afterwards has been insufficient to contend with ongoing waves of COVID-19, the backlog of non-COVID related cases, and high inflation. In a similar vein, the World Health Organization (WHO) (2024a) reported global health spending had dropped to US\$ 9.8 trillion by 2022, a figure which represented 9.9% of the world's Gross

Domestic Product (GDP). This announcement marked the first real term decrease in such spending since the year 2000. The EIU (2023) also reported these decreases, which prompted dissatisfaction in and reflected disruption to healthcare facilities around the world. As we move beyond the pandemic, health systems remain under pressure both to strengthen their resilience in anticipation of future outbreaks and to adapt to shifting health demands. These demands include an ageing population, the rising impact of noncommunicable diseases, and the mounting threats posed by climate change and environmental factors (WHO, 2024a).

As awareness of the link between environmental conditions and health increases, it is expected that greater focus will be placed on climate and health-related issues (Economist Impact, 2025). Healthcare systems themselves directly contribute more than 4% of total global CO₂ emissions; in many developed countries, this share rises to approximately 10% of national emissions (World Economic Forum (WEF), 2022). In the European Union, for example, healthcare emissions account for approximately 5% of the total and the sector will come under increasing pressure to reduce this (EIU, 2023; European Academies Science Advisory Council (EASAC) & Federation of European Academies of Medicine (FEAM), 2021).

Exposure to ambient air pollution remains a near-universal concern, affecting populations in both urban and rural environments (WHO, 2025a). Furthermore, over 2.4 billion individuals are subjected to unsafe concentrations of household air pollutants; such exposure is strongly correlated with an elevated risk of a wide spectrum of harmful health outcomes (WHO, 2025a). In fact, the WHO has developed the Air Pollution and Health Training (APHT) toolkit for health workers in both clinical and public health sectors to help them to appreciate the dangers of air pollution and explore ways to reduce those risks for example (WHO, 2025b).

No part of the world is currently on course to achieve the goal of cutting premature deaths from non-communicable diseases by one-third by 2030 (WHO, 2025a). For context, non-communicable diseases include cardiovascular disease, cancer, chronic respiratory disease and diabetes. Population growth and ageing will also contribute to the relative increase in annual deaths in the years ahead. The WHO (2023a) projects that 77 million of these additional deaths will be attributable to noncommunicable diseases. However, the deaths will not be distributed evenly, ranging from below 30% in Europe

to over 210% in Africa, with the highest number expected in the Western Pacific Region. Socioeconomic factors and inequity can also impact the transmission of infectious or communicable diseases. These factors present challenges to improving healthcare in poorer communities but can also have a global impact (Lucero-Prisno *et al.*, 2023). According to the WHO (2023b), mortality is only part of the story of population health: where survival rates improve, those whose deaths have been averted may subsequently experience poorer health. Addressing this challenge will require policy planning.

In September 2019, global leaders backed "the most ambitious and comprehensive political declaration on health in history at the United Nations High-Level Meeting (UN HLM) on Universal Health Coverage" (UHC2030, 2020, p. 1). This declaration encompasses a series of commitments, targets, and milestones, including investment in digital and technical innovations that help to deliver quality healthcare solutions (UHC2030, 2020). Lucero-Prisno *et al.*, (2023) recommend that as the complexity of global health challenges develops, a multi-faceted approach, one that leverages research, develops scientific knowledge, and increases technical capacities is required to produce sustainable solutions and achieve 2030 healthcare targets. In this respect, supporting early-stage MedTech innovation plays an important role in making groundbreaking treatments and diagnostic tools accessible to patients (Deloitte, 2024).

Medical technologies are defined as "products, services or solutions used to save and improve people's lives" (MedTech Europe, 2024d). Medical devices, *in vitro* diagnostics, and digital health form the main categories of MedTech (MedTech Europe, 2024d). Billions of people around the world currently rely on these technologies each year (McKinsey, 2023). The MedTech industry typically features high levels of research and development (R&D) and product lifecycles of 18 to 24 months, at which point enhanced products become available (MedTech Europe, 2024d). European healthcare expenditure accounts for about 11% of the region's GDP on average (MedTech Europe, 2024d). Of this amount, roughly 7.9% is directed toward medical technologies, representing under 1% of total gross domestic product (GDP) (MedTech Europe, 2024d).

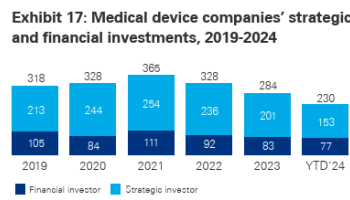
McKinsey & Company (2023) stress both the responsibility of and opportunity for MedTech leadership to innovate, grow, and create value, not only for patients and carers, but also for shareholders. However, continuing this value creation into the next decade will require "industry reinvention, with a bias toward transformation, not incremental

improvement” (McKinsey & Company (2023, p. 6). In a letter to MedTech leaders, which reflected this imperative, McKinsey & Company (2023) counselled them to consider what new capabilities their organizations need to deliver on the sector’s potential and what actions they are taking personally to lead effectively and bolster the resilience of their organizations.

Notwithstanding the opportunities, sectoral challenges remain. For example, MedTech Europe (2025) highlights the growing challenges in transforming research findings into innovative solutions that are adopted within European healthcare systems in ways that are effective. Europe reportedly lags behind global counterparts in certain domains, notably artificial intelligence, resulting in delayed access to advancements for its citizens compared to regions such as North America (MedTech Europe, 2025). This trend is indicative of insufficient investment in the development and implementation of medical and digital health technologies (MedTech Europe, 2025). In conjunction with challenges stemming from the complexity and limited capacity of the regulatory framework, as well as market fragmentation, these factors collectively pose a substantial threat to the competitiveness of European enterprises (MedTech Europe, 2025). According to Deloitte (2022) attractive criteria for investors include strong management teams, technologies with lower regulatory requirements, and lower payment barriers. These factors are considered key to generating a return. Other criteria include scalable technologies that address unmet needs in larger markets, technologies that can help lower healthcare costs, and companies that are profitable despite having limited funding available to them (Deloitte, 2022).

As reported by KPMG (2025), mergers & acquisitions (M&A) activity within the medical device industry remains below pre-COVID levels, at least in terms of transaction volume. In fact, the total number of deals in 2024 declined by 19% compared to 2023. One consistent trend, however, is that strategic buyers continue to dominate the market, completing twice as many acquisitions as financial investors. This trend is illustrated in Figure 1 below, which shows financial investors in dark blue and strategic investors in the lighter shade of blue.

Figure 1: Medical device companies' strategic and financial investments, 2019-2024.



(KPMG, 2025, p. 25, Exhibit 17: Medical device companies' strategic and financial investments, 2019-2024).

In a 2024 report, Deloitte argued that the disparity between Europe and the United States in venture capital availability and merger and acquisition activity posed a significant obstacle to the growth of MedTech startups in Europe. This funding gap not only hinders commercialisation efforts and diminishes the attractiveness of local M&A opportunities but also heightens the likelihood of foreign entities acquiring these startups (Deloitte, 2024). Deloitte (2024) attributed this dynamic primarily to the comparatively risk-averse investment culture prevalent among European investors.

As a final point, governments are also facing financial headwinds when it comes to funding healthcare systems because of shrinking fiscal space, stagnant income growth, and rising debt obligations, all of which are factors that serve to tighten the screws on already limited budgets (WHO, 2024a). With debt servicing costs rivalling health spending in many lower-income countries, the stakes could not be higher (WHO, 2024a). Understood in these terms, the current realities of the sector constitute a real crisis point in the challenges confronting global health: Just how do nations manage long-term investment in health without jeopardizing financial stability? (WHO, 2024a). Some may need to prioritize and to rethink financing mechanisms possibly through innovative public-private partnerships, external support, or more efficient domestic revenue collection (WHO, 2024a). Others might focus on targeting spending more strategically, improving outcomes with the resources available to them (WHO, 2024a). Against this contextual backdrop, medical device companies must chart a path towards an uncertain future, one that is likely to be dominated both by AI-enabled products and capabilities and by the demands of an ageing population for elective procedures (KPMG, 2025).

1.2.1 The MedTech Sectors in Germany, the United Kingdom and Ireland - Highlights

The MedTech sector is vital to the German, British, and Irish economies, as evidenced by the financial and other metrics reviewed in this section.

1.2.1.1 Germany

According to MedTech Europe (2024e) and Germany Trade & Invest (GT&I) (2025), Germany is the largest European medical technology market. It is projected to reach a revenue of €35.31bn in 2025 (Statista, 2025a). Approximately two-thirds of this revenue is derived from operations conducted outside its domestic market and one-third is generated from products less than three years old (GT&I, 2025). GT&I (2025) further reports that the sector comprises ninety-three percent small and medium-sized enterprises (SMEs). Germany employs 257,000 people in the sector, the highest absolute number amongst EU countries (GT&I, 2025). In 2023, Germany led Europe in medical technology patent applications, submitting approximately 1,400 filings to the European Patent Office (EPO), nearly twice as many as the second EU member state ranked, the Netherlands (GT&I, 2025; Statista, 2025b). EPO data also shows that Germany was granted 971 patents in this sector in 2024, more than double the number granted to the Dutch (Statista, 2025b). Overall, medical technology was the second most innovative industrial field across the economy, with 15,985 total applications recorded by the EPO (GT&I, 2025).

1.2.1.2 United Kingdom

In the United Kingdom (UK), according to the Department of Health & Social Care (2024) the medical technology sector comprises 4,190 companies, of which 85 percent are SMEs. A turnover of £27.6 billion was generated by the sector in 2021. According to MedTech Europe (2024e), a total of 117,200 people are currently employed in the sector. The United Kingdom was granted 348 patents in 2024, a figure which gives the country a ranking of ninth globally (Statista, 2025b).

1.2.1.3 Ireland

According to the Irish Industrial Development Authority (IDA), (2025), Irish medical technology exports are currently valued at over €14.9 billion. Moreover, 14 out of 15 top global players in the sector have a base in Ireland (IDA, 2025). 48,000 people are currently directly employed (MedTech Europe 2024) in over 300 companies (IDA, 2025). Ranking above Switzerland, Ireland has the highest number of employees in the sector

per capita in Europe (MedTech Europe, 2024e). Approximately half of these companies fit into the SME category (Irish Business and Employers' Confederation (IBEC), 2025).

1.2.2 The Innovation Imperative

The role of innovation in the European economy is increasing (Gouardères, 2020). It is strongly supported by the European Union, which has committed to investing an excess of €95.5 billion in its research and innovation programme, Horizon Europe 2021 – 2027, with over €8 billion allocated specifically for health R&D (EC, 2025b). Locally too, governments are committed to fostering innovation and R&D in business through dedicated, funded organisations such as UK Research and Innovation (UKRI), Research Ireland, Enterprise Ireland, or through multiple initiatives managed by the Ministry of Science, Research and Arts in Baden-Württemberg.

In its Europe 2020 Strategy, the European Commission (EC) recommended that countries invest 3% of GDP in R&D (EESC, 2014), a target initially set by the Lisbon Treaty in March 2000 (EC, 2010; EC, 2020). However, with the conclusion of the Europe 2020 Strategy, the 3% investment objective no longer has a legal basis (EC, 2020). As of early 2020, despite notable progress over the preceding decade, the EU still lagged behind this target (EC, 2020). Nonetheless, the 3% benchmark has had a strong motivational influence, prompting all Member States to define their own national targets (EC, 2020). It also encouraged broader discussions among them about their economic structures and policy approaches (EC, 2020).

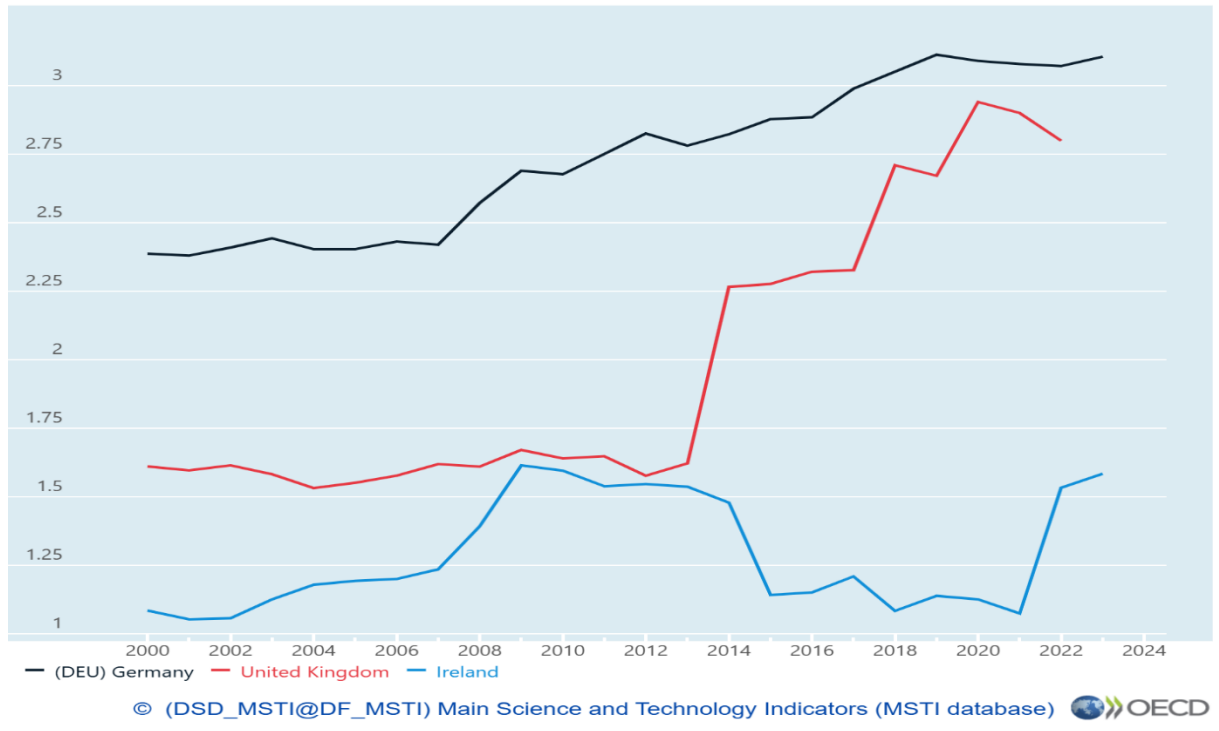
While Germany had exceeded this target by 2018, the UK and Ireland had not. The UK has shown significant progress on this metric, but this may be in part due to the relatively recent change in the methodology used in the UK to calculate these figures (Office for National Statistics (ONS), 2023; Panjwani, 2023). In general terms, these indicators are only one metric to measure innovation performance. Still, they serve to highlight a potential problem at this juncture, especially in Ireland.

The R&D spends of Germany, the UK and Ireland as a percentage of their GDPs from 2000 to 2024 can be seen and compared below in Figure 2.

Figure 2: OECD Gross Domestic Spending on R&D.

(DSD_MSTI@DF_MSTI) Main Science and Technology Indicators (MSTI database)

(MEASURE) Measure: (G) Gross Domestic Expenditure on R&D (GERD)
(COMBINED_UNIT_MEASURE) Combined unit of measure: (PT_B1GQ, _Z, _Z) Percentage of GDP



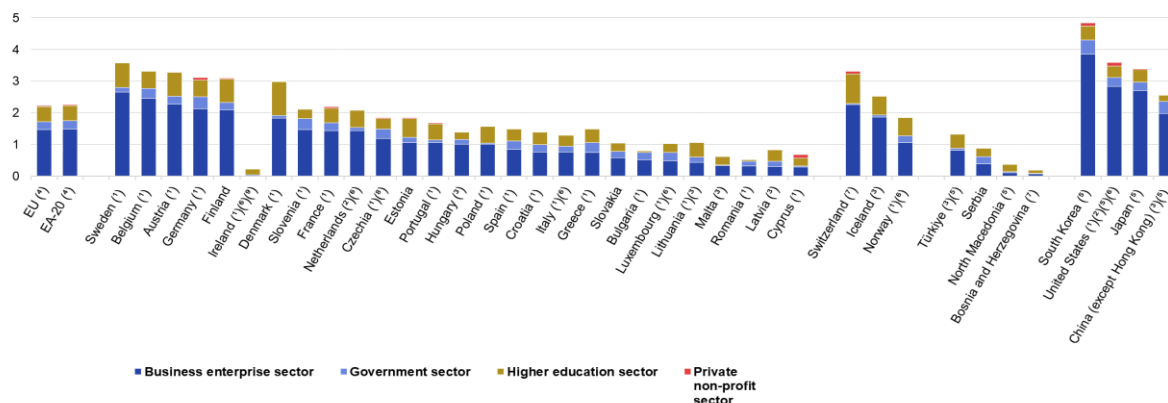
Source: OECD (2025), OECD Data Explorer Gross domestic spending on R&D (indicator).

Further analysis from Eurostat (2025) statistics below in Figure 3 shows the breakdown of this spending in 2023. In Germany for example, the business enterprise sector is responsible for the lions-share of the spend followed by the higher education sector and government:

Figure 3: Gross domestic expenditure on R&D by sector 2023.

Gross domestic expenditure on R&D by sector, 2023

(%, relative to GDP, ordered by the expenditure in the business enterprise sector)



Note: when definitions differ, see http://ec.europa.eu/eurostat/cache/metadata/en/rd_esms.htm.

- (*) provisional
- (†) definition differs for at least one sector
- (‡) Private non-profit sector not available
- (§) all sectors estimated
- (¶) 2022 data instead of 2023
- (*) at least one sector estimated
- (†) 2021 data instead of 2023
- (‡) at least for one sector break in time series
- (§) 2023 data for Ireland not available

Source: Eurostat (online data code: rd_e_gerdot) and OECD database

Source: Eurostat. (2025). *Figure 4 Gross domestic expenditure on R&D by sector, 2023*

Considering the lack of data for Ireland 2023 in the table above, additional data was obtained from the Irish Central Statistics Office (CSO) and reviewed. In 2023, enterprises operating in Ireland reported research and development (R&D) expenditures totalling €7.0 billion, representing an 81% increase relative to the €3.9 billion recorded in 2021 (CSO, 2025). Large enterprises, defined as those employing 250 or more individuals, accounted for €5.4 billion, or 77%, of overall R&D spending in 2023 (CSO, 2025). Irish-owned firms contributed €1.1 billion (16%) to the total, whereas foreign-owned enterprises were responsible for €5.9 billion, comprising 84% of national R&D investment (CSO, 2025). Notably, the ten highest-spending companies accounted for €4.0 billion, equating to 58% of the national total, a significant increase from 37% in 2021 (CSO, 2025). Labour costs emerged as the predominant component of expenditure, rising from €2.0 billion in 2021 to €2.6 billion in 2023 (CSO, 2025). The R&D workforce in 2023 comprised 40,956 individuals, with researchers representing nearly half of this figure (CSO, 2025).

According to the most recent figures available, government spending on R&D equated to 1.1% of GDP in 2021 (Government of Ireland, 2023b). The most recent details on Irish

higher education spending on R&D as a percentage of GDP relates to 2020 and equates to 0.27%. This marks a steady decrease from 2010 when the figure stood at 0.42% of GDP. It had been consistently below the EU average (Government of Ireland, 2023a).

Commenting in an Organisation for Economic Co-operation and Development (OECD) report, Haugh (2016, p. 2) suggested that Ireland's innovation system was still trailing other advanced European economies and that boosting innovation was critical to unlocking "*greater spillovers from the huge pool of foreign investment to Irish owned firms*". He further maintained that there was nothing automatic about the linkages between foreign and local firms; the latter should be better supported in their innovation efforts, as these companies were often the source of very creative ideas. In a later OECD Observer article (2020, p. 1), it was suggested that Ireland's R&D and innovation system should be "further up the field"; that the SME sector could be better served with more direct support for innovation; and that policies should be assessed to ensure that they are not constraining young firms. Kingston (2023) argues that a different policy approach in Ireland is needed: research should be industry-led and supported by academia if it is to have an economic effect rather than the other way around which has been the case to date. Kingston (2023) also lauds the German and American models of the nineteenth century and post-World War Two respectively for facilitating business-led research.

In the UK, the Office for National Statistics changed the methodology it had been using to produce R&D statistical estimates in 2022, which led to a significant increase in the published results (ONS, 2022; Panjwani, 2023). Using the new procedures, R&D spending was reported to total £70.7 billion in 2022, reflecting an increase of £4.4 billion since 2021 and £12.4 billion since 2018 when the redevelopment of R&D statistics began (ONS, 2024b). 71% of this expenditure reflected business R&D activity, 23% higher education, 5% government, and 1% both the private and non-profit sectors (ONS, 2024b). Of the publicly funded research, the most recent figures available for 2021, indicated 21% was spent on health (Panjwani, 2023). Wynarczyk (2013) explained that much of the UK R&D is concentrated in a narrow range of industrial sectors located in mainly prosperous regions, and 100 of the most active companies are responsible for most of the expenditure. He added that "independently owned SMEs account for only 3% of total R&D in UK business" (Wynarczyk, 2013, p.262). This did not appear to have changed much by 2021. Panjwani (2023) reported that 52% of total R&D was performed in

London, the East and South East of England, 19% in the East and West Midlands and the South West, 17% in the North East, North West, Yorks and The Humber, and approximately 6%, 2.5% and 1.8% in Scotland, Wales and Northern Ireland respectively. Computer and IT-related R&D accounts for 23% of R&D performed, miscellaneous business activities, technical testing, and analysis 18%, and chemical and pharmaceuticals 17% (Panjwani, 2023). Pharmaceutical companies spend the most with a combined total of £10.8 billion (Panjwani, 2023).

According to the most recent data available, total research and development (R&D) expenditure in the UK accounted for 2.77% of GDP in 2022, but it is important to note that this figure has yet to reflect adjustments stemming from the updated R&D methodology (ONS, 2024b). According to the Department for Business & Trade (2024), there were 5.5 million private sector businesses in the UK at the beginning of 2024. 5.45 million of these were small businesses (0 to 49 employees), 37,800 were medium-sized (50 to 249 employees) and 8,250 were classified as large (250 employees or more). Buckley (2025) notes that to qualify for R&D Tax Credits in the UK, the criteria for what counts as a small or medium-sized enterprise (SME) are more narrowly defined. A business qualifies as an SME for tax purposes if it has fewer than 500 staff and either a turnover under €100 million or a balance sheet not exceeding €86 million (Buckley, 2025). However, some conditions may disqualify a company from using the SME scheme, such as, for example, receiving subsidies for its R&D activities or carrying out R&D on behalf of another organization (Buckley, 2025). Nonetheless, for the 2022–2023 tax year, HMRC projected that small and medium-sized enterprises (SMEs) accounted for approximately 62,015 R&D claims, a figure which represents 94% of the total claims submitted (Buckley, 2025). While fully acknowledging that this is a simplistic calculation and further research is required, this author suggests that this equates to 2.49% of SMEs who appear to be conducting R&D.

There are further challenges for SMEs attempting to scale. Life sciences is one of the important, high-performing, innovative start-up sectors in the UK, but as is the case with other high-potential sectors, SMEs are facing scaling-up and growth challenges (Gibson & Bhattacharya, 2023). These firms generate 50% of the total turnover of the SME population despite making up less than 0.6% of it; they also report access to skilled human capital as one of their greatest challenges (Gibson & Bhattacharya, 2023).

At this stage therefore, the working hypothesis is that adoption and innovation-related factors may be constraining the level of R&D activity in Ireland and potentially in the UK. It seems reasonable to suggest that a cross-country study of innovative medical device companies across Germany, the UK, and Ireland, using Germany as a benchmark, could provide valuable insights into the underlying dynamics.

1.2.3 Why benchmark against Germany?

Germany has a strong track record of fostering innovation through cluster mechanisms, and it is the strength of these mechanisms that appears to be the significant factor differentiating Germany from the UK and Ireland.

For clarity, clusters were defined by Porter (1998) as follows:

Clusters are geographic concentrations of interconnected companies and institutions in a particular field. Clusters encompass an array of linked industries and other entities important to competition. They include, for example, suppliers of specialised inputs such as components, machinery and services and providers of specialised infrastructure. Clusters also often extend downstream to channels and customers and laterally to manufacturers of complimentary products and to companies in industries related by skills, technology or common inputs. Finally, many clusters include governmental and other institutions - such as universities, standards-setting agencies, think tanks, vocational training providers, and trade associations that provide specialised training, education, information, research and technical support.

Clusters play an important role in fostering innovation in Europe and are actively supported by EU industrial policy. According to the European Commission (2025a) clusters:

- Boost collaboration and connect enterprises, especially SMEs, and build bridges across Europe's ecosystems;
- Support innovation take-up, internationalisation and scaling-up of SMEs;
- Set up transnational partnerships to better help SMEs access global value chains;
- Act as change agents in the digital and carbon-neutral 'green' transformation.

Kramer *et al.*, (2024) reported that, the European Cluster Collaboration Platform (ECCP) featured profiles of roughly 1,200 cluster organisations within the EU27 at this point in time. The total number of such organisations has grown substantially over the past 15 years, with a particularly marked expansion observed among the EU13 Member States (that is, those that joined in the 2004 enlargement) (Kramer *et al.*, 2024). Notably, close

to 60% of all cluster organisations in the EU27 were founded after 2010. Substantial progress is particularly evident within industrial ecosystems with health-related clusters experiencing a 14% increase in employment and a 27% rise in gross value added (GVA) (Kramer *et al.*, 2024). Approximately 100 cluster organisations are now active, reflecting an increase of 50 entities since 2021 (Kramer *et al.*, 2024).

Sölvell (2008) established from his extensive research into clusters that regions with strong cluster portfolios are innovation leaders and those regions are typically at the forefront. Major clusters compete very well internationally thus promoting further innovation and new growth (citing Porter, 2009). However, this has increased the costs for those regions which have not developed some level of clustering (Sölvell, 2008).

In 1976, Baden-Württemberg became the first German state to develop its own technology programme (Hassink, 2002). In the period up to 1990, further state policy initiatives demonstrated clustering characteristics in such fields where organisational and geographical proximity were important. They included support for business start-ups, SMEs and technology transfer as well as technology centres and clusters (Fuchs and Wassermann, 2005; Koschatzky, 2005; Hassink, 1996 and 2002; Cooke and Morgan, 1990, cited in Dohse 2007). According to Grupp *et al.* (1998), innovative activities at the time in the region were primarily dominated by two large companies, Daimler-Benz and Bosch, and by medium-sized companies. Strong innovation clusters in mechanical and general and material processing were present. Comparatively robust clusters in electronics and information technology were also evidenced.

In the mid-1990s, Germany undertook some specific technology policy experiments to strengthen its position in key emerging areas, one of which was biotechnology (hereinafter referred to as 'biotech') (Hassink, 2002). A federally funded competition, called BioRegio, was held at a regional level in which groups of both public institutions and private sector organisations competed for funding for a concept to develop and commercialise biotech research (Hassink, 2002). One of the three winning proposals came from a network of Baden-Württemberg cities: Heidelberg, Mannheim and Ludwigshafen, collectively referred to as the Rhine-Neckar Triangle (Hassink, 2002). These innovative activities delivered rapid results and the Triangle became a national example of cluster best practice, thus consolidating the role of innovation clusters in

German technology policy (Hassink, 2002; Dohse, 2007). Today, Baden-Württemberg is a leading innovative region in Europe, investing 5.6% of GDP in R&D annually (State Ministry of Baden-Württemberg, 2024).

In more general terms, Germany has one of the most extensive systems of innovation in the world (OECD, 2022). Internationally, it leads in both private and public investment in innovation. This is backed by strong research and industry cooperation with innovation in manufacturing and technology being key strengths (OECD, 2022). At German national, federal, and regional levels including in the region of Baden-Württemberg, there is a strong commitment to cluster development (Federal Ministry for Economic Affairs and Energy and Federal Ministry of Research, Technology and Space, 2025). It should be noted that clusters align well with the concept of open innovation (EC, 2008). For example, Chesbrough (2012) envisioned the future of open innovation to include greater collaboration between a higher number of actors. He believed universities would become more accepting of the concept and public policy more supportive. There is much evidence to suggest that the adoption of collaborative approaches in the form open innovation supports the rate of innovative engagement (González-Benito *et al.* 2016, Savory and Fortune 2015).

The healthcare sector in Baden-Württemberg encompasses approximately 1,100 firms specializing in biotechnology, pharmaceuticals, and medical technology. All are actively involved in research, development, and production (State Ministry of Baden-Württemberg, 2024). These industries collectively employ over 88,000 individuals and generate annual revenues nearing €25 billion (State Ministry of Baden-Württemberg, 2024). Characterized by innovation and future-oriented employment opportunities, these sectors play a critical role in sustaining long-term economic prosperity. Representing 9.2% of the region's total economic output, the healthcare industry is the most rapidly expanding sector and holds strategic importance for state policy (State Ministry of Baden-Württemberg, 2024). With a workforce of nearly one million, it ranks among Baden-Württemberg's most prominent industrial sectors (State Ministry of Baden-Württemberg, 2024).

For the reasons set out above, the author proposes, that research conducted with companies based in medical device clusters specifically in Baden-Württemberg has the potential to provide a useful benchmark for this study.

1.3 Current Developments in the Medical Device Sector

The term 'medical device' covers an extensive range of tools and technologies used for diagnostic, monitoring and therapeutic purposes to prevent and treat diseases or injuries (Jadhav & Shendge, 2024, p.502). In Europe, a medical device is defined in more specific terms by MedTech Europe (n.d.) "as any instrument, apparatus, appliance, software, implant, reagent, material, or other article, whether used alone or in combination, intended by the manufacturer to be used for human beings for one or more specific medical purposes." While there is little to be gained for the purposes of this study by examining the definition in any greater detail, it is important to be aware of the differences in regulatory approach across Germany, Ireland, the UK, and more widely.

1.3.1 United Kingdom

In the United Kingdom, responsibility for the regulation of the medical device market rests with the Medicines and Healthcare products Regulatory Agency (MHRA) (Gov.UK, 2024). The Medical Device Regulations 2002 have given effect in UK law to earlier European Union (EU) directives, specifically Directive 90/385/EEC, Directive 93/42/EEC and Directive 98/79/EC (Gov.UK, 2024).

1.3.2 Europe

These directives were replaced in Europe with new Medical Device Regulations (MDRs) (Regulation (EU) 2017/745) and new regulations on In-Vitro Diagnostic Devices (Regulation (EU) 2017/746), which changed the European legal framework for medical devices (European Medicines Agency (EMA), 2024). The former came into effect on 26 May 2021, providing for a transitional period for certain devices. The latter came into effect a year later, on 26 May 2022, and also provided a transitional period for certain devices (EC, 2025c). These regulations introduced new responsibilities for the European Medicines Agency (EMA), as well as for the national competent authorities, in the assessment of certain classifications of medical device (EMA, 2024). They repealed several earlier Directives and required compliance from manufacturers when launching

new medical devices on the market (EMA, 2024). These MDRs categorize medical devices into one of four classes: Class I, Class IIa, Class IIb, and Class III medical devices depending on the device's potential risk of harm to users (Caetano, 2024). The intention of the new regulations is to better monitor medical device manufacturers, and to better document the performance of medical devices (Carl & Hochmann, 2024).

1.3.3 United States

The Food and Drug Administration (FDA)'s Center for Devices and Radiological Health (CDRH) "is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States" (U.S. FDA, 2024). There are three medical device classifications: Class I, II, and III with regulatory control increasing from Class I to Class III and within each classification the regulatory requirements for a general device type are defined (U.S. FDA, 2024).

1.3.4 International Standards

In terms of internationalisation, the International Organization for Standardization (ISO) certification, ISO 13485, is the global standard for quality management systems (QMS) for medical devices and has been harmonized by all regulators around the world (ISO, 2020).

1.3.5 Clinical Data

Svempé (2024) cites a study by Fink and Adra (2023) which explores the similarities and differences in the regulations between the United States and Europe. The scope of this report is quite extensive and complex addressing both legal and regulatory issues. However, there are some high-level points to note. For example, while there are some similarities in the medical device classification system, the distribution of products between them differ. Moreover, depending on the level of risk involved, there are differences between the approval pathways. Some of these differences are linked to the collection of clinical data and reflect the fact that EU has tightened its rules around post-market surveillance (PMS). For example, manufacturers are expected systematically to collect data on an ongoing basis and produce specific reports (Fink and Adra, 2023). In contrast, the FDA requires more general post-market activity (Fink and Adra, 2023). Additionally, the FDA acts as a central approval mechanism in the United States while in the EU, a more decentralized approach is taken with a system of 'notified bodies', albeit this brings with it a risk of different interpretation of the rules (Fink and Adra, 2023). The

development of a centralized European database (Eudamed) for medical devices is still in progress although one is already established in the United States (Fink and Adra, 2023).

Some formal and technical definitions are required at this point. For example, a clinical evaluation is defined under the European MDR in the following terms:

[It is] a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including the clinical benefits of the device when used as intended by the manufacturer.

(Eur-Lex, 2017).

A post-market surveillance system forms a critical part of a quality management system, and its purpose is “to collect safety data, information, and experience from real-world use of the marketed device for the duration of its lifetime” enabling the producer to respond quickly to any safety concerns in compliance with the regulations (Kearney & McDermott, 2023a, p. 7). A clinical evaluation report is produced by the manufacturer and submitted to the notified body and, once their approval is granted, and a Conformité Européenne (CE) mark obtained, the device may be sold (EC, 2019; Kearney & McDermott, 2023a). As more data is collected over the lifespan of the device, the clinical evaluation report is updated (Kearney & McDermott, 2023a). Clinical data may come from several sources but there is greater emphasis now under the new regulations for manufacturers to generate their own (Kearney & McDermott, 2023a).

1.3.6 Notified Bodies

A ‘notified body’ is the agent of the regulatory authority or the competent authority (EC, n.d.c) and, within the EU, before going to market, a manufacturer must convince the notified body that the device is safe and does no harm to a patient if used as intended (Kearney and McDermott, 2023a; Kearney and McDermott, 2023b). The importance of these bodies is reflected in the statement that “[t]hey are an indispensable part of the regulatory system since they grant a CE [Conformité Européenne] mark to each device before it can be placed in the EU market” (MedTech Europe, n.d.). The new regulations referred to above also aimed to improve supervision of the notified bodies by increasing

the inspections of their evaluation of clinical reports and inviting expert opinion in complex cases (Kearney and McDermott, 2023b).

According to the most recent survey from the European Commission (2024a), 38 notified bodies are currently designated under the MDR only, 11 notified bodies are designated under both the MDR and in vitro diagnostic regulations (IVDR), and 1 notified body is designated under the IVDR only. In Germany, there are currently ten notified bodies and in Ireland there is one (European Commission, n.d.a) even though Ireland boasts the highest employment in the sector per 10,000 inhabitants (Svempé, 2024). The Irish notified body has reached full capacity with one of E1's clients being told it was not taking on any new customers (E1, 2024). McKernan and McDermott (2023) report that Ireland has lost its competitive advantage in getting new medical devices to market quickly and as a result over half of the medical device executives surveyed would deprioritize entering the European market accordingly. There are 9 notified bodies in the UK (MHRA, 2025) and the current backlog is about 12 months. The situation is the same in Europe and these delays are exacerbated in the case of complex products (E1, 2024). According to the European Commission (2024a), the number of applications filed at the end of June 2024 was 26,185 and 8,905 certifications had been granted.

1.3.7 Investment Landscape

Mazzocchi (2018) reports that the field of venture capital has changed significantly in the last twenty years. Venture capitalists who remain in the medical sector now conduct deeper evaluations of a technology before making investment decisions, which in turn places more pressure on the entrepreneur/inventor to provide the required information. This includes an assessment of potential market opportunities, the intellectual property position, the identification or development of a team of collaborators to manage the project as well as the preparation of a formal business plan with operating goals, milestones and details of the funding needed and for what purpose it is to be used (Mazzocchi, 2018). Previously this work would have been done once the funding was secured (Mazzocchi, 2018).

Private equity funds too have changed their strategies to provide 'development-stage investments as part of a longer-term "roll-up strategy"', by which is meant potentially including another company or idea to strengthen the portfolio (Mazzocchi, 2018, p.80). This too requires significant advance preparation by the entrepreneur but there can be

an opportunity to form more of a partnership with the team providing a longer-term focus. Collaboration with larger companies may also be an option, but Mazzocchi (2018, p.81) urges caution, advising that the goals of both parties must be aligned, otherwise there is a risk the collaboration may be destructive as competitive forces come into play. Mazzocchi (2018) argues this line of finance may even be considered a 'last resort' which is not quite in line with the principles of open innovation (Chesbrough, 2006a, Chesbrough, 2006b). Mazzocchi (2018) advises that the fundraising process to develop a new innovation is very tedious, and an inefficient use of entrepreneur's time given that they would not typically have the skills and expertise needed. For this reason, he recommends using professional support.

1.4 Why This Research is Needed

Significant and well-documented challenges continue to confront global healthcare systems. The United Nations' "Universal Health Coverage 2030" declaration outlines a comprehensive framework of commitments, targets, and milestones aimed at promoting equitable access to quality healthcare. Notably, this initiative emphasizes the importance of investing in digital and technological innovations to enhance healthcare delivery (UHC2030, 2020).

Despite ongoing efforts, MedTech Europe (2025) identifies persistent difficulties in translating research outputs into practical and widely adopted innovations within European healthcare systems. In particular, Europe appears to be lagging behind other global regions, most notably North America, in areas such as artificial intelligence, leading to delayed access to cutting-edge solutions for European populations (MedTech Europe, 2025).

According to McKinsey & Company (2023), MedTech industry leaders have both a responsibility and a unique opportunity to foster innovation, drive sectoral growth, and create value not only for patients and caregivers but also for shareholders. Achieving this objective, however, will necessitate a fundamental reinvention of the industry, favouring transformational strategies over incremental change (McKinsey & Company, 2023).

The MedTech sector plays a pivotal economic role in Germany, the United Kingdom, and Ireland. As the leading market within Europe, Germany may serve as a valuable benchmark for comparative analysis. Preliminary observations suggest there are

potential areas of concern regarding sectoral performance in the UK and Ireland. These concerns merit further examination and form the basis for the research aims and questions outlined below.

1.4.1 Aims

Drawing on this provisional analysis of the sector and its contexts, it is possible to articulate the aims of this thesis in the following terms:

- To explore the relationship between outbound open innovation (OI) and the resource-based view (RBV) of the firm;
- To determine whether engagement in outbound open innovation can support the development of dynamic capabilities;
- To develop a managerial framework to support the adoption of outbound open innovation practices.

With these aims in mind, two Research Questions were identified by the author and formally articulated as follows:

1.4.2 Research Question 1

What challenges do SMEs face commercializing new technologies and collaborating with partners through outbound open innovation practices?

1.4.3 Research Question 2

What knowledge, skills and organisational capabilities do companies need, to develop within, and capitalize on the potential of, the MedTech sector?

1.5 Breakdown of the Content of the Chapters

The next chapter, chapter two, is divided into two distinct sections. The first section offers an overview of the concept of open innovation, followed by a discussion of the theoretical foundations that inform this study, and a presentation of the overarching research aims. The second section comprises a systematic review of the relevant literature, culminating in the articulation of the study's research questions.

Chapter three outlines the methodological framework adopted in this thesis. It presents the underlying philosophical assumptions, elaborates on the ontological and epistemological positions, and describes the theory development approach. Furthermore, it details the research strategy as well as the methods employed for data collection and data analysis.

Chapter four, which presents the findings and analysis, is structured in two distinct sections. Through thematic analysis, six overarching themes were identified. The first section outlines the themes associated with the Medical Technology Industry, while the second section focuses on themes pertaining to new product development, to collaboration and skills.

Chapter five presents a comprehensive discussion of the study's findings and analyses. It further outlines key theoretical contributions and examines the practical implications of the research. The chapter concludes by acknowledging its limitations and proposing several directions for future research.

Chapter 2: Literature Review

Part 1

2.1 An Introduction to Open Innovation

The concept of innovation has changed in recent decades. Over the course of the twentieth century, a closed or vertically integrated innovation model dominated. This meant that companies maintained full control over their innovation activities: from the point of idea discovery, through the research and development process, to the commercialisation of the idea (Chesbrough, 2003b, 2006b; Duarte & Sarkar, 2011). However, by the turn of the twenty-first century, environmental factors compelled a shift towards a newer, more open innovation model (Chesbrough 2003b, 2006b).

While it is reported that Swaheny and Prandelli (2000) originated the term "Open Innovation" (OI) (Reed *et al.*, 2012), Professor Henry Chesbrough is credited with championing it (Dahlander & Gann, 2010; Elmquist *et al.*, 2009; Goffin & Mitchell, 2017; Helm *et al.*, 2017; Huizingh, 2011; Schroll & Mild, 2012).

The definition of open innovation has evolved since it was first introduced. Initially, it was described as "a paradigm that assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as the firms look to advance their technology" (Chesbrough, 2006b, p. xxiv). Later, Chesbrough (2006a, p. 1) defined open innovation as "the use of purposive inflows and outflows of knowledge to accelerate internal innovation, and expand the markets for external use of innovation, respectively." Purposive inflows of knowledge or *technology exploration* mean improving internal innovations using external knowledge. Purposive outflows of knowledge or *technology exploitation* mean leveraging internal innovations outside the organisation (van de Vrande *et al.*, 2009).

Bolisani and Bratianu (2018) argue that knowledge is an abstract construct detached from the material world and, despite its significance, it still lacks a precise definition. They maintain that attempts to clarify it, from ancient Greek thinkers such as Plato to contemporary knowledge-management scholars, remain inconclusive (Bolisani & Bratianu, 2018).

Bolisani and Bratianu (2018) note Nonaka and Takeuchi's (1995) contribution, which shifts epistemological debates into managerial practice, maintaining this justification is best understood within the social conditions in which knowledge is generated and exchanged, namely, the organisational context. Bolisani and Bratianu (2018) also noted that Nonaka and Takeuchi (1995) advanced this perspective by introducing practical evaluative criteria such as cost, profit margins, and the extent to which a product increases a firm's economic performance. Knowledge, increasingly recognized as a strategic asset within organizations, must be conceptualized in practical, operational terms that align with real business contexts rather than treated as an abstract construct belonging to a purely theoretical realm of ideas (Bolisani & Bratianu, 2018). Bolisani and Bratianu (2018) also proposed the work of Swedish organizational theorist, Professor Leif Edvinsson, as of interest. Edvinsson (2002) proposed that new models and metaphors are required to advance our understanding of knowledge and one of these is 'knowledge as energy'. The energy metaphor is thus proposed to reinterpret knowledge: Bolisani and Bratianu (2018) map three key attributes of energy onto the knowledge domain which is presented in summary form by this author:

1. Energy exists as an intangible field that extends through space and time. Applying this idea to knowledge shifts the paradigm: knowledge is no longer viewed as a tangible object or fluid but as an invisible, dynamic field similar to gravity. Like energy fields, knowledge fields vary across contexts and evolve over time.
2. Energy appears in diverse forms such as mechanical, thermal, electrical and this diversity is mapped onto knowledge. Knowledge likewise manifests in different forms shaped by how the brain processes it. Tacit knowledge arises from unconscious processing, while explicit knowledge is consciously articulated. The framework identifies three fundamental forms:
 - Rational knowledge (explicit, language-based reasoning)
 - Emotional knowledge (nonverbal, rooted in feelings)
 - Spiritual knowledge (values and ethical principles)
3. Thermodynamics shows that energy can transform from one form to another irreversibly. Similarly, knowledge can shift between forms under certain conditions. For example, fear (emotional knowledge) can trigger protective

reasoning (rational knowledge). These irreversible shifts constitute entropic knowledge dynamics, where entropy reflects the degree of irreversibility.

Together, these mappings support a new paradigm: knowledge functions as a multi-field system whose dynamics involve continual, irreversible transformations between forms equipping managers and leaders with new avenues for influencing people during periods of change and uncertainty. (Bolisani and Bratianu, 2018).

This author takes the view that paradigm aligns with the dynamism and complexity of medical device sector which has technology at its core. Christensen (2006) applies two concepts to technical knowledge distinguishing between specialized technological skills and integrative, adaptive competencies, as well as between abstract technical knowledge and practice-based, context-specific knowledge. As new technical knowledge increasingly emerges in small firms, these firms often set new technological directions for larger companies. Consequently, large firms must strengthen their dynamic, outward-oriented, and systems-integration capabilities beyond what is typically emphasized in core-competency models (Christensen, 2006).

Chesbrough (2006a) asserted that companies could and should engage in open innovation, emphasising that the use of external pathways to market (that is, technology exploitation) is particularly critical. Notably, Chesbrough (2006b, p. xxiv) argued that “open innovation combines internal and external ideas into architectures and systems whose requirements are defined by a business model”. It is the business model that determines how value from technology is acquired and thus open innovation and business models are synonymous (Vanhaverbeke & Chesbrough, 2014).

Later, Chesbrough and Bogers (2014, p. 17) reported a broad interest in open innovation, as well as the increase, development, and influence of scholarly research around the concept. A further refinement of the open innovation definition was developed and presented in the following terms:

....[The term ‘open innovation’ describes] a distributed innovation process based on purposively managed knowledge flows across organizational boundaries, using pecuniary and non-pecuniary mechanisms in line with the organization’s business model. These flows of knowledge may involve knowledge inflows into the organization (leveraging external knowledge sources through internal processes), knowledge outflows from a focal organization (leveraging internal knowledge through external

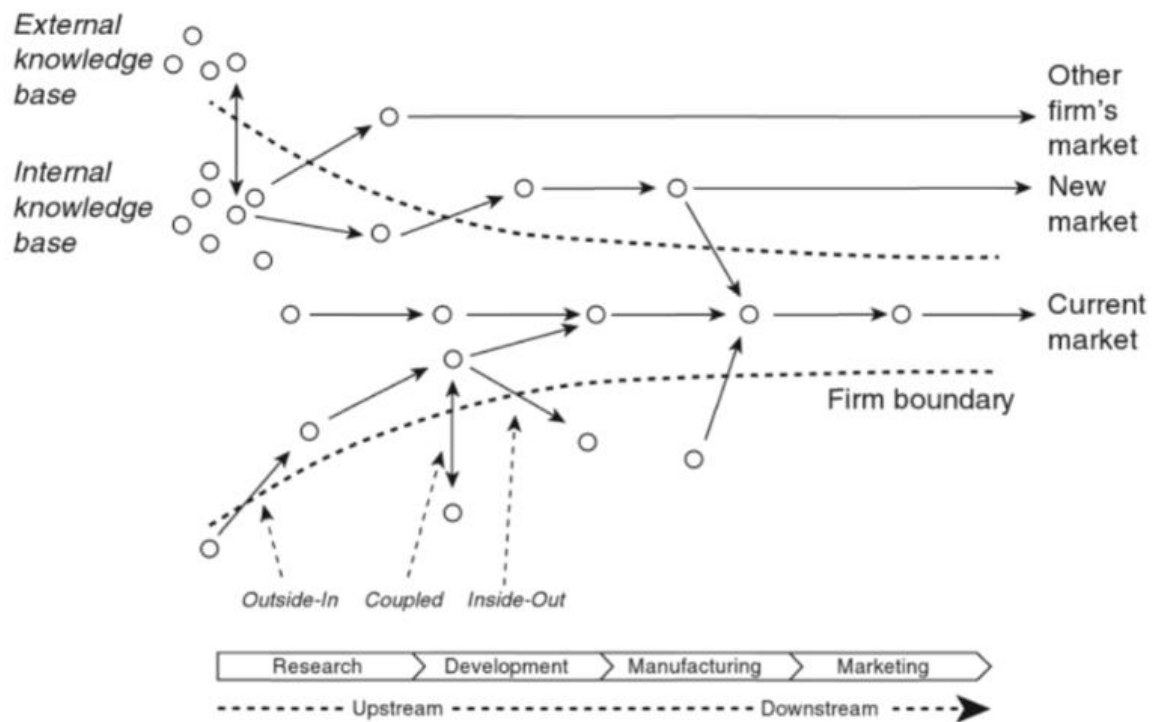
commercialization processes) or both (coupling external knowledge sources and commercialization activities).

Chesbrough and Bogers (2014) emphasised the inclusion of purposively managed flows of knowledge in the definitions. While, at least initially, the intention was to formalize the definition and link it to earlier academic research, especially to economic literature relating to “spillovers” resulting from firm R&D activity (Chesbrough *et al.*, 2020; Chesbrough & Bogers, 2014), the conviction that inflows and outflows of knowledge can, in fact, be purposively managed is a distinguishing feature of open innovation, and this characteristic distinguishes the concept from other iterations of innovation (Chesbrough & Bogers, 2014). This is a significant point of difference as previously “spillovers” were considered an R&D cost and regarded as unmanageable but, in the context of open innovation, it is understood that processes and procedures can be established to manage them purposively, thereby enabling commercialisation (Chesbrough & Bogers, 2014).

Furthermore, these authors clarify that, in this most recent definition, ‘innovation’ includes “the development and commercialisation of new or improved products, processes or services” (Chesbrough & Bogers, 2014, p.17).

The flow of knowledge, both into and out of the firm, is illustrated in Figure 4 below (Chesbrough & Bogers, 2014, p. 18):

Figure 4: The Open Innovation Model.



(Chesbrough & Bogers, 2014, p. 18, Figure 1.5, The Open Innovation Model)

Gassmann and Enkel (2004) classify and describe these open innovation processes as 'outside-in' and 'inside-out'. A third dimension, which they refer to as a 'coupled process' also forms part of the model. They maintain the relative importance of each process varies and is dependent on a firm's open innovation strategy.

This terminology is briefly explained follows:

- Outside-in: This process involves incorporating internally external knowledge acquired from customers, suppliers, patents, universities, start-ups and regional innovation clusters (Gassmann & Enkel, 2004). These authors, citing Hermes (1993), advocate the use of external technological sources in the following circumstance: (1) when a firm is deficient in in-house resources; (2) when the external resources are superior; and (3) when knowledge is easily transferrable and the market barriers low (Gassmann & Enkel, 2004).
- Inside-out: This process involves the transfer of internal knowledge to external actors through such mechanisms as licensing, outsourcing and the management of patents (Gassmann & Enkel, 2004).

- Coupled: This third process combines both the outside-in and inside-out processes and involves companies collaborating in strategic networks (Gassmann & Enkel, 2004).

A key point is that Chesbrough's interpretation of openness is extensive and emphasises that worthwhile ideas can be commercialised either within the company or externally. Dahlander and Gann (2010, p. 699), who also make this point, suggest it relevant for four specific reasons:

1. Work patterns are changing, and firms need to find new ways to access talent as professionals are no longer looking for life-long employment with one employer;
2. Globalization has developed markets to such an extent as to facilitate an increasing division of labour;
3. Better market structures support the trade of ideas;
4. New technologies are being developed to facilitate new forms of collaboration.

Acknowledging the work of Dahlander and Gann (2010), Huizingh (2011) discusses the significance of Chesbrough's early work. Huizingh (2011) notes many open innovation activities are not new *per se*. The examples he gives include the concept of absorptive capacity presented by Cohen and Levinthal (1990) or complementary assets by Teece (1986). However, by describing these activities using a single overarching term, Huizingh (2011) suggests further study, both by academics and by practitioners, has been facilitated. Huizingh (2011, p. 3) refers to the opportune timing of Chesbrough's work given the interest in "...outsourcing, networks, core competences, collaboration and the internet." Furthermore, and of particular interest to this research, Huizingh (2011) describes the scope Chesbrough's work affords for the integration of open innovation with additional management constructs. Moreover, through the classification of internal and external knowledge flows as inbound and outbound open innovation, a more systematic framework is provided.

The concept of open innovation is now well-established (Aquilani *et al.*, 2020; Battistella *et al.*, 2017; Bogers *et al.*, 2019; Burcharth *et al.*, 2017). However, despite its increased adoption, a fully comprehensive understanding of the performance effects or the benefits and limitations of open innovation remains incomplete (Bogers *et al.*, 2017;

Bogers *et al.*, 2019). These authors assert that variances exist amongst empirical studies concerning how open innovation contributes to innovation performance. A consequence of this is that interest in the context-dependency of open innovation has increased. Context-dependency refers to "when" open innovation is practised, and from this starting point its effectiveness may be context-dependent (Huizingh, 2011). In this respect, Zhang *et al.* (2023) argue that the impact of inbound and outbound open innovation on performance is contingent upon contextual influences - it is not a universal approach - so firms must tailor their resource allocation and account for contextual variables when adopting it.

In more academic terms, Bogers *et al.* (2019, p. 90) stress that the limitations of open innovation require significantly more scholarly attention. They suggest that future research should "focus on the particular attributes that are related to leveraging and enhancing internal capabilities, either to enhance one's own business model through Outside-In open innovation or to explore a new business model through Inside-Out open innovation." This insight would inform "how to strategically manage this new innovation imperative." (Bogers *et al.*, 2019.). Burcharth *et al.* (2017, p. 1247) made a complimentary recommendation adding that a more in-depth understanding should mitigate against open innovation being used as an "'all-purpose' solution in any setting." Burcharth *et al.* (2017, p. 1246) refer to "great heterogeneity not only in the extent of adoption, but also in the extent to which firms are able to capture value from openness" emphasising that the reasons for this are not fully known.

Chesbrough (2010) presents the advantages of open innovation for small and medium enterprises (SMEs) in the context of collaboration with larger organisations, suggesting SMEs' specialisms may make them useful partners in facilitating the speedier completion of a project or facilitating access to multiple customer groups. For example, SMEs can play a role in developing products and enhancements for larger technology platforms, including open-source platforms, as well as facilitating access to user networks for larger companies (Chesbrough, 2010). Furthermore, highly profitable SMEs or "hidden champions" who operate in narrow markets but may have a global reach, enabling them to scale, may also be of interest to larger organisations (Chesbrough, 2010). Alassaf *et al.*, (2020) found differences in the level adoption of open innovation based on firm size, with small and micro-organisations less likely to engage in open innovation than larger

ones not least due to the range of resources available to the latter. Aliasghar *et al.* (2025) broaden this perspective by incorporating factors such as heightened risk exposure, significant fixed costs, stringent minimum investment requirements, and severe financial limitations. Nevertheless, it is important to remember that academic research about open innovation and SMEs is still scarce (Brem *et al.*, 2017; Hossain & Kauranen, 2016; Natalicchio *et al.*, 2017).

Current research is also exceptionally limited in the case of inside-out or outbound practices (Aloini *et al.*, 2020; Baima *et al.*, 2020; Bauer *et al.*, 2018; Natalicchio *et al.*, 2017; Wikhamn & Styhre, 2018). Moreover, the work that has been done is primarily conceptual rather than empirical (Baima *et al.*, 2020). For renewed clarity, inside-out or outbound innovation practices involve transferring internal knowledge to external actors through such mechanisms as licensing, outsourcing, and the management of patents (Abdulkader *et al.*, 2020; Burcharth *et al.*, 2017; Gassmann & Enkel, 2004). Abdulkader *et al.* (2020) add further examples such as strategic alliances, joint ventures, and spin-offs. As a stream of open innovation, external technology transfer also describes both inbound (external technology acquisition) and outbound (external technology commercialisation or exploitation) practices (Bauer *et al.*, 2018). However, there is no single agreed list of open innovation practices (Carrasco-Carvajal & García-Pérez-De-Lema, 2021).

While bearing these limitations in mind, this author nonetheless presents a summary of open innovation practices identified as part of the review of literature for this study in Table 1 below:

Table 1: Summary of Open Innovation Practices or Modes.

Outside-in (Inbound) Practices <i>(Technology exploration)</i>	Inside-out (Outbound) Practices <i>(Technology exploitation)</i>
Contracted R&D services	Co-operations
Crowdsourcing	Corporate business incubation
Customer & consumer co-creation	Corporate venture capital
External networking	Donations to commons or non-profits
Idea & start-up competitions	Employee involvement
Informal networking	Internal exploitation
In-house R&D	IP out-licensing
IP in-licensing	Joint-venture activities
Joint-ventures activities	Minority equity investments
Mass customisation	Outsourcing
Mergers and acquisitions	Participation in standardisation (public standards)
Other forms of collaborative R&D	Partnerships
Other forms of technology purchasing	Selling market-ready products
Publicly funded R&D consortia	Spin-offs (spinouts)
Scouting/searching for/collecting information from external sources	Supplying R&D services
Specialized OI Intermediaries	Technology sales
Supplier innovation awards	Technology Transfer
Technology Transfer	
University research grants	
User innovation	

(Data extracted from Battistella et al., 2017, pp.1322-1323; Bauer et al., 2018; Chesbrough & Brunswicker, 2014, p.19; Helm et al., 2017, p.330; Holgersson & Granstrad, 2017, p.1268; van de Vrande et al., 2009, pp. 423-425)

When moving beyond this basic list of items, and, as a wider point, it is important to bear in mind that an outbound open innovation strategy can involve financial and non-financial approaches (pecuniary and non-pecuniary mechanisms): that is, both selling and revealing

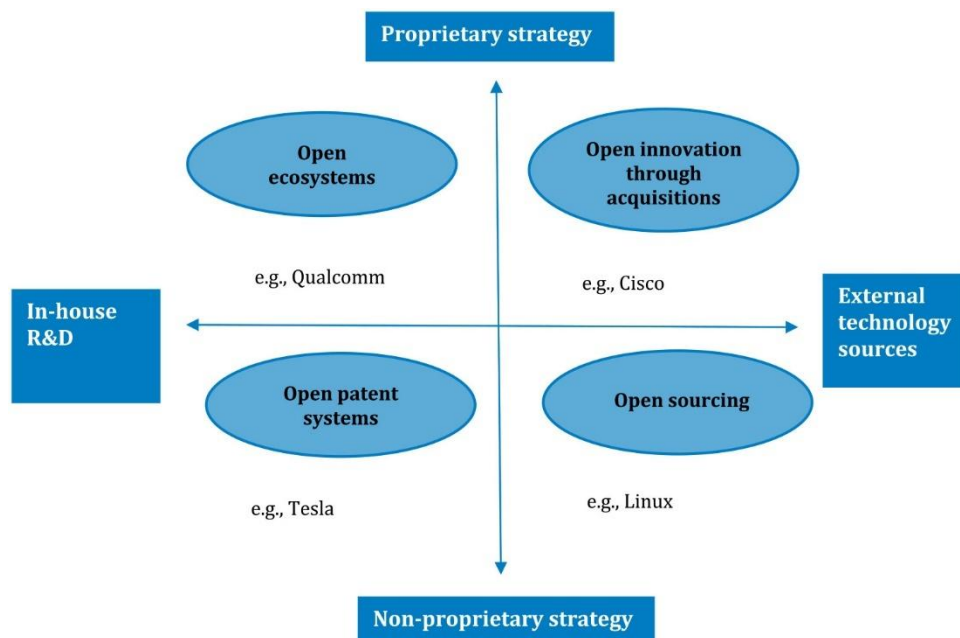
(Dahlander & Gann, 2010). It can positively or negatively influence company performance depending on the possible benefits and risks of the technology transfer (Carrasco-Carvajal & García-Pérez-De-Lema, 2021).

2.2 Theoretical Underpinnings

2.2.1 Overview

In their open innovation review, West and Bogers (2017) highlighted the need for further synthesis with concepts in management theories; for example, absorptive capacity, open distributed innovation, and the role and nature of the post-Chandlerian firm. Other theories emphasized include the firm's resource-based view and dynamic capabilities. It is suggested that these would provide scope to demonstrate how firms build competitive advantage using open innovation strategies (West & Bogers, 2017). Bogers *et al.* (2019) presented two basic decision variables for managing open innovation: (1) the technology development business model, which informs the proportion of R&D that should be conducted in-house relative to the proportion that should be conducted externally; and (2), the IP strategy, which determines the degree to which proprietary IP is utilized when compared to non-proprietary IP. West and Bogers (2017) further linked both these variables to a dynamic capabilities view so as to establish a preliminary framework for open innovation management. This framework is illustrated in Figure 5 below:

Figure 5: Preliminary Framework for Open Innovation Management.



(Bogers et al., 2018, p. 82. Figure 1: Different forms of open innovation by technology development business model and IP strategy.

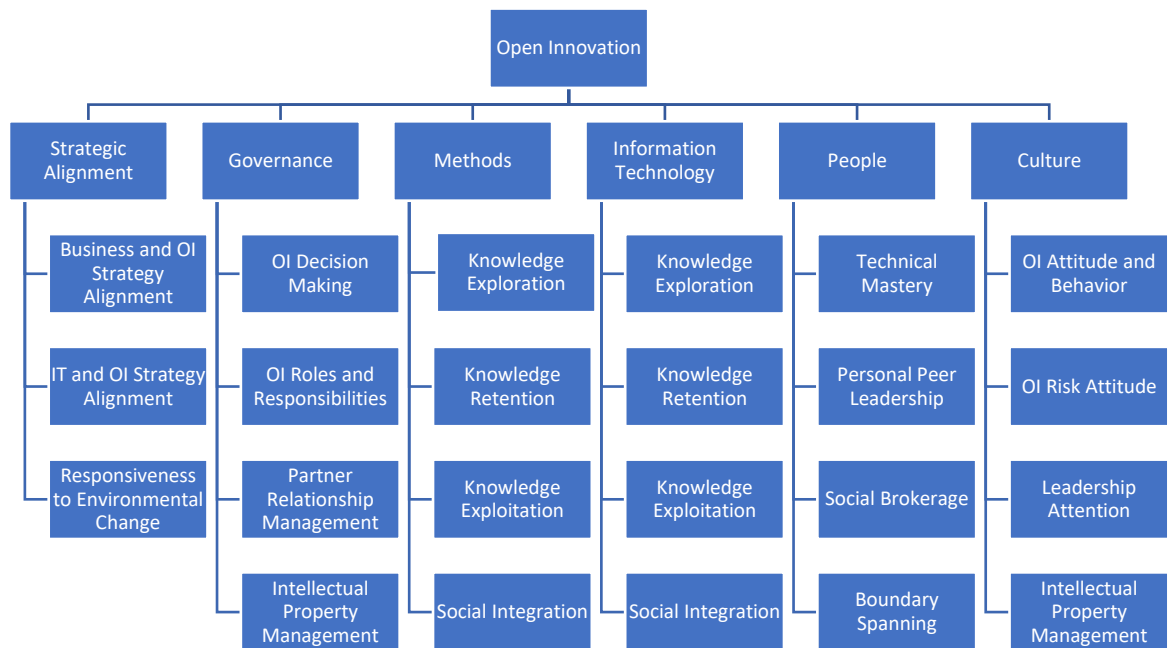
Note: IP = intellectual property; R&D = research and development.)

Dynamic capabilities describe the ability of a company to update and align its competences to a changing business environment and the importance of strategic

management in maximising the skills, resources, and functional competencies necessary to support this process (Teece *et al.*, 1997). It is an approach that attempts to analyse value creation and capture in firms (Teece *et al.*, 1997). The resource-based view of strategy holds "that the competitive advantage and superior performance of an organisation are explained by the distinctiveness of its resources and capabilities." (Johnson *et al.*, 2017, p. 97) Resources are the usable assets of a company, and capabilities refer to how they are utilized (Johnson *et al.*, 2017, p. 98).

Open innovation is complicated, and so, by implication, the management and organisation of innovation processes are also typically complex (van de Vrande *et al.*, 2009). Hosseini *et al.* (2017) developed a framework called the Open Innovation Capability Framework (OICF), listing and structuring the capabilities necessary to implement open innovation and thereby creating a useful management tool that allows managers to benchmark their current capabilities and plan. Reflective of previous research on capability frameworks and validated by both academic and industry experts, the scope of this framework includes both outside-in and coupled open innovation processes (Hosseini *et al.*, 2017). The OICF groups twenty-three capabilities into six factors (1) strategic alignment, (2) governance, (3) methods, (4) information technology, (5) people and (6) culture. The framework is set out in Figure 6 below:

Figure 6: Open Innovation Capability Framework (OICF).



(Hosseini et al. (2017), p. 92, Figure 1, Open Innovation Capability Framework (OICF))

Hosseini *et al.* (2017, p. 91) explain that the factors used are based on Rosemann and vom Brocke’s seminal business process management (BPM) capability framework. This framework, not only “structures capabilities holistically” but reflects the fact that both BPM and open innovation are dynamic capabilities. How the six factors in the OICF embody this perspective is discussed below.

It is crucial to note that **strategic alignment** between both business and open innovation strategies, combined with a supportive IT strategy, which enables organisations to respond flexibly and quickly to environmental changes, is necessary for companies to benefit from open innovation (Hosseini *et al.*, 2017).

The selection of an appropriate **governance** model is context-dependent, and decision-makers need to determine the appropriate one. Moreover, citing Du *et al.* (2014), Du Chatenier *et al.* (2010) and Felin and Zenger (2014), Hosseini *et al.* (2017, p. 94) highlight the open innovation requirements for “well-defined procedures regarding the assignment of IP emerging from OI among collaborators, the compilation of OI teams, and the definition of OI success”. Clearly defined roles and responsibilities support successful open innovation and can help to avert both “absorptive capacity” and

“attention allocation” problems (Hosseini *et al.*, 2017). Care must be taken also to select and motivate suitable open innovation partners necessitating the establishment of appropriate processes to achieve both (Hosseini *et al.*, 2017). IP management processes are needed too due to the strategic importance of IP in open innovation and the need to determine the appropriate amount of information to disclose (Hosseini *et al.*, 2017).

Methods refer to the use of knowledge. Hosseini *et al.* (2017) explain knowledge exploration in two parts, both internal and external. These refer to a company’s “ability to create and integrate knowledge” and the methods used to develop possible absorptive capacity respectively (Hosseini *et al.*, 2017). Knowledge retention is also explained in two parts, both internal and external, which involves the methods used to integrate explored knowledge into the in-house knowledge base; that is, keeping this knowledge “live” and “maintaining knowledge in inter-organisational relationships respectively” (Hosseini *et al.*, 2017, p.95). Knowledge exploitation refers to the methods used to convert both explored and retained knowledge into products or services for sale (Hosseini *et al.*, 2017). Social integration refers to the methods deployed to “facilitate the interaction, coordination, and communication” between open innovation partners (Hosseini *et al.*, 2017, p.95).

The capabilities listed under the **IT** factor map can be explained as the technology solutions used to enable the knowledge exploration, knowledge retention, knowledge exploitation and social integration. For example, to enable knowledge exploration IT solutions may comprise environmental scanning tools or advanced data mining tools; knowledge repositories or organisational memory systems can support knowledge retention and simulation tools and computer-based design applications can support knowledge exploitation (Hosseini *et al.*, 2017). Concerning social integration in this context, the IT solutions deployed to “facilitate the interaction, coordination, and communication” between open innovation partners are significant (Hosseini *et al.*, 2017, p. 95).

People need to be able to use the IT solutions supportive of open innovation for maximum effect (Hosseini *et al.*, 2017). Peer leadership can motivate others to achieve a common goal, especially if formal structures do not exist (Hosseini *et al.*, 2017). Social brokerage refers to the capability of individuals to “connect the right actors that would normally not be in contact and, thus, ensure that external ideas and knowledge are

utilised” (Hosseini *et al.*, 2017, p. 96). People with boundary spanning capabilities can synthesise diverse knowledge, facilitate cross-boundary communication and understanding, which can be critical to the success of open innovation (Hosseini *et al.*, 2017).

The not-invented-here (NIH) syndrome and not-connected-here attitudes are barriers to open innovation, which, if present, will require a **cultural** change (Hosseini *et al.*, 2017). Hierarchical structures also hinder the development of open innovation, making it essential for managers to discourage rigid, top-down approaches in the workplace (Parveen *et al.*, 2023). Similarly, an attitude of risk aversion may impede open innovation and will require a cultural shift towards greater tolerance of entrepreneurial risk (Hosseini *et al.*, 2017). The effectiveness of open innovation is strongly influenced by the commitment of top leadership to it, and they must create a culture supportive of it (Hosseini *et al.*, 2017; Parveen *et al.*, 2023). Parveen *et al.* (2023) found that open innovation flourishes in market-driven and adhocracy-oriented environments, suggesting that leaders should prioritize strengthening these cultural frameworks within their organizations.

This finding was supported by Aliasghar *et al.*, (2025) who also determined that SMEs prefer market-driven strategies over research ones, thus placing a greater reliance on non-R&D based innovation activities. Additionally, managers should implement initiatives that facilitate external partnerships in technology, thereby enriching the organization's learning environment (Parveen *et al.*, 2023). Collaborating with external entities enables the effective transfer of technological advancements from outside sources, further enhancing innovation potential (Naqshbandi & Jasimuddin, 2022; Parveen *et al.*, 2023). While acknowledging the governance aspect of IP management referred to earlier, legal teams, instead of taking a defensive position relating to the use of IP, to support open innovation, should seek out more win/win opportunities including sharing more information for greater returns (Chen, 2022; Hosseini *et al.*, 2017).

However, managers need to consider their organisational context and perhaps adapt the framework to suit individual circumstances (Hosseini *et al.*, 2017). The framework does not guide managers in the operationalisation of the capabilities, nor does it accommodate the inside-out process of innovation. These authors stress the need for

further research to determine the specific capability areas for different contexts and how to operationalise and develop them (Hosseini *et al.*, 2017).

2.2.2 The Resource-Based View (RBV)

The Resource-Based View (RBV) examines the link between the internal characteristics of a company and its performance, exploring the effects of resource heterogeneity and mobility to analyse sources of sustained competitive advantage (Barney, 1991). Liao *et al.* (2019) suggest it is a useful framework to understand why companies perform differently and, for this reason, it is utilized in this study.

According to the RBV positioned within Structure Conduct Performance (SCP)-based theory favoured by Barney (1991 and 2001), firm resources are classified into physical, human and organisational capital. These categories include all assets (both tangible and intangible), capabilities, processes, routines, management skills and knowledge and information that enable a company to develop and implement strategies to improve organisational efficiency and effectiveness (Barney, 1991; Barney *et al.*, 2011; Teece *et al.*, 1997) and thereby provide a foundation for success (Liao *et al.*, 2019). More specifically, resources which have the potential to contribute to sustained competitive advantage, need to be valuable, rare, inimitable and non-substitutable (Barney, 1991) and, additionally, organized to ensure value is captured (Alexy *et al.*, 2017). A sustained competitive advantage is achieved by a firm when its value-creating strategy is not being simultaneously executed by either existing or prospective competitors nor can these competitors replicate the strategic advantages (Barney, 1991). The competitive advantage is sustained for as long as other firms are unable to duplicate it and ends when they are (Barney, 1991). However, Sirmon *et al.* (2011) highlight the importance of the role of management in accumulating, bundling and leveraging resources to create this advantage. Citing Hansen *et al.* (2004), they emphasise that what is done with resources is at least as important as the resources available. Xie and Wang (2021) argue that firms must continuously update their resource bases by integrating advanced technology and knowledge, strengthening their niche advantages and fostering innovation.

The RBV, which is protective of resources, contrasts with that of an open view, which encourages companies to relinquish some asset control (Alexy *et al.*, 2017). Openness reduces or eliminates inimitability which, in turn, affects the rarity of a resource (Alexy, *et al.*, 2017), creating a paradox between RBV and openness. The challenge of

maintaining a balance between external collaboration and internal innovation may become increasingly pressing as more stakeholders engage in tackling societal issues (Zhang *et al.*, 2023). Therefore, examining how firms can navigate the tension between openness and control to optimize open innovation (OI) collaboration is a valuable endeavor (Zhang *et al.*, 2023). Within intermediated crowdsourcing contests, Foege *et al.* (2019) highlight the challenges of balancing, sharing and safeguarding knowledge in individual-driven outbound open innovation. They contend that the paradox of openness is particularly pronounced in this setting, where the tensions between both ends of the spectrum carry economic and psychological costs; however, this issue remains comparatively underexplored (Foege *et al.*, 2019). The question that poses itself at this point is: Can we determine if there are times when openness might be appropriate? Alexy *et al.* (2017, p. 1706), employing mathematical modelling, find that if the production costs of a bundle of resources are reduced or the value captured from a “still-proprietary” complementary asset increases in a monopoly situation, then openness is a reasonable choice. These authors further suggest that in an oligopolist situation, “the substitutability of the open resource in the firm bundle” as well as the number of competitors will influence the decision to open a resource (Alexy *et al.*, 2017, p.1706). However, their models do not take uncertainty into account (Alexy *et al.*, 2017). For this study, where medical technology lifecycles range from 18 to 24 months (MedTech Europe, 2024d) the author proposes uncertainty must be considered. Foege *et al.* (2019) identify three formal and four informal strategies that solvers in crowdsourcing environments use to navigate tensions. The formal strategies include ‘patent thickening’, which establishes an impenetrable patent barrier, patent pending status, and non-disclosure agreements. Meanwhile, the informal strategies consist of selective revealing, solution black-boxing, where only a sample solution is shared without disclosing the underlying processes or technology, controlling complementary assets, and bypassing intermediaries (Foege *et al.*, 2019). Foege *et al.* (2019) propose a model to guide problem solvers in addressing the paradox of outbound open innovation in crowdsourcing. However, challenges persist (Foege *et al.*, 2019). Crowdsourcing platform designers must implement measures to safeguard knowledge exchange, ensure fair participation, and establish appropriate mechanisms for value appropriation (Foege *et*

al., 2019). Additionally, other stakeholders, such as solution seekers and intermediaries, bring diverse perspectives that warrant further investigation (Foege *et al.*, 2019).

Dynamic capabilities extend the RBV. The capabilities are defined as “the firm’s ability to integrate, build and reconfigure internal and external competences to address rapidly changing environments” (Teece *et al.*, 1997, p. 515). Considered strategic, high-level competences, these are increasing in importance as businesses need to continue to develop their capabilities to facilitate firm collaboration to deliver customer value and are thus critical to success (Teece, 2012). Chesbrough *et al.*, (2020) and Kim *et al.* (2021) suggest that while the focus of the RBV is on competitive advantage, the focus of dynamic capabilities is on competitive survival matters relevant to the current dynamic business environment. For example, in a study of Mexican SMEs, Valdez-Juárez and Castillo-Vergara (2021) describe technological capacity quite similarly to dynamic capabilities whereby financial and human resources are used to achieve efficiency, and practical and theoretical knowledge support new product improvement and development. Valdez-Juárez and Castillo-Vergara (2021) found that of the SMEs studied, those demonstrating efficient technological capacity and innovative and sustainable business models, were able to be more competitive and profitable for longer periods of time.

To determine what a firm’s dynamic capabilities are, Teece *et al.*, (1997) propose three classifications: processes, positions and paths commenting that managerial and organisational processes (or routines) are developed based on the company’s asset positions and informed by its evolutionary paths. This, in turn, is where the firm’s competitive advantage lies (Teece *et al.*, 1997). Consequently, the dynamic capabilities framework supports the creation of sustainable competitive advantage in uncertain business environments and companies whose dynamic capabilities are strong fare better (Chesbrough *et al.*, 2020). This may be especially relevant to this study as an increasing skills gap has been identified in the medical technology sector (Deloitte, 2018).

Three sets of organisational processes underpin dynamic capabilities: sensing, seizing and transforming capabilities (Bogers *et al.*, 2019; Teece, 2012). “Sensing” refers to the “identification and assessment of an opportunity”; “seizing” involves utilizing resources to pursue and capture value from the opportunity; and “transforming” relates to ongoing renewal to implement and maintain innovation at scale (Chesbrough *et al.*,

2020, p. 249; Teece, 2012, p. 1396). Naqshbandi and Jasimuddin (2022, p. 3), recognising absorptive capacity, namely, “the ability of a firm to explore and exploit knowledge”, as a dynamic capability, hypothesized that absorptive capacity mediates the relationship between managerial ties and outbound open innovation. Managerial ties refer to activities that extend beyond an organization's boundaries and involve interactions with external parties (Naqshbandi & Jasimuddin, 2022 citing Geletkanycz & Hambrick, 1997). More precisely, they encompass relationships with key stakeholders such as suppliers, buyers, competitors, and other relevant entities (Naqshbandi & Jasimuddin, 2022 citing Kull *et al.*, 2016; Peng & Luo, 2000). These relationships ultimately help managers to acquire and use the internal and external resources needed to support open innovation.

This author suggests alignment with sensing, seizing and transforming capabilities and managerial ties. Naqshbandi and Jasimuddin (2022) determined that the managerial ties of a firm’s management with counterparts in other organizations play a crucial role in enabling outbound open innovation and their hypothesis that absorptive capacity mediates the relationship between managerial ties and outbound open innovation carried. These relationships also strengthen organizational resilience by fostering adaptive behaviors, encouraging diverse perspectives, enhancing flexibility, and improving the ability to navigate uncertainty (Ju, 2023). The entrepreneurial and leadership skills of senior management in relation to sensing, seizing and transforming play an important role in sustaining dynamic capabilities (Teece, 2012). Highly effective entrepreneurial management teams and “robust organizational designs” are characteristics of companies with strong dynamic capabilities (Teece, *et al.*, 2016, p. 14). Gonzalez (2024) explored how knowledge-oriented leadership (KOL) fosters a learning-driven environment, where employees are encouraged to experiment through trial and error. This approach enabled them to discover and utilize knowledge effectively, ultimately driving innovation. Gonzalez (2024) too maintains that organizational leaders are key to facilitating knowledge exchange, both in acquiring insights from external networks and in converting knowledge into valuable assets that drive revenue. Additionally, leaders focused on knowledge management should not only provide employees with guidance on methods and tools but also ensure they understand how their individual contributions align with the broader organizational objectives (Gonzalez, 2024).

2.2.3 RBV, Dynamic Capabilities and Open Innovation

Chesbrough *et al.* (2020) state that dynamic capabilities are necessary for an open strategy and demonstrate the importance of coherence between the two approaches. They posit that this relationship is complimentary. Extending both the RBV and open innovation theories, Zhou *et al.* (2019) found that companies need to align suitable knowledge structures to the type of open innovation they pursue in order to increase their levels of innovation. They also warn of the consequences if this is not achieved. As part of their research, Hassan and Iqbal (2020) examined the impact of organisational capabilities on knowledge management capability and the impact of the latter on open innovation. Hassan and Iqbal (2020) considered entrepreneurial orientation, information communication technology (ICT) and organisation structure as components of organisation capabilities. As open innovation largely requires a combination of internal and external knowledge “new management approaches and deep (systems) capabilities in technology ‘integration’” are needed, but these are not without their challenges (Bogers *et al.*, 2019, p.83).

Burcharth *et al.* (2017, p. 1247) assert that, in stressing a direct relationship between external engagement and innovation performance, the literature does not provide clarity in terms of what organisational activities are required “to exploit external paths for innovation generation and commercialisation.” However, Chen and Liu (2018) found that exchanging knowledge between organizations fosters shared norms and a mutual understanding of the importance of learning. This, in turn, supports the idea that openness encourages a willingness to learn (Chen and Liu, 2018). Companies should actively enhance their expertise and absorptive capacity, as these capabilities enable them to translate the outcomes of open innovation into a sustainable competitive edge (Lopes and de Carvalho, 2018). This position is supported by Çera *et al.*, (2024) who advise SMEs should prioritize recruiting skilled professionals and providing them with comprehensive training to deepen their understanding of open innovation and cross-organizational collaboration. It is not just beneficial but essential to create opportunities for employees to apply their newly acquired knowledge and skills in practice (Çera *et al.*, 2024). Such initiatives not only strengthen individual expertise but also align with the organization’s broader innovation objectives, fostering a culture of continuous learning and strategic innovation (Çera *et al.*, 2024). Zhou *et al.* (2019) recommend a system to

manage intellectual property be established to prevent knowledge spillover and excessive sharing of knowledge assets. Open innovation performance varies depending on how well the challenges are mastered through the smart orchestration of assets combining internal and external technologies to align with the business model (Bogers *et al.*, 2019; Kim *et al.*, 2021). It is this mastery that makes open innovation work (Bogers, *et al.*, 2019).

Carrasco-Carvajal and García-Pérez-De-Lema (2020, p. 20) determined that innovation capability supports the development of outbound open innovation practices and those companies that improve their knowledge acquisition capabilities “increase the number of new external licensing agreements.” Closely aligned with this idea is the concept of “desorptive capacity”, which refers to a company’s ability to convert internal resources into commercial value (Joseph, 2023; Kim *et al.*, 2021). Research indicates that this capability is positively linked to financial performance as well as to enhanced strategic outcomes, such as fostering new knowledge, reducing learning curves, and co-opetition efforts; for example, forming collaborative partnerships (Joseph, 2023; Kim *et al.*, 2021). This is an increasingly important capacity because product life cycles shorten, the demand for value creation and large capital investment intensifies (Joseph, 2023). This author suggests desorptive capacity is particularly relevant in the field of medical technology development. However, Kim *et al.* (2021) advise that research into organisational resources and capabilities is still immature.

Reflecting the above exposition of the key issues, several influences were identified as core to this study. These include variances which exist among empirical studies concerning the contribution of open innovation to innovation performance (Bogers *et al.* 2019; Bogers *et al.* 2017); the need to understand context in greater depth (Zhang *et al.*, 2023; Huizingh, 2011); and the need to understand which attributes leverage and enhance internal capabilities. Also critical is the need to underpin the study with the resource-based view (RBV) and dynamic capabilities in order to demonstrate how firms can build competitive advantage using open innovation strategies (Zhang *et al.*, 2023; West & Bogers, 2017). As mentioned, the RBV, which is protective of resources, contrasts with an open view (Alexy., 2017). This paradox, the author suggests, requires further attention. This is especially the case given that research into organisational resources and capabilities is still immature (Kim *et al.*, 2021). Insight into SMEs from an open

innovation perspective is also inadequate (Brem *et al.*, 2017; Hossain & Kauranen, 2016; Natalicchio *et al.*, 2017). Current research is also exceptionally scarce in the case of inside-out or outbound practices (Aloini *et al.*, 2020; Baima *et al.*, 2020; Bauer *et al.*, 2018; Natalicchio *et al.*, 2017).

2.2.4 Thesis Aims

Thus, the aims of this thesis are:

- To explore the relationship between outbound open innovation (OI) and the resource-based view (RBV) of the firm;
- To determine whether engagement in outbound open innovation can support the development of dynamic capabilities;
- To develop a managerial framework to support the adoption of outbound open innovation practices.

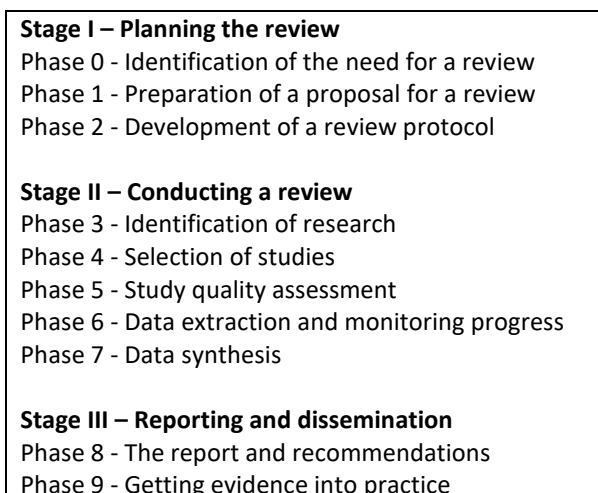
Part 2

2.3 The Systematic Literature Review Process

A systematic literature review is presented. The benefit of a systematic review is the opportunity to minimise researcher bias by adopting a clear, methodical, and repeatable approach (Tranfield, Denyer & Smart, 2003).

The systematic literature review process proposed by Tranfield *et al.* (2003) and outlined in Figure 7 below, provided the basis for this part of the work:

Figure 7: Stages of a Systematic Review.



(Tranfield, et al., 2003, p. 216, Figure 2: Stages of a systematic review)

The deviation from the Tranfield *et al.* (2003) approach was that the initial scoping study was conducted by the researcher rather than a review panel.

This scoping study identified the following keywords and search terms:

"Outbound open innovation" OR "inside out open innovation" OR "external tech* transfer" OR "external open innovation" AND "literature review".

The next steps included searches of the Web of Science Core Collection and Scopus (the latter described by Aquilani *et al.* (2020) as the main resource in management studies) to ensure thorough literature coverage (Battistella *et al.*, 2017).

More precisely, using the Web of Science Core Collection, the following search was undertaken:

The terms "Outbound open innovation" OR "inside out open innovation" OR "external tech* transfer" OR "external open innovation" (similar to Aloini *et al.*, 2020) AND "literature review", under the "Abstract" category were used.

'Article' was selected within a five-year time frame from 2017 to 2021 inclusive.

This search yielded thirty-nine results.

Using SCOPUS, the following search was undertaken:

The terms "Outbound open innovation" OR "inside out open innovation" OR "external tech* transfer" OR "external open innovation" (similar to Aloini *et al.*, 2020) AND "literature review", under the Abstract/Keyword/Author category.

'Article' was selected as the document type, journal as the source type, English as the language and the timeframe was refined to five years from 2017 to 2021 inclusive.

This search yielded eighty-two results.

After the duplicates were checked, the final list consisted of one hundred and ten articles.

Neither search was limited to business-related fields but left open to include all disciplines to ensure an inclusive result.

To further narrow down the focus of the study, a lexical analysis of the one hundred and ten articles was conducted using Cortext Manager software to identify the main themes.

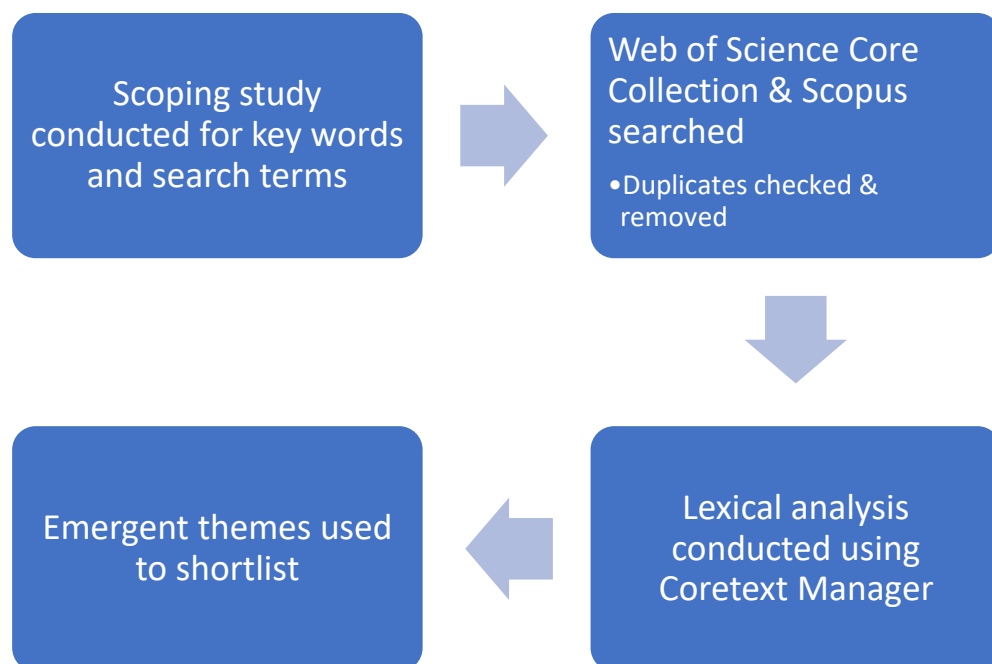
The Scopus articles were analyzed collectively, and the Web of Science articles were analyzed in the same manner. Between both sets of data, excluding the initial keywords and search terms, the following themes emerged, occurring at a higher frequency i.e., equal to or greater than ten: innovation strategy/strategies, innovation activities, radical innovation, intellectual property and management capability. These themes formed the basis for shortlisting the articles for a more detailed review and informed the development of the research questions for this work.

The articles were then reviewed and shortlisted based on the themes identified. 28 articles were deemed relevant.

This process was later repeated for the timeframe 2022 to 2025 when thirty articles were identified of which twelve were considered relevant.

The steps are summarised below in Figure 8.

Figure 8: Systematic Literature Review Steps.



2.4 Systematic Review of the Literature

An open innovation strategy offers opportunities for enterprise growth (Li *et al.*, 2024) and improved innovation performance but the capability to manage knowledge flows is essential (Casprini *et al.*, 2017; Zhou *et al.*, 2018). Despite the increased adoption of open innovation practices, there is still much that remains unknown (Bogers *et al.*, 2017;

Bogers *et al.*, 2019), specifically about timing and context (Huizingh, 2011). A deeper understanding is required to mitigate the concept being used as a “one-size-fits-all” solution (Burcharth *et al.*, 2017, p. 1247; Zhang *et al.*, 2023). Of note, too, for this study is the dearth of research into inside-out or outbound practices (Aloini *et al.*, 2020; Baima *et al.*, 2020; Bauer *et al.*, 2018; Natalicchio *et al.*, 2017).

Thus, to address the aims of this research, this review will start with a more in-depth exploration of outbound open innovation. Despite the limited scope of existing research (Aloini *et al.*, 2020; Baima *et al.*, 2020; Bauer *et al.*, 2018; Natalicchio *et al.*, 2017), it is still important to have as comprehensive an understanding as possible to maintain clarity, not least because the contextual focus of this thesis, the medical technology sector, is broad, dynamic and often highly complex (MedTech Europe, 2024d).

2.4.1 Outbound Open Innovation Explored

Aloini *et al.* (2020, p. 25), while acknowledging the usefulness of the aforementioned macro processes of outside-in, inside-out and coupled knowledge flows to managers and other professionals, contend that neither the process of outbound open innovation and its associated activities are “univocal nor complete in the literature”. Following a comprehensive review of the open innovation literature from 2003 (when Chesbrough published his first work on open innovation) to 2018, they put forward a process-oriented definition of outbound open innovation. This definition provides a useful framework to underpin the aims of this study.

Aloini *et al.* (2020) describe two key phases of outbound open innovation: 1) an opportunity identification phase and 2) an external technology transfer phase. Each phase can be further subdivided (Aloini *et al.*, 2020, pp. 27-28). The opportunity identification phase includes both an “assessment of the company’s technological portfolio” and the “exploration of markets and technologies” (Aloini *et al.*, 2020, p. 27). The external technology transfer phase refers to the sale or licensing of internally developed technologies to external partners (Helm *et al.*, 2017). It includes an evaluation and selection of potentially interested actors and the choice of transaction type (Aloini *et al.*, 2020, p. 28). Similarly, Bauer *et al.* (2018, p. 2), citing Lichtenthaler (2005), define technology transfer as

“...the deliberate action of an organisation to acquire or commercialise technology from or to another independent organisation involving a contractual obligation for compensation in monetary or nonmonetary terms, potentially in addition to [their] own exploration or exploitation.”

Each of the two key phases of outbound open innovation will be explained in more detail below.

2.4.1.1 Opportunity Identification Phase

2.4.1.1.1 Assessment of the company's technological portfolio

Even though technology transfer is becoming more important, it should be noted, in terms of performance, companies differ significantly (Bauer *et al.*, 2018). Ferrari, Scaliza and Jugend (2019), citing Carrijo & Botelho (2013), explain performance in terms of patents, new job creation, the publication of articles and the launch of new products. The value of a technology can vary depending on the company (Bauer *et al.*, 2018) and estimating its value can be challenging, which in turn, impacts the decision whether or not to proceed with the development of a project or its commercialisation (Aloini *et al.*, 2020). Bauer *et al.*, (2018), citing Bianchi *et al.* (2011), highlight the difficulty associated with defining property rights, which is a necessity for the successful application of any technology to secure royalties and for the management of the complexity of internal cross-departmental coordination. The assessment of the technology portfolio is essential for corporate decision-making (Aloini *et al.*, 2020). These issues apply to the medical technology sector given that 75% of medical device start-ups fail (Shah, 2024) and input costs are increasing (Ernst & Young (EY), 2024).

2.4.1.1.2 Exploration of markets and technologies

The opportunity identification phase, therefore, involves not only the identification of the exclusive technologies which can be transferred externally but also the identification of potential markets or buyers for which the technologies are suited (Aloini *et al.*, 2020; Bauer *et al.* 2018) even if these are not ones the company currently serves (Aloini *et al.*, 2020). However, Bauer *et al.* (2018) suggest prospective buyers and suppliers may be difficult to identify as they could well be positioned in different sectors. The identification of opportunities requires insight into customer needs and demand, potential applications for the technology, and market structures (Aloini *et al.*, 2020). The sources of this insight and information are varied and can include formal and informal

relationships with intermediaries and corporate networks as well as the adoption of analytical frameworks, patent data analyses, trend analyses and intelligent data mining tools (Aloini *et al.*, 2020). This, in addition to supporting the identification of opportunities, contributes to the identification of threats, collectively informing the transfer process (Aloini *et al.*, 2020). Market misalignment is a serious concern in the development of new medical devices and can lead to the failure of projects (Shah, 2024). The exploration of markets and technologies is, therefore, of key importance.

2.4.1.2 External Technology Transfer Phase

2.4.1.2.1 Evaluate and select the actors potentially interested

To advance the rate of transactions and value capture, companies may use push or pull strategies or both (Aloini *et al.*, 2020, p. 30). What this means is the company is proactive in its search for buyers or it may exploit patent databases as well as the internet to promote itself and its intellectual property respectively (Aloini *et al.*, 2020). Regardless of which strategy is pursued, there must be a robust business case for the technology (Aloini *et al.*, 2020).

2.4.1.2.2 Choose the type of transaction

There are several methods of commercialising technologies with each impacting both management and the organisation differently due to the levels of risk and potential profits involved (Aloini, *et al.*, 2020). These methods are classified according to either the transfer of ownership or the transfer of usage rights (Aloini, *et al.*, 2020). Within the former classification, the asset may be sold without restriction, a “contribution to a company” may be made or a joint venture developed (Aloini, *et al.*, 2020, p. 30). Within the latter classification, matters such as licensing patents, know-how and copyright are considered as well as joint ventures with licensing agreements (Aloini *et al.*, 2020). However, Zhou *et al.* (2019) suggest that, to date, researchers have not formed a compelling opinion on how a firm’s innovation outputs and overall performance are affected by open innovation; contradictory findings (some scholars suggest it has positive impact and others suggest negative) need further investigation. However, Zhou *et al.* (2019) have determined that “outbound open innovation has a curvilinear (inverted U-shaped) effect on innovative performance” which implies that after a certain optimum point costs will exceed benefits, and that therefore, a balanced approach is required. The reasons for this are the potentially significant returns, both economic and strategic, stemming from such an approach (Zhou *et al.*, 2019). These authors

recommend managers put a system in place to protect intellectual property to avoid any risks associated with knowledge spillover, ensure knowledge resources are adaptable and where rich component knowledge exists outbound modes of open innovation should be used to commercialise it (Chen, 2022; Zhou *et al.*, 2019).

Illustrating these ideas, Wikhamn and Styhre (2018) examined an outbound open innovation initiative at AstraZeneca, identifying three managerial challenges that hindered progress. They described these as transactional, psychological and communicational. The first challenge involved deciding whether to spin out a project or sell it (Wikhamn & Styhre, 2018). Management had to weigh the benefits of retaining a percentage of future income against the immediate returns of a sale, which could be reinvested into other ventures, each option entailing distinct risks and opportunities (Wikhamn & Styhre, 2018). The second challenge emerged when external interest in a spinout project sparked renewed internal attention, leading to some reconsideration of strategic priorities (Wikhamn & Styhre, 2018). The resolution involved spinning out assets that were significantly distanced from the core business (Wikhamn & Styhre, 2018). Thirdly, the company struggled to secure investors whose strategic goals aligned with the project's direction (Wikhamn & Styhre, 2018). Selecting the right type of transaction is therefore a complicated process that requires careful evaluation to reduce risk and enhance benefits, particularly in fast-changing environments. Therefore, this author maintains, having appropriate capabilities is critical.

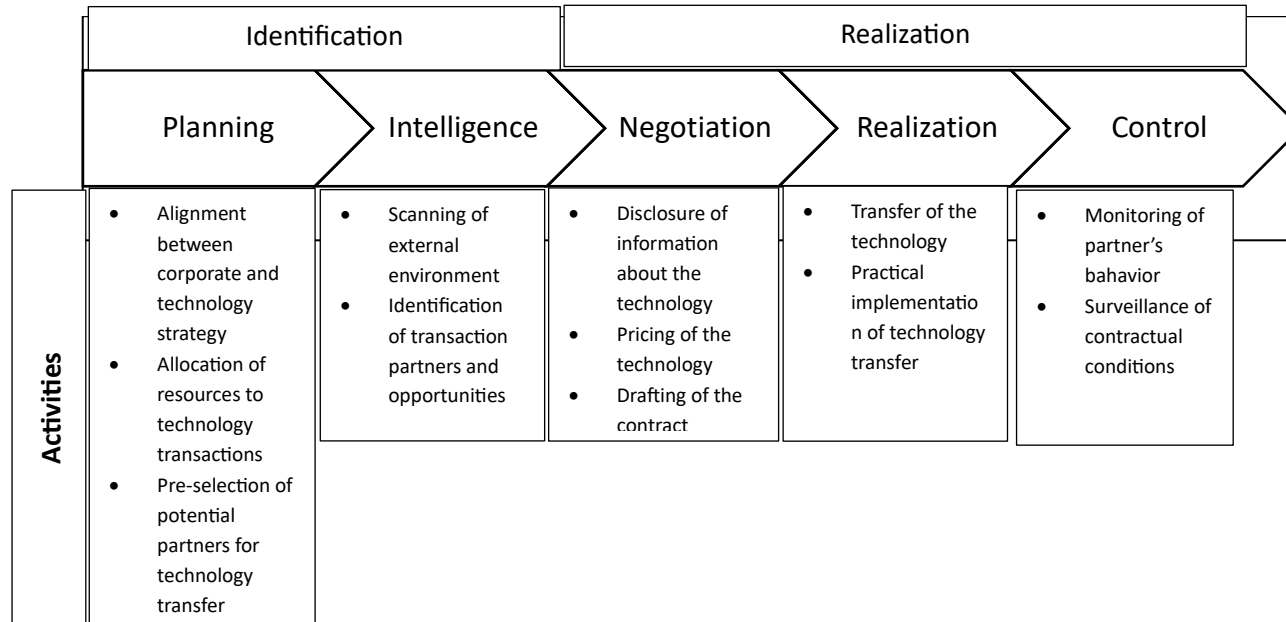
2.4.2 Outbound Open Innovation in Action

2.4.2.1 Performance and Capabilities

Bauer *et al.* (2018), noting the varying performance levels of companies engaging in technology transfer practices, undertook an analysis of the organisational capabilities that differentiate the more successful companies from the less successful ones. While acknowledging that specific attributes of technologies may be the reason behind a failure, these authors suggest that "...certain organisational capabilities are required to cope with these challenges and, hence, be successful in technology transfer" (Bauer *et al.*, 2018, p.6). To understand these, these researchers classify the processes of technology transfer into two stages: identification and realisation. The former involves planning and intelligence gathering, while the latter focuses on negotiation, realisation and control (Bauer *et al.*, 2018), making five steps in total. This author suggests these are

aligned to the “opportunity identification” and “external transfer of technology” phases described by Aloini *et al.* (2020, pp. 27-28) above. The processes and classification are combined and presented as a model in Figure 9 below.

Figure 9: Processes and classification for technology transfers.



(Bauer et al., 2018, p. 5, Figure 2: The processes of technology transfers, and p. 6, Figure 3: Classification of technology transfer processes. The two figures are combined by the author for illustrative purposes)

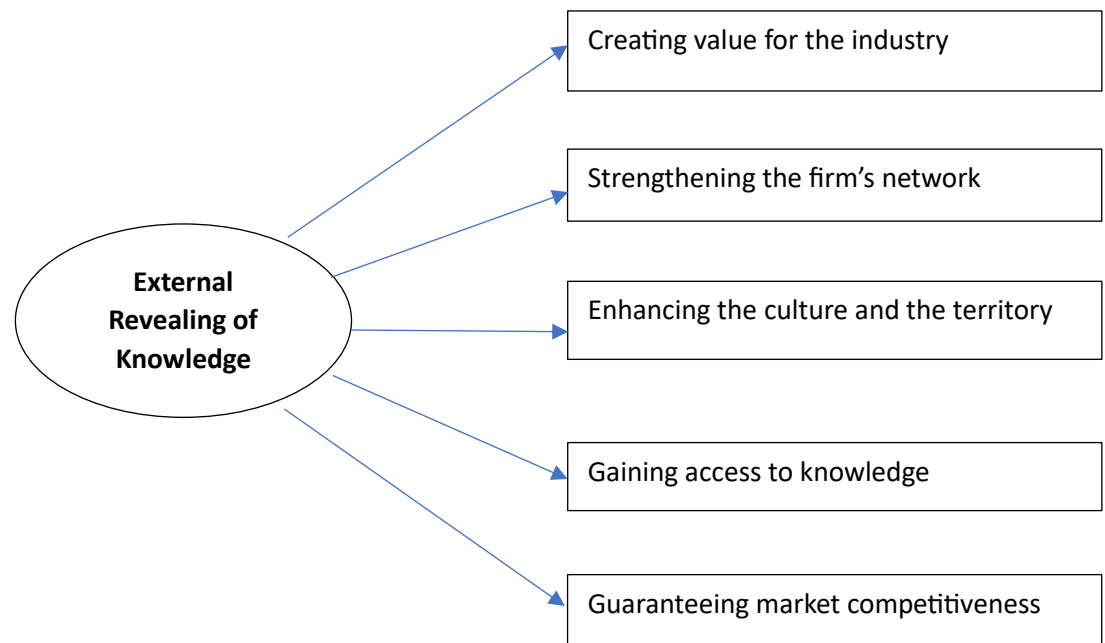
The previously mentioned term “desorptive capacity” is relevant in the context of external technology exploitation or external technology commercialisation. It involves two capabilities pertaining firstly to identification, both of a commercial opportunity and a transaction partner; and, secondly, to the actual transfer and application of the technology following the negotiation, realisation, and control processes (Bauer *et al.*, 2018). Identification capabilities should be developed simultaneously for both inbound and outbound transactions, whereas realization capabilities are experience-dependent. In this respect, it is important to note that experience is instrumental to organizational performance yet accumulates gradually (Bauer *et al.*, 2018). Furthermore, the application of the technology is crucial to commercial success influencing the financial gains to be made (Bauer *et al.*, 2018). In addition to depicting the five steps in the model, an overview of the key activities for each step is also presented (Bauer *et al.*, 2018). Joseph (2023, p. 325) relatedly asserts that desorptive capacity emerges “through firm-specific experience in dealing with tacit knowledge and prior knowledge,” thereby underscoring the temporal dimension of capability building. According to Bauer *et al.* (2018), technology transfer, consequently, constitutes a foundational element of effective technology management.

The work of Bauer *et al.*, (2018) focused on large German, R&D-intensive companies and their findings may not necessarily be transferable to other contexts. Joseph (2023) conducted a synthesis of the literature and, echoing Bauer *et al.*, (2018), maintains research across different industries is needed. Bauer *et al.*, (2018, p. 21) did not consider risk, but recommend it ought to be the focus of future research as competitors can be strengthened “if important knowledge is commercialised”. Similarly, Keinz and Marhold (2021, p. 197) refer to “technological competence leveraging” or TCL as an outbound open innovation strategy that involves “searching for, evaluating and exploiting new market opportunities for existing technologies” in a systematic way. Keinz and Marhold (2021) maintain that TCL is ingrained in the resource-based view, and such competences are critical to innovation and wealth creation. However, they note that many organisations do not benefit fully from open innovation as they lack these competences. While their research explores the use of intermediaries to fill this competency-gap, it highlights the lack of research into outbound open innovation (Keinz and Marhold, 2021). Carrasco-Carvajal and García-Pérez-de-Lema (2021, p. 19) confirmed the

importance of SME innovation capability for the practice of open innovation and determined a positive relationship between a “commitment to learning and innovation capability” and open innovation performance. In particular, these researchers noted the critical role of knowledge-based capabilities in the effectiveness of outbound open innovation demonstrated by an increase in external licensing agreements (Carrasco-Carvajal and García-Pérez-de-Lema, 2021).

In their qualitative, single-case study of a large (> 300 employees) Italian company operating in the craft beer industry, Baima *et al.* (2020) examined the consequences of adopting an outbound open innovation strategy using an external transfer approach. The strategy utilises multiple methods to encourage knowledge-sharing amongst industry participants to benefit all stakeholders (Baima *et al.*, 2020). The authors identified five strategic outcomes, which they presented as illustrated in Figure 10:

Figure 10: Main Findings.



(Baima et al., 2020, p. 1192)

In terms of creating value for the industry, two strands of activity are identified. The first focuses on delivering value to the consumer or "prosumer", who then becomes an advocate (Baima *et al.*, 2020). The second relates to sharing knowledge and commercialisation opportunities to foster 'coopetition' amongst competitors, thus stimulating interest, demand and value for the industry as a whole (Baima *et al.*, 2020).

Knowledge sharing also strengthens the firm's network by simultaneously reinforcing the firm's reputation as well as its own role as a collaborative partner (Baima *et al.*, 2020). Additionally, the external revealing of knowledge has the effect of reforming and improving the cultural perceptions of the product and the geographic region or territory (Baima *et al.*, 2020). An indirect advantage of its outbound open innovation strategy is inbound open innovation, as the company benefits from the knowledge and cultures shared by others (Baima *et al.*, 2020). Ultimately, the process becomes self-perpetuating and self-reinforcing.

Despite the potential risks associated with knowledge sharing, the company has not compromised its competitiveness by taking this approach. On the contrary, by adopting the view that all stakeholders will grow if the market grows, and by focusing on both product and brand differentiation, 'coopetition' is viewed positively (Baima *et al.*, 2020, p.1194). Relatedly, Aloini *et al.* (2020) referred to both formal and informal sources of information with external professionals such as intermediaries and corporate networks in the context of outbound open innovation. As companies increase their open innovation practices, the impact of their ecosystems (collaborative partner networks) on business model development becomes more significant, i.e., creating and capturing value (Abdulkader *et al.*, 2020). Xie and Wang (2021) advise that those companies positioned within leading innovation ecosystems often gain valuable insights and resources from knowledge-rich partners within it and recommend they actively cultivate and sustain collaborative relationships with new partners, leveraging these connections to compensate for resource limitations. Additionally, Xie and Wang (2021) maintain firms must integrate the complementary knowledge and resources acquired from their network into their existing knowledge base to support both exploratory and exploitative innovation efforts. When changes occur in this innovation ecosystem, the enterprise's dynamic capabilities help it adapt resources in response (Abdulkader *et al.*, 2020). Fu *et al.*, (2019) determined that while outbound open innovation can have a short-term negative impact on performance, in the longer term, the performance impact can be improved with higher levels of outbound open innovation engagement.

Liao *et al.*, (2019) studied the moderating effect of technological capability on both inbound and outbound open innovation strategies on company performance and, in addition, the moderating effect of market information management capability on

technological capability. Citing Sears and Hoetker (2014), Liao *et al.*, (2019) describe technological capability as the proficiency level in acquiring and transforming technological knowledge. Market information management capability concentrates on the use of external market information to enhance technological innovation (Liao *et al.*, 2019). Liao *et al.*, (2019) established that technological capability enhances company performance in the context of inbound open innovation but not in the context of outbound open innovation. However, when high technological capability is supplemented by a high level of market information management capability both inbound open innovation performance improves (Liao *et al.*, 2019; Liao *et al.*, 2020). A particular contribution of this research is the consideration of the effect of two capabilities simultaneously on the open innovation-performance relationship (Liao *et al.*, 2019). Hassan and Iqbal (2020, p. 982) explored knowledge management capability in SMEs and determined that “organizational structure, ICTs, and entrepreneurial orientation have direct and positive relationships with knowledge management capability” and, in turn, knowledge management capability has a significant and important effect on open innovation which then impacts the innovative behaviour of organisations.

Taking a slightly different perspective, Charmjuree, Badir and Safdar (2021) explored the relationship between inbound innovation or, otherwise known as external technology acquisition (ETA), and outbound open innovation or external technology exploitation (ETE), and concluded that, by engaging in both modes, there was a positive impact on a firm’s process innovation performance (PIP). Increasing ETA has multiple benefits including fostering stronger collaborative relationships with partners, and gaining improved insight into market needs, which in turn leads to improved ETE opportunities (Charmjuree *et al.*, 2021). In turn, these opportunities have a positive impact on process innovation performance (Charmjuree *et al.*, 2021). Where uncommitted resources or unabsorbed slack (UASL), referred to in this study as financial resources, are available and can be deployed, they moderate positively the relationship between ETA and EFE (Charmjuree *et al.*, 2021).

The impact of this, in addition to new commercial opportunities, is an improvement in the firm’s competitiveness through improved process innovation (Charmjuree *et al.*, 2021). Charmjuree *et al.*, (2021) encourage practicing managers, who may be slow to

engage in outbound open innovation for fear of losing competitiveness, to see beyond just sales and, through internal process improvement, to increase competitiveness instead. Charmjuree *et al.*, (2021) acknowledge that their research focused on software development SMEs in an emerging market, assuming these firms had insufficient technological resources, and suggest that further research is required to test their model in other sectors.

The management of knowledge outflows requires resources and time hence the longer timeframe for a return (Fu, Liu and Zhou, 2019). In today's business environment, building and investing in the necessary skills to strengthen organisational capabilities, is strongly recommended (Bogers *et al.*, 2019), though further study of related processes and costs is needed (Bauer *et al.*, 2018). Overall, there is a dearth of literature in this regard (Fu, Liu and Zhou, 2019; Greco, Grimaldi and Cricelli, 2019) and a longitudinal or dynamic perspective is also an imperative for future research (Bauer *et al.*, 2018; Joseph, 2023; Keinz & Marhold, 2021).

2.4.2.2 Enabling Mechanisms

2.4.2.2.1 Job Design

At this juncture, the work of Burcharth *et al.* (2017) is interesting. Rather than focus on the performance effects of openness, these researchers explore the mechanisms that may or may not enable open innovation and thus ask how "internal organisational activities that promote employee autonomy relate to the performance outcomes of inbound and outbound OI" (Burcharth *et al.*, 2017, p. 1246). They contend this autonomy, more specifically strategic autonomy, understood as 'planning and conducting a job', enables open innovation practices to improve performance (Burcharth *et al.*, 2017, p. 1248). In terms of the actual activities involved, these researchers paid particular attention to the role of job design. Their research established that while outbound open innovation practices did not affect product innovation, outbound open innovation practices positively impacted innovation sales (Burcharth *et al.*, 2017). Therefore, they recommend three key actions to managers to support employee autonomy: support employees to develop their ideas, allow time for creativity and permit employees to engage in intrapreneurial activity (Burcharth *et al.*, 2017). However, the researchers fully acknowledge that this requires cross-functional coordination within the company and an effort to balance the need for this autonomy on the one hand and

control on the other (Burcharth *et al.*, 2017). Carrasco-Carvajal and García-Pérez-De-Lema (2020) determined that the risks entrepreneurs take positively impact idea generation within the company which in turn improves management capabilities. Through the support of employee learning, radical changes to products are developed, and innovation capabilities improve, thus supporting company growth and competitive advantage (Carrasco-Carvajal and García-Pérez-De-Lema, 2020).

2.4.2.2.2 Leadership

Naqshbandi *et al.* (2019) suggest that empowering leadership facilitates outbound open innovation. These authors cite Arnold *et al.*, (2000) and Zhang and Bartol, (2010) to describe this leadership style as one which promotes trust and autonomy among employees to set and manage their own goals. Companies with such leaders are successful in the dissemination and deployment of knowledge and thus the development of such leadership ought to be encouraged (Naqshbandi *et al.*, 2019). Chan *et al.* (2017) identified four key criteria for successful team leadership and determined which innovation process they were most suited to. Innovation knowledge, cognitive capability, and personality style with a conducive aptitude were deemed suited to leading coupled innovation teams; innovation motivation, whereby leaders bolster their capabilities to improve innovation performance, was considered important to lead inbound open innovation teams (Chan *et al.*, 2017). Both Chan *et al.*, (2017) and Naqshbandi *et al.*, (2017) propose the use of rewards to increase motivation.

Chan *et al.*, (2017, p. 96) go further to propose “a complete enterprise and leadership system to include reward and promotion mechanisms” as motivation impacts knowledge acquisition, development, and creativity contributing to the creative process and innovativeness. In turn, Naqshbandi *et al.*, (2019) argue empowering leaders contribute to developing an organisational climate, a phenomenon described as an employee involvement climate, which supports knowledge exchange and innovation. However, in the case of outbound open innovation, Naqshbandi *et al.*, (2019) did not determine that the employee involvement climate mediated the relationship between empowering leadership and open innovation, and further research is required. The research of Burcharth *et al.*, (2017) too had its limitations: specifically, the practices were investigated at an aggregate level, and as such, the researchers recommend further, more detailed research. Chan *et al.*, (2017) acknowledged limitations in their research

to the investigation of the relationship between team leaders' innovation traits and open innovation. Thus, future research could consider the influence of these traits on innovation performance (Chan *et al.*, 2017).

2.4.2.2.3 Technological Entrepreneurship Capabilities

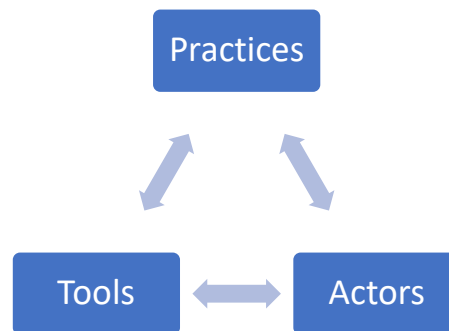
Hejazi *et al.*, (2017) explore the effects of open innovation on technological entrepreneurship capabilities or TEC. In general terms, these scholars describe TEC as a variety of capabilities needed for competitive advantage but, more specifically, and citing Abdullah (2008), suggest these capabilities include an ability to identify changes in the firm's context and, employ newly acquired technologies, along with operating the business well to be both successful and sustainable. Regarding outbound open innovation, Hejazi *et al.*, (2017) explore the impact of the outbound open innovation practices of selling and revealing on three TEC dimensions: core competency, the technology paradigm, and linkage. Core competency refers to the integrated and exclusive corporate knowledge that provides competitive advantage; the technology paradigm refers to unmet technology needs as well as the scientific rules and material technology to be deployed; and linkages refer to those relationships made with "customers, markets, suppliers, competitors or external sources of knowledge" (Hejazi *et al.*, 2017, p. 191), all of which impact corporate performance and competitiveness. Hejazi *et al.*, (2017) determined that selling, which includes licensing intellectual property, joint ventures, and spin-offs, while strengthening all three dimensions referred to above, has a particularly strong and direct impact on the technology paradigm. Revealing must be treated more cautiously as the company may sacrifice financial gains for other benefits and Hejazi *et al.*, (2017) determined that the impact of revealing was stronger on linkage. Hejazi *et al.*, (2017) thus highlight the importance of outbound open innovation in enabling rapid and effective technology paradigm shifts, facilitating new market entry and building relationships.

2.5 Managerial Choices

Here, the work of Battistella *et al.* (2017) is relevant. These researchers studied the managerial choices necessary at project level for effective open innovation in a sample of 85 European SMEs (Battistella *et al.*, 2017, p. 1312). This was in response to the limited research available on the practical application of open innovation, especially in SMEs. From a systematic review of the literature, a reference framework for managerial

decision-making was devised based on three fundamental blocks: practices, tools and actors (Battistella *et al.*, 2017). The practices capture the multiple ways 'how' open innovation is exercised; tools refer to the “instruments, interfaces and technologies supporting the concrete adoption and implementation of open innovation”; and actors refer to multiple stakeholders involved, including agents and networks (Battistella *et al.*, 2017, p. 1315). The empirical research determined interdependencies between these blocks; for example, the practical choice of how to implement open innovation determines which tools are appropriate and which actors should be involved. Alternatively, the selection of tools may determine the proper practice and so forth (Battistella *et al.*, 2017). These interdependencies are presented in a simple diagrammatic form in Figure 11 and are explained further below:

Figure 11: Interdependencies.



(Battistella *et al.*, 2017)

2.5.1 Practices

Twenty-three practices were identified in total and categorised under the three core processes of open innovation: inbound, outbound and coupled (Battistella *et al.*, 2017). Specifically, concerning outbound practices, the list these researchers provide is as follows:

- Commercializing/selling technologies;
- Corporate venture capital or incubators;
- Donations to commons or non-profits;
- IP [intellectual property] out-licensing and patent selling/outward licensing of IP;
- Minority equity investments;
- Participation in public standardization;
- Supplying R&D services/activities;
- Venturing (spin-offs and spin-outs).

Battistella *et al.* (2017) found that the practices of outbound open innovation are less prevalent than inbound ones and that more IP is acquired than sold. However, further research on a larger sample would be required to generalise these results (Battistella *et al.*, 2017). The researchers stress the importance of maintaining an SME perspective due to the challenges these companies face in terms of limited resources. This is a point that has been referred to indirectly by Alassaf *et al.* (2020) and, more directly, by others, including Aliasghar, (2025), Çera *et al.* (2024), Zhang *et al.* (2023) for example.

2.5.2 Tools

Battistella *et al.* (2017) identify multiple tools to support open innovation but do not link them to a specific open innovation process. The tools range from events such as workshops to intermediaries to technologies (Battistella *et al.*, 2017). This author suggests the work of Aloini *et al.* (2020) complements and extends the findings of Battistella *et al.* (2017) on technologies through their development of "a conceptual framework matching the OI process phases" with appropriate types of ICT. Aloini *et al.* (2020, p. 26) suggest that the process of outbound open innovation is "characterised by complex, sometimes low structured tasks and decisions" which could be significantly enhanced through the use of ICT. By aligning the sub-phases of the outbound open innovation process referred to previously, namely: the exploration of markets and technologies, the assessment of technological portfolios and the external transfer of technologies, to the processes of knowledge management (KM), it is possible to identify and classify the appropriate ICT tools to support the practices in each sub-phase and thereby create a separate conceptual framework (Aloini *et al.*, 2020) presented in Table 2 below:

Table 2: The outbound OI classification framework.

	Exploration of markets and technologies	Assessment of technological portfolio	Technology transfer
Collaborative tools			
Content management tools			
Business analytics			

(Aloini et al., (2020), p. 31, Table 1: The outbound OI classification framework)

In addition, Aloini *et al.* (2020) propose that absorptive capacity, which supports outbound open innovation, could be significantly improved by using suitable ICT tools. Ultimately, this framework provides an initial guide to help practitioners manage their outbound open innovation activities more efficiently.

2.5.3 Actors

In terms of those actors involved in the process of open innovation, Battistella *et al.* (2017) classified them into four categories to reflect their connection to the company and the role they play. These categories are headed: value chain actors, internal actors, external actors and third-party actors. Extracted from their research is the following summary in tabular form (Table 3) below:

Table 3: Actors of open innovation process in literature.

Category	Actor
Value chain	Customers Lead users Other companies Spin-offs and spinouts Suppliers
Internal	Employees
External/public	Communities Community of Practice Government Policy makers Universities (higher education) and public research centres/organisations/institutions
External/private	Experts External consultants Private R&D service providers/institutes Start-ups (and entrepreneurs) Venture capitalists
Third-party actors	Accelerators and incubators Intermediary of collaboration Networks Technology brokers and scouts

Data extracted from Table VII: Actors of open innovation process in literature (Battistella et al., 2017, p. 1326)

2.5.4 Organisation and Culture

Alassaf *et al.* (2020, p.2285) determined that a valuable organisational culture facilitates the successful adoption of open innovation processes. It does this by detecting dynamic problems relating to resource integration, employees and rules; for example, to make external relationships more effective. These same researchers found that while organisational culture can be a potential barrier to successful open innovation, employees' knowledge and rewards positively impact the adoption of open innovation: the more open the culture is, the more employees will engage and be rewarded for it (Alassaf *et al.*, 2020). Thus, the relationship between organisational culture and the adoption of open innovation is positive when open innovation actions are compensated (Alassaf *et al.*, 2020). These points are all in line with the literature; for example, the findings of Chan *et al.*, (2017) and Naqshbandi *et al.*, (2017) previously highlighted. In a similar vein, Li *et al.*, (2024, p. 5138) determined that an open culture as well as an open organisation are the “critical soft power and hard power that affect the growth of enterprises” in a positive manner. Madrid-Guijarro *et al.* (2021) emphasized that constituting an innovation strategy plays a crucial role in fostering open innovation,

enhancing the influence of human capital and reinforcing a culture of continuous learning while Mirza *et al.* (2022) determined that the effect of outbound open innovation on strategic innovation is promoted by exploratory learning. Helm *et al.* (2017) posit that to pursue an external technology commercialisation (ETC) strategy, a company needs time and specialist employees often working together in a licensing or Technology Transfer Group and the ETC strategy applied will have a significant impact on the success or failure outcomes (Helm *et al.*, 2017). Gentile-Lüdecke *et al.* (2020) identified the need to understand the change process a company moves through when opening for innovation, concluding that specialist expertise may play an important facilitating role.

Santoro *et al.* (2020) argue that as a growing proportion of information and knowledge is generated beyond a firm's boundaries, organisations must develop new systems and structures to accommodate this shift. Consequently, adjustments in organisational frameworks and task delegation become increasingly crucial within an open innovation environment (Santoro *et al.*, 2020). Gentile-Lüdecke *et al.* (2020) highlighted the importance of the Chief Executive Officer (CEO) in creating an environment supportive of open innovation and reported the usefulness of a centralised structure within which individuals have both the authority and responsibility necessary to make decisions to enable outbound open innovation practices (Gentile-Lüdecke *et al.*, 2020). Relatedly, Santoro *et al.* (2020) determined that an entrepreneur's willingness to delegate to and trust both internal and external collaborators increases the likelihood of an organisation engaging in open innovation. This effect is further strengthened by the competence and preparedness of managers and employees to take on responsibility and cope with risk (Madrid-Guijarro *et al.*, 2021; Santoro *et al.*, 2020). Thus, human resource management practices related to financial incentives, job satisfaction, and employees' personal connections enhance the advantages of open innovation and innovation performance (Papa *et al.*, 2020; Santoro *et al.*, 2020).

2.5.5 Intellectual Property

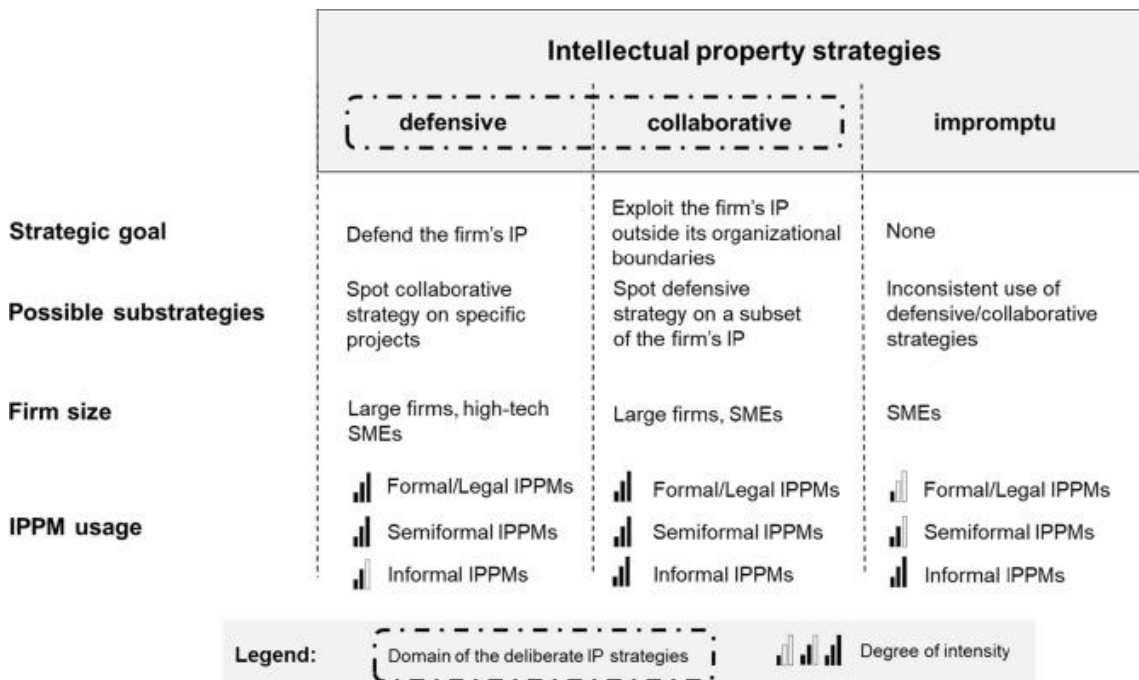
Intellectual property (IP) is becoming increasingly important as an enabler of open innovation. It both facilitates the sharing of ideas across company boundaries and acts as an effective complement to partner collaboration (Bogers *et al.*, 2019). IP protection, through licensing and the generation of adequate royalties, is key to securing needed

investments for innovation success (Bogers, *et al.*, 2019). It is significant in the management of what is referred to in this study as ‘the open innovation paradox’, namely, how to balance the tension between knowledge sharing on the one hand and knowledge protection on the other (Bogers, *et al.*, 2019). Chen (2022) suggests that when SMEs have a robust intellectual property management system in place, they are better positioned to share innovation-related information transparently, enabling them to remain competitive in the market.

However, this is a complex area of activity. While IP protection may provide useful defences, it may also introduce significant constraints (Grimaldi, *et al.*, 2021). In this respect, it is important to bear in mind that the purpose of relinquishing some control is to achieve superior growth (Orlando *et al.*, 2021).

Grimaldi *et al.* (2021) demonstrate that the IP strategies adopted by a company can impact its potential to realise the benefits from its IP. They offer a framework, identifying the three different IP strategies set out in Figure 12 below: defensive, collaborative, and impromptu.

Figure 12: Intellectual Property Framework.



(Grimaldi, Greco & Cricelli, 2021, p. 158, Figure 1: The Intellectual Property Framework)

Companies may use different strategies in different contexts and may transition from one strategy to another (Grimaldi *et al.*, 2021). The findings from their survey indicated that almost half of the respondents used an impromptu strategy, twelve percent a defensive one and approximately forty percent a collaborative one (Grimaldi *et al.*, 2021). The predominance of an impromptu strategy “underlined the lack of strategy in the management of IP”. Furthermore, while those firms who used a defensive strategy were found to be more involved in open innovation activity, those who had adopted a collaborative strategy performed better (Grimaldi *et al.*, 2021).

This study has prompted questions about the underlying reasons for these results and why companies might switch strategy. The relevance of these strategies for commercial success, as well links to overall business strategy, were highlighted (Grimaldi *et al.*, 2021, p. 162). Greco *et al.* (2022) expanded this framework to include two additional strategic approaches: purposely defensive and developing impromptu. Firms which adopt a purposely defensive approach do not constrain the information they share with their partners, but they protect their innovations to avoid the risk of being copied (Greco *et al.*, 2022). They have an organisational function to manage their IP and do not neglect IP protection due to its cost (Greco *et al.*, 2022). Firms which adopt a developing impromptu approach seldom safeguard their intellectual property because of the high costs involved, lack the internal structures needed to manage it effectively, and do not view it as a source of revenue (Greco *et al.*, 2022). Nonetheless, they follow specific guidelines and limitations when it comes to sharing information with other organisations (Greco *et al.*, 2022).

Cabaleiro (2018, p. 48) is of the view that “little is known about the abilities of the parties to take possession and extract value from licensing” and cites a dearth of consistent licensing data, a phenomenon consistent with the prevalence of confidential agreements and the way licensing revenues are reported on income statements as reasons. Thus the ‘Revenue Effect’ is difficult to assess and quantify, which prompted Cabaleiro’s investigation into the determinants of the appropriation capacity of licensors. She set out two hypotheses: Firstly, that “licensors are better able to appropriate benefits from licensing when they license out in the same sector (characterized by lower information asymmetries) than when they license out to another sector (characterized by higher information asymmetries)”; and second “licensors that lead a specific sector (i.e., have

the highest market share) appropriate fewer benefits from licensing than those that are followers” (Cabaleiro, 2018, p.48). Both hypotheses were carried (Cabaleiro, 2018).

In respect of the first hypothesis, if the licensee is from the same sector as the licensor, this sends a positive message to the stock market, communicating the licensor’s sectoral dominance, highlighting the weaker competitive position of the licensee with respect to the technology as well as the potential for the sectoral standardization of the technology (Cabaleiro, 2018). However, the bargaining power of the licensor was found to be crucial and a function of two considerations: cash limitations and information asymmetries. A company with limited cash may decide to license its technology in favour of short-term earnings, but this sends a message to the markets that the company negotiated the deal from a weak bargaining position, which, in turn, impacts the market value and it adds little to it (Cabaleiro, 2018, p.56).

While it appears from these findings that it is more advantageous to license a technology within the same sector, another risk, linked to the second hypothesis, has also been identified (Cabaleiro, 2018). This risk is associated with cost of imitation should the company be a market leader in its sector, and, in such situations, companies are advised not to licence out unless “the licensing payments exceed the potential cost of imitation” (Cabaleiro, 2018, p.56). Bauer *et al.* (2018) identify what is almost the same risk, namely of strengthening competitors with the commercialisation of important knowledge, as one requiring further research.

This situation contrasts with companies considered followers, whose licensing activities in the same sector send out messages of growth and development to the markets and thus increase their related revenues and market value (Cabaleiro, 2018). When licensors and licensees operate in different sectors and the licensor is a leader, appropriation is very low (Cabaleiro, 2018). Cabaleiro’s (2018) study focussed on the measurement of increases in market values using cumulative abnormal returns or CARs to derive the conclusions for a defined group of companies in the United States. However, questions remain, not least relating to “additional organizational and industrial characteristics that might affect the distribution of bargaining power in licensing agreements and the consequences of this distribution” (Cabaleiro, 2018).

Holgersson (2024) discusses the suitability of different technology types for an outbound open innovation business model, differentiating between discrete and complex or systems technologies: that is, one of few inventions versus one of multiple interdependent inventions respectively. The intellectual property (IP) decisions and the contract design are critical in the context of supporting an open business model for a discrete technology. But there is more flexibility for complex or systems technologies which are subject to a “more multidimensional design of openness” depending on the technology and the product architecture (Holgersson, 2024, p.173). The architectural design can be integral or modular (Holgersson, 2024 citing Baldwin & Clark, 2000; Chesbrough, 2003; Schilling, 2000). Modularity enables a company to selectively reveal IP which may be beneficial while simultaneously protecting other proprietary knowledge (Holgersson, 2024). Given the broad range of technologies in the sector, further research is required to determine if those companies who do not currently use their full IP portfolio, could be supported to do so.

2.6 Benefits of Outbound Open Innovation

Li *et al.* (2024) found that both inbound and outbound open innovation positively impact enterprise growth, both individually and when combined. Embracing either approach, but especially in combination, serves as a strategic pathway for business growth. However, successful outbound innovation requires a culture of openness to overcome employee resistance when transferring technology externally for commercialization (Li *et al.*, 2024).

Greco *et al.*, (2019) identified three categories of benefits to outbound open innovation: First, an expansion of the company’s target market with licensing being a common tool to achieve this; second, an improvement of the company’s internal knowledge with those companies delivering ‘new-to-the-world innovations’ more likely to report ‘improved know-how’ and third, improved market success due to innovative products. To realise outbound open innovation, the companies need to develop desorptive capacity (Joseph, 2023). Greco *et al.*, (2019) noted an increase in costs associated with the development of desorptive capacity. Joseph (2023) too noted appropriability concerns regarding outbound open innovation. However, as previously mentioned, Joseph (2023) stated that the management of patents can alleviate some of these concerns and stressed that “desorptive capacity will lead to spin-offs, new licencing

deals, open-sourcing, revenue from unused IP, mutual technology transfers, collaborations (joint R&D, joint research) and divestment of company units” (Joseph, 2023, p. 326).

Usman and Vanhaverbeke (2017), in their analysis of two case studies, one a small, innovative start-up with a newly patented technology and the other a multinational corporation, highlighted mutual benefits for both parties. The start-up could commercialize its technology without the need to invest in complementary assets, retain the flexibility to target niche markets, and secure royalties that could support the development of other technologies (Usman & Vanhaverbeke, 2017). Conversely, the multinational benefited from acquiring new technology without incurring research and development costs, could get to market faster and then secure the technology if it proved commercially viable (Usman & Vanhaverbeke, 2017). Furthermore, the collaboration enabled the multinational to strengthen its reputation as a reliable partner for start-ups (Usman & Vanhaverbeke, 2017).

Shin *et al.* (2018) reported similar results in a larger scale, longitudinal study which showed that smaller, highly specialised companies pursue exit strategies of either selling their technologies or allowing themselves to be acquired because later research and development steps are not financially feasible for them. On the other hand, it is this research and development work, which may not be viable for a larger company, that makes the smaller companies an attractive proposition, so that research and development are more efficient for the larger firm and their risk of failure is lowered (Shin *et al.*, 2018). Other benefits highlighted by Shin *et al.*, (2022) for the larger firm include the opportunity of direct selling, resulting in the creation of direct cash flows and profits, as well as other unqualifiable benefits; for example, developing collective corporate intelligence, accumulative learning and absorptive capacity, as well as developing a supportive corporate culture (Shin *et al.*, 2022).

Start-ups are well positioned to develop disruptive technologies which, through collaboration, can create new opportunities for larger companies if they collaborate (McKernan & McDermott, 2024). It is recommended that larger companies ensure they have the competences necessary to integrate these smaller companies and to scale quickly. They must also develop the regulatory skills necessary to enable the launch of

these new products and support programmes must therefore focus on growing these capabilities (McKernan & McDermott, 2024).

2.7 Standards

Compliance with ISO 13485 facilitates market access for medical devices in many countries by “demonstrating adherence to internationally recognized quality standards” (Jadhav & Shendge, 2024). In addition, compliance also brings business benefits in terms of customer satisfaction, supplier relationships, operational efficiency, competitive advantage and continuous improvement, as well as enabling companies to remain agile and adaptable in responding to global challenges (Jadhav & Shendge, 2024). Jadhav and Shendge (2024) suggest customer satisfaction is increased when a firm can consistently produce safe and reliable devices. Manufacturers frequently prefer certified suppliers and subcontractors due to their compliance commitment (Jadhav & Shendge, 2024). The standards also help firms to rationalise their manufacturing processes to reduce both errors and waste and thus enhance operational efficiency (Jadhav & Shendge, 2024). However, there are “inherent complexities” in achieving this. The process requires substantial effort, and, in fact, this is where most of the compliance efforts are directed (Pacheco *et al.*, 2025).

Carl and Hochmann (2024) identified the implementation of a quality management system as problematic particularly for smaller companies with fewer than 50 employees. Nonetheless, this commitment to certification and quality can provide a competitive advantage to companies by helping to attract new customers and generate more business opportunities (Jadhav & Shendge, 2024). However, in their study of Class I medical device companies in Germany, Carl and Hochmann (2024) reported a significant decline in the perception of competitiveness from 24% to 5% two years after the implementation of the regulations. Jadhav and Shendge (2024) maintain the synchronization of standards provides clarity and certainty for medical device developers, which, in turn, supports investment for innovation, research and development. It should be noted that this argument is contradicted somewhat by Carl and Hofmann (2024), who reported one third of the companies surveyed feared a reduction in their portfolios because of the regulatory requirements and 14% indicated they had or would have to reduce their R&D activity to ensure compliance.

Svempe (2024) poses the question: How can the regulations be improved without impeding innovation? This is arguably the key tension in the literature, limited as it is. In formulating the point in these terms, Svempe (2024) raised the concern that, while, on the one hand, the regulations are intended to improve patient safety, on the other, slower innovation and the longer lead time in getting improved products to market could reduce patient safety. Svempe (2024) suggests specific challenges for those companies seeking to launch first-to-market products, which have been noted as taking 34% longer. These challenges include an absence of specific guidance and clinical data, which can result in higher costs due to the longer development and approval processes. This point must be balanced, however, by the potential for the innovator to gain the largest market share (Svempe, 2024).

2.8 Summary

Outbound open innovation has gained increasing attention as organisations seek new avenues for growth, competitiveness, and value creation. Although open innovation is widely adopted, scholars highlight persistent gaps in understanding, particularly regarding outbound practices, timing, contextual factors, and the capabilities required for effective implementation (Aloini *et al.*, 2020; Baima *et al.*, 2020; Bauer *et al.*, 2018; Casprini *et al.*, 2017; Bogers *et al.*, 2019; Bogers *et al.*, 2017; Huizingh, 2011; Natalicchio *et al.*, 2017; Zhou *et al.*, 2018). These gaps are especially relevant in complex sectors such as medical technology, where high failure rates, rising costs, and market misalignment pose significant challenges.

Aloini *et al.* (2020) provide a foundational process-oriented definition of outbound open innovation, comprising two phases: opportunity identification and external technology transfer. The first involves assessing a firm's technological portfolio and exploring markets and technologies to identify commercially viable assets and potential buyers. This requires insight into customer needs, market structures, and technological applications, supported by analytical tools, networks, and intermediaries. The second phase focuses on evaluating potential partners and selecting appropriate transaction types ranging from licensing and joint ventures to outright sales, each carrying distinct risks and strategic implications. Research by Zhou *et al.* (2019) suggests that outbound open innovation has an inverted U-shaped relationship with innovation performance, underscoring the need for balance and strong intellectual property protection.

Capabilities play a central role in determining success. Bauer *et al.* (2018) identify two capability sets: identification and realisation, collectively termed descriptive capacity. These capabilities enable firms to recognise opportunities, negotiate agreements, transfer technologies, and manage partnerships. Experience is critical, as realisation capabilities develop over time. Additional studies emphasise the importance of technological competence leveraging, knowledge-based capabilities, and learning orientation, particularly for SMEs (Carrasco-Carvajal & García-Pérez-de-Lema, 2021; Keinz & Marhold, 2021). Outbound practices can generate strategic benefits such as enhanced networks, improved knowledge flows, and strengthened competitiveness, as illustrated in Baima *et al.*'s (2020) case study of the craft beer industry.

Enabling mechanisms further shape outbound open innovation outcomes. Job design that promotes employee autonomy supports idea development and innovation sales (Burcharth *et al.*, 2017). Leadership, especially empowering leadership, facilitates knowledge sharing and fosters climates conducive to innovation (Naqshbandi *et al.*, 2019). Technological entrepreneurship capabilities, including core competencies, technology paradigms, and linkages, are strengthened through outbound practices such as selling and revealing (Hejazi *et al.*, 2017). Managerial choices also matter such as selecting appropriate practices, tools, and actors which require alignment with organisational strategy, resource constraints, and ecosystem dynamics (Battistella *et al.* 2017).

Organisational culture, structure, and human resource practices influence the adoption and effectiveness of outbound open innovation (Alassaf *et al.*, 2020). Open cultures, reward systems, and decentralised decision-making enhance engagement, while specialist expertise and structured processes support technology transfer (Chan *et al.*, 2017; Li *et al.*, 2024; Papa *et al.*, 2020; Santoro *et al.*, 2020). Intellectual property management is a critical enabler, helping firms navigate the tension between knowledge sharing and protection (Bogers *et al.*, 2019). Different IP strategies such as defensive, collaborative, impromptu, and their variants, shape firms' ability to appropriate value from licensing and partnerships (Grimaldi *et al.*, 2021).

Outbound open innovation offers multiple benefits, including market expansion, improved internal knowledge, enhanced innovation performance, and opportunities for collaboration between start-ups and large firms (Li *et al.*, 2024; Greco *et al.*, 2019,

McKernan & McDermott, 2024; Shin *et al.*, 2022; Usman & Vanhaverbeke, 2017). However, challenges remain, particularly in regulated sectors such as medical technology, where compliance requirements can both support and constrain innovation (Carl & Hochmann, 2024; Pacheco *et al.*, 2025; Svempe, 2024). Overall, the literature highlights the need for stronger capabilities, strategic alignment, and further research to fully realise the potential of outbound open innovation.

Technology transfer is becoming increasingly important (Bauer *et al.*, 2018; Bogers, *et al.*, 2019) with intellectual property an ever more significant enabler (Bogers, *et al.*, 2019; Meng, *et al.*, 2021). However, company performance is in this regard inconsistent (Bauer *et al.*, 2018; Bogers *et al.*, 2019) and researchers have not formed a compelling opinion on how a firm's innovation outputs and overall performance are affected by open innovation (Zhou *et al.*, 2019). Research into organisational resources and capabilities is still immature (Kim *et al.*, 2021) and knowledge is scarce in relation to the capabilities of companies to acquire and derive value from licensing (Cabaleiro, 2018). New management approaches are required (Bogers, *et al.*, 2019) and the literature does not provide clarity in terms of what the necessary organisational activities are (Burcharth *et al.*, 2017). Zhou *et al.* (2019) and Chen (2022) recommend a system to manage intellectual property be established in companies both to prevent knowledge spillover and to limit excessive sharing of knowledge assets to facilitate the innovation process.

Kim *et al.* (2021) suggest that while the focus of the RBV is on competitive advantage, dynamic capabilities are increasingly critical to success (Teece, 2012). To identify them, Teece *et al.*, (1997) propose three classifications: processes, positions and paths. They recommend that managerial and organizational processes (or routines) are developed based on the company's asset positions and informed by its evolutionary paths.

Bauer *et al.* (2018) determined "identification" and "realisation" as the two key capabilities needed for both technology acquisitions and commercialization with the latter having a considerable and positive effect on performance. However, this research was based on large R&D companies in a single country and did not examine how the capabilities are developed. Bauer *et al.*, (2018) acknowledged these capabilities develop with experience over time and, are thus path-dependent. In their study, focal companies were in the preliminary stages of developing their processes which, in consequence, were evidenced by low levels of formalization.

Grimaldi *et al.* (2021) determine that collaborative strategy intellectual property strategies are conducive to positive performance and suggest further research into the factors that could lead companies to embrace either defensive or collaborative strategy could be beneficial.

Chapter 3: Methodology

3.1 Introduction

In determining their overarching approach to the study, the researcher must state their philosophical assumptions to explain the research design and the precise research methods to be used (Creswell & Creswell, 2018). Guba and Lincoln (1994) advise however that matters of method are secondary to those of paradigm. Similar views are widely shared (see for example, Cunliffe, 2011; Cunliffe *et al.*, 2015; Kaushik & Walsh, 2019). In this chapter, the author puts forward their philosophical perspective and justification, an explanation of how theory will be developed, followed by a description of the methodological choice, research strategy, data collection and analysis procedures.

3.2 The Philosophical Assumption of this Thesis

A useful starting point for the approach pursued in this study is the directive given by Cherryholmes (1992, p. 16), who instructs researchers “not to block the road to inquiry” but to “look to the consequences”. For pragmatists, the importance of the research question, and the direction in which it leads, supersedes the underlying worldview (Tashakkori & Teddlie, 1998). Pragmatists reject the notion of selecting one worldview over another and will consider the views of positivism, postpositivism, and interpretivism, choosing the appropriate methods for the research question (Tashakkori & Teddlie, 1998). Equally, pragmatists may adopt objective and subjective orientations during the research process (Tashakkori & Teddlie, 1998). Saunders *et al.* (2019) state that a problem provides the research starting point for pragmatists, who then look for solutions to advance future practice. Cherryholmes' (1992, p. 13, citing Dewey) view is that it is the practical consequences of the research, namely the findings, that matter to the pragmatist, "because they are the bases for organising future observations and experiences". It is this future orientation, which this author adopts, that sets pragmatism apart from other philosophies which are limited to looking for meaning in prior experience (Elkjaer & Simpson, 2011).

It will be helpful at this point to restate the aims of this thesis, which are as follows:

- To explore the relationship between outbound open innovation (OI) and the resource-based view (RBV) of the firm;

- To determine whether engagement in outbound open innovation can support the development of dynamic capabilities;
- To develop a managerial framework to support the adoption of outbound open innovation practices.

The aims of this research are of special importance given that the purpose of the research is to develop a managerial framework to support the adoption of open innovation practices. To determine whether engagement in outbound open innovation can support the development of dynamic capabilities, the author will need to ascertain the challenges associated with engagement in outbound OI practices. In particular, consideration will have to be given to the "values, aesthetics, politics, social and normative preferences" (Cherryholmes, 1992, p. 13), in addition to situation, and context. Situation and context are essential in addressing one of the research gaps identified. This author is of the view that innovation is dynamic and that the actions, situations, and contexts in which it happens are inseparable. If they change, so will the consequences. From this standpoint, worldviews can be considered "individually unique and socially shared" (Kaushik & Walsh, 2019, p.3).

Pragmatism as a philosophy has been a very practical school from its inception. Notwithstanding the fact that its diversity has created problems for scholars, it has had a significant impact across many domains including law (Elkjaer & Simpson, 2011). Elkjaer and Simpson (2011, p. 80) identified four concepts which, they suggest, are potentially useful to organizational scholars; these concepts are "experience", "inquiry", "habit" and "transaction". Collectively, they can be understood to be "mutually informing and interdependent aspects of all social practices" (Elkjaer and Simpson, 2011, p. 80). Elkjaer and Simpson (2011) further explain that, for a pragmatist, "experience" relates explicitly to the "dynamic relationship between knowledge and action"; "inquiry" involves critically interrogating the status quo and is prompted when habits are no longer working; "transaction" is where "experience", "inquiry", and "habit" are endlessly explored and improved. This researcher takes the view that there is an alignment between this position and the research two questions of this thesis:

The first asks about the challenges SMEs have in the commercialization of new technologies and collaborating with partners including what challenges exist in the practice of outbound open innovation.

The second explores what knowledge, skills and organizational capabilities companies should develop to capitalize on the potential of the MedTech sector.

Given the aims and research questions of this study, a pragmatic approach is deemed suitable because:

1. Problems provide the starting point for this research. For example, McKinsey & Company (2023) maintain that delivering value to both patients and shareholders over the coming decade will demand a fundamental reinvention of the industry, favouring bold transformation over gradual enhancements. According to J.P. Morgan (2025), overall investment levels remain below their 2021 peak. Although first-quarter 2025 showed modest growth compared with the same period in 2024, the total number of transactions has declined (J.P. Morgan, 2025). This shift reflects venture capital's growing emphasis on more mature companies in sectors such as medical devices, diagnostics, therapeutic digital health, and commercial MedTech solutions (J.P. Morgan, 2025). The German medical technology sector is also facing challenges associated with increasing foreign competition, inappropriate financing models, increasing costs as a result of keeping R&D local, and increasing regulation (Hempel, 2018). In the UK, developments in technology, policy regulatory activity, digital transformation and cyber readiness are ongoing issues (Snyder and Naaz, 2020). In Ireland, even though a significant number of medical technology companies based in the country conduct R&D, not all of this work is carried out there, and it remains a key challenge to address this issue (Irish Medtech Association, 2019). IBEC (2025) highlights that securing a highly skilled workforce continues to be the sector's most critical challenge, with 63% of firms citing difficulties in attracting and retaining talent as a key concern.
2. In exploring the relationship between outbound open innovation (OI) and the resource-based view (RBV) of the firm and, to determine whether engagement in outbound open innovation can support the development of dynamic capabilities, the goal is to develop a managerial framework to support the adoption of outbound

open innovation practices. This purpose is aligned to the search for solutions to advance future practice as advised by Saunders *et al.* (2019).

3. In line with Creswell and Creswell (2018, pp. 10-11), as discussed above, this research too will happen within “social, historical, political, and other contexts”. Pursuing Elkjaer and Simpson (2011, p. 80), again as discussed above, “experience” or the “dynamic relationship between knowledge and action” can be mapped to the exploration of the relationship between outbound open innovation (OI) and the resource-based view (RBV) of the firm. The status quo regarding outbound open innovation will be investigated in-depth to determine if, by comparing MedTech companies in three different markets - Germany, the UK and Ireland - improvements can be identified and incorporated into the managerial framework previously identified.
4. Finally, pragmatism’s practical leaning aligns well with Claeys’ (2018) application of “practical reason” to the study, given the flexibility within the paradigm to do what ‘works best’ (see Tashakkori & Teddlie, 1998, for example).

3.3 The Ontological Position of this Thesis

In developing an ontological standpoint, the researcher considers what can be known about the nature and form of social reality (see for example Azzopardi & Nash, 2014; Guba & Lincoln, 1994). Morgan and Smircich (1980, p. 492) outlined the evolution of ontological approaches, presenting them as an objectivist - subjectivist continuum on which a researcher positions themselves depending on their point of view (Morgan & Smircich, 1980). However, Cunliffe (2011) replaced this subject-object distinction with three knowledge problematics: subjectivism, intersubjectivism, and objectivism. This was to reflect the changes in complexity and richness in organisation and management theory (OMT) since Morgan and Smircich first published their work in 1980; and to respond to challenges to the subject-object distinctions. Therefore, the pursuit of an ontology of the intersubjective problematic is of interest to the author as the "process of sensemaking at an individual or community level" (Cunliffe, 2011, p. 657) can be aligned to the research aims. An intersubjective problematic assumes “[s]ocially constructed realities, emerging, objectified, & sometimes contested in the routines & improvisations of people” is appropriate (Cunliffe, 2011, p. 654). The context is “human action & interpretation”, which overlaps with pragmatic knowledge as an

epistemological orientation organisation (Cunliffe, 2011, p. 654). This permits the researcher to work from within or from outside the organisation (Cunliffe, 2011). These ideas establish the ontological position for this study.

3.4 The Epistemological Position of this Thesis

Epistemology refers to the relationship between the researcher and reality (Punch, 2014, p. 15), the knowledge claims, or, in other words, "the nature of the relationship between the knower or the would-be knower and what can be known" (Guba & Lincoln, 1994, p. 108). Cunliffe *et al.* (2015, p. 21) characterise epistemology as the "assumptions about the nature and purpose of knowledge, and what "good" knowledge should look like". Bryman (2003, p. 31) however, describes epistemology more succinctly as "the theory of knowledge". He explains that it follows logically from ontology, and thus the ontological position adopted will indicate a certain epistemological position. Ontologically, this research traverses both subjective and intersubjective problematics. Citing Saunders *et al.* (2019, p. 145), the epistemology of pragmatism relates to the "practical meaning of knowledge in specific contexts": "[t]rue theories and knowledge are those that enable successful action" and contribute to future practice. This perspective is aligned to the aims of this work and this reflects the position of the researcher.

3.5 Theory Development: An Inductive Approach

Citing Ketokivi and Mantere (2010), Saunders *et al.* (2019, p. 152) explain that "in inductive reasoning, there is a gap in the logic argument between the conclusion and the premises observed, the conclusion being 'judged' to be supported by the observations made". Saunders *et al.* (2015) advise that for those using an inductive approach, the context will probably be important as a deeper understanding of the problem is sought. The author suggests this is compatible with pragmatism, which stresses the importance of the consequences of the research and is aligned with aims the of this thesis. Locke (2007) put forward guidelines, which are summarised below, for the development of inductive theories and which are useful:

"Start With Valid Philosophical Axioms as the Base" (Locke, 2007, p. 880)

Citing Rand (1990), Locke (2007, p.880) describes an axiomatic concept as "the identification of a primary fact of reality, which cannot be analyzed" and states that the

three primary axioms are “existence (reality), identity (everything has a specific nature, to be is to be something specific), and consciousness (awareness)”. Locke (2007) suggests that these axioms are an essential foundation for knowledge. Locke (2007, p.880) regards the question of how this knowledge is acquired as part of epistemology and further requires a “valid theory of concepts”.

“Develop a Substantial Body of Observations or Data” (Locke, 2007, p. 881)

He recommends, not least in management, the use of a range of methods, all of which will play a role in the identification of potential boundary conditions and potential measurement problems. Locke (2007) also refers to the importance of introspection as a valuable source of data in parts of management: this is essential to comprehend concepts such as “thought, emotion, perception, belief, [and] goal[s].” According to the Stanford Encyclopaedia of Philosophy (2019), introspective knowledge is often considered especially reliable: it can form a basis for other knowledge and is a vital part of epistemology.

“Formulate Valid Concepts” (Locke, 2007, p. 881)

Referencing Rand’s (1990) theory, Locke (2007, p. 881) states that “all valid concepts begin at and are ultimately traceable to the perceptual level” and the process of formulating a valid concept involves the assimilation of similar objects, without any measurements into an individual mental unit. Higher-order concepts are formulated through the integration of lower-level ones (Locke, 2007). The process of concept formation is finished by selecting a word to represent the concept and a definition which serves to link the concept to reality and distinguish it from other concepts (Locke, 2007).

“Look for Evidence of Causality and Identify Causal Mechanisms” (Locke, 2007, p. 882)

Locke (2007, p.882) states that “concepts are formed inductively, from observing reality”, suggesting we notice initial causal relationships directly, but that valid concepts are needed for more complex causal generalisations. Locke (2007) proposes three methods to demonstrate causality: experimentation (acknowledging this may not always be possible at management level); discovering legitimate mathematical relationships; and discovery of mediators. Locke (2007, p. 883) further suggests that causal explanations are multi-layered, with each new layer contributing to our “causal understanding and our ability to generalise”.

“Tie in Valid Concepts From Other Sources and Theories Where Applicable” (Locke, 2007, p. 883).

Locke (2027) maintains that the terms should denote concrete, real-world concepts, and the links among those concepts must be empirically verifiable.

“Integrate the Totality of Findings and Concepts Into a Noncontradictory Whole” (Locke, 2007, p. 883)

This guideline, suggests Locke (2007, p. 883), is the start of the development of theory and ought not to be restricted to one’s research or that of other theorists in the relevant domain, but the conclusions ought to be “consistent with all of one’s knowledge”. Locke (2007, p. 883) stresses the importance of the “law of contradiction”, which requires that where contradictory findings be investigated and a solution found.

“Identify the Domain and Boundary Conditions for the Theory” (Locke, 2007, p. 884)

Locke (2007) states no single theory covers everything; each must focus on a specific domain and clearly define its scope. Within that scope, boundary conditions, essentially interactions or moderator variables, must eventually be identified.

“Make Theory Building a Careful, Painstaking and Gradual Process” (Locke, 2007, p. 884)

Locke (2007) suggests that for a theory to be securely connected to reality and therefore be of value, it should be developed from the accruing evidence. Locke (2007, p. 884) adds that theory building may start from a “simple, core idea” which has the potential to form the basis of a theory but with one rule, which is that the core idea must be bound to reality. Once the theory is presented, deductions from this new theory are possible and it is possible to move between both deduction and induction at this point.

3.6 The Research Methodology

Hesse-Biber (2010, p. 11) describes research methodology as “a theoretical bridge that connects the research problem with the research method”. These connections lead the researcher to ask questions and determine which questions are critical to the study. Bell *et al.*, (2022) suggest that ‘methodology’ refers to the theory of how research should be done, while ‘method’ relates to practice. Duignan (2016) defines research methodology

as broadly the choice between qualitative and quantitative study. The methods selected should reflect the researcher's methodological assumptions, which, in turn, are informed by their ontological and epistemological beliefs (Bell *et al.*, 2022). While there is a view that matters of method are secondary to those of paradigm (Cunliffe, 2011; Cunliffe *et al.*, 2015; Guba & Lincoln 1994; Kaushik & Walsh, 2019), the research question for pragmatists takes precedence over the methods or underpinning worldview (Tashakkori & Teddlie, 1998). Therefore, in considering the most appropriate methodology, the pragmatist will consider the nature of the research question, the context, and the potential outcomes of the research (Saunders *et al.*, 2019).

Saunders *et al.*, (2019, p. 189) define a research strategy as a “plan of how a researcher will go about answering their research question” while Bell *et al.*, (2022) describe it as a general approach to the assumed research, one which is reflective of the methodological assumptions of the researcher. Bell *et al.*, (2022) further advise two discrete research strategies - quantitative and qualitative - which differ in their epistemological foundations. The first choice in the design of a research study is whether quantitative, qualitative, or mixed methods should be used (Saunders *et al.*, 2019).

In the following paragraphs, the systematic literature process, the adopted research methodology and strategy, and the form of their design to enable data collection and analysis, are discussed.

3.7 Qualitative Strategies

Punch (2014, p. 3) puts forward a simple definition for qualitative research:

Qualitative research is empirical research where the data are not in the form of numbers.

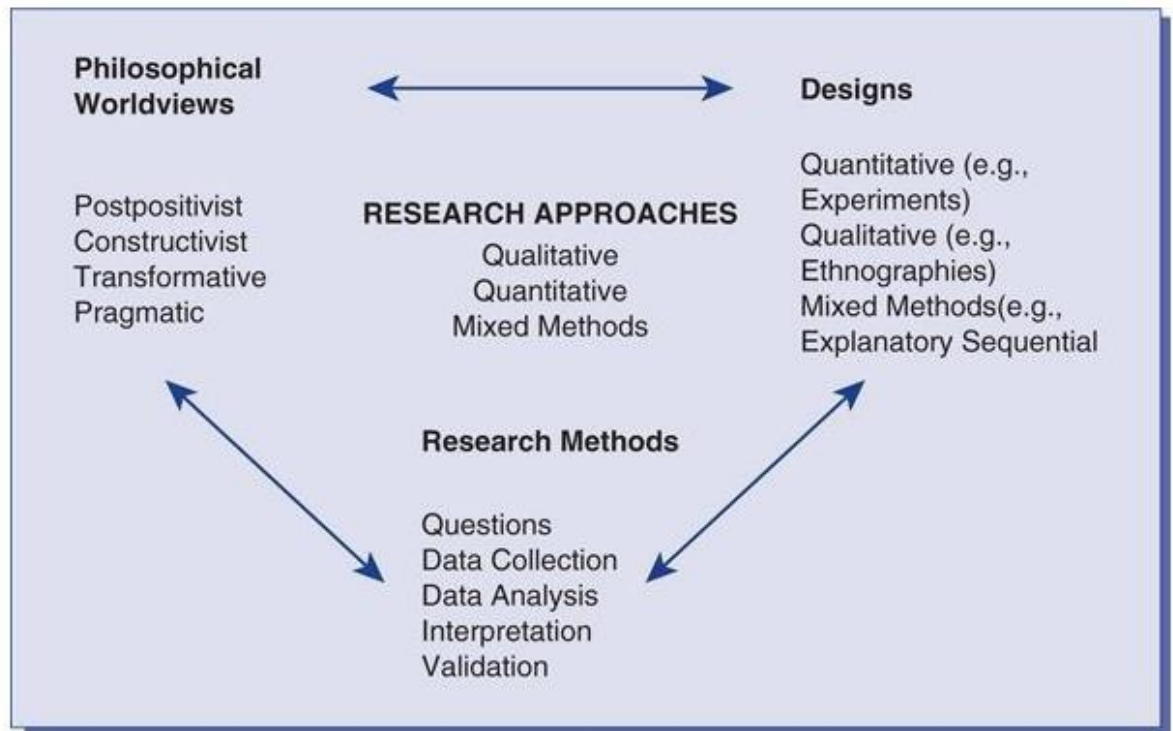
However, Punch (2014) acknowledges the simplicity of this definition, clarifying it is just a starting point.

Qualitative research, stresses the use of words and images in the collection and analysis of data using an inductive approach to generate theory (Bell, *et al.*, 2022). Importantly, it is discovery-oriented, generates ideas from data, and uses an inductive approach (Hair *et al.*, 2020). The field of qualitative methods is complex, encompassing many methodologies and research practices, and is “multidimensional and pluralistic with

respect to paradigms” (Punch, 2014, p.117) but these methods are devised to enable researchers to understand people and their social and cultural contexts (Myers, 2022).

The following diagram in Figure 13 from Creswell and Creswell (2018) summarizes the interconnectivity between philosophical stances or worldviews, research design, and methods:

Figure 13: “A Framework for Research – The Interconnection of Worldviews, Design, and Research Methods”.



(Creswell & Creswell, 2018, p. 5, Figure 1.1)

3.7.1 The Rationale for a Qualitative Strategy for this Study

Ontologically, this research traverses both subjective and intersubjective problematics of socially constructed realities contextualised in human action and interpretation. The epistemological position reflects the “practical meaning of knowledge in specific contexts” which enables successful action contributing to future practice (Saunders *et al.*, 2019, p. 145). Therefore, in line with the ontological and epistemological approach, qualitative research is proposed. Creswell and Creswell (2018) suggest a qualitative approach is merited when a concept has not been extensively researched and needs further study. As previously mentioned, a need for more synthesis of open innovation

with management theories has been identified (West & Bogers, 2017). Insight into SMEs from an open innovation perspective is required (Hossain & Kauranen, 2016), and current research is exceptionally limited in the case of inside out or outbound practices (Natalicchio *et al.*, 2017).

A qualitative approach is preferred when:

1. Little is known about a research concept or phenomenon (Creswell & Creswell, 2018; Hair *et al.*, 2020);
2. Earlier research only partially addresses the issue (Hair *et al.*, 2020);
3. Phenomena are complex or changing and they need to be either organized or simplified for further study (Hair *et al.*, 2020);
4. If themes or patterns in the phenomena need to be better understood (Hair *et al.*, 2020);
5. If the main goal of the research is to propose a conceptual or theoretical framework representing current reality which might be further tested quantitatively (Hair *et al.*, 2020).

The key features of qualitative research can be set out as follows:

1. In using an inductive approach, researchers try to develop a theory or a conceptual framework from the data collected (Bell *et al.*, 2022, p. 400; Hair *et al.*, 2020).
2. This requires a natural setting. Participants studied in their natural settings where an understanding of their social reality is sought and the researcher has no influence on the situation. Within the understanding of naturalism, participants are active in the creation of their social world and assign meaning to behaviour (Bell *et al.*, 2022, p. 400; Punch, 2014; Saunders *et al.*, 2019).
3. Qualitative research involves developing a direct, trusting relationship with participants thereby enabling a deeper understanding of the issues (Saunders *et al.*, 2019).

A qualitative approach therefore aligns well with the study's aims and research questions.

3.7.2 Designing the Research Strategy

In determining the most appropriate approach or strategy, the researcher must consider the research aims and questions, the extent of existing knowledge, the amount of time

and other resources available as well as access to potential participants and other data sources (Saunders et al., 2019). Bell et al (2022, p. 47) further state that "a research design provides the framework for the collection and analysis of data". For their part, Creswell and Creswell (2018, p. 11) describe research designs as forms of investigation within qualitative, quantitative, and mixed-method approaches which give a certain direction to the processes of a research study.

Hair *et al.* (2020) present four of the most widely used approaches used to conduct qualitative research:

1. Phenomenology including hermeneutics
2. Ethnography
3. Grounded theory
4. Case studies

This work utilizes a case study approach which the author will justify.

3.7.3 Case Study Research Approach

3.7.3.1 Multiple Case Study

Yin (2018) presents a twofold definition of a case study. The first part of the definition addresses the scope suggesting the approach examines a current phenomenon, referred to as the 'case', thoroughly and in its authentic, real-world setting, particularly when the distinction between the phenomenon and its surrounding context is ambiguous. The second part addresses the methodological challenge of having more variables of interest than available data points (Yin, 2018). Consequently, it draws on pre-established theoretical frameworks to inform research design, data gathering, and analytical strategies (Yin, 2018).

Hence the need for case studies stems from "the desire to understand complex social phenomena" Yin (2018, p. 5). Yin (2018, p. 12) also states that "case studies are preferred when the relevant behaviours still cannot be manipulated and when the desire is to study some contemporary event or set of events". This author believes these are the most relevant factors applicable this research. Gibbert *et al.* (2008) report that case studies are suitable in the key, early stages of the development of new management theory. Moreover, they are fitting for the creation of managerial knowledge because of the cooperation between researchers and practitioners in real situations for the research. Cases provide an in-depth, systematic way of collecting, analysing and

reporting data (Hair *et al.*, 2020). Bryman *et al.* (2022) refer also to the frequent use of qualitative methods for case studies, but advise quantitative and mixed methods are also possible.

This research will employ a multiple-case study approach, recognizing the importance of contextual understanding in addressing real-world issues (Saunders *et al.*, 2019; Yin, 2018). The primary focus will be on small and medium-sized enterprises (SMEs) within the medical device sector in Germany, the UK, and Ireland, supplemented by insights from larger companies that innovate alongside SMEs.

Yin (2018) refers to two important sources of case study data - direct observation and interviews - but also acknowledges that a full variety of evidence can be used. This author will use interviews for practical reasons. According to Yin (2018, p. 11) research questions need substance and form, the latter dictating the appropriate research method with “how” and “why” questions possibly favouring “a case study experiment or history.”

Table 4 below provides a summary of the characteristics of case study research that supports the rationale for the choice of method in this study:

Table 4: “Characteristics of the case study approach”.

One setting	rather than	Many instances
Depth of study	rather than	Breadth of study
The particular	rather than	The general
Relationships/processes	rather than	Outcomes and end-products
Holistic view	rather than	Isolated factors
Multiple sources of data	rather than	One research method

(Denscombe 2017, p. 57, Figure 3.2)

While this research will require the study of more than one case, the focus is narrow, and depth is required. Multiple sources of data will be obtained in so far as companies in the MedTech sector across three countries will be studied.

3.7.3.2 Case Study Design

Before further detail about the methods of data collection is provided, the number of cases to be studied and the sampling techniques to be employed should be determined.

In respect of the number of cases or sample size, it appears that this is an ambiguous area and one that lacks any pre-defined rules (Saunders *et al.*, 2019; Yin, 2018). Denscombe (2017) advises that the main idea behind a case study approach is a narrow focus. Moreover, in taking this approach and thereby delving deeper, valuable insights can be identified and formulated that would otherwise be missed. Denscombe (2017) further suggests that while the findings are of course important, what is significant is being able to unravel the complexity of the context. Therefore, taking a pragmatic approach, and given the aims of the thesis as well as the available resources and time constraints, the author will begin by examining ten cases across Germany, the UK and Ireland. Recognizing the complexities related to saturation, the author will evaluate the richness of the dataset and its relevance to the needs of the study (Braun and Clarke, 2022), and will make adjustments accordingly.

In terms of sampling, Saunders *et al.* (2019) describe two types of sampling technique: probability-based and non-probability sampling. With the former, the probability of selection of each case from the target population is equal and known; for the latter, the probability is not known and so it is not possible to derive statistical inferences on this basis. Saunders *et al.* (2019) present four types of non-probability sampling: quota sampling, purposive sampling, volunteer sampling, and haphazard sampling. Purposive sampling is where cases are selected for their importance (Saunders *et al.*, 2019) but Yin (2018) cautions against misleading readers by this usage of the word 'sample', advising a clear caveat be stated specifically for this form of sampling. Denscombe (2017) states that the selection of cases is not random, and the suitability of a case will be determined by the issue the researcher wants to study. However, the researcher must explicitly justify their decisions.

While Denscombe (2017) wrote about the benefits of focusing on a single case, a focus on multiple cases is also possible with the benefit of potentially providing compelling and robust results (Yin, 2018). Equally, there are risks, where one case may prove critical, and the study of multiple cases may require extensive resources and time (Yin, 2018).

For this study, purposive sampling will be used. The reason for this is to enable the researcher to include cases that she believes will be particularly informative and suited to meet the aims of the thesis and address the research questions. However, the researcher is mindful of the fact that there are multiple cases that will be compared

across three countries, and thus the research is considered cross-national (Bell *et al.*, 2022). For this reason, consistency in the collection of data will be important. The main benefit of a multiple-case study is that it improves theory building and helps to obtain a more in-depth understanding of social reality in diverse national contexts (Bell *et al.*, 2022).

The companies chosen for this study include three SMEs located in Baden-Württemberg, the leading region for medical technology in Germany (BioPro, 2025a). Additionally, three SMEs and one large company based in the West Midlands Health Technologies Cluster in the UK were selected. A further three companies were selected in Ireland: two SMEs and one large company. The large companies were chosen for their open innovation approach and their experience in collaborating with SMEs to develop new technologies. Their insights were considered highly relevant for this research. A summary is provided in Table 5 below.

Table 5: Interview Summary.

Country	Company Identifier Code	Role of Interviewee	Company Category	Date of Interview	Duration of Interview
Ireland	IRL1	Founder and CEO	SME	10 November 2023	40 minutes
Ireland	IRL 2	Director	SME	9 February 2024	60 minutes
Ireland	IRL 3	CEO	Large	5 March 2024	50 minutes
Germany	D1	Founder and CEO	SME	13 March 2024	36 minutes
UK	UK1	CEO and Co-founder	SME	15 March 2024	40 minutes
UK	UK2	CEO and Co-founder Head of Communications	SME	18 March 2024	40 minutes
UK	UK3	Strategic Head - Technical	Large	14 June 2024	40 minutes
Germany	D2	CEO	SME	3 April 2024	45 minutes
UK	UK4	Ethical Advisor	SME	13 August 2024	30 minutes
Germany	D3	Head of R&D and Technical Manager	SME	21 August 2024	50 minutes

3.7.3.3 Assessing the quality of qualitative research

According to Cho and Trent (2014), three main issues confuse the assessment of qualitative research: (1) there is no consensus on how qualitative studies should be evaluated, (2) positivist evaluation standards continue to influence qualitative research, and (3) there are widespread political debates about what counts as evidence. Cho and Trent (2014, p.678-679) developed a platform called 'evaluating qualitative research' or 'EQR' using Lincoln and Guba's (1985) criteria for developing the trustworthiness of a qualitative inquiry as one of six their categories. Lincoln and Guba's (1985) criteria include (1) credibility, (2) dependability, (3) confirmability and (4) transferability and are explained briefly in the summary in Table 6 below:

Table 6: Lincoln and Guba's (1985) Trustworthiness Criteria for Qualitative Inquiry.

Criteria	Description
Credibility	Establishes that qualitative findings are credible and believable to the participants themselves.
Dependability	Addresses whether the same findings would emerge if the phenomenon were observed again.
Confirmability	Relates to how easily other researchers could verify the results.
Transferability	Focuses on how far the qualitative findings can be applied beyond the original context.

In line with Cho and Trent's (2014) EQR category and to ensure that Lincoln and Guba's (1985) criteria were met, my actions are explained below. Credibility was strengthened by grounding interpretations in the most relevant characteristics of the situation, supporting the trustworthiness of the findings. Dependability was enhanced through detailed documentation of data collection and analysis procedures, enabling the study to be followed or repeated in similar conditions. Confirmability was supported by maintaining transparent records of data, interpretive decisions, and analytic steps, ensuring that the findings reflected participants' perspectives rather than any bias from the researcher. Finally, transferability was addressed by clearly delineating the study's contextual boundaries including time, place, nationality allowing readers to judge the applicability of the results to other contexts.

The data for this study was collected over an eleven-month period between November 2023 and October 2024.

3.8 Data Collection

Hair *et al.* (2007) suggest that the most important characteristics of qualitative data analysis include its discovery orientation, the use of data for idea generation, and the fact that it is based on inductive reasoning. The latter demonstrates the effectiveness of a researcher in the identification of patterns in large amounts of data (Hair *et al.*, 2007). Saunders *et al.* (2019) confirm the consensus that these large volumes of data must be broken down using codes and category classifications in the analysis phase. In this case, NVivo software was used to assist with this.

3.8.1 Semi-structured Interviews

Yin (2018) lists six sources of evidence for case studies: documentation, archival records, interviews, direct observations, participant observation and physical artefacts. Punch (2013, p. 144) states that an interview is "a very good way of accessing people's perceptions, meanings, definitions of situations and constructions of reality". In short, it is one of the most robust ways we have to understand other people. Hence, it has been selected as the appropriate data collection technique for this study. Punch (2103) presents a continuum of interview types ranging from structured to focused or semi-structured to unstructured. This work will adopt a focused or semi-structured approach that enables both in-depth exploration and meaningful comparison of responses. Denscombe (2017) says that in adopting this approach, while the interviewer will have clarity on the issues to be focused on and the questions to ask, they will be flexible in facilitating for the interviewee a process to develop, expand and elaborate on their answers. Jordan and Gibson (2004, pp. 222-223) summarise the advantages and limitations of semi-structured interviews. The key points have been abbreviated slightly and captured in Table 7 below:

Table 7: "Advantages and limitations of semi-structured in-depth interviewing".

Advantages:
It is an adaptable technique enabling probing of specific themes and the taking into account of each participant's particular experiences. This, in turn, makes it a flexible technique because as data collection progresses and new ideas relevant to understanding the research topic emerge, interview schedules can be refined to collect these insights.
The face-to-face nature of the interview enables the researcher to read body language and other non-verbal forms of communication, in addition to speech, which can elicit valuable insights.
The personal nature of the interviews may enable the researcher to develop empathy with participants, thereby creating a more comfortable environment for both parties.
Little equipment is required, so the location can be varied easily to accommodate preferences of the researcher and the participant.
Possible interconnections between experiences and views can be explored.
The technique is useful for generating experiential data that can then be theorised.
It can provide contextual background for studies using multiple methods.
Semi-structured interviews provide inexperienced researchers with some structure, while also allowing them to develop their own approach to interviewing.
Semi-structured interviews also allow for comparability across interviews, as the same questions are asked of each respondent.
They can provide rich, descriptive data.
This technique can be highly valid, as interviewers can ensure that questions are understood by the interviewees by adapting the wording or by probing to elicit more in-depth responses.
Limitations:
Misinterpretation of views by the researcher and/or participant is possible.
The method requires training and confidence to be fully effective.
It can be difficult to replicate.
The researcher may, consciously or unconsciously, steer the interviewee towards expressing views that agree with the research themes sought.
Interviewing can be an awkward and uncomfortable experience, especially for inexperienced researchers.
The value of the data is dependent on the honesty of the interviewee.
The interviewer may be reactive to responses from the interviewee rather than structuring the interview themselves.
The technique relies on interviewees to volunteer to participate in what can be a time intensive process.
Recoding of interviews can be problematic if the interviewee does not want it.
Interviews, transcription and analysis of interview data are all time-consuming activities.

Interviews can generate a large amount of data extraneous to the topic and it may be problematic to generate comparable themes (especially for a single researcher).

(Jordan & Gibson, 2004, pp. 222-223. Box 13.1)

3.9 Ethical Approval

In accordance with university policy, ethical approval for this study was obtained from the University's Research Ethics Committee (Reference: ER52824331) on 15 May 2023. A copy is presented in *Appendix 1*.

3.10 Data Analysis

As some qualitative research strategies are affiliated with certain methods (Saunders *et al.*, 2019), in order to determine the most appropriate way to analyse the data in this study, the author first compared the recognised methods and articulated a rationale for rejecting all but thematic analysis. With reference to the perceived limitations of thematic analysis, the reader is referred to Braun and Clarke's (2022) treatment of the "myths" that are attributed to the method, in particular the point that the sophistication of the method, which has many different versions, derives from *how* it is used.

3.10.1 Thematic Analysis

Braun and Clarke (2006) contend that thematic analysis or TA should be considered an autonomous method. They describe it as a flexible method, one that allows for the identification, analysis, and reporting of patterns or themes within a body of data, noting that it does so in a way that is both theoretically and methodologically robust (Braun & Clarke, 2006). These authors stress that transparency 'around the process and practice' of thematic analysis is crucial and further emphasize the importance of the alignment between the theoretical framework and methods and the researcher's research question(s) (Braun & Clarke, 2006). They caution specifically against a passive form of analysis whereby the researcher simply allows themes to be discovered (Braun & Clarke, 2006).

It will be useful at this point to restate the aims of the thesis and the two research questions for clarity.

The aims of this thesis are:

- To explore the relationship between outbound open innovation (OI) and the resource-based view (RBV) of the firm;

- To determine whether engagement in outbound open innovation can support the development of dynamic capabilities;
- To develop a managerial framework to support the adoption of outbound open innovation practices.

The research questions that derive from these aims are:

1. What challenges do SMEs face commercializing new technologies and collaborating with partners through outbound open innovation practices?
2. What knowledge, skills and organisational capabilities do companies need, to develop within, and capitalize on the potential of, the MedTech sector?

With reference to the variations of TA as presented by Braun and Clarke (2022, p. 10), the research aims and questions outlined above can be positioned within a fully qualitative framework, one “where the analysis aims to capture and explore people’s own perspectives and understandings” based on their experience. The orientation to data (Braun & Clarke, 2022, p. 10) is inductive, which is to say that “where the analysis is located within, and the coding and theme development are driven by, the data content”. Of particular relevance in evaluating this approach, is the observation made by Braun and Clarke (2022), who note that because it is grounded in a qualitative paradigm, this form of thematic analysis rests on a well-defined philosophical and ethical base that shapes, strengthens, and sets boundaries for its open and evolving practice. This author suggests that this is very much aligned with pragmatism, as previously referenced, and the point is underlined by Cherryholmes (1992, p. 13), who argues that “values, aesthetics, politics, and social and normative preferences are integral to pragmatic research, its interpretation and utilisation”. For these reasons, this author argues that there is a good fit between the theoretical and conceptual underpinnings of the research.

Data for thematic analysis can be collected in various ways. Braun and Clarke (2022, p. 27) give examples such as interviews, focus groups, social media, or existing research. The research employed for this study employed semi-structured interviews.

To conduct the analysis and identify the emergence of themes, specialist qualitative data software, NVivo, was used.

3.10.2 Overview of the Process of Thematic Analysis

Following the guidelines presented by Braun and Clarke (2022, p. 35-36, 2006), the analysis of the data collected was conducted through six phases of analysis. These phases of the analytic process are explained in greater detail below.

3.10.2.1 Phase 1: Familiarisation with the dataset

Braun and Clarke (2022) describe this first phase as comprising three practices. Firstly, in-depth insight into the research data is developed. This is followed by a period of critical engagement with the data. Then the researcher makes detailed notes.

Ten interviews were conducted initially, three in Germany, four in the UK and three in Ireland. All were conducted with owners or senior managers with responsibility for innovation, new product development, and commercialization. Eight companies fit within the EU definition of an SME and two companies, one in the UK and one in Ireland were considered large by the same EU definition with six hundred, and four hundred and seventy employees respectively. The two large companies were included in the data as they work with smaller companies as part of their outbound open innovation activities and the researcher considered their insights potentially to be a rich and important data source. Two of the interviews with SMEs were conducted initially as pilot interviews but the data obtained was sufficiently rich to justify their inclusion in the data set.

A second set of four semi-structured interviews was carried out to further investigate the unexpected issues identified during the initial interviews. The additional semi-structured interviews included one with a specialist equity investor in the medical technology sector, and three with Medical Device Regulation experts operating in Germany, the UK, and Ireland.

Each participant was provided with a 'Participant Information Sheet', presented in *Appendix 2*, in advance of the interview. Details of the study, data management, and confidentiality were outlined. The interview questions which guided the company interviews are available in *Appendix 3*; those that guided the interviews with the Medical Device Regulation experts are available in *Appendix 4* and the questions which guided the interview with the specialist equity investor are available in *Appendix 5*.

Following the completion of a series of semi-structured interviews, the researcher personally prepared each of the transcripts. These transcripts are available in *Appendix*

6. Acknowledging the importance of capturing 'real speech' as well as the fact that transcription is a process of transformation involving some decision-making about what should and should not be included, the author was mindful of the factors that contribute to the quality of a transcript (Braun & Clarke, 2022). The process set out below was employed:

- Contextual information was noted at the beginning of the script and anonymized; that is, interview codes, by which the researcher could identify the company, the location, and length of the interview were included.
- Each page was numbered.
- The interviewer's questions and the interviewee's answers were clearly indicated.
- The text was initially written verbatim.
- The researcher listened to the audio recordings two to three times paying attention to the pace and tone of voice of the interviewees. Stutters, where it was very clear they had no meaning and did not contribute to the dialogue, were removed from the text.
- Grammar was not corrected.
- Punctuation marks were added during the second and third reviews of the audio recordings. The researcher deemed this essential for readability purposes afterwards. To verify the accuracy and intended meaning of the transcripts, they were shared with the interviewee for feedback and approval.
- Recordings were deleted after the interviewee approved the transcript.

To critically engage with the data, the researcher re-read the transcripts and made notes (Braun & Clarke, 2022). These notes were then collated in matrices based on the whole set of transcripts. The matrices incorporated, in the first instance, a listing of the key points relevant to a question underneath it (horizontal) per interviewee (vertical). The researcher then reconstructed this information, for comparative purposes, with the questions listed vertically and the interviewee information presented side-by-side horizontally. This layout provided useful initial insights and a level of depth which helped the researcher to become more familiar with the data.

3.10.2.2 Phase 2: Coding

The next step was more systematic and aligned with the recommendations of Braun and Clarke (2022, p. 53). Each data item was read again and all segments of the text relevant

to the research questions were tagged with an appropriate fitting code label. Using the dataset as a starting point to engage with meaning is consistent with an inductive orientation. However, the researcher acknowledges that a 'pure' inductive approach is not possible as researchers will always bring perspectives to meanings (Braun & Clarke, 2022, p. 56). That said, a systematic coding process is, according to Braun and Clarke, (2022, p.54) important for both insight and rigour.

The data set was reviewed several times until the researcher felt no new codes ('Nodes' using NVivo) were possible. The researcher moved to the next phase.

3.10.2.3 Phase 3: Generating Initial Themes

When embarking on the process of generating initial themes, it is important to remember that "[a] theme captures the *patterning* of meaning across a dataset" (Braun & Clarke, 2006 cited in Braun & Clarke, 2022, p. 76). These authors advise that for thematic analysis (TA) "a theme has to capture a wide range of data that are united by, and evidence, a *shared idea*.....". They specifically caution against summarising what the interviewees said about a topic (Braun & Clarke, 2022, p. 77). A theme in the sense in which they use their word has its own "distinct central organising concept" (Braun, Clarke & Rance, 2014, cited in Braun & Clarke, 2022, p. 77). The task of the researcher is thus "to explore the expression of shared or similar ideas or meanings across different contexts" (Braun & Clarke, 2022, p. 77).

The following are examples of useful theme evaluation questions that were employed:

- Does this provisional theme capture something meaningful?
- Is it coherent, with a central idea that meshes the data and codes together?
- Does it have clear boundaries?

Twenty themes were initially identified.

3.10.2.4 Phase 4: Developing and Reviewing the Themes

Six final themes were developed using NVivo after thorough review and merging of initial themes. The researcher verified the data and coding, with no new codes appearing.

3.10.2.5 Phase 5: Refining, Defining and Naming the themes

The final themes were labelled as follows:

1. The Medical Technology Industry
2. Markets
3. Finance
4. Collaboration for new product development

5. Distribution
6. Skills

A coding tree which summarises the codes and themes is provided in *Appendix 7*.

3.10.2.6 Phase 6: Writing up

The themes were explained and compared to theory.

3.11 Summary

This thesis is underpinned by a pragmatic worldview, one which reflects the importance of the practical consequences of the research. The ontological position reflects the intersubjective problematic where “human action & interpretation” provide the context organisation (Cunliffe, 2011, p. 654). As Saunders *et al.* (2019, p. 145) note, the epistemology of pragmatism relates to the “practical meaning of knowledge in specific contexts” and “[t]rue theories and knowledge are those that enable successful action”. In other words, they contribute to future practice, which is an attitude that aligns with the aims of this study. An inductive approach to theory development was used, which reflected a qualitative methodology, and this was backed by a case study strategy using semi-structured interviews to collect data. Thematic analysis following the guidance of Braun and Clarke (2006; 2022) was employed for the analysis.

Chapter 4: Findings and Analysis

4.1 Introduction

In this chapter, the author presents the results of the thematic analysis and examines them in relation to the broader context established through the literature review, recent studies, and contemporary industry reports. The rationale for this integrated style is to ensure that the findings are not interpreted in isolation but are instead situated within the existing body of knowledge, thereby strengthening the analytical depth and theoretical coherence of the study.

The themes are organised into two sections or parts. The first one addresses the initial three themes: the Medical Technology Industry, Markets, and Finance. The second one focuses on Collaboration for New Product Development, Distribution, and Skills. This structure reflects the logic of the research design and maintains a clear alignment with the overarching research questions, enabling a coherent progression from industry-level dynamics to organisational and capability-related considerations.

4.2 Themes

The first research question posed in this study concerned the challenges SMEs face in the commercialization of new technologies, including the challenges that exist in the practice of outbound open innovation. The second focused on what knowledge, skills and organizational capabilities companies need, to develop within and to capitalize on, the potential of the MedTech sector.

In addressing the first question, and somewhat unexpectedly for this researcher, concerns about aspects of the Medical Technology (MedTech) industry itself were frequently raised by the interviewees, and these emerged as a key theme. One interviewee, IRL3 (2024), was particularly concerned about the 'industry effect', stating "the whole thing about the industry effect is, you could have the smartest guys in the room, but it's still going to beat you".

In addition to this key finding, the data collected for this study using the methodology outlined in the previous chapter, are now presented in two parts according to the six themes referred to above:

1. The Medical Technology Industry;
2. Markets;
3. Finance;
4. Collaboration for new product development;
5. Distribution;
6. Skills.

The coding tree, which summarises the codes and themes, is provided in *Appendix 7*.

Again, the first part of this chapter addresses the first three themes, and the second part focuses on the remaining three.

Part 1

4.2.1 The Medical Technology Industry

The PESTEL (Political, Economic, Social, Technological, Ecological and Legal) framework is typically used to categorize uncontrollable factors within a firm's macro-environment that may impact its strategy. The macro-environment includes both market and non-market factors (Whittington *et al.*, 2020). The market environment concerns economic activity with predominantly suppliers, customers and competitors; the non-market environment concerns political, social, ecological and legal factors that can, in turn, be impacted by economic factors (Whittington *et al.*, 2020). A non-market strategy therefore acknowledges that businesses are not just economic actors, but social and political ones too, and, as such, they are subject to a multitude of external influences from which they cannot escape (Bach and Allen, 2010). In connection with the research conducted for this study, political, legal and economic factors were apparent throughout the interview process. Specifically, regulations, intellectual property, government support, and finance were critical to the development of the first theme and will thus form the basis for this part of the discussion.

The medical technology industry was described by D2 (2024) as very fragmented due to the variety of products and applications available. The World Health Organization (WHO) (2024) suggests there are approximately 2 million different kinds of medical device on the global market, and these are classified into more than seven thousand generic device groups. Yet D2 (2024) explained, "[W]ithin a certain area of products,

technologies or applications, it's pretty tightly knit, and quite a bit incestuous, as well". IRL3 (2024) described the industry as quite heterogeneous, with the industry effect differing, by way of example, between the United States (US), the United Kingdom (UK) and even France. As mentioned in the Introduction, there are very clear differences in the regulatory environments in each of these markets.

For context, it is worth noting that, the Food and Drug Administration (FDA)'s Center for Devices and Radiological Health (CDRH) "is responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices sold in the United States" (U.S. FDA, 2024). In the United Kingdom, responsibility for the regulation of the medical device market rests with the Medicines and Healthcare Products Regulatory Agency (MHRA) (Gov.UK, 2024; IRL2, 2024). The new European Medical Device Regulations (MDRs) has meant new responsibilities for the European Medicines Agency (EMA), as well as for the national competent authorities, in the assessment of certain classifications of medical device (EMA, 2024).

According to E1 (2024), "[T]he regulations are an important development, because they fundamentally keep patients safe. The question for manufacturers then becomes, is it an acceptable burden? Of course it's a burden. It is a major overhead." E1 and E2 (2024) advised that regulations change because of incidents, the most recent catalyst being the Poly Implant Prothèse (PIP) breast implant scandal (which could be characterized as a deliberate attempt to defraud the public and the industry). E1 (2024) referenced a second catalyst, an issue with metal joint replacements (one which was not intentional). As advised by Carl and Hochmann (2024), and confirmed by E2 (2024), the intention of the new regulations is to better monitor medical device manufacturers, and to better document the performance of medical devices. The varying requirements in each jurisdiction mentioned provide a snapshot of the heterogeneity of the sector.

The global standard for quality management systems (QMS) for medical devices, ISO 13485, has been harmonized by all the regulators around the world, who confirm that compliance with this standard confers acceptance under their local regulations (E1, 2024; ISO, 2016). Standards exist not only for quality management systems, but also for risk management, for the safety of software devices, and for electronic medical equipment. In short, there are many and varied sets of standards (Pacheco *et al.*, 2025; E1, 2024). Compliance with ISO 13485 plays a pivotal role in enabling access to

international markets for medical device manufacturers. Beyond this, compliance provides a range of organizational benefits, including enhanced customer satisfaction, improved supplier relations, increased operational efficiency, competitive differentiation, and sustained adaptability to evolving global challenges (Jadhav & Shendge, 2024). The ability to consistently produce safe and reliable medical devices directly supports client confidence and certified firms are often favoured by manufacturers due to the demonstrable quality commitment this provides (Jadhav & Shendge, 2024). The standard further promotes process optimization, reducing errors and waste (Jadhav & Shendge, 2024). Nonetheless, Pacheco *et al.* (2025) emphasize that meeting ISO 13485 requirements entails significant complexities, requiring considerable organizational effort and resources.

It is at this point in the process that it appears that companies are challenged. This is because they are “trying to have one procedure that (a) fits all and it fits no one or [(b)] trying to make them so complicated that they cover every eventuality or possibility at all times that they become unusable” (E3, 2024). This is in line with Carl and Hochmann's (2024) observation that the adoption of quality management systems presents significant challenges for small enterprises, especially those with fewer than 50 employees. However, Jadhav and Shendge (2024) have highlighted that a firm's dedication to quality certification can nonetheless serve as a strategic asset, enhancing its appeal to potential clients and fostering expanded commercial prospects.

Carl and Hochmann (2024) observed a marked decrease in the perceived competitiveness among Class I medical device firms in Germany, noting a drop from 24% to 5% within two years following regulatory implementation. While Jadhav and Shendge (2024) argued that harmonized standards enhance clarity and predictability, thereby fostering investment in innovation and R&D, this perspective is partially challenged by Carl and Hofmann (2024), who found that approximately one-third of surveyed companies anticipated portfolio reductions due to regulatory pressures, with 14% reporting actual or planned cuts to R&D efforts to ensure compliance.

The regulatory burden is thus a factor when considering which market to enter. D2 (2024), reported that the first question they ask themselves is whether the market potential justifies it. Where the regulatory burden is high or where nobody approaches them, they are not in those markets as they believe there are lower-hanging fruits to be

found elsewhere (D2, 2024). Similarly, the nuances and differences in the regulations are a consideration when selecting which countries UK1 wants to run its clinical trials in. However, they claimed that “it's not as if we have an easy route to sales in one country and a dramatically more complex route in a different country. Actually, the stages we need to go through are different” (UK1, 2024). IRL3 (2024) maintained that while markets share certain traits in terms of the difficulty of getting into them, they are structured completely differently. In fact, IRL3 stated (as previously mentioned) that the “... whole thing about the industry effect is, you could have the smartest guys in the room, but it's still going to beat you”. E3 (2024) suggested that just because a device has regulatory approval “doesn't mean to say people are going to buy it and getting into the sales in all the markets is incredibly difficult, and I think that's where a lot of companies don't have the resource for the length of time it takes to get those sales” (E3, 2024).

In brief therefore, the medical-device industry is inherently complex and regulated primarily to ensure patient safety. Implementing robust quality-management systems can be especially burdensome especially for smaller firms, yet achieving formal approval markedly enhances commercial credibility and market access but does not guarantee it.

4.2.2 Views on the Regulations

4.2.2.1 *Hindering Innovation*

These new European Medical Device Regulations have been harshly criticized by some interviewees. One commented, “You've heard of that monster, right? Regulation straight out of hell. It's one of the most stupid things ever happened in the industry. Unbelievable, unbelievable” (D2, 2024). Another suggested “the EU is doing its best to have no new products in Europe with the regulations, they're going out of their way to kill everything. They're doing a good job of it” (IRL3, 2024). In fact, in November 2022, European lawmakers expressed concern to the EU Health Commissioner about the risks associated with a medical device shortage. They noted, “In practice, the MDR is leading to a decrease in the availability of medical devices across Europe. Consequently, patient care in the EU is worsening instead of improving” (Holmgaard Mersh, 2022). A survey conducted in 2022 by MedTech Europe, which represented approximately 60-70% market revenue coverage, found that 54% of respondents planned portfolio reductions as they did not intend to transition some of their products to the new regulations, and

one third of these companies' medical devices were planned for discontinuation (MedTech Europe, 2024c).

Overall, manufacturers' portfolios were expected to reduce by an average of 20%, which was deemed significant (MedTech Europe, 2024c). E2 suggested that having a negative impact on innovation was not the intention of the EU authorities when the MDRs were drafted and enacted but argued that the new regulations while "well-intentioned" were "poorly executed" (E2, 2024). E3 (2024) referred to expectations noted that and moving from the old device directive, which was less restrictive, into the era of regulation complexity had "tied everyone up in knots". In this connection, Carl and Hochmann (2024) identified several challenges for companies, including an increase in the workload pertaining to technical documentation, increased costs, and a lack of clarity regarding the requirements. The EU Commission acknowledged the challenges and started to develop appropriate responses (Holmgaard Mersh, 2022). These were published by the European Parliament and the Council on 15 March 2023 in the form of new transitional provisions (EUR Lex, 2023).

The CEO of D3 (2024) was reported as saying there are fewer innovations in the medical sector because of the regulations and there is a tendency for companies to pursue projects in areas where they already have knowledge or technological experience. This approach is the alternative to investing in new technologies when the investment is too big and the medical regulations too complex (D3, 2024). E1 (2024) agreed with this to an extent but explained that all the regulators are asking companies for is that they put in place a methodology to demonstrate the stages they have gone through to develop their product. The questions the companies need to ask themselves are: Does the company have product requirements? Does it have project plans? Does it have design documentation? Does it have the implementation code? Does it have the testing and the validation? E1 (2024) elaborated by saying that if the company is going to say 'no' in response to any of these questions, because it doesn't like the regulations, then he really would not want to be using the product in question (E1, 2024). E3 (2024) is of the view that people are stymied in the old way of doing things, namely "of trying to have one procedure that (a) fits all and it fits no one or (b) [trying] to make [things] so complicated that they cover every eventuality or possibility at all times that they become unusable."

E2 (2024) explained that from the perspective of the legislator, the MDRs are intended to promote innovation. However, the resources necessary to meet the MDR requirements (often large parts of the development departments) divert from working on innovations and the high approval costs and long approval times are hostile to innovation (E2, 2024; Carl & Hochmann, 2024). E2 (2024) suggested that “many smaller companies are overwhelmed by the new requirements and the resulting efforts and costs, which will lead to the disappearance of many medical devices and companies from the market in the medium term.” This view is supported by Carl and Hochmann (2024) who reported that 25% of their respondents were concerned about the future viability of their companies. The start-up environment as well as the commercialization of medical devices is tough (IRL3, 2024; Carl & Hochmann, 2024). Even if companies are enthusiastic, have solved all the technical problems with their products, have good intellectual property and, good patents, the industry is still going to hurt them (IRL3, 2024).

D2 (2024) maintained that if their company had to start from scratch, it would be very, very difficult because the industry has changed a lot over time and it's hard to finance a new venture. He explained that the approach his company founders had and he himself had followed over decades, whereby profits generated were re-invested into the business, would not work today due to the high initial start-up costs. He stated “[Y]ou have to either be rich and it's your hobby or you take other people's money, investors' money, and that almost always involves an exit strategy, and the sale of the company at some point or an IPO in rare cases” (D2, 2024). E1 (2024) suggested that building a new product under the new MDR regulations in was easier than reclassifying and transitioning existing products: “...legacy systems, reclassification of other medical devices for the sake of the new regulations does seem to be problematic. I would agree with that. That is definitely the case”(E1, 2024).

E3 (2024) noted that, on the one hand, you have “...the innovators, the device designers, the manufacturers who just want to run and build and do. And you have quality people at the other side saying ‘...we need some restrictions because we do need to make them safe and effective’” so the solution is to have the quality management system grow with the company from the very beginning and doesn't stifle it (E3, 2024). In this regard, Svempe (2024) asks how the regulations can be improved without impeding innovation.

He raises the concern that, while on the one hand, the regulations are intended to improve patient safety, on the other, slower innovation and the longer lead time in getting improved products to market could reduce patient safety. Svempe (2024) suggested specific challenges for those companies seeking to launch first-to-market products such as an absence of specific guidance and clinical data. This can result in higher costs due to the longer development and approval processes, which have been noted as taking 34% longer. This factor must be balanced however by the potential for the innovator to gain the largest market share (Svempe, 2024).

IRL3 (2004) cited an example of a start-up company which received a Horizon 2020 grant of approximately €17 million, developed a product and, because of the MDR regulations in Europe, decided to launch it in the United States instead of in Europe. Thus, one branch of the EU funded the development of a product to benefit American patients, and no one called this out (IRL3, 2024). The MedTech Europe survey previously referenced reported half of EU based innovation will benefit patients in the USA first – not the EU (MedTech Europe, 2024b). Linking back to the study by Fink and Adra (2023), as cited by Svempe (2024) in the Introduction, the authors observed that some European approval pathways are more restrictive than those in the United States. For instance, the EU has strengthened its post-market surveillance (PMS) regulations, requiring manufacturers to collect ongoing data and submit specific reports. This contrasts with the broader post-market requirements mandated by the FDA (Fink & Adra, 2023). Moreover, the FDA operates as a centralized regulatory body, unlike the EU's decentralized network of notified bodies, which can result in varied interpretations of the rules (Fink & Adra, 2023). Additionally, while the U.S. maintains a centralized medical device database, the EU's equivalent, Eudamed, is still under development (Fink & Adra, 2023) and is not expected to be complete until 2027 (EC, 2024b).

4.2.3 Regulatory and Notified Bodies

A notified body functions as a representative of either the regulatory or competent authority (E1, 2024). As previously mentioned, within the European Union, prior to market entry, manufacturers are required to demonstrate to the notified body that their medical device is safe and will not cause harm to patients when used as intended (Kearney & McDermott, 2023a; Kearney & McDermott, 2023b). Recent regulatory reforms have sought to enhance oversight of notified bodies by increasing scrutiny of

their clinical report evaluations and incorporating expert assessments in particularly complex cases (Kearney & McDermott, 2023b). E1 (2024) explained that one of the outputs of the PIP scandal referred to earlier in this chapter was the fact that the notified body did not execute its responsibilities correctly, hence the EU response to bring in more requirements. A further issue highlighted was that some notified bodies were offering consultancy services and then conducting the QMS audits, a clear conflict of interest and so there was an attempt to cull as many of these organizations as possible (E1, 2024). There is still a potential problem in so far as the notified bodies need to be paid and larger companies who bring in higher revenues may be able to leverage their positions at the expense of SMEs (Svempe, 2024). The date of 26 May 2024 was the deadline for medical device manufacturers to file their applications for conformity with a notified body under the new MDRs; however 11% of companies surveyed did not have an agreement in place then, with specific issues noted in the case of SMEs (MedTech Europe, 2024b). Only 34% of SMEs had both a notified body agreement and QMS certification. The cause was not identified but considered to be linked to finding or retaining employees suitably qualified in regulatory affairs, being able to afford the costs of the notified body, or a lack of awareness of deadlines and the complexity of the regulations (MedTech Europe, 2024b).

As referred to in the Introduction to this thesis, there are capacity challenges within the notified bodies in all three countries: Germany, the UK and Ireland (McKernan and McDermott, 2023; MHRA, 2025; Svempe, 2024). The Irish notified body has reached full capacity. One of E1's clients was told it was not taking on any new customers (E1, 2024) and there is a 12-month backlog in the UK for example (MHRA, 2025). E3 (2024) added that a lot of senior regulators have left the sector, which has led to a knowledge deficit within the notified bodies. The notified bodies are taking on more work and engaging people who do not have twenty- or thirty-years' experience and "everybody's trying to muddle their way through it as best they can" (E3, 2024). Another issue identified by Svempe (2024) is that 15%, and possibly up to 30%, of SMEs across the EU do not have access to a notified body. The impact on companies, however, is that the length of time it takes to certify a product has now doubled, ranging from 13 to 18 months for the larger proportion of applications. This is evidenced by a recent survey designed to monitor and analyze the availability of devices on the EU market led by the Austrian National Public

Health Institute (European Commission, 2025d). The lack of access increases cost pressures and delays market launches which will have commercial implications as well as delay patient access to the technology.

E1 (2024) expressed the view that the reclassification and transitioning of a product from the legacy systems to comply with the new regulations seemed to have been problematic and may, in fact, be a differentiator between the larger companies. According to MedTech Europe's survey (2024b), of the respondents who had an MDR QMS certificate, 51% had certified over half of their medical devices under the new regulations but most of these were larger companies: only 12% of SMEs had done this. D2 (2024) and D3 (2024) both reported the huge time investment required of seasoned experts to reregister and have reapproved essentially all their company's products to ensure regulatory compliance.

In addition, substantial challenges appear to have existed with the regulatory bodies themselves. D3 (2024), one of the first companies to receive new certifications, reported having the "craziest time of all companies in Europe" even though they have had long experience and success in securing regulatory compliance for new products. For this company, as an early mover, they were viewed as a test case whereby the notified body always presented *their* cases, *their* documentation, *their* audits, to the government for review, which then, in return, harshly criticized the notified body for the quality of its work. The impact of this experience on D3 was especially trying because they had to work for one and a half years to change everything. It formed the view that neither the notified body nor government knew what they were doing. Moreover, communication was poor and there was a distinct lack of transparency. The situation was described as "a complete mess". For a small company, not only did this cause a lot of stress for those involved, it was 'a really complicated time', but the company felt unimportant and badly treated, and audits were constantly repeated without explanation even when certifications had been issued (D3, 2024). E2 (2024) confirmed such challenges in Germany where the authorities make high demands, and the demands of the notified bodies are not always appropriate.

While E2 (2024) had reported a mixed picture in Germany concerning notified bodies, it now noted an improvement regarding following correct processes, collaboration with government and working in a transparent way. E2 (2024) stated that the longer

certification times are, in most cases, due to the poor quality of the technical documentation provided by the manufacturer and the resulting review loops. While this is certainly an issue, according to the European Commission (2024a) the majority of MDR applications are refused as they fall outside the scope of notified body's designation and, to a lesser extent, refusals are a result of insufficient resources within the notified bodies. However, E2 (2024) added that “there are sometimes discussions between manufacturers and notified bodies that ultimately the ‘BfArM’ [the Federal Institute for Drugs and Medical Devices in Germany], as the responsible federal authority, would have to clarify. However, their response time for such questions tends to be measured in years rather than months/weeks”. In contrast, E2 (2024) advised they were hardly aware of any cases where no agreement had been reached with the notified body.

4.2.3.1 Suppliers

Suppliers, too, must be compliant (E1, 2024). D3 (2024) started a product improvement process, for example, which had to be stopped after a couple of weeks when it transpired that the supplier for the initiative did not have MDR certification. Regarding the selection of suppliers, quite often companies have got one of two choices. The first is that they can choose a critical supplier that already has the accreditation for medical devices, for example, a device contract manufacturer or a sensor manufacturer: this is the easiest and best option (E1, 2024). Second, if a supplier is chosen that does not have regulatory approval, the onus is now on the contracting company to make sure that they assess and monitor all the supplier processes as they develop or manufacture the contractor's product, and this is going to increase the workload significantly (E1, 2024). This can be further complicated should this work be outsourced to other countries such as China, for example. In this case, the contracting company would still have to audit the supplier by sending out auditors and bear the cost of this exercise (E1, 2024). IRL2 (2024) confirmed extra vigilance is needed when collaborating with suppliers in the Far East “because not in all cases everyone is up to the mark, there is a lot of red tape and bureaucracy in the system which means you can actually pay your way through”.

4.2.4 Access to MDR expertise

Expertise in regulatory affairs matters. In the medical technology area defined processes for research and development must be followed, the processes are very structured and are checked through audits (D2, 2024; D3, 2024). One interviewee remarked, “It's a lot

of paperwork; there's no space to be creative" (D3, 2024). Another noted, "It needs to deliver all those deliverables that we need for regulatory compliance and for regulatory approvals in the various markets" (D2, 2024). While several interviewees reported having in-house experts, concerns were raised by some that these experts might be headhunted. This was the case for D3, for example.

An MDR expert, E2, advised that "large companies have appropriately qualified regulatory and clinical affairs departments. Small companies usually have one or a few experts. There is a great need here, which is currently being met by service providers and will be met in the future by AI-supported tools". This author suggests a concern here because small and medium-sized companies (SMEs) make up around 90% of the medical technology sector in Europe, with the majority of these employing less than 50 people (MedTech Europe, 2024c). Again, it is important to note Carl and Hochmann's (2024) point, highlighted the literature review, that the implementation of regulations is problematic particularly for smaller companies with fewer than 50 employees. This is because of the additional work associated with the extended scope of the MDR, the new clinical investigation and evaluation requirements, the implementation of the new Unique Device Identification (UDI) system, and the obligation to use the new Eudamed database as well as other post-market surveillance tasks (Carl & Hochmann, 2024).

Medtech Europe (2024b) found that 65% of SMEs are finding it "highly difficult" to recruit suitably qualified regulatory affairs staff, speculating this could be due to shortage of and or the affordability of this expertise. E3 (2024) noted that financial considerations were relevant here because access to this type of expertise can be expensive for companies and may not be included in their budgets. E3 (2024) explained investors wanted to see tangible results, resulting in the following scenario:

"[I]f you have design engineers or you have software engineers, if you have manufacturing facilities, if you have a trial, you can see it. There are actual physical things there. When you're talking quality people and having those systems in and running in the background, it's never seen as value adding because there's no direct output. And so, you very rarely get headcount, very rarely budgeted in from the very beginning."

It is often the case that is an individual within the company who wears the quality hat in addition to many other tasks, and consultants must be engaged at exorbitant rates (E3,

2024). However, E3 explained that finding a good consultant is difficult because people can work in big quality systems for several years, know that system well, but find themselves challenged to adapt the principles to a smaller operation or a different device type, or a different manufacturing model, especially now with outsourcing happening as well.

E3 (2024) reported seeing a lot of bad consultants trying to adapt a “system in a box” and unsuccessfully try to make it fit for purpose. E1 (2024) shared different experiences, noting that in Ireland, funding has been available for regulatory experts to build quality management systems but highlighted the risks for companies thinking that the sort of “system in a box”, as referred to by E3, or a template system, would work. E1 (2024) suggested the biggest challenge companies experience is being compliant with their own system. In other words, if they write procedures in a way that's alien to how they want to run their business, they are in trouble. They are in trouble before they have done a thing (E1, 2024). Hence, “good consultants should understand how companies want to operate their business and be able to merge the requirements from both their business and what the regulations are demanding, and to come up with a tailored solution” (E1, 2024).

4.2.5 Clinical Evaluations

Clinical evaluations are an ongoing and complex part of the MDRs (MedTech Europe, 2024b). E1 (2024) advised that the clinical evidence now required is probably the biggest challenge at the current time, describing it as the “big killer”. E1 (2024) went further to question how new start companies can fund clinical studies, saying, “It's absolutely the biggest challenge with the regulations as they stand now, probably in the world, the clinical evidence that's required....”. Kearney and McDermott (2023a) also suggest that the significant costs in this regard can be inhibiting, especially if the costs exceed the potential return. E1 (2024) additionally highlighted the issue of post-market surveillance systems, noting that the new MDR define precisely the requirements for each classification. It may be possible to use secondary research in some instances if there is a comparable or technically equivalent product on the market, and if the necessary data is available. However, this is not an option in the case of innovative products (Svempe, 2024) as the data has not yet been generated. MedTech Europe (2024b, p. 21) reported

the top three reasons given to companies who were strongly challenged on their clinical evaluation applications in the following terms:

- “Insufficient evidence generated while the devices have been on the market.” Note that 60% of companies reported this as a major obstacle and 26% described it as a medium one.
- “No clear definition of sufficient clinical data.” For reference, 53% described this as a major obstacle and 33% described it as a medium one.
- “Difficulty in agreeing on appropriate Post-Market Clinical Follow-up plan with Notified Body”. In this respect, 33% of companies described the issue as a major obstacle, 29% described it as a medium one, and 22% as a minor one.

Currently, there is a risk to manufacturers if they cannot discuss their clinical strategy with their notified body in advance of submitting their application. They may be challenged much later after the company has been implementing the same strategy for months or even years (MedTech Europe, 2024b). There is also a concern relating to the use of Real-World Evidence (RWE) as a source of clinical data for post-market clinical follow-up (PMCF), as many discrepancies exist within the notified bodies in their acceptance of it (MedTech Europe, 2024b). 65% report the acceptance of RWE as an additional data source, while 23% do not accept it at all. It is thought that this discrepancy is related to the quality and reliability of the data sources (MedTech Europe, 2024b).

UK3 (2024) explained that conducting cross border post-market surveillance for devices has become much more difficult for UK based companies since BREXIT due to General Data Protection Regulation (GDPR) and information governance regulations. The process was described as an “absolute minefield”. As a responsible company where the protection of personal data is clearly central to what they do working in the clinical space, the amount of work involved in a post CE mark post market survey just to get some feedback from patients is “just ridiculous” (UK3, 2024). Driving innovation is difficult anyway but these challenges seem unreasonable and put companies at a disadvantage (UK3, 2024). The post-market surveillance requirements have indeed increased considerably under the new regulations with the introduction of “obligations for data collection, evaluation, documentation and reporting to increase patient safety through early identification of potential safety issues and to confirm long-term efficacy

of the devices” (MedTech Europe, 2024b, p. 31). The implication of this, depending on the device classification, is that it takes up to 70% of companies up to 4 months to complete their reports, and a minority even longer, up to 20 months, and companies are struggling (MedTech Europe, 202b). MedTech Europe (2024b) reports that the duplication or repetition of information across various reports and strict deadlines for data collection appear to be particularly problematic. D3 (2024) reported increasing costs associated with getting doctors to collect data, while in both the UK and Ireland concerns were raised regarding the excessive workloads of doctors whether in general practice, in secondary or in tertiary care. They simply did not have time available and were thus difficult to engage with (IRL3, 2024 and UK2, 2024). MedTech Europe (2024b) has reported half of the medical device companies they surveyed advising their costs of PMS doubling with a third of companies experiencing increases of up to 100%.

UK2 (2024) explained that the adoption cycle requires double evidence, both clinical and economic. While the company may have addressed its clinical evidence requirements, the provision of economic evidence is more complex. However, they recommended looking at this in detail because the NHS requires real-world evidence, not a model based on assumptions (UK2, 2024). Evidence from the use of a particular technology used in comparison with current technology or current methods must be provided (UK2, 2024). UK2’s technology addresses patients who are effectively on acute care pathways, people in hospitals or outside hospitals who are quite ill, and it is the front-line medical staff, who are already known to be overworked, who have access to these patients (UK2, 2024). UK2 (2024) continued saying:

“...[I]f you want to introduce something new and you say that needs to be tested on exactly those same patients that the doctors are treating, the doctors and nurses are treating, you are effectively, asking overworked people to do double the amount of work. There is no slack in the NHS to be able to implement the real-world programmes that they insist are necessary for the adoption of new methods and new technologies”

In fact, E3 (2024) added that approval from the NHS Institute of Clinical Excellence (NICE) was critical to accessing NHS Hospitals. E3 (2024) predicted a change of approach regarding clinical trials, envisaging the adoption of a pharma-style model. What this means in practice is using commercial clinical trials units to get the first ‘in-human’ trial

completed and then spin out the company. As an approach they noted, this is “going to kill a lot of the small companies” (E3, 2024). In a similar vein, Svempe (2024) notes of the lack of financial resources amongst SMEs for large-scale clinical trials, sharing concerns about them either leaving European markets or delaying product launches. Kearney and McDermott (2023a) reported an increase in companies outsourcing this clinical trial work due to a lack of internal expertise and knowledge, noting difficulties experienced by some in hiring the people needed. The risk here, this author argues, is that the development of internal expertise and knowledge may not be maximized if this work is continually outsourced, which, potentially compromises an important source of competitive advantage.

Thus, while markets may differ structurally, they share some common challenges, not least their conservative nature, which, although described by UK2 (2024) as justifiable in many ways, nonetheless makes technology adoption difficult. While one of the biggest challenges some companies face is trying to operate in a sector where innovative solutions are continuously being introduced (UK2, 2024), the length of time it takes for technology adoption is also a consideration. MedTech Europe (2024d) reports a lifecycle of only 18 to 24 months for many products, before an improved one becomes available.

In markets where healthcare is not politicized, where medical technologies are better funded, and hospital management “isn’t distracted by having to play politics, cover up errors, and generally try to protect themselves, they can make these sensible decisions” (UK2, 2024), adoption is faster. Nurse shortages being addressed with technological solutions in Scandinavia were cited as one example (UK2, 2024). However, E1 (2024) articulated a blunt perspective confirming the conservative nature of the healthcare sector, advising that those making purchasing decisions select market leaders, not because of the appropriateness of their technologies, but because “nobody gets fired for buying big blue”. E1 (2024) further asserted that “the NHS being the biggest healthcare organization in the world, is the hardest one to get into”.

In addition to the increasing costs associated with the medical factors mentioned, the costs of laboratory and technical tests must also be factored into the planning of projects (D3, 2024). Problems and the development of solutions need to be anticipated, and problems can be expected with documentation. For example, D3 (2004) explained, technical issues have to be proven (for example, if “the electromagnetic field is too high”

or other issues), but they suggested everything was possible once you had an expert and funds. For example, IRL1 was engaged in really important clinical studies which were funded by stakeholders who understand the opportunity (IRL1, 2023). Note that it takes on average 19.6 months for both SMEs and large companies to complete their QMS certification and the technical documentation assessment takes 22 months (MedTech Europe, 2024b).

4.2.6 Intellectual Property

Chen (2022) contended that a strong intellectual property management framework allows SMEs to disclose innovation-related insights more openly, which in turn helps sustain their competitive edge. Bogers *et al.*, (2019) argued that intellectual property has assumed a pivotal role in fostering open innovation. Nevertheless, a mixed picture from those interviewed for this study is presented concerning intellectual property. It is indeed a complex area of activity as advised by Grimaldi *et al.*, (2021). The German companies interviewed were unequivocal in their approach, proactively protecting the outputs of their R&D work for both defensive purposes (D1, D2 and D3, 2024) and to gain credibility with customers (D2, 2024). The Irish and UK companies interviewed shared some pragmatic views and a greater level of openness in their approaches (IRL1, IRL3, UK3 and UK4, 2024).

D2 (2024) has always had a desire to protect their intellectual property and demonstrated a closed approach to its management (Chesbrough, 2006; Chesbrough *et al.*, 2008). The company does not share intellectual property, maintaining “it's very, very difficult and rarely works” and claiming it to be an ivory tower ideal (D2, 2024). Hence, if D2 patents something and they are using it, they don't license it because a lot of the value added is in the manufacturing for them. They allow unused patents to sit because trying to commercialize a patent that they don't actively use for whatever reason is a lot of work and they don't have the resources to do with this where the outcome is in the realm of the unknown (D2, 2024). Patents are reviewed every couple of years and fees are paid for those patents which are needed, or others are allowed to “wither away, die, you know rendering it invalid” (D2, 2024). This approach is in direct contrast to the proponents of open innovation who view intellectual property as an asset that can be used to deliver further revenues either to the current business model or through newer ones (Bogers *et al.*, 2019; Chen, 2022; Chesbrough *et al.*, 2008). This is also similar to the

view of Orlando *et al.*, (2021), who suggest that purpose of relinquishing some control is to achieve superior growth. Bogers *et al.*, (2019) acknowledge the risks but, nonetheless, assert that, in many cases, when using licenses with reasonable royalties, revenue bases to facilitate scale can be broadened. However, as mentioned, this is not a straightforward area.

D2 is involved in innovation clusters where there is a lot of exchange happening predominantly on regulatory issues “because that's a big one, and everyone suffers from it.” However, not a lot of IP is shared, just some know-how along the lines of “this how this is how we did it in Taiwan” for example (D2, 2024). D3 only pursues the patents they need using government funding. They described a German system of a ‘Gebrauchsmuster’ (German, ‘utility model’). This is like a small version of a patent which allows companies or their lawyers to do a sort of pre-check for similar (full) patents and see if others are doing comparable work or if the company is, in fact, doing something new (D3, 2024). This system, they advised, could also be used to develop a strategy to block technologies (D3, 2024), an approach which is aligned to Grimaldi *et al.*’, (2021) defensive strategy. The Head of R&D is proactive in monitoring new patents through regular newsletters and competitor activities using market scanning techniques (D3, 2024). D1 (2024) also takes a defensive approach to intellectual property. The company currently has six patents which have been granted in Germany and 30 further independent patents which are in the process of being granted (D1, 2024). They explained a patent mechanism of which Germany is part, called the PCT (Patent Cooperation Treaty) system, which means the company has reserved rights in one hundred and thirty-four States and, after 12 months, the company must decide in which country to apply for patents (D1, 2024). Europe, the US, Japan, China will be selected. The reason for selecting China includes the ease of filing a patent there and blocking others from entering the market (D1, 2024).

Not every company is so concerned about patents. IRL1 (2023) maintained it may not be the be-all and end-all for a start-up if their patent isn't granted as the company may still have the momentum required to make a successful business. Others, IRL2 (2024) for example, took a more pessimistic stance on patents, questioning their relevance or value. The Director asked who was going to police the patent and even if there was an infringement, not only the cost of paying lawyers to launch a challenge has to be

considered, assuming the company can access the lawyers in the first instance, but there is also the cost of diverting attention from the business and the commercialization of the technology to address as well (IRL2, 2024). The Director added that, by the time any legal challenge was complete, the defendants would already have made their returns (IRL2, 2024). IRL3 (2024) described their relationship with IP, trademarks and patents as chequered and suggested, that patents are only as good as the money available to defend them. Their experience in China, for example, was that patents were treated like instruction manuals and were of no use there. While IRL3 held several patents, five or six, they were not a top priority, and they had dropped some they were not using (IRL3, 2024). However, the investor interviewed advised that intellectual property is “make it or break it in this scenario”; that is, if it is not fully in order they would not invest, especially in this sector (FM1, 2024). This is in line with Mazzocchi (2018, p. 78), who advised that it is one of the first questions an investor needs answered before any developmental work is done. However, legal expertise may be needed for this in order to determine if the innovation justifies a filing with a “new set of marketable claims” to protect it.

UK3 (2024) has observed too often, particularly in their specialist field, lots of defensive patents being created by competitors, and they describe having fallen into that trap somewhat themselves, patenting anything and everything (UK3, 2024). However, they advised some caution, recommending companies to look at what competitors are doing (UK3, 2024). UK3 (2024) was critical of the European Patent Office for granting patents for technologies that are not novel, or in their words, not “an inventive step over any prior art that's gone before in this field”. They cited a case, in which a major player sued them as they launched a new product. While UK3 won the case, had the competitor’s patent revoked and had their own costs refunded, the tactic of the competitor was to slow the product launch down by putting up as many hurdles as possible.

UK3 reflected on its guiding principles: which were articulated in the following terms: to realize the potential of their people, to improve many more lives worldwide than they do now; and to reduce their impact on planet Earth. Thinking in those terms, it had started to consider a change to its patenting strategy (UK3, 2024). The company planned to become more judicious about where it established its IP in the future, possibly even making some open source depending on some of the features of the product. The idea

was encapsulated in the remark, “[i]t kind of dawns on you at a point, where you go even if we were ten, fifteen times bigger than we are now, we wouldn't be able to service every single patient on the planet anyway” (UK3, 2024). Accordingly, they asked, why would they stop any other company in a position to help and share the technology whether on a favourable royalty basis or by making it open source (UK3, 2024). While they had yet to take this step, they are forming the view that change was needed, and that IP was quite restrictive and a barrier to innovation (UK3, 2024). If, in fact, a company wants to protect every aspect of what they do, every aspect of IP, they would never speak to anyone according to the interviewee (UK3, 2024). This point was explained by UK3 (2024) in the following terms:

“What I see in terms of IP in fields or areas of our technology that have been, you know, long standing and just very subtle tweaks to a fundamental principle that's now being claimed as a new novel invention and being protected because it's wrapped in IP legal speak. It genuinely isn't innovation, it really isn't innovation, all it's doing is creating a barrier and it's an attempt to carve out a monopoly that actually doesn't contribute to innovation that drives improving a life or better outcomes for patients. So, you know, we're trying to take a step back from that kind of approach and trying to think a little bit more holistically about how we do this. It's interesting when you look at what, he's a bit of a marmite character isn't he: Elon Musk, but you know he's made a lot of his IP open source”.

UK3's strategic approach appears to be consistent with either the collaborative strategy described by Grimaldi *et al.* (2021) or, to some extent, the purposively defensive strategy outlined by Greco *et al.* (2022). The collaborative strategy emphasizes the deliberate use of intellectual property protections not only to generate additional revenue streams, but also to signal firm capabilities and foster new partnerships. Within this framework, IP management is integrated into the business model, enabling the firm to profit by selectively granting competitors access to its technological assets (Grimaldi *et al.*, 2021). Grimaldi *et al.* (2021) note that such a strategy involves conscious and selective disclosure, wherein firms determine both the nature of the information they share and the extent of legal control they retain over it. The purposively defensive strategy described by Greco *et al.* (2022) entails open knowledge sharing with partners while

concurrently safeguarding innovations to mitigate the risk of imitation. UK3's practices suggest elements of both these approaches: when identifying potentially integrable technologies, the company initiates research and development agreements that clearly delineate IP protections and mutual expectations. These initial agreements evolve into comprehensive contracts that outline commercial terms once feasibility has been established. The author suggests this is evidence of how a firm can navigate the tension between openness and control to optimize open innovation (Zhang *et al.*, 2023). To institutionalize these practices, UK3 has developed an in-house legal function responsible for managing supply agreements, research contracts, demonstration projects, confidentiality protocols, and broader IP and trademark matters (UK3, 2024). Regardless of the strategic orientation, collaborative or more defensive, UK3 demonstrates an intentional management of knowledge flows both inbound and outbound reflecting the principles of open innovation as articulated by Chesbrough and Bogers (2014, p. 17).

Holgersson (2024, p. 173) argues that a technology's fit with an outbound open innovation model hinges on its complexity: discrete technologies, involving only a handful of inventions, demand tightly defined IP strategies and contractual terms to preserve an open position, whereas complex or systems technologies, comprising many interdependent inventions, allow for what he calls a "more multidimensional design of openness", shaped by both the nature of the technology and its product architecture. Drawing on Baldwin and Clark (2000), Chesbrough (2003), and Schilling (2000), Holgersson (2024) distinguishes between integral and modular architectures. In a modular configuration, firms can strategically disclose certain IP elements to external partners while keeping other proprietary knowledge under wraps. Given the sector's technological diversity, Holgersson (2024) concludes that further research should explore how organizations that currently under-exploit their IP portfolios might be guided to deploy these assets more fully in open innovation initiatives.

The CEO of UK1 advised that the company has IP for UK, Europe, and South Korea and is working to secure the IP for the United States (UK1, 2024). However, he explained, the costs for this IP are huge especially for a small company like theirs (UK1, 2024). Their technology is complex, and while certain parts of the technology are patented, there is a lot of know-how and a lot of copyright in the software that runs in the system, which

is what really protects it (UK1, 2024). The company cannot expose itself to any risks and thus the IP is for defensive purposes (UK1, 2024). The high IP costs are a concern for many reasons: the company is in the pre-clinical development stage, and two years away from conducting its first in-human studies and is consequently pre-revenue and, reliant on investors' funds (UK1, 2024). So, there is a requirement for judicious financial management, and the company is currently negotiating its way through credit terms with lawyers, and with insurance people (UK1, 2024). Solvency is a concern (UK1, 2024). This must be balanced with the longer term when the company may gear up to do business with a large corporation, but they have concerns about who will hold the power in such a relationship. To mitigate risk in this regard, they prefer to collaborate with smaller partners (UK1, 2024).

There is a tension between IP and open innovation (Bogers, 2011; Laursen & Salter, 2014, cited in Holgersson, 2024). Where an innovation is protected by IP, including patents and copyright, licensing can be used to control and manage how much knowledge is shared. This enables the coordination of and/or the limiting openness (Holgersson, 2024). When the licensed technology is critical to both parties, the licensor and the licensee, a joint venture may be the preferred solution so that the IP can be shared (Holgersson, 2024, citing Granstrand & Holgersson, 2013). Specifically, regarding outbound open innovation and discrete technologies, the focus is on maximizing value capture and, while straightforward, decisions must still be made whether to sell the IP, or license it, and to whom (Holgersson, 2024). In the case of complex technologies, many decisions are required when designing the appropriate level of openness. These include the modularity of the technology, the IP and the contract design (Holgersson, 2024). As presented in the literature review, Bogers *et al.* (2019) outlined two key decision factors for open innovation in diagrammatic form: the technology development business model, which refers to the balance between internal and external R&D, and the IP strategy, which concerns the extent to which technology is proprietary or shared. They emphasized that these decisions affect both how value is created and how it is captured (Bogers *et al.*, 2019). In this study, IP has been used mainly for defensive purposes (Grimaldi, *et al.*, 2021), some skepticism was shared, and one company was reviewing its strategy. The findings in this regard cannot be generalized and the author would share the view of Holgersson (2024, p. 180) that there is still a need for further research, not

least to understand how “well-functioning combinations of decisions” along the dimensions of modularity of the technology, the IP and the contract design enable both value creation and value capture.

4.2.7 Government Support

Interviewees shared mixed views and experiences, sometimes contradictory, of government policies and support. The sector is very dynamic and there are significant policy developments currently at EU level and at national levels in all three jurisdictions.

D1 (2024) reported that the regional government in Baden-Württemberg, Germany, supported them in many ways. For example, when attending a major global health trade show in Dubai, ‘Arab Health’, the government engaged a liaison for German companies to broker contacts in the United Arab Emirates and to network between Baden-Württemberg and the Emirates. The government also provided cultural insights which were appreciated as this information would otherwise be too expensive for the company to access using consultants (D1, 2024). However, D1 was of the view there is a structural problem in Baden-Württemberg due to the lack of State grants to scale start-ups, saying there are few opportunities. The founders expressed strong views regarding the need for change in the environment for female entrepreneurs especially. They explained that they had achieved “a target that only one percent of female founders achieved in Europe”, raising an initial investment of more than one million to build their company and four million in the second funding round (D1, 2024).

D3 (2024) reported the availability of significant government funding for R&D and training in the same region. However, this funding is not advertised, and, as a result, many companies do not know about it and thus need to be proactive to access it (D3, 2024). R&D funding is available for companies to collaborate with universities as well as funding for staff training and upskilling where up to 100% of course fees are covered and 75% of salaries (D3, 2024). This does appear to be the case. BioPro Baden-Württemberg GmbH was founded in 2003 as part of the government's “Zukunftsoffensive” (German, ‘Future Offensive’) Programme and has been proactive since then in developing the healthcare sector including medical technology, biotechnology and pharmaceuticals through the provision of funding and networking supports (BioPro, 2025b).

In the UK, fewer concerns were raised about the medical device regulations than elsewhere. UK3 stated for example, that “the regulations around our products and our sector, I don't think you'd find anyone has any particular difficulty with them, they're clear, they're understandable. We understand what we need to do, we're certified to 13485, it's a bit like riding a bike”. This aligns with the fact that the UK has been following European Union (EU) directives from 1990, 1993 and 1998, which were enacted in UK law in 2002 (Gov.UK, 2024). Thus it is reasonable to assume familiarity.

UK1 (2024), acknowledged that regulations vary a lot between countries. In their area, at the most regulated end of MedTech, namely as a Class III device, there are differences between Europe and the US once the nuances are properly examined. However, the CEO explained they are more aligned at this level than they are for slightly lower-class devices, therefore the steps that UK1 needs to go through are fairly clear (UK1, 2024). UK1 (2024) reported having an expert full-time in-house staff member who worked with external consultancies to supplement this knowledge and to provide geographical insights: a US regulatory consultancy that provided support with the FDA, and another consultancy that provided support for dealings with the UK agencies (UK1, 2024). UK2 reported challenges associated with the maintenance of regulatory approvals on what is effectively a digital platform, one which is continually evolving. Fortunately, they have the capability to do this and believe this capability is a high value-added skill set as this work is difficult to do. UK3 has an in-house legal function and UK4 also possess in-house expertise. Their CTO has gone through the ISO 13845 registration and certification with two other products already, and it was remarked that “even though he's a really young man, he understands this area extremely well”.

Setting new standards and influencing certification bodies when novel materials are developed is another challenge (UK2 and UK3, 2024). UK3 (2024) provided an example whereby British Standards need to be convinced of the benefits of a new grade of mask using the company's propriety technology, which both improved the experience of using the mask and trapped virus material in a way that was considered very novel. UK2 also highlighted similar challenges. While their technology is fully approved on the regulatory side, it is still not what is called ‘standard care’. They commented, “[I]t's not the way things have been done for the last 50 years, and therefore it takes a whole set of

procedures to get something that is not currently standard care adopted as standard care” (UK2, 2024). The regulatory landscape is changing in the UK; for example, the Medicines and Healthcare products Regulatory Agency is publishing details of new regulations and requirements to improve safety and access, and to ensure that the UK remains attractive for innovation (MHRA, 2025).

IRL2 (2024) referenced support models provided by the Irish business development agency, [Name]. One initiative, akin to a business accelerator programme, a company is supported with a pathfinder into a market. However, this pathfinder is only available for a short duration, typically three to six months, and is therefore considered limited in effectiveness. Achieving meaningful success in a market requires a far deeper level of insight, detail, and understanding, which typically develops over several years.

IRL2, (2024) also referenced the metrics against which the Irish business development agency performance is measured. These include the number of exports, the number of jobs the client company has increased in Ireland, as well as the physical presence that a company has opened in the market (IRL2, 2024). These metrics increasingly favour companies capable of rapid scaling, while deprioritizing support for smaller firms with longer gestation periods (IRL2, 2024). As mentioned in the literature review, start-ups have a strong potential to create disruptive technologies that, through collaboration, may open new avenues for larger firms (McKernan & McDermott, 2024). To benefit from these partnerships, it is advised that large companies cultivate the capabilities required to integrate smaller firms efficiently, scale operations rapidly, and navigate regulatory frameworks. As a result, support programmes should prioritize strengthening these competencies (McKernan & McDermott, 2024).

However, McKernan and McDermott (2023) caution of another risk to Irish medical device companies. That is, despite the overall growth in the market, the prices for undifferentiated products are falling (McKernan & McDermott, 2023). There are several reasons for this such as, for example, hospitals in the United States centralizing their purchasing; cost-conscious, doctor-owned Office-based Labs (OBLs) being used more frequently for out-patient procedures; these doctors receive price discounts for medical devices; and, the purchasing of medical devices in China has been centralized (McKernan & McDermott, 2023). There are two competitive strategic options available to Irish medical device companies: to either adopt a low-cost strategy or adopt a differentiated

one which enable companies to develop new markets and with little competition (McKernan & McDermott, 2023). This author would argue that companies would need to consider carefully the technology development business model and the IP strategy it should adopt (Bogers *et al.*, 2019 and Holgersson, 2024).

4.3 Markets

4.3.1 Market Challenges

The United States is the largest market for medical devices in the world with a market share of just over 38% in 2023 (BMI, 2024; Fortune Business Insights, 2025) and it is the most important export destination for European medical technologies accounting for 40.4% of exports (MedTech Europe, 2024d). Conversely, it is the leading import supplier to the European medical devices market, accounting for 45.4% of imports (MedTech Europe, 2024d). Unsurprisingly therefore, for several of the companies interviewed, factoring in market entry to the United States forms a core part of their strategic planning. D2 (2024) stated that, if compelled to choose between the United States and the European Union, he would opt for the United States due to its scale. He justified this preference by noting that although the U.S. comprises only 4% of the global population, it accounts for over 40% of global healthcare expenditure.

However, there are some advance considerations for companies. UK1 (2024) explained that the US market is different, which is partly to do with how their healthcare system works. First, the health care system is privatized and for profit (UK1, 2024). Next, a system of medical insurance exists whereby codes called Diagnostic Related Group (DRG) or Current Procedural Terminology (CPT) codes must be issued for a procedure (UK1, 2024). Companies introducing novel products must obtain a new code, a process managed by the American Medical Association that is both lengthy and complex, often requiring up to three years to complete (UK1, 2024). To sell a device to an American hospital these codes need to be in place to allow the hospital to invoice the insurer and to receive reimbursement for any procedure carried out using the device (UK1, 2024). This can be problematic for a new start-up, as the lead in time for payment for their technology has the potential to be quite protracted which, in turn, means astute cashflow management will be key. There is also the possibility that the start-up will require some form of bridging finance. The regulatory burden is another consideration, whereby companies need to see a reasonable return for any financial outlay. D2 (2024)

outlined the demands of the Brazilian Health Regulatory Agency (ANVISA) and the Argentinian market as unattractive examples (D2, 2024). The fragmented nature of the Gulf markets was another example provided by IRL2 (2024). These markets must be approached with full insight into the costs and benefits (IRL2, 2024).

D1 reported a difficult market environment in Germany. The pandemic, the war in Ukraine, the energy crisis have all had an impact. The increased energy costs for example have put pressure on financial resources in hospitals and the uncertain political situation has caused a delay in venture capitalists making investment decisions (D1, 2024).

BREXIT has been another source of challenges. UK3 (2024) was scathing of it describing it as "...a fur-lined, ocean-going disaster..." and, further stating, "...it really has killed us." UK3, (2024) continued, "It's made the job of working with European partners incredibly difficult when it didn't need to be", and, "it should never have happened." UK3 (2024) faced a sudden rise in cross-border costs, driven by its reliance on European-sourced raw materials: even getting samples over the border became problematic (UK3, 2024). While exports to Ireland settled over time, a significant amount of 'insane' bureaucracy remained (UK3, 2024). E1 (2024) confirmed that as a UK manufacturer, an authorized representative in Europe is needed, and a European manufacturer needs an authorized representative in the UK. This is an obvious challenge to trade and has added another level of control or bureaucracy on top of everything (E1, 2024). To further complicate matters, BREXIT added further complexity to the Northern Irish situation where the European Medical Device Regulations came into force as a result of the Windsor Agreement, despite the legal jurisdiction being the UK (Gov.UK, 2025). Dayan *et al.*, (2023) discuss the unsolved tension within the political arena in the UK proposing three regulatory orientations: the first is to move in parallel with the EU; the second is to diverge and make different policy choices; or, the third, to drift by not making deliberate decisions while the EU updates its policies and regulations. Dayan *et al.*, (2023, p. 2566) also aired concerns "about the lack of consistent, strategic regulatory action" in the UK. While a medical technology strategy policy paper was published in April 2024 by the Department of Health & Social Care, there has been a change of government since so there may yet be a change in this policy.

4.3.2 Market Research

One of the two key phases of outbound open innovation according to Aloini *et al.*, (2020), includes an opportunity identification phase which comprises an evaluation of the company's technological assets, and the active exploration of new markets and technologies. This is also aligned to Bauer *et al.*'s, (2018) technology transfer identification stage whereby intelligence gathering is a key component. This involves scanning the external environment as well as the identification of transaction partners and opportunities, which, in turn, enables capability building as a constituent part of effective technology management (Bauer *et al.*, 2018). This author suggests that by undertaking these tasks, the development of desorptive capacity is supported. As a reminder, desorptive capacity describes a company's ability to convert internal resources into commercial value. This, not only contributes positively to financial performance, but also drives strategic benefits such as cultivating new knowledge, shortening learning curves, and advancing co-opetition through collaborative partnerships (Joseph, 2023; Kim *et al.*, 2021). As product life cycles continue to shorten, and the pressure for value creation and significant financial investment grows (Joseph, 2023), the importance of desorptive capacity is becoming more pronounced, especially within medical technology innovation. The resource-based view of strategy holds "that the competitive advantage and superior performance of an organisation are explained by the distinctiveness of its resources and capabilities" (Johnson *et al.*, 2017, p. 97) underscoring its relevance. Keinz and Marhold (2021, p. 197) referred to 'technological competence leveraging' or TCL as an outbound open innovation strategy that involves 'searching for, evaluating and exploiting new market opportunities for existing technologies' in a systematic way. Keinz and Marhold (2021) maintain that TCL is ingrained in the resource-based view, and such competences are critical to innovation and wealth creation. However, Keinz and Marhold (2021) note that many organisations don't benefit fully from open innovation as they lack these competences.

Several distinct market research approaches were observed amongst the companies interviewed during the initial data collection process. D1 (2024) reported the difficulty a small company has in getting detailed market information saying it required multiple costly advisors. However, market insights, particularly relating to culture, were provided by the local business development agency and Chamber of Commerce when they

participated in events abroad (D1, 2024). D3 (2024) involved its sales team when conducting research in order to evaluate the viability of potential markets, while conducting patent searches in tandem. IRL1 (2023) argued that desk-based research alone was insufficient to grasp the nuances of market dynamics. To address this gap, they enlisted an exceptional sales professional to support them and to co-develop messaging tailored to the expectations of clients and stakeholders. IRL1 (2023) was engaged in significant clinician-led studies funded by key stakeholders, which reflected the strategic opportunities these parties identified. The research team at UK3 (2024) proactively scanned scientific technical literature, updating the Head of Research on new thematic developments monthly. This work included compiling a list of industry contacts that the company engaged with over time, spanning outreach periods of one month, six months, and twelve months (UK3, 2024).

The Fund Manager interviewed explained that his team rejected approximately sixty-five percent of first pitches due to their inadequate market research (FM1, 2024). He specifically noted that the start-ups overlook key market dynamics, namely, how markets respond, who holds influence over them, and who governs purchasing decisions on the buyer's side (FM1, 2024). Therefore, his team facilitates collaboration between the investment-seeking start-ups and their network of market experts, many of whom are also fund partners, by jointly conducting and accurately analyzing market research (FM1, 2024). Often, when the market analysis is complete, the investors adopt a different position (FM1, 2024). The Fund Manager asserted that this service was highly valuable, enhancing the start-up's chances of survival. He maintained that even if his team ultimately chose not to invest, the support provided improved the company's positioning to secure funding from other sources (FM1, 2024). As put forward by Aloini *et al.*, (2020), the identification of opportunities requires insight into customer needs and demand, potential applications for the technology, and market structures which not only helps to identify opportunities, but threats as well.

However, Kim *et al.* (2021) note that research into organizational assets and competencies remains underdeveloped. This author suggests that further study would be beneficial to better understand the specific challenges faced by start-ups in this area.

4.3.3 Competitors

The research reveals that, although competitors are proactively monitored, organizational practices vary and are not uniformly aligned. IRL1 (2023) looked at competitors for two main reasons: technological proximity and social media engagement. To monitor the former, IRL1 (2023) reviewed patent publications and relevant journals. D3 (2024) deployed a similar strategy then suggested patents could be used as a blocking mechanism. IRL1 (2023) reviewed the social media channels where competitors dominate and, used this insight to inform their own promotional strategy. UK2 (2024) proactively sought customer feedback and combined this with technological advancements to stay ahead of its competitors.

UK3 (2024) benchmarked its R&D spending relative to turnover against competitors, indicating that it invested more heavily than the market norm. However, this was seen as a short-term strategy aligned with its broader ambition to disrupt the industry. Rather than focus solely on protecting every new product, the company leveraged its strategic flexibility to pursue unconventional and bold initiatives, making its actions harder for competitors to replicate. (UK3, 2024).

UK1 (2024) had identified a single competitor holding a 15% market share, highlighting a blue ocean opportunity. Accordingly, UK1's strategic intent centered on capturing this untapped potential (UK1, 2024). However, ongoing surveillance of the competitor remained critical to reassure investors of UK1's superior value proposition in terms of quality, cost-efficiency, and commercial viability (UK1, 2024). D1's (2024) product was a worldwide first in the field of operation room (OR) robotics and, as such, their priority was to start to generate revenue.

IRL3 (2024) highlighted a widespread lack of confidentiality within the sector, noting that individuals frequently engaged with both distributors and competitors. As a result, stakeholders exercised caution in disclosing information. Knowing when to be open with information is not always clear. Alexy *et al.* (2017. p. 1706), through mathematical modelling, found that if the production costs of a bundle of resources are reduced or the value captured from a "still-proprietary" complementary asset increases in a monopoly situation, then openness is a reasonable choice. They also argue that in an oligopolistic setting, the choice to open a resource depends on how easily it can be substituted within the firm's bundle and on the number of competitors (Alexy *et al.*, 2017). Their models,

however, do not account for uncertainty (Alexy *et al.*, 2017) and this author therefore, in line with Bauer *et al.*, (2018) and Joseph (2023) for example, recommends further research.

4.4 Finance

Financial issues, especially for newer, smaller businesses, were highlighted repeatedly. These issues ranged from fundraising and investment to reimbursement.

The larger or more established companies interviewed acknowledged the sector's financial challenges but indicated they had some resilience. D2 (2024) suggested, for example, that "...a company like mine would, today, would not happen anymore. I mean the way we were created, and how my parents built [it] and later how I myself built the business over the decades without other people's money". IRL1 (2023) stated that funding is the number one concern of every medical technology company in the world.

In a highly competitive sector, suboptimal valuations constrained companies' ability to secure funding (IRL1, 2023). Reluctant to pursue equity financing due to concerns over dilution, many firms adopted more cautious go-to-market strategies, resulting in slower commercial momentum (IRL1, 2023). UK1 (2024) identified "fundraising, fundraising, fundraising" as their foremost challenge, underscoring a difficult investment climate marked by investors failing to raise new funds and retrenching from both risk and investing. Available funds were being channeled into existing portfolios rather than into new ones or into businesses such as digital healthcare apps that could be self-supporting in a relatively short time frame (UK1, 2024).

At the time of interview, D1 (2024) was struggling to raise bridging finance to commercialize its world-first product. This was despite the fact they had already achieved a target only one percent of female founders in Europe had achieved, raising more than five million euros in their first two investment rounds (D1, 2024). The Fund Manager interviewed reported few women seeking investment and had heard, anecdotally, from other investors that women tend to back away from the investment process if due diligence procedures take too long or become complicated (FM1, 2024). While the law in Germany means that hospitals should deploy D1's technology, the hospitals do not have the financial resources to do so (D1, 2024). The Fund Manager added that, in his experience, public sector hospitals in Germany are very hard to work

with citing bureaucracy and prolonged processes. He added, they are often lobbied by larger companies, forcing start-ups to work with privately owned medical facilities where they can communicate directly and achieve sales in a shorter timeframe (FM1, 2024). However, he advised that if investors are in a situation where the company takes a longer time to generate sales, they usually issue a convertible debt to those companies, saying “[I]t's usually the combination of the investment into equity at first and then the convertible debt ... to overcome the prolonged period” (FM1, 2024).

Seeking funding for patents, marketing activities, and staff training to supplement their own investment in training, was core to D3's new product development strategy (D3, 2024). They considered this important for a small company like theirs to mitigate risk (D3, 2024). In the past, D2 (2024) reinvested its profits, with an occasional small bank loan, to finance the development of new products but acknowledged this approach no longer works because initial costs are now so high. D2 (2024) explained the use of borrowed funds “almost always involves an exit strategy, and the sale of the company at some point or an IPO in rare cases”. Thus, D2 leveraged its technical expertise, market insight, and manufacturing know-how to co-finance commercialization efforts with industry partners, occasionally extending this cost-sharing to development and design transfer activities. (D2, 2024). The product is owned by the industry partners, while D2's value lies in the manufacturing side. This tailored arrangement suits D2, who noted that “starting from scratch would be very, very difficult” (D2, 2024).

Another company reported partnering on good terms both with academia and with other businesses, sharing some of the benefits of scaling a new filtration technology, by way of example (UK3, 2024). The company supported the research and launched the product enabling it to reap the rewards of first mover advantage. The benefit for their partner, who handled component manufacturing, is that they could scale and expand production elsewhere, even with competitors, in a way that supported both parties and ultimately benefits patients (UK3, 2024).

Despite the strength of its technology and scientific foundations, UK1 (2024) struggled to attract investment. The primary concerns were not technical, but rather related to extended timelines and perceived risk. The company required two, potentially three, additional funding rounds before reaching a viable exit. Investors were hesitant, questioning whether the company could successfully progress beyond the next round of

financing (UK1, 2024). UK1 was also concerned about being reliant on one big partner but suggested it could be a large established corporate in emerging technologies with longer term strategic alignment objectives that would provide a solution (UK1, 2024). The Fund Manager advised that in the case where a start-up required a longer lead in time to get to market and needed a larger investment, then a portfolio of investors in the form of a mutual fund, or a really big B-fund, was preferred so that no single investor would be overly exposed (FM1, 2024). UK2 (2024) also reported difficulties with funding explaining that private equity and VC type funding had been in short supply in recent years, and this had been a significant barrier to their development, despite the clear value of their offering to hospitals and patients. Notwithstanding this, their experience of the heavy administrative workloads associated with grant funding had, nonetheless, deterred them from pursuing such sources.

Mazzocchi (2018) observed that over the past two decades, venture capitalists have shifted toward much more rigorous pre-investment scrutiny. Entrepreneurs are now expected to provide comprehensive analyses of market potential, intellectual property positions, team structures and a formal business plan outlining goals, milestones and precise funding needs, tasks that previously only began once financing was secured (Mazzocchi, 2018). This is in line with the view of the Fund Manager presented earlier (FM1, 2024). Private equity firms have adopted a similar stance by offering development-stage investments within longer-term “roll-up strategies,” integrating additional companies or ideas to strengthen their portfolios (Mazzocchi, 2018, p. 80). While this approach can foster deeper, more strategic partnerships, it also demands substantial advance preparation and alignment of objectives between entrepreneurs and investors (Mazzocchi, 2018).

Mazzocchi (2018) cautions that collaborations with larger corporations carry significant risks if the partners’ goals diverge, potentially leading to destructive competition. He even characterizes certain corporate investment options as a “last resort,” arguing that they may not be in the best interest of the smaller company. This author suggests there is potential for a conflict of interest with the principles of open innovation articulated by Chesbrough (2006). Given the tedious and skill-intensive nature of fundraising, which often drains entrepreneurs’ time and falls outside their core expertise, Mazzocchi (2018)

recommends securing professional support to navigate the complex requirements of modern investment processes.

The General Manager of IRL3 sits on the board of an angel investment fund and has eighteen years of investment experience (IRL3, 2024). While a new technology must fulfil an unmet or poorly addressed need, and comply with the regulations in each market, the hardest question to answer, he maintained, is “Who is going to pay for it?” (IRL3, 2024). He had seen many failures at this juncture (IRL3, 2024). Several companies interviewed needed to finance their marketing and sales support requirements (IRL1, 2023; IRL3, 2024; UK2, 2024, UK4, 2024 and D1, 2024). For example, UK2, (2024) summarized their needs as follows:

“Senior commercial people cost, right? And so basically, that's the use of the funds. How can we really scale up commercially? And in all other ways in the business. And scale-up money in the UK is notoriously difficult to get. And you probably hear this from a lot of people. That's been a tough one”.

Having sufficient funds to get the necessary regulatory approvals in export markets was another significant cost as highlighted by IRL2, (2024) who supports Irish Medtech companies to commercialize, especially in the Middle East. While companies need to finance good staff and pay for intellectual property, they are mindful of managing costs (UK1, 2024; UK2, 2024; UK4, 2024; D1, 2024; D3, 2024; IRL1; 2023). UK1 (2024) explained “Our cash is quite precious because we're pre-revenue, we're just spending our investors' money, so I need to be confident that it's being well spent and on all the right people.” UK4, (2024) as a micro firm whose employees are working for “sweat”, said “[I]f we just had one full time employee...the whole company would be moving a lot faster”.

UK4, as a Technology Readiness Level (TRL) 4 company or an early development company, was not yet VC ready and was reliant on personal funds. Access to capital, a quarter of a million pounds, was proving difficult at the time of interview. If the company was unable to secure the funds within months, they were expecting to become insolvent (UK4, 2024). The fund manager advised that investors focus more mostly on major cities where the universities and the big tech hubs are located leaving the outskirts or the smaller cities or smaller regions in central Europe or Germany undercapitalized, because the funds only cover certain areas (FM1, 2024). At the time of interview, UK4 was in the

process of joining an accelerator programme, based on a university campus, where they were hopeful of accessing the necessary supports (UK4, 2024).

4.4.1 Reimbursement

Reimbursement has been highlighted as the most difficult of challenges. IRL3 (2024) put emphasis on the facts that companies can have the best regulatory compliance, the best regulatory experts in the world, the best technical people in the world, have identified a clear unmet need, but paying customers have still got to be found. IRL3 (2024), stated, “That’s the killer, it’s tough, really, really tough and a lot of them [companies] get taken out.” Payment systems vary from market to market so, for example, in the United States, if the doctor isn’t going to make money, then IRL 3 (2024) stressed, “it’s not going to happen, that’s a given”. UK1 (2024) held a similar view and were reflecting on how they could generate extra revenue for American hospitals with their new product. As previously mentioned, the acquisition of insurance codes is critical in the US (UK1, 2024), but in the UK and Europe too, where publicly led insurance systems are in place, it can also be a battle to acquire them (IRL3, 2024; UK1, 2024). In fact, IRL3 (2024) reported that it is almost impossible for companies to go it alone, and the situation is getting worse. UK1 (2024) argued that reimbursement considerations outweigh regulatory concerns in determining market success. Their product was projected to be roughly one-third more cost-effective than the incumbent’s, with superior performance. The payment model was tied to the additional months of life gained by patients. As the CEO noted, “In the UK, in European countries, a major premium is attached to that kind of cost effectiveness” (UK1, 2024).

Part 2

4.5 Collaboration for New Product Development

Aligned with the study’s focus on outbound open innovation, the companies interviewed reported active engagement in new product development, distribution, and commercialization collaborations. While the specific forms of collaboration varied across contexts, all were recognized as practices within the open innovation paradigm. For ease of reporting, these collaborations are categorized as academic, enterprise and professional expert collaborations below.

4.5.1 Academic

In all three countries there is robust engagement in both national and international university collaborations.

Two Irish companies reported collaboration with several Irish universities as well as universities in the UK and institutions further afield in the United States, and in Canada. In addition to supporting research projects, PhDs and post doctorates are also sponsored (IRL1, 2023 and IRL3, 2024). UK companies report strong collaboration with research institutions and different healthcare organizations with one company citing heavy investment in academic research, providing an example of funding PhDs and post doctorates at the Healthcare Technology Institute at [Name] University and investing in its own new research facility at its headquarters (UK2, 2024; UK3, 2024 and UK4, 2024).

Several advantages to these collaborations were cited ranging from the benefits of knowledge exchange to strengthen capability in cutting edge fields enabling further growth (UK2, 2024), to accelerated project completion and the option of recruiting the entire research team (IRL1, 2023). IRL1 (2023) described this collaboration for them as an opportunity to “reignite research while development is still strong, to keep costs relatively low, and then, by the time the two years are up and we have a new patent family and a new value proposition from a technology perspective, we have the opportunity of bringing that resource in”. A university partner is required in Germany if a company is using state funding to develop a product and the Professor in charge receives the funds which he or she then uses to pay their scientific employees (D3, 2024).

Timelines and expectations need to be addressed when working with universities (IRL3, 2024). Companies cite their need for a product versus the universities’ need to publish papers and PhDs do not want to stop their research, so there is a need to find a balance (IRL3, 2024). Furthermore, companies did not want to release too much information too soon for competitive reasons but acknowledged the usefulness of papers from a marketing point of view (IRL3, 2024).

Lucero-Prisno et al. (2023) argue that the growing complexity of global health challenges demands an immediate, comprehensive strategy that combines rigorous research, the expansion of scientific knowledge, and the strengthening of technical capacities to

develop sustainable solutions and meet the healthcare targets set for 2030. Fostering early-stage medical technology innovation is also critical for translating cutting-edge treatments and diagnostic tools into accessible options for patients (Deloitte, 2024). Therefore, the academic collaborations described above are an imperative.

4.5.2 Enterprise

Several examples of successful collaborations were identified.

A German start-up company was working with a service provider for the engineering of their electronic system and writing their software (D1, 2024). A significant part of the business for a more established German company involved working with other medical device companies and multinational companies within their sphere of expertise, where they either developed and manufactured or co-developed and manufactured, medical devices (D2, 2024). Products were later brought in under their own brand or under a co-branding agreement to the market (D2, 2024).

UK3 (2024) explained they worked with some of their automation partners to try and create new and different ways of manufacturing some of their products, so that they 'wouldn't be a kind of an off-the-shelf kind of solution'. In terms of products and technologies, UK3 (2024) was working with [Name] on scaling some existing, completed research instead of trying to do that themselves. They further reported another successful case of taking a product to market, which they had co-developed with a small US-based technology start-up with an exceptionally smart founder (UK3, 2024). UK1 (2024) outlined various subcontractor relationships, including one with a contract development and manufacturing organisation (CDMO). In this case, the CDMO was responsible for preparing specific components of the product development process, while also providing platform technologies that UK1 licensed for integration into their final products. UK4 (2024) pro-actively reached out to university spinouts with a view to establishing joint ventures where complementarities were identified between their technologies. They reported excellent collaboration with partners providing an example whereby one partner will own the rights for a product (a sensor) development, however, this would be under the umbrella of the start-up, a win for both sides (UK4, 2024).

Start-ups have a distinct advantage in creating disruptive technologies that, when harnessed through strategic collaboration, can unlock new growth avenues for larger

enterprises (McKernan & McDermott, 2024). Accordingly, established firms must develop the capabilities to integrate these smaller innovators and scale rapidly, while also acquiring the regulatory expertise required to bring novel products to market; support programs should therefore prioritize strengthening these specific competencies (McKernan & McDermott, 2024).

However, not all companies enjoy successful enterprise collaborations. The issue of culture is omnipresent. IRL3 (2024) cited strong cultural clashes which have deterred them from future engagement with a US based company, but D2 (2024) has got used to such collaborations because they have been doing them for so long, explaining how different it is to work with a German family-owned business than a global US publicly traded company (D2, 2024). Another SME aired concerns about conducting R&D with a competitor citing the risk they [the competitor] may act disingenuously (D3, 2024). Some further concerns were highlighted for SMEs working with larger companies, with UK1 articulating some anxieties, “You don't know what's going to happen, they can have a management change, be bought out by somebody else, all sorts of things could happen that can really change the dynamics in that relationship” (UK1, 2024). Nonetheless, while engaging in partnerships with larger corporations may be considered a viable strategy, Mazzocchi (2018, p. 81) cautions though that such collaborations require careful alignment of objectives between the involved parties. Failure to establish congruent goals could render the partnership counterproductive, as competitive dynamics may undermine its effectiveness (Mazzocchi, 2018).

Internal communication challenges between sales and R&D were reported and had to be addressed so that the team could develop appropriately with the right requirements (D3, 2024). Capability and capacity to manage projects had to be increased within another company as the research function grew over time: the company recruited numerous postdocs in the field of material science and clinical research (UK3, 2024). They appointed a programme manager to oversee all the relationships in the research portfolios which meant the work “got a whole lot easier” (UK3, 2024).

4.5.3 Experts

UK4 as a start-up, stressed the importance of having a key opinion leader on board with them, and, in this instance, he happened to be a well-known European expert in the field. He advocated for the product and the technology, was based in a leading hospital

and personally assisted in the development of the device (UK4, 2024). As the start-up's most prominent advocate, the team actively sought his recommendations for additional supporters, specifically individuals across Europe and the UK who could publicly align with him, offer their backing, and serve as fellow champions for the venture (UK4, 2024). IRL2 (2024) specialized in the commercialization of medical technology in the Middle East and was the partner of choice for market entry, management and sales in the region for multiple medical device companies. D3 (2024) reported a preference for collaborating with consultants as needed but was exploring how a collaborative project with a competitor might work.

According to Xie and Wang (2021), firms embedded in leading innovation ecosystems derive substantial insights and resources from knowledge-rich partners and therefore, should proactively cultivate and maintain collaborative ties with new network members to alleviate resource constraints. Furthermore, they argue that organizations must integrate the complementary knowledge and assets obtained through these relationships into their existing knowledge base to support both exploratory and exploitative innovation (Xie and Wang, 2021).

4.5.4 How Companies Find Partners

An interviewee emphasized the importance of finding multiple alternatives when searching for partners (UK1, 2024). Starting a new collaboration will involve change during the process requiring some agility to solve a problem quickly, "design a new component that we can remove this from our system, and get around a costly kind of royalty, or whatever it is" and then identify the right partner to do it (UK1, 2024).

The importance of networks and networking was highlighted in many interviews with one interviewee cautioning however they are not a silver bullet (IRL1, 2023). Firstly, a company must understand its own needs clearly and then follow with some good conversations with people within its network (IRL1, 2023). The next step is to determine if these people have genuinely understood what those needs are (IRL1, 2023). Smaller companies reported a less formal approach to networking than bigger corporates, suggesting the latter have procurement teams, conduct due diligence on various partners and may have spent years sometimes negotiating contracts (UK1, 2024). Smaller companies don't have that time, don't have that luxury (UK1, 2024). In Germany, in terms of cluster collaboration, an interviewee explained there is a lot of information

exchange within the cluster, but less emphasis on project collaboration although it happens (D2, 2024). Clusters are well aligned with the concept of open innovation (EC, 2008) and play an important role in fostering innovation and supporting company collaboration especially SMEs. Despite this, D2 (2024) described the idea of identifying and working with partners within a cluster to develop an idea as an academic notion saying, “it's been tried over and over again and failed consistently”. He clarified however, that such arrangements can be effective under certain conditions: specifically when the business relationship is clearly defined: where one company is responsible for commercialization and the other for R&D and/or manufacturing (D2, 2024). Success is more likely when there is a strong linkage between R&D and manufacturing, or between manufacturing and commercialization (D2, 2024). D2 reported being well-known in the industry and, as such, partners found them (D2, 2024).

A preference for collaborators with proven track records was noted (UK1, 2024). Positive prior experiences significantly increased the likelihood of continued collaboration, with the interviewee emphasizing that the initial learning curve, often steep for both parties, tended to ease over time, leading to more effective and efficient collaboration (UK1, 2024). Decisions to initiate collaboration were informed by personal meetings, technical discussions, and a careful weighing of potential benefits and drawbacks, including cost implications and projected timelines (UK1, 2024).

4.5.5 Formal Partnership Agreements

Due to the stringent regulatory environment governing the medical device sector, a multitude of structured processes have been established to ensure compliance and quality assurance (D2, 2024). Projects involving standard components typically commenced with multiple contracts established at the outset (D2, 2024). The starting point was usually a non-disclosure agreement (NDA) followed by a ‘Statement of Work’ agreement on the project (D2, 2024). These would be followed by a quality and general business agreement which would include a delivery contract and other commercial conditions: this framework was considered standard (D2, 2024). Given the structured nature of the formal R&D process, the R&D team and project manager typically engaged with their counterparts on the customer side to ensure alignment and coordination (D2, 2024). The process began with an ideation and design phase, during which the customer

was engaged to a certain extent (D2, 2024). From this collaboration, a commercial relationship emerged, encompassing order management, manufacturing, shipping, and invoicing (D2, 2024). Others too framed a research and development agreement to protect their intellectual property, but also to frame very clearly the expectations of both parties (UK2, UK3 and UK4, 2024). Once there was evidence of the efficacy of the technology, the company started to build a more thorough agreement around commerciality (UK3, 2024). Where funding bodies and or universities were involved, once their requirements were understood, the formal agreement process was reported as being straightforward (UK2, 2024).

UK3 (2024) described this process positively by saying “OK, we've got some chips here, we're at the table, we can afford to spend this on some speculative research to see if something might work, and we frame within the bounds of a research and demonstration agreement. Due diligence was deemed essential, particularly in contexts involving the use of investor capital (UK1, 2024). Territorial jurisdiction was a consideration for UK3, and any issues were generally resolved through compromise, with Dublin often accepted as the legal seat due to its practical viability (UK3, 2024). The company encountered only one instance in which a collaborator insisted on retaining their own national jurisdiction for an agreement (UK3, 2024).

The open innovation paradox which concerns balancing the tension between knowledge sharing on the one hand and knowledge protection on the other has been mentioned (Bogers, *et al.*, 2019) and the preceding paragraphs are evidence of how companies try to manage it As Chen (2022) suggested, when SMEs have a robust intellectual property management system in place, they are better positioned to share innovation-related information transparently, enabling them to remain competitive in the market.

4.5.6 Ideation

Ideas originate from multiple sources. Several companies reported receiving frequent input from customers, including individual surgeons and nurses (D2, 2024; UK2, 2024). These contributions often extended beyond the immediate context of use, encompassing suggestions applicable to other domains such as gynecology or general surgery (D2, 2024). Often these ideas proved useful (D2, 2024). Other interviewees stressed the importance of building a product that clinicians want to use because this would drive sales eventually as they had the critical knowledge (UK1, 2024; D2, 2024).

UK2 explained that listening to their customers' needs and feedback enabled them to develop their product citing an example of screens of their technologies, explaining that all the technological advancements were all due to that type of feedback (UK2, 2024).

Others take a more systematic approach whereby the sales manager records all customer feedback and then, monthly, the team discusses it at a product strategy meeting and then prioritizes it (D3, 2024). In line with this systematic approach, another company uses specialized software for their idea management. Every two months the staff meet for a day to review all the ideas in the system, they evaluate them based on whether the idea is an 'opportunity' or a 'threat', if it's neither, it's dead (IRL3, 2024).

4.6 Distribution

Distribution structures are critical. However, they are very expensive to create and take a long time (D2, 2024; IRL3, 2024). IRL2, (2024) explained that identifying that distributor, working and appointing them, getting the legal through, was a process of three to four months minimum and this was working eight to nine hours a day, knowing what to do, knowing the market, knowing how to navigate it, and who to talk to. Over time, stable structures developed but, as D2 (2024), reported, "[T]here's always change, for whatever reason, they don't perform, they go out of business, they change their focus...". UK1 (2024) described hearing many stories of distributors signing a distribution agreement, and then, after a few months, or a year, they actively stopped promoting the product, strategically tried to devalue the business and acquire it cheaply. Others also reported difficulties in finding good distributors suggesting it was even more difficult than finding good employees (IRL3, 2024). The criteria for distributor selection vary, with one senior manager suggesting that "the good ones, you have to woo them, you're not doing them a favour" and they can make or break a business (IRL3, 2024).

4.6.1 Criteria / Strategies for Distributor Selection

D2 (2024) proactively sought distributors at medical shows and medical congresses, where they spoke to doctors, other companies, and friends in the industry. In this way they developed a shortlist of potential distributors, and made an assessment to determine who would best work with them (D2, 2024).

Another company had developed a complete average weighted system for distributor selection (IRL2, 2024). Despite this, what stood at the very top of the pyramid for them was, what they described as ‘the hunger factor’. IRL2 (2024) emphasized, “If this ‘hunger factor’ is missing, it’s over. You need to be able to identify the hunger factor”. However, he added, the process doesn’t end with the hunger factor alone. Even when it is present, distributors must also demonstrate physical capability and a degree of cultural understanding. Without both, there was still no true fit (IRL2, 2024). This was echoed by a German company, where they stressed the necessity of understanding the minute details of culture to be able to negotiate with a distributor but reported difficulty in finding the required information (D1, 2024). IRL3 (2024) confirmed it was completely about people working with people at the end of the day (IRL2, 2024).

The most important criteria, according to one company, included whether the distributor sold a similar product, whether they had the same clients, whether they sold into the operating room and whether they had contact with surgeons and clinics (D1, 2024). UK2 (2024) reported notable success in this regard. For instance, a Portuguese distributor had begun generating interest amongst hospitals with whom they already collaborated. Their familiarity with the specific pain points faced by these institutions enabled them to identify where the patient status engine could be integrated into existing workflows (UK2, 2024). As a result, the distributor was engaging clinicians in targeted, relevant discussions (UK2, 2024).

Other criteria included market coverage and what complimentary products the distributor had (IRL3, 2024). IRL3 (2024) had engaged with a range of distributors characterized by high-volume client acquisition strategies. They noted that such distributors often operated under the assumption that “if enough mud is thrown at the wall, something will stick,” yet this indiscriminate approach tended to undermine sustained attention to individual products (IRL3, 2024). While five or six lines were generally deemed sufficient, strict exclusivity was not considered ideal either (IRL3, 2024). A combination of five or six complementary lines could present an appealing offer to medical staff; however, IRL3 (2024) maintained a firm stance against collaborating with distributors who carried competing products. The expected turnover a distributor would generate was also a serious consideration, with IRL3 (2024) stating “If you can’t

make a minimum of a hundred to two hundred thousand a year, it's not worth doing....so we're quite selective, we want to go narrower and deeper”.

The complexity of the medical device is another consideration. UK1 (2024) explained that many companies with simpler medical devices use distributor models whereby they design the device and may launch in their home country and outsource it to somebody else abroad. However, UK1 was developing a highly sophisticated implantable device and, as such, needed to be confident that whoever they were outsourcing to would allow them to have very close control of the quality of the service they were providing, and they also had to be confident that they were going to do a good job (UK1, 2024). This company expected that when their device would be ready for the market, they would sell it directly. However, the situation was more complex in this case: as a VC-backed start-up, the company was under pressure to deliver a viable exit for its investors. This could entail bypassing traditional distributors altogether, particularly if the company was acquired by a larger MedTech firm with an existing sales and distribution infrastructure (UK1, 2024). If the product would fit the acquirer's portfolio, was proven, de-risked, performing well, and generating revenue, then it could be marketed very quickly (UK1, 2024). By then the job of the development team would be complete and the exit made (UK1, 2024).

It can happen that options are limited when it comes to distributors with UK2 (2024) explaining the choice was often more arbitrary, opportunistic and cited a small market such as Singapore as an example (UK2, 2024). In India, UK2 (2024) reported the non-existence of a suitable medical device distributor because their technology needed to be embedded within the hospital. Furthermore, heavy investment in the initial marketing of their product was needed and any solution had to be one they could control. However, good fortune prevailed, and they found a company that recognized the value of what they were trying to achieve and who could fund the roll out of the technology into Indian hospitals (UK2, 2024).

Companies then need to determine how they get to a certain market share with their distributor in their respective markets. For example, D2 drives the business with the distributor through people employed especially for this purpose: in Asia they have two

people, in the United States they have a team of seven, and in Europe, a team of four (D2, 2024).

IRL1 (2023) sold directly to customers because they saw this as a “challenger sales approach and process” meaning there was a need to probe deeply into the needs of customers. IRL1 believed “you need to nitpick” and to do this certain skill sets, which take time to develop, are required, and distributors won't give that time (IRL1, 2023). IRL3 (2024) sold directly in the UK employing seven or eight full-time respiratory therapists to advise customers on the correct usage of the medical devices. The company always sold directly in the UK, there was a history there and they believed selling indirectly in this market wouldn't work at all, it wouldn't be possible to train a distributor to the required standard. However, in other markets, an indirect approach was taken due to the prohibitive costs of establishing a sales operation. The Managing Director of IRL3 said “It's one of the better ways to go bust: to set up a sales operation!” Therefore, the company was moving towards hybrid models where they sold indirectly but put local support in place for the distributors (IRL3, 2024). In the US market, IRL3 reported dismal sales despite the fact they had been in this market for many years and, mindful it would cost tens of millions to establish a US sales force, they were following this hybrid approach (like D2). Thus, they employed local people: two at the time of interview, with three or four more to join them, to support the distributors focusing on education, clinical applications rather than the sales process (IRL3, 2024).

4.7 Skills

4.7.1 Skill Set Challenges

Two categories of skill set challenges were identified. The first was related to product training and the second to staff skills sets and training.

4.7.2 Product Training

Given the range of medical device classifications, it follows that different levels of user training are required, and different approaches are deployed depending on complexity and geographic proximity. Distributor training must also be considered to facilitate sales.

D2 offers training in different formats: the company goes to the market and trains directly if the size of market justifies it; or, medical staff come to the company for on-

site training (D2, 2024). D2 also supports medical societies when they offer courses and provide the equipment (D2, 2024). An online training tool is offered which is more than just videos, it offers training modules with a test and certificate at the end (D2, 2024). Every other year, the company hosts a Distributor Conference where doctors are invited to give talks, sales representatives are invited to present examples of best practice, and product management talks inform delegates about features and new products (D2, 2024). On the company website, instructions and procedure guidelines, which have been co-created with doctors, are published (D2, 2024). In addition, doctors have published articles in scientific journals (D2, 2024). Today their devices are the industry standard “but at the time, ten, fifteen, twenty years ago” the company provided a lot of support to get people trained (D2, 2024).

For IRL3 (2024) education and training are important for commercialization, “Training people, training distributors”. If a new way of doing something has been developed, this poses challenges: if the end users need to understand how a product will solve their problems, then the company has to find ways of being able to train the distributors, both on the overall proposition, and then at a different level how to use it, how the nurses can use it, how the doctors can use it (IRL3, 2024). IRL3 (2024) shared the view that doctor education has a lot to do with technology adoption citing the introduction of stents as an example. IRL3 further explained, this market is dominated by large companies who quickly buy out any company that brings a better stent to market, and these companies have held the market through having an education focus on the decision makers who adopt the technologies, in this instance, cardiologists (IRL3, 2024). UK1 (2024) must train surgeons in the use of their device due to the complexity of surgical implants and provide technical support in the operating theatre in the event of a problem which could need an immediate response. As a result, the sales process was described as personal in a way, critical to both product success and patient safety and one which the company felt they must control themselves (UK1, 2024). UK2 (2024) reported a challenge convincing medical staff to change from doing certain tasks manually to their automated system. UK2 maintained they need to find ways of getting the end users to understand how the system solves problems for them and benefits them and their patients in ways they didn’t imagine possible (UK2, 2024). Training is the solution, and they have done a lot of work in this regard, not just for medical staff but

for distributors also (UK2, 2024). UK4 (2024) will need to provide training and education for medical care providers as well as those who will provide transportation services and they will require support to do this. However, there is scope the company feels for a broader impact within the NHS with potential training they may provide regarding ethical decision making, “especially when you're dealing with minoritized patients. We know there is a bias, we know, I don't know if you know, but the in the NHS, sadly, it is proven that racially minoritized patients get different treatment. And our technology reduces this bias, increases the fairness which can lead to transparency and addressing the health disparities” (UK4, 2024).

4.7.3 Staff Skill Sets and Training

According to D2 (2024), the shortage of skilled staff poses a significant challenge across Europe, with Germany experiencing particularly acute difficulties.

The first challenge pointed out by D2 was, that Germany has the lowest number of hours of work per employee in the Organisation for Economic Cooperation and Development (OECD) region and, due to limited childcare supports, many women work part-time (D2, 2024; OECD, 2024). Furthermore, D2 (2024) reported many people are dropping out of the workforce making it hard to find people. For a small or medium-sized company in their very specific field, considering R&D, or production related activities, or process engineering, experts were rare (D2, 2024). The company could not compete with the salaries of larger firms and so much of their approach was just hoping to maintain a loyal staff, find younger employees and train them (D2, 2024). This of course was a time consuming process – years – and then just they “hope and pray that they stay” (D2, 2024). D2 (2024) has tried to work with outside experts, often found through networking, when they didn't have the capability or capacity to do what was needed in-house, but experienced mixed results. A particular challenge was associated with the new MDRs, whereby, to ensure regulatory compliance, D2 had to “reregister, and reapprove essentially all the products, all the legacy products again” (D2, 2024). This meant the seasoned experts engaged had to be redeployed to address this work instead of dedicating their time to training younger staff (D2, 2024). D1 (2024) was finding it difficult to source the right salespeople, there were few on the market, and it was not easy for a high-risk start-up to offer an attractive package. D1 was seeking cultural

expertise and insights particularly in terms of how to “get into the process for negotiation with the distributors with the right information” as well as addressing contracts in terms of what is usual that in a specific region (D1, 2024). The biggest concern for D3 related to expertise in regulatory affairs. The company had an expert who dealt with complicated matters managing ‘a thousand pages of everything’ as well as risk management issues, work that not many people were interested in (D3, 2024). Given his level of expertise, he was a target for headhunters, and D3 could not manage without him (D3, 2024).

Irish companies are facing similar challenges. This was confirmed in a recent IBEC report which highlighted that, the sector’s primary concern remains the recruitment and retention of highly skilled personnel, with 63% of companies reporting ongoing struggles in this area (IBEC, 2025).

The founder of IRL1 (2023) was a mechanical engineer who described himself as trained to solve problems with a mechanical twist which had been useful for him from a sales perspective. He could understand real customer problems, hold “challenger conversations”, build a tailored value proposition and execute it from a sales perspective. His skill set carried across both business development and sales and it was not easy to find people with this combination of skills (IRL1, 2023). Besides, time is required to develop them (IRL1, 2023). Furthermore, IRL3 explained, a salesperson from a multinational who is used to having a support team will fail in a start-up context, but will be successful the other way around “if you put someone from a start-up into a multinational, they end up being the head of sales within two years because they have the lateral skillset required to pull this all together. The business intelligence, sales execution, communication style, challenger questioning, emotionally intelligently questioning the customer, what is it you really need? How can I help you? it's a broad skill set. And it's rare” (IRL1, 2023). Another issue was associated with finding the personnel needed for an in-house research team in the field of deep machine learning: these people were not only hard to find but they were expensive too (IRL1, 2023). The solution in this instance was to partner with a university (IRL1, 2023). The company did not have the capability or the capacity to develop case studies, webinars and testimonials from a marketing perspective either (IRL1, 2023). IRL2, (2024), reported very significant challenges regarding the availability of the necessary expertise to register new products in different markets and advised, in his experience, this was why very few

SMEs made it successfully. This expertise was in limited supply and many companies did not have adequate resources to pay for it as well as pay for the necessary registration costs (IRL2, 2024). The solution IRL2 offered created a unique business model: to take an equity share in the business in return for registering the new technology and to take an agreed share of the sales afterwards, a win for both parties (IRL2, 2024). IRL3 also reported challenges in finding talent especially as there was full employment in Ireland but, knowing they could find R&D people in a particular region, was the reason why they based the company there. Two years ago, IRL3 brought in a team of expensive sales and marketing employees but this investment paid off with sales growth of 38% and 35% recorded. IRL3 took a pragmatic approach to finding expertise, either training in-house or trying to find the required experience externally, but admitted, “there’s a whole package around commercialization because of education and training. Training people, training distributors”, especially if there is a new way of doing something and behaviour has to change – this, they maintained, was a battle (IRL3, 2024).

UK1, as a start-up with a small team and a complex, multi-faceted product, had to find external experts and outsource some of its work as it was not feasible to have the full skill set in-house. UK2 was searching for very capable people to work with the CEO to set up distributor networks and position the company for growth. At the time of interview, UK4 operated entirely through voluntary efforts. The team felt confident in their ability to access the necessary skills and build networks, noting that many individuals had willingly offered support at no cost. However, they emphasized that financial backing was essential for scaling their operations. Alongside funding, UK4 expressed interest in recruiting “some eager postgrad students or even PhD researchers” to assist with sensor testing and contribute to the development of a robust data bank.

According to FM1 (2024), where a start-up did not appear to have adequate human resources and the product was not yet market ready, investors would worry that even if they did invest, the product still may not get to the completion stage (FM1, 2024). Hence, the investors would usually ensure that their investment would cover the full-time salaries of those overseeing the development of the product, whether they would be programmers or researchers, to cover the human resources gap and to “bring the product to the stage where we want it to be”. He continued to explain, when considering the overall size of the company, it could be a concern for investors, depending on the

circumstances, if the team was already overworked and could not handle a new project. Equally, investors did not invest in companies to hire new people but preferred to stabilize the core team already working on the project (FM1, 2024). Therefore, any investment decision would be influenced on how efficient and how over or underworked the core team was (FM1, 2024).

Organizations must deliberately cultivate their knowledge base and absorptive capacity, as these competencies are critical for converting open innovation outcomes into enduring competitive advantages (Lopes & de Carvalho, 2018). Çera *et al.* (2024) reinforce this argument by recommending that small and medium-sized enterprises (SMEs) prioritize the recruitment of qualified professionals and implement robust training programs to deepen employees' comprehension of open innovation and inter-organizational collaboration. Moreover, providing practical opportunities for staff to apply their newly acquired skills is not simply advantageous but imperative to embed learning within daily operations (Çera *et al.*, 2024). Such strategic initiatives not only bolster individual capabilities but also synchronize with the organization's overarching innovation agenda, thereby fostering a sustained culture of learning and strategic renewal (Çera *et al.*, 2024). Dynamic capabilities, as strategic, higher-order competences, have become increasingly vital for organizations seeking to continually enhance collaborative efforts and deliver customer value, making them crucial drivers of competitive success (Teece, 2012). Bogers *et al.*, (2019) strongly advocate in today's business environment to build and invest in the necessary skills to strengthen organizational capabilities although they advise further study of related processes and costs is needed (Bauer *et al.*, 2018). Overall, there is a dearth of literature in this regard (Fu *et al.*, 2019; Greco *et al.*, 2019) and a longitudinal or dynamic perspective is also an imperative for future research (Bauer *et al.*, 2018; Joseph, 2023; Keinz & Marhold, 2021).

4.7.4 Leadership

By way of example, IRL1 (2023) described leading his business as a dictator but in a positive way. When the business started every decision had to go through him whether it was related to marketing, sales, engineering or other matters because he was answerable to his investors, and he needed to be certain he understood everything in the business, that he wasn't over-selling or over-promising anything. Over time, as the business became more established and had "a good base of operations in terms of

revenue generation, in terms of manufacturing, regulatory and engineering” as well as a history of a product, the structure was changing from a hierarchal ‘hub and spoke’ model to a cross matrix structure “which is more of a neural network” to encourage each employee to become a high performer (IRL1, 2023). The organization was thus positioned for growth and to get to “a level of proficiency and maturity that we now have pockets of innovation emerging across different subgroups” (IRL1, 2023). Admittedly, IRL1 (2023) had challenges from time to time articulating what he wanted from his team and was not always able to give certain projects or groups the attention and the time they required. Therefore, removing himself as the hub was important to allow “teams to focus and take ownership and start having really good cross-functional drivers for quality, for ideas, for solutions, for execution, implementation” (IRL, 2023). This approach was aligned to Teece (2012) who maintained that senior management’s entrepreneurial and leadership competencies in the processes of sensing, seizing, and transforming were fundamental to the development and preservation of dynamic capabilities (Teece, 2012). Firms that exhibit strong dynamic capabilities typically possess highly effective entrepreneurial management teams alongside robust organizational structures (Teece *et al.*, 2016, p. 14).

Gonzalez (2024) examined how knowledge-oriented leadership cultivated a learning-driven culture by encouraging employees to engage in trial-and-error experimentation, thereby uncovering and leveraging critical knowledge to spur innovation. Gonzalez (2024) also contended that organizational leaders are instrumental in facilitating knowledge exchange, both by tapping into external networks for fresh insights and by converting that knowledge into revenue-generating assets. Furthermore, Gonzalez (2024) argued that leaders should not only equip employees with guidance on relevant tools and methodologies but also ensure that individuals understand how their contributions align with the organization’s strategic objectives (Gonzalez, 2024). Naqshbandi *et al.* (2019), citing Arnold *et al.*, 2000 and Zhang and Bartol, (2010) argued that empowering leadership, marked by trust and employee autonomy, enhanced outbound open innovation by promoting effective knowledge dissemination. Chan *et al.* (2017) highlighted four leadership attributes for innovation: expertise, cognitive capability, and personality style coupled with a conducive aptitude. This author would argue that given the complexity of the sector, the regulatory challenges, the funding

challenges, the recruitment challenges, fostering such leadership is strongly advised. However, more research in this area could be highly beneficial.

Chapter 5: Conclusion

5.1 Overview of this Thesis

The provision of healthcare services is critical to both society and the economy, but the associated challenges to provide these services are significant and complex. The Economist Impact (2025) contends that global health is undergoing a critical transformation. Although technological innovations and expanded healthcare access signal progress, mounting financial pressures, workforce shortages, and emergent disease threats, each intensified by climatic change, digital disruption, and geopolitical turbulence, present formidable challenges to sustained improvement (Economist Impact, 2025). In the aftermath of the COVID-19 pandemic, worldwide health expenditures have contracted (EIU, 2023; WHO, 2024a), even as healthcare systems continue to face mounting demands to enhance their resilience. Thus, as these global health challenges continue to intensify, Lucero-Prisno *et al.* (2023) advocate for an urgent and integrated strategy that encompasses the advancement of research, the cultivation of scientific knowledge, and the enhancement of technological capabilities to enable sustainable health solutions and the realization of the 2030 healthcare objectives. Deloitte (2024) highlights the significance of fostering early-stage medical technology innovation in expanding patient access to novel treatments and diagnostic methodologies. McKinsey & Company (2023) underscore the dual imperative facing MedTech executives to actively advance this strategic agenda, while also identifying the emergent organizational capabilities required to realize the industry's full potential. Furthermore, they emphasize the personal leadership commitments necessary to strengthen organizational resilience (McKinsey & Company, 2023).

The MedTech sector is vital to the German, British and Irish economies. In Germany for example medical technology was the second most innovative industrial field across the economy, with 15,985 patent applications recorded by the European Patent Office in 2024 (GT&I, 2025). In contrast, the UK ranked ninth globally for patents in the same period securing 348 patents and Ireland ranked eleventh with 206 patents (Statista, 2025b). The European Commission's Europe 2020 Strategy advocated for a national R&D investment target of 3% of GDP, a benchmark first articulated in the Lisbon Treaty in March 2000 (EC, 2010; EC, 2020; EESC, 2014). Germany had surpassed this target by

2018, whereas both the UK and Ireland fell short. Despite notable advancement observed in the UK, its improvement may be partially attributed to methodological changes in how R&D expenditure is calculated (ONS, 2022; Panjwani, 2023). Although patent numbers and R&D investment are not exhaustive measures of innovation performance, they are indicators of innovation challenges. The author concluded that limited adoption and innovation-related barriers may be hindering R&D activity in Ireland, and to a lesser extent in the UK. Consequently, a cross-country study of medical device innovators in Germany, the UK, and Ireland, with Germany serving as a benchmark, was proposed to help identify key factors contributing to these disparities.

In recent years, innovation management has shifted towards a more open and collaborative model. A key component of this model, known as outbound or inside-out open innovation, as described by Gassmann and Enkel (2004), involves transferring internal knowledge to external stakeholders via mechanisms such as licensing, outsourcing, and patent management. This facet of open innovation has been recognized as an area requiring further scholarly investigation (Aloini *et al.*, 2020; Baima *et al.*, 2020; Bauer *et al.*, 2018; Natalicchio *et al.*, 2017; Wikhamn & Styhre, 2018). West and Bogers (2017) called for deeper integration of open innovation with key management theories, including absorptive capacity, distributed innovation, and post-Chandlerian firm structures. They also emphasized other theories such as dynamic capabilities and the resource-based view (RBV) illustrate how firms can gain competitive advantage through open innovation (West & Bogers, 2017). The resource-based view, as articulated by Barney (1991), investigates how a firm's unique internal assets, characterized by heterogeneity and limited mobility, drive its performance and underpin sustainable competitive advantage. Building on this foundation, Liao *et al.* (2019) contended that the RBV offers a powerful explanatory lens for variations in firm outcomes, which rationalises its adoption in the present study. Dynamic capabilities, as conceptualized by Teece *et al.* (1997), denote an organization's capacity to reconfigure and realign its competences in response to a shifting business environment, emphasizing the pivotal role of strategic management in optimizing the skills, resources, and functional proficiencies that underpin this adaptive process. Chesbrough *et al.* (2020) argued that dynamic capabilities are vital for pursuing an open strategy and that aligning these capabilities strengthens their complementary effects. Alexy (2017) observed a

tension between the resource-based view's emphasis on safeguarding assets and an open perspective, suggesting this paradox merits deeper exploration. Kim *et al.* (2021) further noted that research on organizational resources and capabilities remains in its early stages.

Through the review of literature, several issues and considerations pertaining to outbound open innovation were identified and which are summarized below.

The definition of open innovation was further explored by Aloini *et al.* (2020, p. 25), who contended that neither the process of outbound open innovation and its associated activities are "univocal nor complete in the literature". Thus, Aloini *et al.* (2020) described two key phases of outbound open innovation: 1) an opportunity identification phase and 2) an external technology transfer phase with each phase being further subdivided (Aloini *et al.*, 2020, pp. 27-28). The opportunity identification phase includes both an "assessment of the company's technological portfolio" and the "exploration of markets and technologies" (Aloini *et al.*, 2020, p. 27). The external technology transfer phase refers to the sale or licensing of internally developed technologies to external partners (Helm *et al.*, 2017) and includes an evaluation and selection of potentially interested actors and the choice of transaction type (Aloini *et al.*, 2020, p. 28). Each phase involves critical specific tasks and competences. Bauer *et al.* (2018), noting the varying performance levels of companies engaging in technology transfer practices, undertook an analysis of the organisational capabilities that differentiate the more successful companies from the less successful ones identifying capabilities associated with planning and intelligence gathering, negotiation, realisation and control as key. However, further research is needed in this area (Bauer *et al.*, 2018; Keinz & Marhold, 2021; Joseph, 2023). Carrasco-Carvajal and García-Pérez-de-Lema (2021, p. 19) emphasized that SMEs' innovation capabilities are essential for implementing open innovation and showed that a strong dedication to learning coupled with robust innovation capacity leads to better open innovation performance. Researchers highlight the need to retain an SME perspective considering their resource constraints, a point Alassaf *et al.* (2020) alluded to indirectly and that Aliasghar (2025), Çera *et al.* (2024), and Zhang *et al.* (2023) emphasized more explicitly. Most companies in the MedTech sector in Europe and the UK fit into the SME category (MedTech Europe, 2024d; Department of Health & Social Care, 2024).

Burcharth *et al.* (2017, p. 1248) examined factors influencing open innovation and argued that strategic autonomy, defined as the ability to plan and execute one's work, enhances innovation outcomes, especially through thoughtful job design. They advised managers to promote autonomy by encouraging idea development, allocating time for creativity, and supporting intrapreneurial initiatives (Burcharth *et al.*, 2017). Similarly, Carrasco-Carvajal and García-Pérez-De-Lema (2020) found that entrepreneurial risk-taking fosters internal idea generation, strengthens management skills, and, through employee learning, drives product innovation and boosts competitive advantage. Naqshbandi *et al.* (2019) argued that empowering leadership supports outbound open innovation by fostering employee trust and autonomy, drawing on descriptions by Arnold *et al.* (2000) and Zhang and Bartol (2010). Battistella *et al.* (2017) studied the managerial choices necessary at project level for effective open innovation in a sample of eighty-five European SMEs devising a reference framework for managerial decision-making based on three fundamental blocks: practices, tools and actors identifying interdependencies between them. In turn these would advise managers which tools to select to determine best practice.

Intellectual property (IP) is becoming increasingly important as an enabler of open innovation facilitating the sharing of ideas across company boundaries and acting as an effective complement to partner collaboration (Bogers, *et al.*, 2019). Chen (2022) argued that strong IP management helps SMEs share innovation openly and stay competitive. Nonetheless, this domain involves considerable complexity, and although IP can serve as a valuable safeguard, it may also impose notable limitations (Grimaldi *et al.*, 2021). Continuing the legal theme, the relevance of compliance with international standards for medical devices was raised and the associated complexities (Jadhav & Shendge, 2024; Pacheco *et al.*, 2025). Svempe (2024) raised the issue of compliance with medical device regulations.

To address the issues identified through both the literature review and an analysis of industry reports, ten semi-structured interviews were conducted with senior management in companies across the three countries: Germany, the UK, and Ireland. These initial interviews revealed several unexpected insights, prompting the author to conduct an additional three interviews with medical device regulatory experts operating in each of the three countries, as well as one interview with a specialist Fund Manager.

Guided by the thematic analysis recommendations of Braun & Clarke (2006, 2022), six themes were identified providing some insights into the two research questions including 1) What challenges do SMEs face commercializing new technologies and collaborating with partners through outbound open innovation practices? and, 2) What knowledge, skills and organisational capabilities do companies need, to both develop within and to capitalize on, the potential of the MedTech sector. The themes included 1) the medical technology industry directly, 2) markets, 3) finance, 4) collaboration for new product development, 5) distribution and 6) skills. The findings are summarized below.

5.1.1 The Medical Technology Industry

Very significant and serious challenges for companies were identified within the medical technology industry itself specifically concerning regulations, intellectual property, government support and finance.

The medical technology industry is notably fragmented, encompassing approximately 2 million device types organized into more than 7,000 categories (D2, 2024; WHO, 2024b). Regulatory environments vary across markets, adding layers of complexity for manufacturers. The introduction of the European Medical Device Regulations (MDRs) has expanded the responsibilities of both the European Medicines Agency (EMA) and national competent authorities in evaluating certain medical device classifications (EMA, 2024). These changes have imposed substantial compliance burdens on innovative companies. As one industry expert remarked, “The regulations are an important development, because they fundamentally keep patients safe. The question for manufacturers then becomes, is it an acceptable burden? Of course it's a burden. It is a major overhead” (E1, 2024). ISO 13485, the global standard for medical device quality management systems, is recognized by regulators worldwide (E1, 2024; ISO, 2016). Beyond quality systems, standards also cover risk management, software device safety, and electronic equipment (Pacheco et al., 2025; E1, 2024). Compliance with ISO 13485 not only facilitates international market access but also enhances customer satisfaction, supplier relations, operational efficiency, competitiveness, and adaptability (Jadhav & Shendge, 2024). Companies often struggle to develop procedures that are either too generic to be effective or overly complex and impractical (E3, 2024). This reflects Carl and Hochmann’s (2024) view that implementing quality management systems poses particular challenges for small firms, especially those with under 50 employees.

Nevertheless, Jadhav and Shendge (2024) argue that commitment to quality certification can be a strategic advantage, attracting clients and expanding business opportunities. However, companies interviewed expressed strong criticism of current regulatory requirements, describing them as detrimental to innovation (IRL3, 2024). This sentiment was reflected in a MedTech Europe (2024b) survey, where over half of respondents indicated plans to reduce their product development portfolios. One company reported limited innovation, noting a tendency to pursue safer projects aligned with existing knowledge or technological capabilities (D3, 2024). E2 (2024) observed that smaller firms were overwhelmed by the new regulations, predicting that many medical devices would disappear from the market in the medium term. E1 (2024) argued that developing a new product under the revised framework was less complex than reclassifying and transitioning existing ones. Svempe (2024) emphasized the challenges faced by first-to-market companies, including insufficient guidance and limited clinical data, which have extended development timelines by up to 34%. In contrast, several companies highlighted the United States' centralized decision-making system and unified database as offering a more straightforward compliance process, compared to Europe's fragmented approach involving multiple notified bodies and a still-developing database. Multiple issues have been reported concerning notified bodies, including potential conflicts of interest and capacity limitations that have led to significant delays in approval processes (E1, 2024). These delays have, in turn, contributed to increased development costs and postponed market launches (D2, 2024; D3, 2024). Furthermore, companies also have oversight of their supplier compliance, another complication (D2, 2024; E1, 2024; IRL2, 2024)

A shortage of expertise in regulatory affairs was highlighted with this difficulty felt by smaller firms especially (E2, 2024). D3 (2024) was very concerned that their in-house expert might be headhunted for example. There is evidence that Artificial Intelligence tools are being used but these 'systems in a box' are not always fit for specific purposes (E3, 2024). Clinical evaluations under MDRs remain complicated and demanding (MedTech Europe, 2024b). According to E1 (2024), the stringent requirements for clinical evidence are viewed as a major barrier, particularly for startups facing the financial burden of compliance. E1 (2024) highlights this as a globally significant challenge, while Kearney and McDermott (2023a) argue that the associated costs may outweigh potential

returns, thereby hindering innovation. Intellectual property (IP) management facilitates SMEs' openness in sharing innovation insights, thereby reinforcing competitiveness (Chen, 2022). IP has become central to enabling open innovation (Bogers *et al.*, 2019) and addressing the open innovation paradox (Holgersson, 2024) though interview data revealed varied perspectives. As noted by Grimaldi *et al.* (2019), IP remains a complex domain. German firms adopt a defensive and credibility-oriented stance, actively safeguarding R&D outputs (D1, D2, D3, 2024), whereas Irish and UK firms exhibit more pragmatic and open strategies (IRL1, IRL3, UK3, UK4, 2024) with one company taking a negative view of their relevance maintaining patent compliance is difficult to monitor, is expensive and distracts from the importance of other business tasks (IRL2, 2024). For investors, patent protection is essential (FM1, 2024). Interviewees conveyed a diverse and, at times, conflicting range of perspectives regarding governmental policies and forms of support. The sector remains highly dynamic, with notable policy developments unfolding at both the European Union level and across national contexts in each of the three jurisdictions. In Germany, although substantial innovation support exists, some firms remain unaware of these opportunities due to limited publicity (D3, 2024). In the UK, difficulties to persuade government to establish standards for novel materials were emphasized (UK2; UK3, 2024). IRL2 (2024) identified deficiencies in formal business development initiatives, while McKernan and McDermott (2023) cautioned that, despite overall market expansion, declining prices for undifferentiated products are narrowing strategic options for Irish medical device companies. These firms must pursue either a low-cost approach or adopt a differentiation strategy to access niche markets with limited competition (McKernan and McDermott, 2023).

5.1.2 Markets

The United States dominated the global medical device market in 2023, holding a 38% share and serving as both the primary export destination (40.4%) and leading import supplier (45.4%) for European medical technologies (BMI, 2024; MedTech Europe, 2024c; Fortune Business Insights, 2025). Reflecting this strategic significance, firms prioritize US market entry, with D2 (2024) favouring it over the EU due to its scale and high level of healthcare spending. However, acquiring a nuanced understanding of market dynamics remains essential such as how insurance codes are issued and how

invoicing processes function for example. Payment systems vary from market to market also. For other markets the regulatory burden remains a key deciding factor (D2, 2024).

D1 (2024) highlights Germany's challenging market conditions shaped by the pandemic, Ukraine war, and energy crisis. Rising energy costs have strained hospital finances, while political uncertainty has delayed venture capital investment. UK3 (2024) cites multiple problems associated with BREXIT for example and the Windsor Agreement has complicated Northern Ireland's position, as EU Medical Device Regulations now apply there despite the UK's legal jurisdiction (Gov.UK, 2025). Conducting market research is another concern but companies are, within the scope of their resources, proactive.

5.1.3 Finance

Financial issues, especially for newer, smaller businesses, were highlighted repeatedly. IRL1 (2023) stated that funding is the number one concern of every medical technology company in the world. Several reasons for this were identified.

The sector remains highly competitive, with suboptimal valuations impeding firms' access to funding. Many companies are reluctant to dilute ownership, resulting in delays to their go-to-market strategies (IRL1, 2023). In this context, venture capitalists now require comprehensive pre-investment assessments, including evaluations of market potential, intellectual property portfolios, organizational structures, and detailed business plans, prior to committing capital (Mazzocchi, 2018). Private equity firms likewise invest at earlier stages, employing roll-up strategies to scale their portfolios. These developments foster strategic coherence but also necessitate considerable upfront preparation (Mazzocchi, 2018). In addition, UK1 (2024) reports that available funds are increasingly directed toward existing portfolios rather than new ventures, with preference given to businesses, such as digital healthcare applications, that can become self-sustaining in a relatively short time frame. Reimbursement has been highlighted as the most difficult of challenges. IRL3 (2024) put emphasis on the facts that companies can have the best regulatory [compliance], the best regulatory experts in the world, the best technical people in the world, have identified a clear unmet need, but paying customers have still got to be found. IRL3 (2024) stated 'That's the killer, it's tough, really, really tough and a lot of them [companies] get taken out.'

5.1.4 Collaboration for new product development

Collaboration for new product development was found to be unique to each context and were categorized as academic, enterprise and professional expert collaborations.

All interviewees reported either domestic or international academic collaborations. These partnerships offered multiple strategic advantages, including enhanced knowledge exchange that bolstered expertise in advanced research domains (UK2, 2024), expedited project timelines, and the potential to onboard entire research teams (IRL1, 2023). Moreover, such alliances allowed firms to revitalize early-stage research during active development phases, contain costs, and, within a short time-frame, yield new patent families and technological value propositions, thereby facilitating seamless resource integration (IRL1, 2023). Collaborative efforts between companies and universities require clear alignment of timelines and expectations (IRL3, 2024). While firms prioritize the development of market-ready products, academic institutions focus on publishing scholarly work. Doctoral researchers are particularly hesitant to interrupt ongoing investigations, underscoring the necessity of balancing research continuity with commercial objectives (IRL3, 2024). Moreover, although companies are cautious about prematurely disclosing proprietary information, they recognize that academic publications can serve as strategic tools for enhancing visibility and market positioning (IRL3, 2024).

Strategic collaborations between start-ups and established firms can serve as catalysts for innovation, particularly in leveraging disruptive technologies to drive growth (McKernan & McDermott, 2024). However, successful partnerships are not guaranteed. Cultural tensions and trust issues, such as fears of intellectual appropriation, pose significant barriers, especially for SMEs engaging in joint R&D with potential competitors (D3, 2024). Additional challenges arise when collaborating with larger corporations, where misaligned strategic objectives may lead to counterproductive outcomes due to underlying competitive tensions (Mazzocchi, 2018, p.81). Furthermore, internal organizational constraints, including poor communication between sales and R&D and limitations in project management capabilities, further complicate collaborative efforts (UK3, 2024).

Interviewees stressed the importance of key opinion leaders, partner diversity, and agility in collaboration (UK1 & UK4, 2024). Networking was valued but not seen as a

universal solution (IRL1, 2023). In Germany, cluster collaboration favoured information exchange over joint projects, despite clusters' alignment with open innovation principles (D2, 2024). Practical success depended on well-defined roles and trusted relationships, with collaboration decisions shaped by personal interactions and feasibility assessments (D2, 2024; UK1, 2024).

The medical device industry operates under stringent regulatory oversight, necessitating the implementation of extensive procedural frameworks to facilitate collaboration (D2, 2024). In projects utilizing standardized components, it is customary to initiate multiple contractual arrangements at the outset (D2, 2024). This typically begins with the execution of a non-disclosure agreement, followed by a formal Statement of Work outlining the project scope (D2, 2024). Subsequently, parties enter into quality assurance and general business contracts encompassing delivery terms and other commercial provisions, all of which represent conventional practice within the sector (D2, 2024).

5.1.5 Distribution

Distribution structures are essential but resource-intensive and time-consuming to establish (D2, 2024; IRL3, 2024). IRL2 (2024) highlighted that appointing distributors and completing legal formalities typically requires three to four months of sustained, full-time effort with deep market knowledge. Although stable relationships may eventually emerge, they remain vulnerable to disruptions such as underperformance, business closure, or strategic shifts. The companies interviewed have developed their own selection criteria for distributors. Examples included networking at medical shows and the use of average weighted systems (IRL2, 2024), the range of competitor products the distributor sells (D1, 2024; UK2, 2024) and expected revenue (IRL3, 2024). The complexity of the device is another consideration depending on the information needs and client support (UK1, 2024). Ultimately, companies then need to determine how they get to a certain market share with their distributor in their respective markets.

5.1.6 Skills

Two primary skill-based challenges were identified: those pertaining to product-specific training and those related to the competencies and development of staff. Given the diverse classifications of medical devices, varying degrees of user training are necessary, with training approaches tailored according to product complexity and regional factors. Distributor education also emerges as a critical component for supporting sales efforts.

As emphasized by IRL3 (2024), education and training are pivotal to successful commercialization, underscored by the focus on “training people, training distributors.” The introduction of novel procedures further complicates this landscape, particularly when end users must comprehend how a product addresses their needs. In such cases, firms must establish multi-tiered training frameworks that not only convey the overarching value proposition to distributors but also provide detailed, role-specific guidance, covering usage for medical professionals such as nurses and physicians (IRL3, 2024).

5.2 How The Aims Have Been Met

Again, the first aim of this thesis was:

- to explore the relationship between outbound open innovation (OI) and the resource-based view (RBV) of the firm.

As a reminder, the resource-based view (RBV) links a firm's internal attributes to performance, emphasizing resource heterogeneity and mobility as drivers of sustained competitive advantage (Barney, 1991). Within the SCP-based framework (Barney, 1991; 2001), resources are categorized into physical, human, and organizational capital, encompassing both tangible and intangible assets, capabilities, routines, and knowledge essential for strategic execution (Barney *et al.*, 2011; Teece *et al.*, 1997). To yield lasting advantage, resources must be valuable, rare, inimitable, non-substitutable, and effectively organized (Barney, 1991; Alexy *et al.*, 2017).

This study highlights the prominence of internal assets that are critical, not only for maintaining competitiveness, but also for ensuring organizational survival. Specifically, the analysis indicates that, irrespective of geographic location, the acquisition of financial resources and reimbursement emerged as key concerns, particularly for early-stage companies. Start-ups face substantial financial burdens during the initial phases of product development and regulatory compliance. These include, but are not limited to, costs related to intellectual property registration and maintenance, fees charged by notified bodies, and often the expense of securing specialized MDR expertise. In addition, companies must invest heavily in post-market surveillance and clinical evaluations to meet stringent regulatory requirements. Given that revenue generation timelines can vary significantly, this period is often marked by considerable financial

strain. Many companies have voiced concerns about the sustainability of their operations under these conditions (D1, 2024; UK1, 2024; UK4, 2020).

Concerns relating to human capital also emerged. These concerns included limited access to appropriate regulatory expertise, exacerbated by a knowledge deficit within notified bodies following the departure of experienced regulators, and difficulties in recruiting and retaining suitably qualified employees. Firms further face a shortage of the skills required to develop and implement quality management systems, as well as insufficient insights and resources to navigate the often-protracted timeframe needed to generate sales (E3, 2024). The scarcity of experts capable of conducting clinical evaluations and post-market surveillance persists, and although outsourcing may offer short-term relief, this author suggests it can impede the development of dynamic capabilities if internal learning is not enabled through collaboration with the consulting firm. Finally, obtaining robust market intelligence remains prohibitively costly for smaller companies and demands highly specialized expertise.

The thesis has effectively examined the relationship between outbound open innovation and the resource-based view (RBV) of the firm in so far as critical resources were identified. The identification and articulation of these resources constitute an important contribution to both management practice and policy, given their essential role in organizational survival. They can be assumed to be critical too for competitive reasons. Nevertheless, definitively determining whether these resources confer sustained competitive advantage by virtue of their value, rarity, inimitability, non-substitutability, and effective organization (Barney, 1991; Alexy *et al.*, 2017), remained somewhat beyond the scope of the current investigation, nor does the analysis fully explain variations in firm performance (Liao *et al.*, 2019). However, a foundation for further research in this regard is provided. Given the sector's inherent heterogeneity, the diversity of its markets, and the pronounced regulatory and financial constraints identified across all three countries, further research is certainly warranted, and this author would argue, urgent. A strategic-groups perspective, may for example, offer deeper insights into the structural dynamics and resource configurations that underpin performance differentials within this sector.

The first aim was therefore, achieved but with some limitations.

The next aim of this thesis was:

- to determine whether engagement in outbound open innovation can support the development of dynamic capabilities.

To recap, dynamic capabilities extend the RBV, and are defined as “the firm’s ability to integrate, build and reconfigure internal and external competences to address rapidly changing environments” (Teece *et al.*, 1997, p. 515). Considered strategic, high-level competences, these are increasing in importance as businesses need to continue to develop their capabilities to facilitate firm collaboration to deliver customer value and are thus critical to success (Teece, 2012). Chesbrough *et al.*, (2020) and Kim *et al.* (2021) suggest that while the focus of the RBV is on competitive advantage, the focus of dynamic capabilities is on competitive survival matters relevant to the current dynamic business environment.

Regarding this next aim, the author would argue that it was achieved. Companies are proactively seeking to develop and integrate critical skills relating to the medical device regulations, the implementation of quality management systems, develop marketing and sales insights, conduct clinical evaluations and post-market surveillance activities to enable their businesses to, not only survive, but to grow within a highly dynamic sector. Companies are making efforts to deliver training in two respects: to their employees on the one hand, and to medical staff and distributors on the other.

With regard to employee training, while company needs are context specific, thematic needs were similar. IRL1 (2023) was implementing training initiatives across the entire company, not just for sales, but around what they described as challenger selling to enable employees to understand the deeper needs of customers. Other companies needed similar sales related training for example, but for different products and different customer needs (D1, 2024; IRL1, 2023). Furthermore, IRL1 (2023) reported positioning the company to be able to recruit R&D academics from a university at the end of a project. In Germany, for example, government supports are available, particularly for apprenticeships which D3 (2024) described as being valuable to their company. However, training and developing experience takes time (IRL1, 2023). Again, and as mentioned above, in contexts where skills are scarce and firms rely on external expertise,

companies, this author suggests, potentially risk weakening their dynamic capabilities unless close collaboration with consultants and service providers is maintained.

In addition, companies also reported providing training to medical staff and distributors. This work is not only essential for adoption purposes but also for safety reasons. The latter being more critical with the higher classification of the medical device. For example, a Class III implantable device such as the one UK1 (2024) had in development, can only be used by expert neurosurgeons.

Drawing on Teece *et al.* (2016, p. 14), firms with strong dynamic capabilities are generally characterized by effective entrepreneurial leadership and resilient organizational frameworks. Building on this insight, the author contends that the firms currently navigating market challenges exemplify exceptional resilience and managerial effectiveness. Furthermore, to support the adoption of their technologies, companies

Nonetheless, after investing in employee training, SMEs often face the difficult task of retention, constrained by their limited capacity to offer competitive employment terms. But, as advised by Carrasco-Carvajal and García-Pérez-De-Lema, (2020), through the support of employee learning, radical changes to products are developed, and innovation capabilities improve, thus supporting company growth and competitive advantage.

E3 (2024) anticipated a shift in the sector toward a pharmaceutical-style development model, cautioning that this transformation may entail significant costs and threaten the survival of smaller firms. The author argues that, in response, the cultivation of dynamic capabilities will become increasingly critical and companies must remain vigilant.

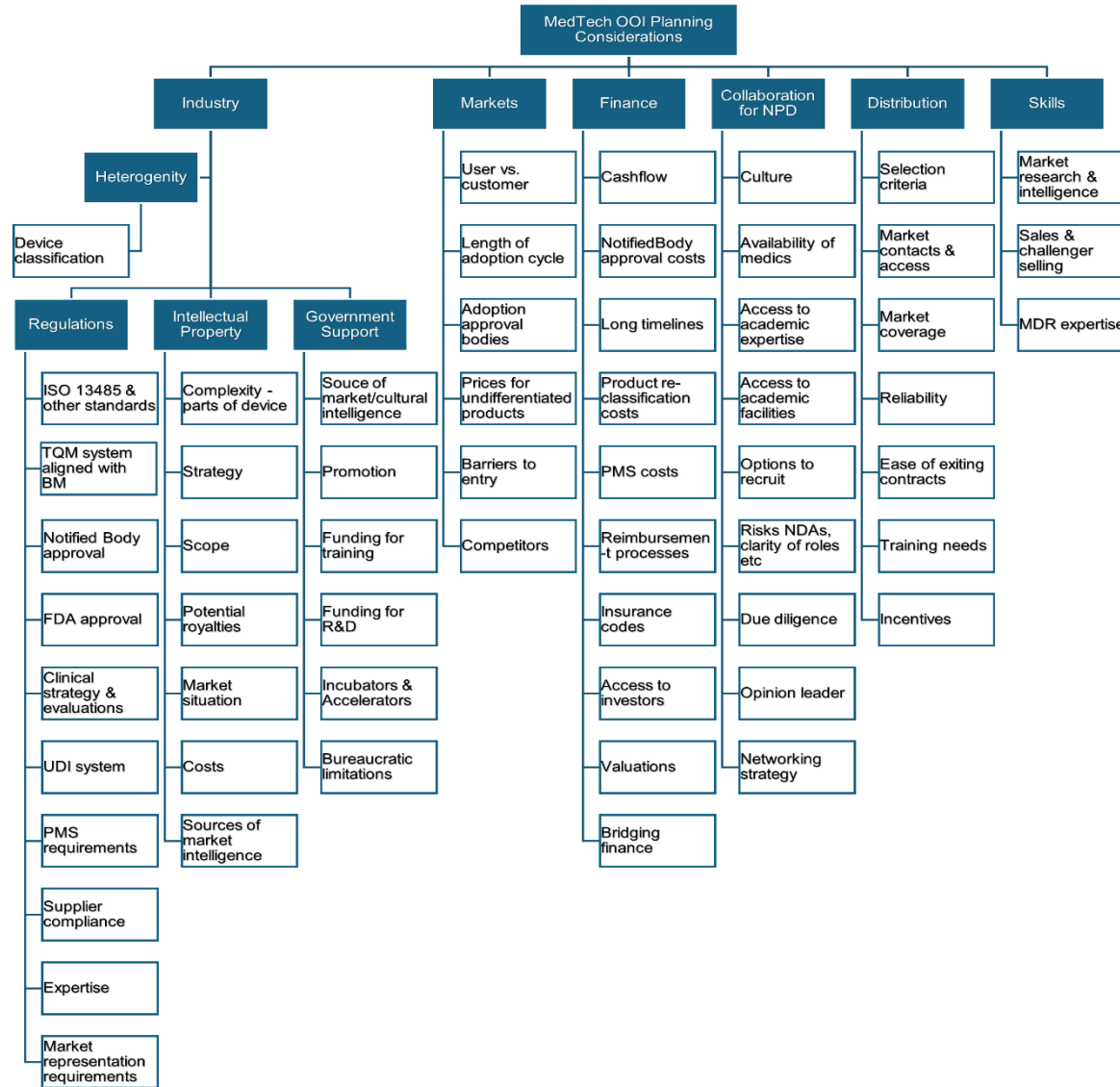
The final aim of this thesis was:

- to develop a managerial framework to support the adoption of outbound open innovation practices.

Looking ahead, the fact that the MedTech sector faces a range of critical challenges, has been highlighted. Beyond the widely acknowledged shortfalls in physical and human resources, deeper structural issues are exerting a compounding impact on the industry. Before initiating any projects to develop a new product, this author proposes that the issues emerging from the thematic analysis offer a guiding framework or high level

checklist for managers to consider for planning purposes in advance of adopting outbound open innovation practices and can be seen in Figure 14 below:

Figure 14: Framework for the Adoption of Outbound Open Innovation Practices.



This framework is relevant across all three countries studied. Contrary to initial expectations, the cluster effect, anticipated to distinguish the German case, did not materialize. Instead, industry-level dynamics transcended national boundaries, exerting influence across all contexts. This framework is available in table format in *Appendix 8*.

5.3 How the Research Questions Have Been Addressed

The first research question was related to the challenges SMEs face commercializing new technologies and collaborating with partners through outbound open innovation practices. For ease of reference, to recap: Aloini *et al.* (2020) outline two main stages of outbound open innovation: (1) opportunity identification and (2) external technology transfer. The first involves assessing the firm's technological portfolio and exploring relevant markets and technologies (Aloini *et al.*, 2020, p. 27). The second concerns selling or licensing internal technologies to external partners (Helm *et al.*, 2017) and includes identifying suitable actors and selecting an appropriate transaction mode (Aloini *et al.*, 2020, p. 28).

5.3.1 The Key Challenges

5.3.1.1 Medical Device Regulations

Regulatory requirements for medical devices vary considerably across jurisdictions, with each authority establishing its own approval criteria. Some stakeholders reported that European regulatory pathways are perceived as more restrictive than those in the United States. Despite such variability, ISO 13485 has emerged as a widely adopted global benchmark for quality management systems. Achieving and maintaining compliance, however, is resource-intensive and places substantial demands on organizational capabilities. It is at this juncture that many firms encounter significant challenges, even though adherence to the standard can offer a strategic advantage.

Several consequences of the evolving regulatory landscape were highlighted. Portfolio reductions have been observed, contributing to a decline in the availability of medical devices across Europe. High compliance costs and prolonged approval timelines were also identified as major sources of difficulty. Additional concerns centred on the performance and capacity of Notified Bodies, including extended waiting times (some having reached full capacity) alongside a reduced pool of experienced assessors. Potential conflicts of interest were also noted, particularly in cases where Notified Bodies provided consultancy services in addition to their regulatory functions.

The reclassification of products under the new regulations created further complications for firms, especially where Notified Bodies were perceived as lacking sufficient competence to assess newly classified devices. Securing suppliers who themselves meet the updated regulatory requirements has become increasingly challenging. Concerns

were also raised regarding the availability of regulatory expertise, with some firms expressing apprehension that their in-house specialists might be recruited by competitors, and reporting difficulties in hiring or accessing suitably qualified personnel. Clinical evaluation requirements were highlighted as a major obstacle. Challenges stemmed from the need to generate primary clinical data, differing market expectations regarding the acceptability of Real-World Evidence (RWE), high associated costs, limited availability and capacity of medical professionals, and the constraints imposed by data protection regulations. Although structural differences exist across markets, several other, common challenges emerged, including lengthy adoption timelines for new technologies and the short product life cycles typical of many medical devices, often ranging from 18 to 24 months.

While several scholars have argued in favour of robust intellectual property (IP) protection, the findings of this study reveal a more nuanced landscape. German firms demonstrated a particularly proactive stance toward safeguarding their R&D outputs, in some cases retaining IP without pursuing commercialization due to insufficient resources. In contrast, Irish firms emphasized the financial burden associated with defending IP rights, noting that the value of protection is contingent on a company's capacity to have it enforced. Adding further complexity, one UK-based firm reported that it was actively considering an open-source strategy, reflecting a divergent approach to managing innovation assets. The tension between intellectual property protection and open innovation was also evident. Potential mechanisms for reconciling this tension included licensing critical technological components or establishing joint ventures. However, both approaches were viewed as complex and resource-intensive, suggesting that the dynamics underpinning these strategies warrant further empirical investigation.

5.3.1.2 Government Support

Participants reported mixed, and at times contradictory, views regarding government policies and support mechanisms. One German firm highlighted the absence of State grants to help scale start-ups and noted significant barriers faced by female entrepreneurs in securing investment. In contrast, another firm operating in the same region acknowledged the existence of funding opportunities but claimed these were insufficiently publicized, limiting their accessibility.

Additional challenges were identified in the UK in maintaining regulatory approvals for digital platforms that evolve rapidly, as well as in the development of standards for novel materials.

In the Irish context, respondents criticized the short-term and superficial nature of official support programmes, arguing that the limited scope of key performance indicators constrained their effectiveness. Irish firms also reported strategic pressures arising from declining market prices for undifferentiated products, driven by a range of external factors.

5.3.1.3 Market Challenges

Differences between national healthcare systems must be anticipated and strategically assessed by firms seeking to enter new markets. In the United States, for example, the healthcare system is predominantly privatized and profit-driven (UK1, 2024). Companies must secure the appropriate medical billing codes, an often lengthy and complex process, before they can commercialize products, making effective cash-flow management essential. The regulatory burden represents an additional layer of complexity, requiring firms to evaluate whether the effort and cost of compliance are justified by the market opportunity.

Broader geopolitical developments have further shaped market conditions in Germany. Recent events have constrained hospitals' investment capacity and contributed to more cautious decision-making among venture capitalists. In the United Kingdom, BREXIT has introduced what participants described as unacceptable levels of inconsistency and bureaucracy, creating additional barriers for firms operating between the UK and EU markets.

5.3.1.4 Market Research

Challenges related to obtaining high-quality market research also emerged. In one case, firms addressed these difficulties by leveraging support from the Chamber of Commerce or by hiring an exceptionally skilled sales professional. According to the fund manager interviewed, approximately two-thirds of initial investment pitches are rejected due to insufficient market research. Common deficiencies include limited understanding of key market dynamics, inadequate insight into how markets respond to new offerings, and a lack of clarity regarding influential stakeholders and the actors who ultimately govern purchasing decisions.

5.3.1.5 Competitors

Given the general lack of confidentiality within the sector, particularly where firms must engage with distributors and, at times, competitors, participants reported exercising considerable caution when disclosing information. However, determining what to share and when to share it was not always straightforward, creating ongoing uncertainty in managing external relationships.

5.3.1.6 Finance

Finance emerged as the most significant challenge across several companies interviewed. Suboptimal company valuations have discouraged some founders from pursuing equity financing, while the broader investment climate has further constrained access to capital. Investors are increasingly redirecting funds toward existing portfolios or have prioritised technologies capable of becoming self-sustaining within relatively short timeframes. Female founders additionally reported a general lack of support for female-led ventures and identifying several gender-specific obstacles that have compounded these financial pressures.

Structural and operational constraints have intensified these difficulties. Tighter hospital budgets, bureaucratic requirements, and prolonged administrative processes created have delays and increased the cost and complexity of commercialisation. Extended development timelines, combined with heightened perceptions of risk, have contributed to investor hesitation. Venture capital firms have also adopted more rigorous pre-investment scrutiny, requiring entrepreneurs to produce more comprehensive market analyses and business plans than in previous years. As a result, achieving alignment with potential partners now demands careful negotiation and a sophisticated understanding of contemporary investment processes.

Commercial challenges were also evident. Securing paying customers, reimbursement and obtaining sufficient resources to support activities in export markets remained pressing concerns, particularly for early-stage firms attempting to scale internationally.

In summary, and addressing the first research question related to the challenges SMEs face commercializing new technologies and collaborating with partners through outbound open innovation practices MedTech firms are navigating an increasingly demanding environment marked by tightening regulatory requirements, rising compliance costs, and significant bottlenecks in clinical evidence generation. Notified Body capacity constraints, inconsistent regulatory expertise, and divergent global

approval pathways compound these pressures, while firms also face strategic uncertainty around intellectual property protection and open-innovation models. Government support is perceived as inconsistent, with gaps in funding visibility, short-term programme design, and persistent barriers for female founders. Market access is further complicated by structural differences between healthcare systems, geopolitical instability, and post-BREXIT bureaucracy. Weak market research capabilities undermine investor confidence, and widespread financial constraints including suboptimal valuations, cautious investment behaviour, and stringent due-diligence expectations, limit access to capital. These dynamics, combined with hospital budget pressures and the challenges of securing reimbursement and early customers, create a complex landscape in which commercialisation and international scaling remain difficult for many firms.

5.3.2 Knowledge, Skills and Organizational Capabilities

The next research question was related to the knowledge, skills and organizational capabilities companies need, to develop within, and capitalize on, the potential of the MedTech sector. Thus, a synthesis of the knowledge, skills, and organizational capabilities identified in this study follows.

Firms demonstrated considerable regulatory and commercialization knowledge, evidenced by routine use of formal agreements such as NDAs, Statements of Work and R&D contracts for example paying careful attention to territorial jurisdiction and funding rules when partnering with universities or public bodies. This regulatory competence was complemented by deep clinical and user-context knowledge as companies routinely draw on the input of clinicians and other experts to shape product design, integrate devices into operating-room workflows, and prioritize patient-safety considerations that, in turn, shape go-to-market choices. Market and distribution knowledge was well developed among interviewees, who understand distributor selection criteria, channel economics, and the long lead times and costs associated with establishing direct sales operations. Academic collaboration practices reveal familiarity with IP management, the trade-offs between publication and commercialization, and the structural requirements of state-funded research partnerships.

Technically, firms possess and access a broad set of R&D capabilities, including electronics engineering, software development, materials science, and device design, often augmented through co-development with contract development with manufacturers or engineering service providers. These technical competencies are matched by training and education capabilities in many instances with companies designing multi-level training programmes for surgeons, nurses, and distributors, deploying online modules with certification, hosting distributor conferences, and co-creating procedural guidelines with clinicians. Commercial capabilities include challenger-style direct sales in core markets, hybrid sales-support models that combine local technical staff with distributors, and the ability to structure co-branding or joint-venture arrangements to scale innovations. Firms also demonstrated partnering and negotiation skills such as conducting due diligence, contract negotiations, as well as strategic scouting, supported by active networking at conferences, within clusters, and through relationships with key opinion leaders and consultants.

At the organizational level, companies exhibited collaboration management capabilities, initiating and formalizing partnerships and governance through contractual frameworks with some appointing programme managers to coordinate research portfolios and manage external relationships. Manufacturing and supply integration capabilities enable co-development and co-manufacturing with partners, while market-entry capabilities encompass distributor selection, onboarding, and ongoing performance management. Talent development is an organizational priority where feasible, sponsoring PhDs and postdoctoral researchers, recruiting junior staff for longer-term training, and creating internal roles to manage expanding research functions. Strategic scouting and alliance capability is evident in proactive outreach to university spinouts and start-ups to secure complementary technologies and advocacy from clinical champions.

Despite these strengths, firms face persistent constraints. Cultural misalignment and partner-fit risks complicate company collaborations, particularly across national and corporate cultures. Talent shortages and retention difficulties, exacerbated by regional labour-market conditions and competition from larger employers, limit capacity in specialized R&D and production roles. The open innovation paradox remains salient: companies must balance knowledge sharing to accelerate innovation with robust IP governance to protect commercial advantage. Distribution presents both strategic and

operational challenges: identifying and onboarding high-performing distributors is time-consuming and risky, and building direct sales forces is capital intensive. Finally, the training burden for complex devices imposes ongoing costs and often necessitates hybrid delivery models to preserve quality while scaling.

Therefore, in summary, with respect to the second research question, to develop within, and capitalize on, the potential of the MedTech sector this study indicates several strategic priorities for firms seeking to strengthen their innovation capabilities. The sector's macro-environment is highly dynamic, and uncontrollable factors, such as evolving medical-device regulations, post-BREXIT trading rules, and the availability of finance amongst other, create persistent constraints that demand organisational agility, specialised knowledge, and strong capabilities. Cultural misalignment and partner-fit risks complicate collaborations, particularly across national and corporate cultures. Talent shortages and retention challenges, driven by regional labour-market conditions and competition from larger employers, restrict firms' capacity in specialised R&D and production roles. The open innovation paradox remains a central tension, as companies must share knowledge to accelerate innovation on the one hand while simultaneously protecting IP to safeguard competitive advantage on the other. Distribution adds further strategic and operational complexity, from identifying high-performing distributors to managing the capital intensity of direct sales forces. The training burden associated with complex devices also imposes ongoing costs and often requires hybrid delivery models to maintain quality at scale. In this context, the development of dynamic capabilities is essential.

5.4 Contribution To Theory and Practice

5.4.1 Theory

This study builds on three key streams of literature. First, it contributes to ongoing debates surrounding the mixed empirical evidence on the relationship between open innovation and firms' innovation performance (Bogers *et al.*, 2019; Bogers *et al.*, 2017). Second, it responds to calls for more nuanced contextual analyses of open innovation processes (Zhang *et al.*, 2023; Huizingh, 2011) recognising that sectoral, regulatory and organisational conditions shape how firms engage in and benefit from openness. Third, it extends work examining the organisational attributes that underpin strong internal

capabilities, particularly those that enable firms to absorb, integrate and exploit external knowledge.

The study's conceptual framing draws on the resource-based view and dynamic capabilities to illustrate the mechanisms through which open innovation strategies can generate sustainable competitive advantage (Zhang *et al.*, 2023; West & Bogers, 2017). By examining how firms mobilise, adapt and renew their resource bases in response to external pressures, the findings offer insight into the capability-building processes that underpin effective openness.

The research also addresses a notable gap in the literature: the limited empirical attention to research on open innovation in SMEs (Brem *et al.*, 2017; Hossain & Kauranen, 2016; Natalicchio *et al.*, 2017), and particularly to outside-in and outbound practices (Aloini *et al.*, 2020; Baima *et al.*, 2020; Bauer *et al.*, 2018; Natalicchio *et al.*, 2017). By focusing specifically on outbound open innovation in SMEs in MedTech, a sector characterised by stringent regulations, rapid technological change and complex stakeholder networks, the study provides a nuanced understanding of the challenges and capability requirements associated with engaging external partners and markets.

Overall, the findings contribute partially to the resource-based view but more substantively to the dynamic capabilities' literature. They demonstrate how firms develop, adapt, and deploy capabilities that are essential not only for survival but also for leveraging outbound open innovation under demanding sectoral conditions. This sector-specific perspective enriches theoretical understanding of how context shapes the enactment and outcomes of out-bound open innovation strategies.

5.4.2 Managerial Practice

In addition to the specialist competencies essential for technological innovation, the successful development and commercialization of new products also depend on the broader set of critical skills and resources described. Before initiating any new project, managers must assess and secure the availability of these resource categories for the entire duration of the development process. Ensuring that the requisite expertise and infrastructure are in place is vital to executing the tasks outlined above and achieving corporate strategic objectives.

5.4.3 Public Policy

The structural challenges identified could in part be addressed by changes in public policy.

On 14 October 2024, MedTech Europe, in collaboration with thirty-nine national associations, issued an open letter to European Commissioner for Health and Food Safety, Stella Kyriakides (MedTech Europe, 2024e). The letter called for urgent reform of the In Vitro Diagnostic Regulation (IVDR) and the Medical Device Regulation (MDR), citing persistent implementation challenges that threaten the availability of medical technologies and the sector's global competitiveness (Medtech Europe, 2024e). The organization warned, that without decisive action, Europe risks losing innovative capacity and facing further withdrawal of critical medical technologies, thereby compromising patient safety and public health (Medtech Europe, 2024e). Based on her research, this author would strongly support this call.

The development of expertise in medical device regulations has become increasingly urgent. Considering persistent application backlogs among notified bodies, industry-wide difficulties in recruiting and retaining qualified specialists, and the sector's substantial economic relevance across all three markets, a compelling case emerges for governmental intervention. Specifically, targeted support for universities to establish relevant academic programmes is warranted as a matter of priority.

Government funding for the development of new medical devices remains inconsistent. Although the sector is inherently complex, illustrated by the World Health Organization's (2024) estimate of approximately two million distinct medical devices globally, categorized into over seven thousand generic device groups, a critical gap persists between the completion of a market-ready product and its initial commercial sale. A more strategic evaluation of funding mechanisms is warranted to reduce the number of companies that succumb to the so-called "Valley of Death." Furthermore, integrating technology development into national healthcare strategies, particularly to facilitate clinical trials, enable market access, and cultivate specialized expertise, should be prioritized as a matter of urgency not only to improve the patient experience but to improve the chances of company survival.

Provision of training in MDRs to develop the next generation of experts is also an urgent

priority. There is a role for both governments and universities to respond.

5.5 Further research

Several avenues for future research warrant exploration.

One promising approach involves concentrating on a single medical device category to enable an in-depth examination of context-specific issues. Alternatively, building on the emerging scholarship on organizational resources and capabilities as highlighted by Kim et al. (2021), is another option. The author contends that although companies frequently collaborate to develop new products and exchange technical expertise, critical shortages in other domains, particularly concerning the medical device regulations, suggest untapped opportunities for expanding collaborative efforts into these and other emerging areas.

There is still room for further study of the paradox of the contrasting logics of the RBV, which prioritizes resource protection, and the inherently open stance of open innovation (Alexy, 2017) but there is evidence of companies questioning the value of intellectual property, considering making their IP open source or if they have the ability to develop their business without concerning themselves with IP.

In addition, another compelling direction emerged from a participant interview. The discussion underscored the systemic barriers that female entrepreneurs in Science, Technology, Engineering, and Mathematics (STEM) fields encounter when seeking investment. These pervasive and consequential challenges have received limited academic attention to date and thus merit rigorous, focused investigation.

5.6 Limitations of the Research

Thematic analysis offers the qualitative researcher flexibility, but it is not without some challenges of which the researcher must be aware. The identification of themes may rely on the interpretation of the researcher resulting in some subjectivity or potentially bias. In this regard, for this work, the researcher used NVivo to mitigate this. The flexibility just mentioned can mean a lack of standardization in thematic analysis but to address this, the guidelines presented by Braun and Clarke (2022) were adopted. To address the critique of thematic analysis being too descriptive, strong the theoretical underpinnings of this work were clear.

Given the complexity of the study's context and the imperative to maintain a narrow analytical focus while generating deep insights, a case study methodology was deemed most appropriate. Nonetheless, constraints on the number of companies available for interview combined with the limited capacity of the researcher, imposed limitations on the study's scope and the generalizability of its findings. The author undertook a rigorous methodological design to mitigate the risk of superficial conclusions; however, given the inherent constraints, some minor degree of superficiality may have been unavoidable.

5.7 Conclusion: Overview

This research has generated as many questions about outbound open innovation as it has answered. When I embarked on this study, I anticipated a thorough examination of the internal resources, skill sets, and organizational prerequisites needed to support outbound open innovation in SMEs in the medical technology sector. Prior study led me to attribute most challenges to resource constraints and skills gaps, and I assumed that Germany's MedTech leaders, given their global success and the sector's robust market demand, would offer an ideal benchmark. In that light, I expected the investigation to proceed in a straightforward manner and make clear contributions to both theory and practice.

However, the empirical findings revealed that, across markets, sector-level complexities far outweighed any internal resource and skills limitations. These demands tested organizational resilience in unforeseen ways and deepened my respect for the ingenuity, tenacity, and perseverance of MedTech entrepreneurs. This insight aligns closely with McKinsey & Company's (2023) articulation of a dual strategic imperative for MedTech executives: to drive the sector's transformation while simultaneously cultivating emergent capabilities necessary for unlocking its full potential. Moreover, McKinsey highlights the critical role of individual leadership commitment in enhancing organizational resilience, an observation I fully endorse but with a caveat: given the economic importance of the sector to all markets, government too has an important responsibility to support as described in the areas of regulation, financial support, training and education.

5.8 Plans with Knowledge Generated

I plan to pursue a dual objective: to advance this agenda and, concurrently, to further

my academic career. To achieve both, I need to explore the most effective strategies for publishing in this field.

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Appendix 1: Evidence of Ethical Approval

Title of Research Study	Ethics Review Reference	Approval Date	Thesis Chapter
Advancing a Managerial Framework for the Adoption of Outbound Open Innovation	ER52824331	15.5.2023	Chapter 3

ADVANCING A MANAGERIAL FRAMEWORK FOR THE ADOPTION OF OUTBOUND OPEN INNOVATION

Ethics Review ID: ER52824331

Workflow Status: Application Approved

Type of Ethics Review Template: Very low risk human participants studies

Primary Researcher / Principal Investigator

Fiona Oster
(Sheffield Business School)

Converis Project Application:

Q1. Is this project i) Doctoral research

Director of Studies

Richard Tresidder
(Sheffield Business School)

Supervisory Team

Michael Benson
()

Re: Converis - Ethics Review - Approval

From: converis@shu.ac.uk <converis@shu.ac.uk>
Sent: 15 May 2023 15:22
To: Oster, Fiona <Fiona.M.Oster@student.shu.ac.uk>
Subject: Converis - Ethics Review - Approval

Dear Fiona

Title of Ethics Review: [ADVANCING A MANAGERIAL FRAMEWORK FOR THE ADOPTION OF OUTBOUND OPEN INNOVATION](#)
 Ethic Review ID: ER52824331

The University has reviewed your ethics application named above and can confirm that the project has been approved.

You are expected to deliver the project in accordance with the University's research ethics and integrity policies and procedures <https://www.shu.ac.uk/research/ethics-integrity-and-practice>.

As the Principal Investigator you are responsible for monitoring the project on an ongoing basis and ensuring that the approved documentation is used. The project may be audited by the University during or after its lifetime.

Should any changes to the delivery of the project be required, you are required to submit an amendment for review.

Wishing you success you with your study

Kind regards,
 Ethics Research Support

*** This is an automatically generated email, please do not reply ***

Appendix 2: Participant Information Sheet

PARTICIPANT INFORMATION SHEET

STUDY:

ADVANCING A MANAGERIAL FRAMEWORK FOR THE ADOPTION OF OUTBOUND OPEN INNOVATION.

1. The University undertakes research as part of its function for the community under its legal status. Data protection allows us to use personal data for research with appropriate safeguards in place under the legal basis of **public tasks that are in the public interest**. A full statement of your rights can be found at: www.shu.ac.uk/about-this-website/privacy-policy/privacy-notice-for-research. However, all University research is reviewed to ensure that participants are treated appropriately, and their rights respected. This study was approved by the University's Research Ethics Committee with reference number ER52824331. Further information at: www.shu.ac.uk/research/excellence/ethics-and-integrity
2. **Overview:** This research involves a comparative study of the outbound open innovation activities (essentially commercialisation of technologies) of small and medium enterprises (SMEs) in the medical technology (MedTech) sector in Germany, the United Kingdom (UK), and Ireland. The overall aim is to develop a managerial framework to support the adoption of outbound open innovation practices. The researcher wishes to understand the challenges SMEs have in the commercialisation of new technologies and if there are challenges in collaborating with partners. The researcher is also interested in what knowledge, skills, and innovation capabilities organisations need to develop and deliver new products to capitalize on the potential of the MedTech sector and what might be needed to bolster the resilience of the organisations.
3. You are invited to participate as your company has a reputation for innovation and new product development in the medical device sector. It shares similar characteristics to the other participating companies in the other markets. / You are invited to participate in your role as an investor in this sector. / You are invited to participate in your role as a regulatory expert in this sector.
4. There is no obligation to participate. A copy of the information provided here is yours to keep, along with the consent form if you do decide to take part. You can still decide to withdraw at any time without giving a reason, or you can decide not to answer a particular question.
5. The research will take the form of a semi-structured interview where the researcher will ask specific questions, but you will be free to expand and give your views.
6. For practicality, online interviews are envisaged. Your permission will be sought to record the interviews. In keeping with university policy, recordings will not be stored in the Cloud but securely on the researcher's laptop until the transcript is agreed. Data will be safely encrypted. The data will then be transferred to the university's secure storage and deleted from the researcher's computer. Where the interviewee refuses permission for the interview to be recorded, a research assistant will be asked to provide support by taking detailed notes. The research assistant will be asked to collaborate on the production of the transcript as appropriate. You will be given the opportunity to validate the transcript.

7. There will be an initial 45-minute to one-hour interview. The transcript will be written up by the researcher afterwards which you may review for accuracy. There may be a second interview to clarify any outstanding issues.
8. This is not a study which should lead to any form of deceit. All parties will act in a transparent manner, data will be anonymized, and transcripts will be checked by all concerned for accuracy prior to further analysis.
9. There are no foreseen risks or disadvantages to taking part in this study.
10. The main benefit of participation to you will be an advanced review of the study which may add value to the management of your business.
11. You will be able to discuss your participation in advance of the interview and afterwards when reviewing the transcript. The researcher welcomes questions.
12. Your identity will be protected. Your company name will be identified by a letter only i.e., Company A or B for example. You will not be identified by name but by your role in the firm in general terms. The country where you are based will be indicated as this will be key to the findings.
13. On completion of the study, the data will be archived in the Sheffield Hallam Research Archive <http://shurda.shu.ac.uk>. According to the university policy, *“items will be retained for at least 10 years from the date of deposition.”*
14. Initially the researcher will have access to the data and her two supervisors. The data will be stored on a secure university drive for this purpose. Any data temporarily stored on the researcher’s own laptop will be fully encrypted in line with university policy. The final thesis may be of interest to future students, academics who may wish to extend the research and managers who may wish to test and/or adopt the framework. The researcher may consider applying for a two-year embargo on the sharing of the thesis and supporting research data to allow for the publication of the main findings, in line with the academic regulations and student policies for research degrees.
15. The data will be used for the purpose of a doctoral thesis. Some academic publications may result from this thesis.
16. The study is expected to be completed at the end of 2024.
17. The results of the study will be shared with you by the researcher.

You may ask any further questions or seek clarification on any issue at any time.

Details of who to contact if you have any concerns are given below.

Researcher Details:

Fiona Oster

Email: Fiona.M.Oster@student.shu.ac.uk

Appendix 3: Semi-structured Interview Questions

The questions below were developed from those posed in the reviewed literature.

Research Questions	
Determine if and in what way the company is involved in Open Innovation. Could use the following framework as a guide:	
Outside-in (Inbound) Practices (Technology exploration)	Inside-out (Outbound) Practices (Technology exploitation)
Contracted R&D services	Co-operations
Crowdsourcing	Corporate business incubation
Customer & consumer co-creation	Corporate venture capital
External networking	Donations to commons or non-profits
Idea & start-up competitions	Employee involvement
Informal networking	Internal exploitation
In-house R&D	IP out-licensing
IP in-licensing	Joint-venture activities
Joint-ventures activities	Minority equity investments
Mass customisation	Outsourcing
Mergers and acquisitions	Participation in standardisation (public standards)
Other forms of collaborative R&D	Partnerships
Other forms of technology purchasing	Selling market-ready products
Publicly funded R&D consortia	Spin-offs (spinouts)
Scouting/searching for/collecting information from external sources	Supplying R&D services
Specialized OI Intermediaries	Technology sales
Supplier innovation awards	
University research grants	
User innovation	
<p>(Data extracted from Battistella et al., 2017, pp. 1322-1323; Holgersson & Granstrad, 2017, p. 1268; Helm et al., 2017, p. 330, Chesbrough & Brunswicker, 2014, p. 19; van de Vrande et al., 2009, pp. 423-425.)</p> <p>If inbound OI practices [External Technology Acquisition (ETA)] are identified, how is the acquired knowledge being assimilated or integrated into the organisation and at what levels? (skills acquired/developed here can impact External Technology Commercialisation (ETC))</p> <p>If outbound practices [External Technology Commercialisation] practices are identified, then</p> <p>Is there a formal planning process? (suggests part of strategy)</p> <p>Are resources allocated to the process?</p> <p>What type of organisations does your company partner with?</p> <p><i>Who, why, how?</i></p> <p>How are they identified, evaluated and selected?</p> <p>What type of knowledge is shared?</p>	

What is the motivation to share this knowledge? (*Monetary, strategic for example*)

How is this knowledge shared? (*process*) (*collaborative and high performance vs defensive – more connections but lower performance*)

Is this knowledge protected in some way? If so, how? (*IP: patent, copyright, trade secrets, trademarks, formal NDAs*)

How could the [collaborative] innovation activity(ies) be classified: discontinuous (breakthrough), dynamically continuous innovation (big improvement in current offering), continuous innovation (incremental) and or imitation? (*risk higher for discontinuous and imitation*)

What are the perceived risks? (*here is the OI / RBV paradox*)

Has a cost-benefit analysis been conducted?

How frequently are technologies transferred out of the organisation and how long does the process typically take?

What resources and metrics are assigned to this process?

Who is involved in these processes and why?

What are the strengths and weaknesses in the skill sets of the staff involved in ETC?

Does the company engage in monitoring and benchmarking itself against competitors?

If so, is there a formal process / methodology?

Who, what, how?

How would the company evaluate its strengths and weaknesses vis a vis those of your competitors? (*valuable, rare,*

Phase 1 of OOI: Opportunity identification phase

Is there a formal assessment process of the company's tech portfolio to determine which technologies to commercialise?

What are the key priorities in this regard?

Issues defining property rights?

Application of the technology issues?

Internal – cross-departmental issues?

How are market opportunities normally identified? (*market scanning, technology intelligence*)

Is there a formal process?

Who, what, how?

Is there a specific allocation of resources?

Are there distinct performance metrics? (the latter 2 Qs could suggest incorporation into strategy...)

Is there an informal process?

Who, what how etc.

In terms of launching new technologies, does the company focus on existing markets or does it proactively seek new ones [*new potential applications for the technology and market structures?*]

Is the company proactive in its search for buyers or, with the information it may make public, buyers come to the company? (push/pull)?

The identification of [new] opportunities requires insight into customer needs and demands. Sources of insight are varied. Where does the company get information? Engagement with consumers? Networks? Wider eco-system? Knowledge sharing? Research?

Phase 2 of OOI: External Tech Transfer

Preferred methods to commercialise? Transfer of ownership or transfer of usage rights...?

Perceived benefits? Perceived risks?

Are patents relevant?

If yes, how would you describe your company's IP strategy?

Defend the firm's IP? Collaborative, exploit outside the firm's boundaries...? Impromptu?

People

How would you describe the Leadership style in your organisation? 'Empowering?' (*promotes trust and autonomy so employees set their own goals? Successful in dissemination and deployment of knowledge?*)

How would you describe the level of employee autonomy (strategic autonomy – planning and conducting a job) in relation to inbound / outbound OI:
Are employees facilitated to develop their own ideas?
Allowed time for creativity?
Permitted to engage in intrapreneurial activity?
How would you describe your organisational climate? (*Employee involvement climate which supports knowledge exchange and innovation?*)
Are employees rewarded for their contribution to innovation?
How would you describe the technological capability within your organisation (proficiency level in acquiring and transforming technological knowledge)? High/low?
How would you describe the market information capability within your organisation (use of external market information to enhance technological innovation)? High/low?
Use of tools to support OI? ICT?
inimitable, non-substitutable and organised??
Are there formal plans to invest in building capability and where are the priorities in this regard?
Have any other enablers and or barriers been identified in the course of the company's outbound practices?

Appendix 4: Semi-structured Interview Questions with MDR Experts

1. When developing new products, medical technology companies are finding Medical Device Regulations (MDR) very challenging. Comments range from “Regulation straight out of hell. It's one of the most stupid things ever happened in the industry. Unbelievable, unbelievable” to “I have grey hair...”, “regulations have gotten out of control” and the regulatory environment is very “harsh” and more! Several senior managers report that companies are suffering badly from the regulatory burden.
2. What is your view?
3. There seem to be particular concerns in Germany relating to some regulatory compliance bodies with companies reporting the following:
 - a. They don't know the correct processes themselves
 - b. They appear to be in conflict with the government
 - c. They don't work in a transparent way
 - d. 18 months redoing documents – a lot of pressure on small firms
 - e. Excessive appointments and audits
 - f. Threaten companies with cancellation of certification if they don't engage
 - g. Would you be able to comment? Have you had any experience working with such bodies?
4. Some companies report that the MDR means fewer innovations while others maintain that MDR is killing innovation completely. *What is your view?*
5. Companies report that the regulatory classification processes are complicated, put companies at a disadvantage due to the volume of work required and the route to market is long. Is this accurate? Is this in line with your experience too? Clarification would be welcome!
6. While some companies have specialist expertise in-house, others don't and find this expertise difficult to access. Has this been your experience too?
7. A CEO reported “The EU is doing its best to have no new products in Europe with the regulations, they're going out of their way to kill everything. They're doing a good job of it” and cited companies using EU funds to develop products which

will then be sold in the US and not in Europe. Have you any thoughts on this situation, have you noticed any similar trends?

8. An R&D manager based in the UK reported that cross border trade UK/EU is very difficult especially now with GDPR and information governance regulations making post-market surveys are difficult. Have you had any experience of German companies struggling to trade in the UK and if so, what are the main challenges?
9. What is the impact of the Global Medical Device Regulations [standards] on SMEs?
10. Are there any other critical challenges for SMEs that I haven't asked about?

Appendix 5: Semi Structured Interview Questions with Sector Fund Manager

1. Funding is a huge challenge for start-ups in the medical device field. Many reasons have presented themselves and there is no one size fits all solution. However, could I ask if there are trends in favour or not with regards to size – some start-ups are really, really small, micro is between one and ten employees. Some of these companies only have staff working part-time and/or for sweat rather than for pay. While this may be the only feasible option available at the start, how might this be viewed by investors?
2. One of the things that I learned as well from interviewing some of these companies where they have the expertise to develop the products and they don't necessarily have the capabilities or the skills that they need to commercialize them, they don't have the marketing expertise and so on. Again, from an investor's point of view [Name], how would an investor see this?
3. In terms of IP protection, I'm getting very mixed messages from companies in terms of how they perceive the importance of IP. From an investor's point of view how critical is it?
4. Is there a leaning amongst the investment community towards devices that can be commercialized quickly and generate cashflow vis a vis more sophisticated, complex products which take time to develop, take time to get through the regulatory processes and take longer to generate revenue? Is this something you would you have observed in your own experience?
5. Are there geographical markets that would be of greater interest to investors than others do you think?
6. In Germany, the medical technology market itself is really difficult right now apparently and it's difficult because the hospitals in particular have actually no finance to buy and to invest in new technologies. Corona: the pandemic had an effect, the war in Ukraine has had an effect and the energy crisis: all of those had an impact on the funding available to hospitals. The political situation in Germany seems to be a bit unstable as well and so the hospitals really don't seem to have

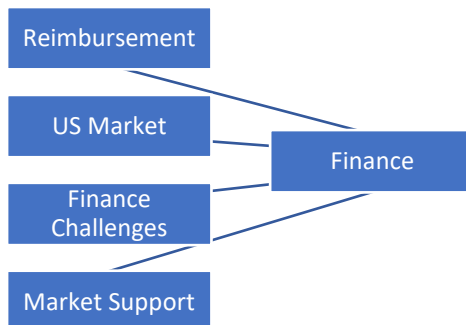
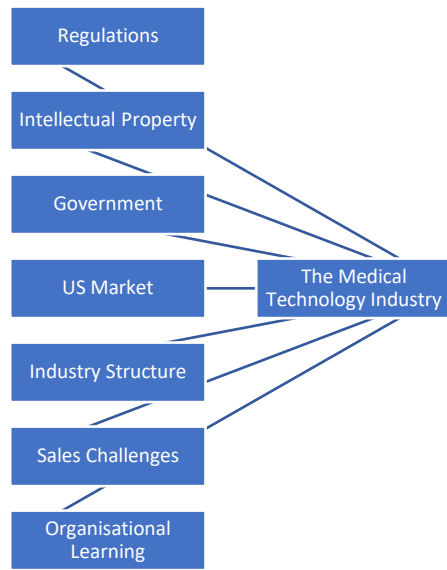
the opportunity that they need to make investment decisions. Have you any thoughts on that or any insight into that at all?

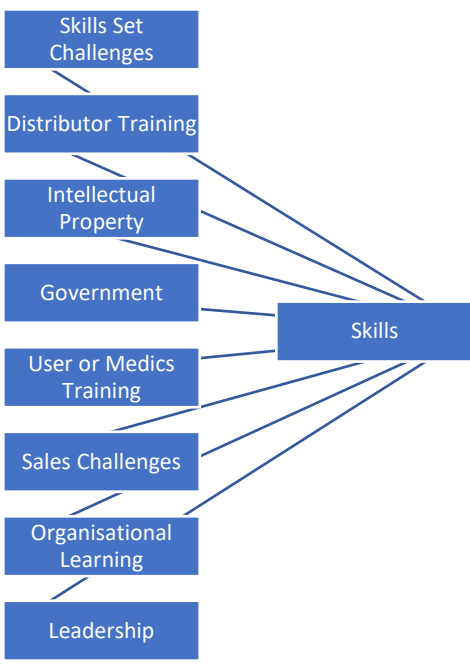
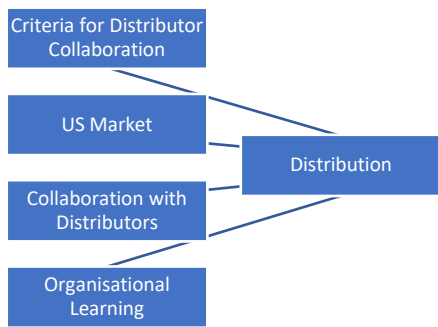
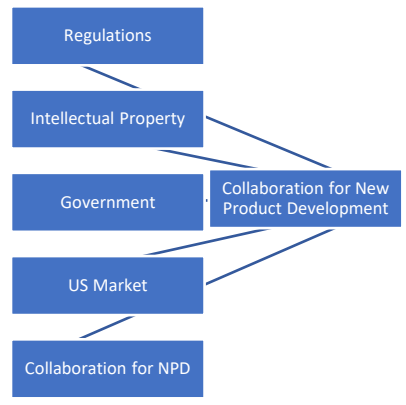
7. The sales cycles, in general, tend to be very long for MedTech up to 18 months, sometimes between getting the agreement to purchase and getting the money in the bank account. So, it means that many companies really need bridging finance. Have you worked with companies in that situation, or could you make any comment on this one?
8. Then a completely different question. [The next one] relates to female founders. I've interviewed a company where females have been at the helm, and they've said to me they found it very difficult to get financing. It seems to be that of female entrepreneurs, only a really, really small minority of females are actually successful in raising funding anyway [in general] and in the sector [specifically]. Have you any experience in that regard, or any thoughts?
9. Now the other question, and I suppose it's linking back to an earlier question in a way, and what I'm seeing is that market insights seem to be difficult for smaller companies to acquire. Have you any observations in this regard as an investor that market research piece, I guess?
10. One final question [Name] is, do you think entrepreneurs consider the cultural factors of markets sufficiently? Has that been something you've come across?

Appendix 6: Interview Transcripts

The interview transcripts originally included in this thesis have been removed from this version of the document in order to protect the privacy and confidentiality of research participants. Although all participants provided informed consent for their involvement in the study, the transcripts contain personal details and identifying information that could, even inadvertently, compromise participant anonymity. In accordance with ethical guidelines and data protection obligations, full transcripts are therefore not included here. The findings and analysis presented in the thesis remain complete and are fully supported by the data collected.

Appendix 7: Thematic Analysis Coding Tree





Appendix 8: Framework for the Adoption of Outbound Open Innovation Practices

Table 8: Framework for the Adoption of Outbound Open Innovation Practices.

Theme	Issue	Factors to consider when planning
Industry	Heterogeneity	Device classification.
	Regulations	ISO 13485 & other standards; Tailored Quality Management System aligned with business model required from outset, to include, for example: <ul style="list-style-type: none"> ○ <i>Product requirements</i> ○ <i>Project plans</i> ○ <i>Design documentation</i> ○ <i>Implementation code</i> ○ <i>Testing & validation plan</i> Notified Body approval – <i>capacity, capability, timelines & requirements</i> ; FDA approval – <i>timelines & requirements</i> ; Clinical strategy & evaluations; Unique Device Identification (UDI) system; Post market surveillance requirements; Supplier compliance; Expertise – <i>caution with ‘out of the box’ solutions</i> ; Market representation requirements.
	Intellectual Property	Required for VC investment; Complexity and may only apply to parts of a device; Company strategy: defensive, collaborative or open; Scope; Potential royalties; Consider the market; Costs to maintain; Source of market intelligence.
	Government Support	Can provide market and cultural intelligence; Trade shows; Funding for training, R&D; Business incubators & accelerators; Caution – <i>limitations and bureaucracy</i> .
Markets	Customers vs purchasers vs controllers	Who is the purchaser? User may differ; Length of adoption cycle; Adoption approval bodies; Falling prices for undifferentiated products; Barriers to entry – <i>BREXIT, regulatory requirements, access</i> ; Competitors.
Finance	Access and cashflow	Cashflow; High Notified Body approval costs and long timelines;

		<p>Potential product reclassification costs; Post Market Surveillance costs; Reimbursement processes; Insurance codes; Access to investors; Valuations; Bridging Finance.</p>
<p>Collaboration for new product development</p>	<p>Multiple considerations</p>	<p>Culture; Availability of medics; Access to academic expertise and facilities; Option to recruit; Potential risks for small / large company collaboration – <i>consider agreements: NDA, Statement of work, clarity of roles;</i> Due diligence; Opinion Leader; Networking strategy.</p>
<p>Distribution</p>	<p>Reliability</p>	<p>Selection criteria; Market contacts and access; Market coverage; Reliability; Ease of exiting a contracts; Training needs; Incentives.</p>
<p>Skills</p>	<p>Availability</p>	<p>Market research & intelligence; Sales and challenger selling; MDR expertise.</p>