

**The role of networking during the internationalisation of
SMEs in the healthcare sector**

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ABSTRACT

The internationalisation of small and medium-sized enterprises (SMEs) in the healthcare sector is perpetually increasing. This thesis aims to research the role of networking in this internationalization process of SMEs in the healthcare sector, in the German healthcare sector specifically. Fifteen interviews with healthcare professionals function as the cement of this study, providing valuable insights into German healthcare SMEs, the German healthcare market, German health insurance companies, and the German regulatory environment. The aim is to obtain comprehensive knowledge about the German healthcare sector and how networks affect the internationalisation of SMEs. A conceptual model is developed to analyse the extent of the effect of networks in the context of the healthcare industry. This research concludes that SME internationalisation is strongly influenced by key opinion leaders and intermediaries, affecting market entry and the position of the SME within a network. The intricate regulatory environment is underscored as well, emphasising the importance of regulatory and political insitutions. Finally, the significance of active networking is consolidated as this positively correlates with successful internationalisation of SMEs.

Keywords: SME; healthcare; networks; internationalization; market entry; relationships

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List of abbreviations

SME - Small and medium-sized enterprises
MNE - Multinational Enterprises
EU - European Union
FDI - Foreign Direct Investment
INV - International New Venture
HTA - Health Technology Assessment
GM - Gioia Methodology
MDR - Medical Device Regulation
MDD – Medical Device Directive
SHI - Statutory Health Insurance
PHI - Private Health Insurance
EMA - European Medicine Agency
CE - Conformité Européenne
MPAnpG-EU - Medical Devices Adaptation Act-EU
MPDG - Medical Devices Implementation Act
MPG - Medical Devices Act
BfArM - Federal Institute for Drugs and Medical Devices, Bundesinstitut für Arzneimittel und Medizinprodukte
BMG - German Federal Ministry of Health
ZLG - Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices
DRG - Diagnostic Related Groups
G-DRG - German Diagnostic Related Groups
InEK - Hospital Remuneration System
NUB -New Methods of Treatment and Screening
ASHIP - Association of the Statutory Health Insurance Physicians
EBM - Uniform Evaluation Scale
G-BA - Federal Joint Committee, Gemeinsamer Bundesausschuss
E.g. - Exempli gratia, for example
I.e. - id est, that is
IQWiG - Institute for Quality and Efficiency in Healthcare
GKV Spitzenverband - National Association of Statutory Health Insurance Funds
PZN - Pharmaceutical Central Number
DiGA - Digital Health Application

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1. Introduction

1.1 Background

The healthcare sector is vital as it is profound to several implications regarding the well-being of the population. The factors and dynamics that regulate enhancements in this sector is becoming significantly more pertinent. Scientific research in this field is directly associated with any progress that has been made in the healthcare sector (Rubini & Pollio, 2017). According to World Health Organization (2022), the healthcare industry is a critical sector that has significant implications for the well-being of individuals and the functioning of society. The healthcare industry is expected to continue to grow due to population growth, aging demographics, and the increasing burden of chronic diseases. SMEs have the flexibility and agility to respond quickly to changes in markets and adapt to new trends. This enables them to bring new products and services to market more rapidly than MNEs, providing the access to latest innovations. Moreover, SMEs often focus on niche areas that are underserved by MNEs, leading to greater innovations¹.

The internationalisation of SMEs has been researched intensively across different industries (Gassmann & Keupp, 2007; Narooz & Child, 2017). This case study will be conducted in the context of the healthcare industry for the reason that this can help illustrate practises that may be employed best to internationalise SMEs in this field. Opportunities and strategies can be identified that can help small and medium-sized enterprises (SMEs) succeed in international markets by examining specific cases, and unique challenges. European SMEs expand into healthcare innovation suggesting that society, citizens including patients, and the economy could benefit significantly (Horgan et al., 2018). Notwithstanding, innovative healthcare SMEs seem to be struggling despite European Union (EU) objectives to emphasise SMEs growth and activities² as states by the European Commission in its Communications “Small Business Act” for Europe³, and “Small Business, Big World”.⁴

The phenomenon of internationalisation is a topic of interest that is ever increasing, whether this regards to licensing, manufacturing overseas, or entering foreign markets (Fletcher, 2001). Scholars are intrigued by internationalisation as it entails the process of expanding business activities across borders, predominantly to increase competitiveness and expand the business of SMEs. Internationalisation provides SMEs with opportunities for its survival as well as growth and success (Dimitratos et al., 2016; Fernández & Nieto, 2005). Johanson & Vahlne (2009) argue that internationalisation is a by-product to improve a firms’ position in a network or because of an entrepreneurial action. Johanson & Vahlne (1977) created the Uppsala model, a framework that explains how SMEs can enter foreign markets gradually through a process of incremental learning and experiential knowledge. This model emphasises on developing relationships with local partners, which enables to make better

¹ European Commission (2023), Entrepreneurship and small and medium-sized enterprises (SMEs)

² European Commission (2008), “Think Small First”: A Small Business Act for Europe. Retrieved on 28 August 2023

³ EUR-Lex (2011), Small Business, Big World – a new partnership to help SMEs seize global opportunities. Retrieved on 28 August 2023

⁴ EUR-Lex (1991), Treaty on European Union – Maastricht Treaty. Retrieved on 28 August 2023

decisions regarding the expansion of the business internationally (Johanson & Vahlne, 2009).

Dunning (1976) suggests the OLI framework, or eclectic paradigm framework, which expounds a firm's engagement in foreign direct investment (FDI). FDI is the process whereby ownership of assets is acquired by the source country to control production, distribution, and other activities in the host country (Moosa, 2002). This process is based on three predominant factors: ownership advantages, location advantages, and internalisation advantages. First, ownership advantages refer to unique advantages, such as expertise or proprietary technology a firm possesses. Second, location advantages refer to the location of a firm that could lead to competitive advantages, which could include favourable labour conditions or a large market. Third, internationalisation advantages concern internal managing and coordinating activities that are beneficial, rather than outsourcing these activities (Dunning & Lundan, 2008b). All three advantages are required if a firm wants to engage in FDI. Although, the cost of FDI cannot exceed the cost of exporting or licensing (Dunning, 1988).

Nonetheless, both the OLI paradigm as well as the Uppsala model are predominantly focused on Multinational Enterprises (MNE) (Dunning & Lundan, 2008a; Vahlne & Johanson, 2013). SMEs behave differently in comparison to MNEs (Knight & Liesch, 2016), employ different strategies, and have different market behaviour and competences (Ribau et al., 2018). MNEs can be subdivided in MNE-subunits with greater autonomy and internationalising SMEs build interdependencies on a worldwide basis. MNEs can be seen as global monoliths, whereas SMEs are relatively isolated niche-specialists in this context (Borghoff & Welge, 2001).

A model that is more focused on SME internationalisation practices is the network model. Johanson & Mattsson (2015) designed the network model of internationalisation. This model is designed to give a perspective on successful internationalisation of SMEs based on social interaction and relationship building with partners and stakeholders. According to the model, internationalisation is a gradual process that involves learning from the network and adapting to new environments. SMEs can acquire valuable information about foreign markets and opportunities by building relationships with actors in their network. Long-term relationships and trust-building are key aspects, which results in legitimacy and credibility in foreign markets. Johanson & Mattsson (2015) argue that firms must be able to balance their relationships with different actors in the network to avoid dependency on actors. The function of networking is to help exploit opportunities and overcome potential constraints (Chandra & Wilkinson, 2017; Kwasi Mensah et al., 2021). The model emphasises the importance of social interaction and relationship building in the internationalisation process (Johanson & Vahlne, 2009).

The International New Venture (INV) model is another popular approach to internationalisation for SMEs that contributes to the holistic view of the internationalisation phenomenon. The INV model suggests that firms can enter foreign markets quickly by exploiting their unique resources and capabilities, such as innovative products, proprietary technology, or managerial skills (Oviatt & McDougall, 1994). Foreign market knowledge is considered to be pivotal for successful internationalisation (Eriksson et al., 1997; Johanson

& Vahlne, 1977). In order to succeed, INV firms must have a strong entrepreneurial orientation, the ability to learn quickly from new experiences, and the willingness to take risks in uncertain environments (Zahra et al., 2000). However, there have been advocates of longitudinal studies that can acquire entrepreneurial orientation and foreign market knowledge development of INVs (Keupp & Gassmann, 2009; Kuivalainen et al., 2012)

The question that arose is how Dutch SMEs in the healthcare sector can expand into foreign markets by means of expanding their business network. Through this research, I aim to provide valuable insights for Dutch SMEs in the healthcare sector to expand their operations into foreign markets and contribute to the growth and innovation of the global healthcare industry.

1.2 Context

This study comprises interviews with both German healthcare professionals and Dutch healthcare professionals, providing data and insights in the healthcare sector and networking. The German healthcare market will differ from the Dutch healthcare market. This will be caused by market saturation, regulations, resource constraints, and cultural differences among others (van de Ven et al., 2013).

The purpose of this thesis is to provide insights on the role of networking in the healthcare market in relation to the internationalisation of SMEs in the healthcare sector, particularly in Germany. The aim of this research would be to address potential gaps in literature, focusing on the role of networking in terms of SME internationalisation. The healthcare market is characterised by high complexity. The institutional relationships and context with legal, political, and business actors are profoundly influenced when entering this market (Hadjikhani, 1998; Hadjikhani et al., 2008). A comprehensive analysis will be conducted in terms of regulatory frameworks, healthcare systems, and economic conditions and dynamics in Germany. This requires engaging with stakeholders, such as health insurance companies and partners in respective facets of the industry. Consequently, this ensures the efficacy and feasibility of the outcomes of this research. Hereinafter, it can be assumed that this entire research focuses on healthcare unless mentioned otherwise.

1.3 Research design

This paper will be based on qualitative research, including desk research. The aim is to conduct interviews with employees of healthcare companies and health insurance companies to obtain information about the concept of networking, specifically in the German healthcare market. In addition, several literature studies about SMEs (in the healthcare sector) and internationalisation will be studied in combination with literature about networking. Altogether, the assessment of all obtained information and data will be consequential for the outcome of this thesis.

The influence of independent variables in the context of networking literature on internationalisation of SMEs in the healthcare sector are to be studied. The assessment of

these influences will be explained and discussed as well as the weight of these independent variables. To do so, a methodology will be designed to gather data. The gathering of data requires a certain research approach, which will be elaborated as well. Finally, an answer to the research question will be given. This answer will be based on the empirical findings. The findings, conclusions, and implications will be reflected upon in the discussion.

1.4 Research gap

There are still several avenues for future research on internationalisation of SMEs in spite of all literature that has already been published. I am going to investigate one avenue for future research. For instance, there are calls for more empirical studies on insidership versus outsidership in business networks during the internationalisation process of SMEs, especially in the healthcare sector (e.g., Lagerström & Lindholm, 2021; Schweizer, 2013). Objectively, how can networking help overcome the liability of outsidership and by what means can a SME in the healthcare sector become an insider in a business network?

1.5 Research questions and objectives

The central research question is based on a theoretical gap initiated by the company I am doing this research for and is formulated as follows:

How do networking and collaborations with stakeholders influence the internationalisation efforts of small and medium-sized enterprises in the healthcare sector and how can these relationships be leveraged to enhance their market entry and growth in foreign markets?

The following research questions are used in order to give an answer to the central research question:

1. How do SMEs in the healthcare sector position themselves in foreign markets?
2. How do SMEs in the healthcare sector position themselves in business networks in foreign markets?
3. How can an SME enter a business network and, consequently, enter a foreign market?

The following objectives could be formulated from the research questions as a result:

- To provide recommendations how to both enter and establish networks in Germany;
- To provide valuable insights in the German healthcare market;
- To provide a valuable conceptual framework for becoming an insider in a foreign market.

1.5 Academic relevance

This thesis aims to contribute to academic literature on how small and medium-sized enterprises in the healthcare sector can internationalise. Various studies have been conducted in the field of SME internationalisation and networking. Nevertheless, little research has been conducted regarding SME internationalisation in the healthcare sector in spite of the fact that SMEs have a rising involvement in internationalisation (Tarek et al., 2016). A multiple case study in the form of fifteen interviews with professionals in this context will reveal insights on internationalisation and networking for SMEs in the healthcare sector.

1.6 Practical relevance

The conducted research in this study is significant as it discusses internationalisation efforts of SMEs in the healthcare sector based on networking. The findings resulting from this study provide insights on how to internationalise by means of networking. Practical implications can be derived, emphasising on overcoming challenges, perceiving and contributing benefits for internationalising SMEs in the healthcare industry to a foreign market. This study might serve as a guide for internationalising SMEs in the healthcare sector by means of networking.

2. Theoretical framework

2.1 Introduction to the literature

As indicated in Chapter 1.1: Background, several scholars argue that the interest in the topic of internationalisation is growing constantly. Therefore, this area is researched continuously within the international business field. Internationalisation is an intriguing concept for scholars since business activities are expanded across borders. By doing so, SMEs can expand their business and enhance their competitiveness (Dimitratos et al., 2016; Fernández & Nieto, 2005).

The dynamics of the internationalisation process is considerably different from that of MNEs (Cho & Lee, 2018; Ojala et al., 2018). The dependency in both the firm's business and social network displays the difference in internationalisation process (Jeong et al., 2017). The created competitive advantage results in an increasing effort to manage the internationalisation process of the organisation (Dutot et al., 2014; Schweizer, 2012). How these companies manage internationalisation-related information directly influences the effectiveness of the internationalisation process (Benito et al., 1993; Child & Hsieh, 2014). Furthermore, learning and applying internationalisation-related knowledge play a vital role in internationalisation (Basly, 2007; Rodríguez et al., 2010). On top of that, the establishment of collaborative networks are imperative (Spence et al., 2008). Nonetheless, there is little research on the internationalisation of SMEs in the healthcare industry, specifically (Barnes et al., 2006; Holden, 2005).

This chapter will address SME internationalisation as well as entering foreign markets by means of the network approach. SME internationalisation is addressed by introducing the concept of internationalisation and SMEs, networking challenges for entering foreign markets, network capabilities, and network engagement. Moreover, entering foreign markets by means of the network approach is addressed by introducing the network approach, network dynamics, insidership versus outsidership, and political and regulatory institutions. Ultimately, the conceptual model of this theoretical framework will provide insights in the effect of these facets on SME internationalisation.

2.2 SME internationalisation

2.2.1 Networking in foreign markets

This subsection emphasises on the role of networking in SME internationalisation, highlighting the significance of building and fostering business relationships with partners and other stakeholders. Hereafter, it becomes clear that legitimacy and credibility are imperative to build long-term relationships and trust within these relationships. The emphasis of the concept of networking in foreign environments lies on balancing network actors, rather than being dependent of solely one actor. As a consequence, challenges can be overcome whilst exploiting opportunities during the internationalisation process as explained below.

The literature on internationalisation of SMEs emphasises the importance of networking (Johanson & Vahlne, 2009; Ojala, 2009a). The development of the international network the firm is related to internationalisation process since internationalisation is facilitated by the bridging mechanism i.e. networks (Kontinen & Ojala, 2011; Mtigwe, 2006). The impact of network alliances between firms has been explored (Cenamor et al., 2019; Dyer et al., 2018). This resulted in a consensus that networks consequently contained valuable information that could lead to strategic advantage providing insights on new techniques, intra-firm and inter-firm discussions, and routines and processes and enabling information mobility (Garousi Mokhtarzadeh et al., 2020; Jiang et al., 2018). The inference was that the use of networks could be seen as a 'means to access capabilities' and an 'inimitable and non-substitutable resource' (Fang et al., 2019; Javalgi & Todd, 2011). Whilst Lechner et al. (2006) note that network partnerships help to access technology, reduce transaction costs and risks, and exchange knowledge and capabilities. All these determinants are vital for SME performance. Foreign markets are dynamic and are different from the domestic market as they can be volatile and, therefore, unpredictable (Johanson & Johanson, 2021).

The perspective of resource allocation has shifted to putting emphasis on committing resources to specific networks over time (Kerr & Coviello, 2020; Sleuwaegen & Onkelinx, 2014). The level of a firm's knowledge and its products represents the commitment by suppliers and customers regarding internationalisation (Johanson & Vahlne, 2009; Mejri & Umemoto, 2010). Additionally, engaging with stakeholders in networks helps overcome any entry barriers due to collaborative partnerships (Hohenthal et al., 2014; Welter et al., 2016).

H1: A business network has a positive influence on internationalisation efforts of SMEs in the healthcare sector. Knowledge exchange and learning are facilitated by business networks since these networks provide insights, regulatory requirements, and cultural differences.

2.2.2 Networking challenges for entering foreign markets

The principles of foreign market entry challenges when utilising a networking strategy is expounded in this subsection, elaborating on complexities, such as regulation, cultural nuances, and compatible partners. By prevailing these constraints, healthcare SMEs can expand their network and prevent any potential slowdown. Vital considerations are addressed for manoeuvring these hurdles hereafter.

Several challenges and barriers occur when SMEs enter foreign markets. SMEs experience several common barriers to growth. These barriers may include competition, lack of experience, lack of knowledge, improper record keeping, limited access to finance, shortage of skill, and the inability to use advanced technology. These barriers are ground for both failure of growing and even survival in spite of the size of the economy (Hulbert et al., 2013). The most important barriers encountered by internationalising SMEs are market entry barriers, trust, and currency exchange (Duarte Alonso et al., 2014). Although, currency exchange is not an issue due to the context within the European Union.

SMEs encounter different types of challenges and barriers when entering foreign markets that affect strategic decision-making with regard to deployment of resources and

commitment to exporting (Kahiya et al., 2014; Kahiya & Dean, 2016). Networking-related market entry barriers could be the lack of local connections or networks. Boehe (2013) stresses the importance of local networking as this pertains to accessing international markets. The reason for this is that local networks help overcome barriers by obtaining referrals through their membership in these networks, such as industry associations or professional bodies. Building relationships pose another challenge and building trust in this relationship in particular. This is due to the fact that trust is built up over decades involving and needs a considerable investment (Johansson & Elg, 2002). Resource-intensive activities, such as the role of a 'knowledge gatekeeper', are considered challenging as well since this role seeks new opportunities and engages in knowledge sharing (Cranefield & Yoong, 2007). However, this type of inter-organisational intermediation is for smaller companies often deemed too expensive (Alexander & Martin, 2013).

H2: A strong position in a well-established network helps overcome network entry barriers and enhance internationalisation efforts.

2.2.3 Network capabilities

This subsection delves into how network capabilities help explain the concept of what capabilities can do for an internationalising SME by means of networks. Internationalisation endeavours are characterised by exploring relationships, influencing networks as well as the exploration and exploitation of resources. An SMEs networking capabilities can be seen as imperative assets used for exploring and exploiting opportunities for internationalising in the healthcare sector in particular. These capabilities can help overcome difficulties experienced by healthcare SMEs, hereinafter elaborated.

Battistella et al. (2017) argue that the network capability is a dynamic capability that is beneficial for the organisation's interdependencies, both within as well as outside the organisation. Walter et al. (2006) describe network capabilities as relationships with partners which are able to initiate, maintain, and utilise these relationships, such as supply chains (Mitrega et al., 2012). By using these network capabilities, organisations in the healthcare sector are able to respond to rapidly changing market needs, identifying opportunities, and gaining access to different resources (Gulati et al., 2000; Solano Acosta et al., 2018). These healthcare SMEs can overcome liabilities by relying on external relationships due to their size (Zacca et al., 2015). A critical factor of the success of these healthcare SMEs is represented by a developed network capability in this context, according to Parida & Örtqvist (2015).

The network capability consists of four dimensions: internal communication, relational skills, coordination, and partner knowledge (Ritter & Gemünden, 2003; Walter et al., 2006). Internal communication is described as the ability to assimilate and disseminate information within the firm about partners (Cohen & Levinthal, 1990). The ability to communicate internally and empathical skills, self-reflection, and extroversion characterise relational skills (Marshall et al., 2003). Coordination is defined as bringing groups together whether this is temporarily or permanently to attain common goals. Structured information about partners, such as customers, competitors, and suppliers are categorised as partner knowledge

(Walter et al., 2006). This last dimension helps reduce conflicts by resolving them due to proactive management and reduction of transaction costs (Cohen & Levinthal, 1990). All four dimensions are being discussed during the analysis of the multiple case study as these complement and elaborate on knowledge exchange, conflict resolution, and resource acquisition, which helps firms leverage their network relationships for resources for the reason that the former can be exchanged for the latter (Bell et al., 2003).

H3a: Strong network capabilities help SMEs in the healthcare sector acquire valuable resources from their network.

H3b: The ability of overcoming liabilities and adapting to market needs are correlated with the extent of network capability of SMEs in the healthcare sector.

2.2.4 Internationalisation through network engagement

The emphasis of this subsection lies on the strategic aspect of network engagement in relation to the internationalisation of healthcare SMEs. Network engagement is imperative due to its leverage to facilitate foreign market entry; the insights provided by network engagement are instrumental for successful foreign market entry, highlighting the role of information exchange, market access, and resource sharing, as explained below.

The importance of international networks have been highlighted by several scholars as internationalising SMEs are provided with various tangible and intangible networks by means of international networks (e.g., Manolova et al., 2010; Oviatt & McDougall, 2005; Udomkit & Schreier, 2017). SMEs are dependent on networks, alliances, and partnerships to engage in endeavours abroad, due to little experience and market knowledge (Ojala, 2009b). Joint ventures, subsidiaries, partners, or directly export products are examples of entry modes to engage in foreign markets (Brouthers & Hennart, 2007; Schwens et al., 2011a). At the heart of internationalising lies developing and engaging in partnerships with the aim to create, develop, and exploit international opportunities (Mainela et al., 2014; Schweizer et al., 2010). Although, Johanson & Vahlne (2009) argue that already existing networks are relied upon, rather than forming a new one due to the fact that these SMEs lack international partnerships at the very beginning in contrast to MNEs (Kalinic & Forza, 2012).

In addition, *“to commit to new partners without established trust and any track of record doing business together”* is considered difficult, according to Galkina & Chetty (2015, p. 667). Trust is an imperative aspect in network development as relationships between the key decision-makers have to develop in order for promises to be kept (Schreier et al., 2020; Wicks et al., 1999), and helps reduce uncertainty by means of affective components with positive emotions, such as security in a situation of vulnerability (Gehani, 2000; Singh & Srivastava, 2016). Furthermore, modifying operations helps firms to keep the business network together which results in mutuality and interdependence (Slotte-Kock & Coviello, 2010). According to Håkansson & Johanson (1982), the execution of the exchange will improve in terms of distribution, production, storage, payment, and technology with the aim to reduce costs and/or increase sales (Liesch et al., 2011).

Boehe (2013) suggests that considerable new opportunities can be generated when a firm's reachability as well as visibility increases in the international market by being part of a local network. For instance, a firm's international competitiveness can be enhanced by collaborating with domestic suppliers that complement a business to attain an increased quality of inputs (Wilkinson et al., 2000). However, the most reliable resource for SME internationalisation is that of both a social and business network (Stoian et al., 2016).

This can be attained through different types of network relationships, according to the network model of internationalisation (Johanson & Mattsson, 2015). Firms can enter foreign markets using different types of relationships, such as formal and informal relationships (Coviello & Martin, 1999; Westphal et al., 2006). Additionally, intermediary relationships are used for entering foreign markets (Chetty & Blankenburg Holm, 2000; Oviatt & McDougall, 2005). Formal relationships are connected directly to the business network, whereas personal relationships are considered to be with friends and family (Coviello, 2006; Coviello & Munro, 1995). Formal relationships influence international market and mode selection (Johanson & Mattsson, 2015; Zain & Ng, 2006). These informal relationship, or social networks, can be both private and professional within or beyond a firm (Agndal & Chetty, 2007; O'Donnell et al., 2001). Social networks engage in both developing and maintaining relationships between individuals and firms (Bai et al., 2021), and mainly influence market entries and the acquisition of market knowledge (Ellis, 2000).

Nevertheless, the importance of intermediary relationships are pointed out by scholars as contact between buyer and seller, facilitated by third parties. Third parties function as brokers to establish network relationships and, thus, international business activities can be initiated in foreign markets (Ellis & Pecotich, 2001; Havila et al., 2004; Oviatt & McDougall, 2005). When a firm is unexperienced and has a lack of transparency in networking (Johanson & Vahlne, 1992), actors in a network get connected with the wider network by means of relying on intermediaries (Ford & Mouzas, 2013). There are some complex network choices to be made and, by doing so, the firm can make choices easier as the intermediary helps to make decisions whether to confront or conform, to coerce or concede, or to create or consolidate (Ford & Mouzas, 2010).

H4: SMEs in the healthcare sector are more likely to successfully internationalise when they have the disposal of pre-existing network relationships.

2.3 Entering foreign markets using the network approach

This subsection discusses how the network approach can be applied by SMEs in the healthcare sector in order to enter foreign markets. This elaborates on leveraging already established relationships, accessing knowledge, overcome entry barriers, and establish credibility. The strategic advantage of the network approach is emphasised since this stimulates smoother entry in foreign markets.

Johanson & Mattsson (2015) argue that the organisation's stakeholders are the actors in the business network, such as its customers, suppliers, distributors, competitors, and the

government. The number of ties within this business network both increase and strengthen as more relationships are established and maintained with counterparts abroad. What happens in one of the business relationships could affect the other and vice versa (Håkansson & Snehota, 2006). Business activities are modified to one another, so that relationships can become significant sources of recognition of new opportunities, knowledge development, and are able to establish a position in a foreign market (Johanson & Vahlne, 2003; Johanson & Kao, 2010). There are three different ways to establish oneself in a foreign market: 1) International extension, establish relationships with counterparts abroad; 2) Market penetration, increase commitment to the already established relationships abroad; 3) International integration, enter networks in various countries. An organisation can establish one of these positions into a business network, for the reason to change relationships with stakeholders within that network (Johanson & Mattsson, 2015). During this study, international extension is predominantly focused on since this study is about establishing a network in a foreign market. Market penetration is partly focused on as relationships might be established already, whereas international integration is not focused on as this study conducts multiple interviews in solely one country.

Firms can strategically change categories by extending their networks, which is influenced by the firm's business relationships (Agndal & Chetty, 2007). Exchange of information in a relationship is linked to the exchange in another relationship by the level of connectedness (Leppäaho et al., 2018). According to the network approach, internationalisation is a consequence of an organisation's endeavours to build relationships and enhance their positions within networks (Johanson & Vahlne, 2009). These networks in markets abroad are viewed as systems for long-term relationships (Guercini & Milanese, 2019).

Especially SMEs are dependent on resources whether this is in the domestic market or abroad. By developing a position in a network, an organisation can obtain resources controlled by other organisations in this network (Johanson & Mattsson, 2015). The participants of a business network have common interests, which is the reason why relationships are developed and maintained to attain mutual benefits (Johanson, 2003; Johanson & Mattsson, 2016, 2015), and act as a bridge to new markets (Johanson & Vahlne, 1990). Several studies signify that networking actively is of importance for, for instance, knowledge acquisition, learning, and foreign expansion (Gabrielsson et al., 2008b; Gilmore et al., 2006; Loane & Bell, 2006). Firms that do not have network relationships whatsoever can develop new relationships to facilitate its market entry by networking actively (Loane & Bell, 2006), whereas firms that network passively are reactive and wait for other actors to take initiative (Ellis, 2000; Johanson, 2003).

H5: Engagement of SMEs in network activities are positively related to acquiring valuable resources, such as market knowledge, and partnerships.

2.3.1 Network dynamics and their impact on market entry

The internationalisation process within the frame of network dynamics focuses on collaboration, power dynamics, trust-building, and the dynamics in general. This subsection addresses how SMEs have to manoeuvre through dynamics, whilst being affected by

challenges and opportunities and their ability to deal with them. Comprehending the concept of managing network dynamics aids successful market entry of healthcare SMEs, which is explained hereunder.

Several studies indicate that networks and market entry, or entry mode, are strongly related based on the internationalisation of knowledge-intensive SMEs (Coviello, 2006; Coviello & Martin, 1999; Coviello & Munro, 1995). When entering a foreign market, firms have to commit to certain stakeholders. This commitment displays the intensity of the cooperation in a relationship (De Clercq & Sapienza, 2006), resulting in trust and, hence, long-term engagement (Musteen et al., 2014). The long-term strategy is prioritised when committing to a business network in a foreign market (Johanson & Vahlne, 2009), since this may improve communication and coordination within the network. This does not necessarily mean that this firm is a customer or supplier (Håkansson & Snehota, 1989).

The consensus that predominantly the customers' experience benefits from a network is not entirely true (Murfield & Esper, 2016), as this influences a firm's experiential learning positively as well (De Clercq & Sapienza, 2006; Jost, 2021; Street & Cameron, 2007). Prashantham et al. (2019) stress that if a firm does not commit to an established business network, a business network cannot be exploited. Customer benefits result in increased sales, or at least sustain sales, resulting in increased entry performance. This positively influences the long-term competitiveness as competitiveness increases. Generally, the sum of resources is limited which, consequently, leads to committing to a network and refraining from other networks. The development of long-lasting relationships is a result of this commitment to a business network and a sustainable position in this business network (Johanson & Vahlne, 2006; Street & Cameron, 2007). A strong relationship with customers and suppliers is fundamental for having long-term competitiveness in the business network of a long-term competitiveness in the business network (Sandberg, 2013).

The inter-firm relationship prioritises quality over costs as commitment and learning increase (Sobrero & Roberts, 2001). Additionally, the inter-firm relationship emphasises on resource-building rather than resource-exchange, and more exploration-oriented rather than exploitation-oriented. These relationships facilitate firms to adapt to new business environments and become aware of foreignness (Lee et al., 2012). Furthermore, the shift from outsidership to insidership is crucial as insiders enjoy numerous benefits (see section 2.3.2: Insidership vs outsidership).

H6a: SMEs with network dynamics that are characterised by both mutual trust and strong ties with actors in the business network will enhance the SMEs market entry process as collaboration and information sharing increase.

H6b: Open communication and exchange of knowledge and information help identify and exploit opportunities in foreign markets.

2.3.2 Insidership vs outsidership

The discussion in this subsection focuses on the implication of insidership versus outsidership in a business relationship and its impact on the internationalisation efforts. Information, market knowledge, and resources are aspects that are vital for successful internationalisation. This is impacted by being an insider or outsider in a business network; an insider has the disposal of resources an outsider has not. This subsection emphasises on the strategic importance of being an insider and how a insider position gains competitive advantage in contrast to an outsider position in relation to SMEs in the healthcare sector. All is explained in the paragraphs hereafter.

According to Lagerström & Lindholm (2021), outsidership is a liability that SMEs have to overcome when internationalising. To accomplish this, network relationships have to be established for the reason that the lack of business market knowledge and legitimacy can be addressed. The construct of the liability of outsidership was introduced by Johanson & Vahlne (2009), explaining obstacles with regard to internationalisation rather than a liability of foreignness. Albeit, the latter is not perceived as unimportant since trust and relationships are more difficult to build with greater differences in culture and institutes and, thus, the positioning of the firm itself in a network. A firm is considered an outsider to a business network when it lacks a relevant position in such a network. The firm is not considered an insider by other members of the business network and is not able to develop relationships as a consequence. This explains the uncertainty and difficulty associated (Vahlne et al., 2012).

“Anything that happens, happens within the context of a relationship, and a firm that is well established in a relevant network or networks is an “insider” [...] it is to a large extent via relationships that firms learn, and build trust and commitment – the essential elements of the internationalisation process”, according to (Johanson & Vahlne, 2009, p. 1415).

In other words, for a firm to become an insider and thus overcome the liability of being an outsider, it needs to convince an insider and form a relationship. An outsider should be able and willing to acquire legitimacy as well as market knowledge (Fiedler et al., 2017; Yamin & Kurt, 2018). Business opportunities, market knowledge, and legitimacy have to be developed gradually as well as the maintenance of relationships to overcome the liability of outsidership (Johanson & Vahlne, 2009; Schweizer, 2013). By doing so, a firm is able to strengthen its position in the business network and gradually shift from outsider to insider (Blankenburg Holm et al., 2015a). Insiders are provided with the opportunity to access exclusive information, which enables identifying and capitalising on opportunities (Lagerström & Lindholm, 2021). The empirical studies of Bangara et al. (2012) and Schweizer (2013) note that motivation and actions is not enough for an outsider to become an insider. Relevant insiders of the network need to accept the outsider. Legitimacy is established and perceived by both parties (Yamin & Kurt, 2018).

Hilmersson & Jansson (2012b) argue that the network entry process consists of three stages: the exposure network, the formation network, and the sustenance network. Firms situated in the exposure network have a low degree of insidership. These firms try to find potential customers and intermediaries by finding hubs that provide information and

contacts. This is done by gradually developing trust. A firm enters the formation network when the firm establishes and strengthens its ties with partners and customers. By trying to do so, the firm tries to explore and exploit the exposure network in order to develop sustainable business. By extending the size of the network, the possibility to create leverage is created. Lastly, a firm enters the sustenance network when dyadic relationships have been established in the formation network. Whether a business stays in the sustenance network or not means they have entered the insider position of a network.

A historical case study from Blankenburg Holm et al. (2015b) about the internationalisation of Elektra, shows that opportunity development in a foreign market is a result shifting from outsider to insider within a business network. Elektra is a Swedish medical device manufacturer that entered China between 1980 and 2010. This case presents a network positions shift due to opportunity recognition as well as opportunity exploitation. Weak network positions are said to manifest ignorance. The firm's relationships in the Chinese market were limited and, hence, they had limited resources. The firm merely had indirect relationships with limited commitment. They recognised an opportunity and exploited this which led to network expansion. This example stresses that an outsider position leads to opportunity recognition because of discovery rather than opportunity creation. It states that opportunity recognition made through discovery, a firm's network is inclined to expand rather than strengthen. A second opportunity of this case study contains Elektra forming a joint venture, an opportunity that is closer to creation. This opportunity results in new relationships with suppliers and, therefore, strengthening as well as expanding its network.

A third opportunity revealed acquisitions made in China led to the impression of Elektra being a legitimate firm with a long-term view on China and a strengthened position. Purchases led to interactions with other actors in the network, which presented them with new and better opportunities to be exploited due to gained knowledge. Lastly, Elektra became a firm with a strong insider position acting on proactive strategies rather than opportunities presented to them. Elektra utilised its strong network position to create opportunities beyond its direct relationships within this business network leading to network expansion. This case shows that opportunity recognition and exploitation are associated with achieving an insider position (Blankenburg Holm et al., 2015b).

H7a: Transitioning from outsidership to insidership in a business network positively influences resource access and acquiring market knowledge in the healthcare sector.

H7b: Commitment to a business network helps SMEs in the healthcare sector is positively correlated to enhancing the position within the business network resulting in a strong insider position.

2.3.3 Political and regulatory institutions in internationalisation

The essence of this subsection is on the role of both political and regulatory institutions on internationalisation. The discussion delves and displays into market entry strategies and how these can be shaped by the interactions between SMEs and these institutions. This

subsections emphasises on regulatory, legal, and political frameworks as well as the critical needs for SMEs to enter foreign markets, as explained below.

Another liability of outsidership is the difference in institutions between the domestic market and foreign market (Fuentelsaz et al., 2020; Pogrebnyakov & Maitland, 2011; Schwens et al., 2011b). Depending on a firm's experience handling institutional challenges in the domestic market determines how they handle institutional challenges abroad (Cuervo-Cazurra et al., 2018). North (1990, 1991) argues that the 'rules of the game' are depicted by institutions. These rules can be distinguished between formal and informal and from human action. The former entails official regulations, laws, and tariffs. The latter emphasises on beliefs of a social group, such as cultural norms, codes, and conventions. When firms cross borders to expand their business, materialising problems are often emphasised by institutions (Ghemawat, 2007; Peng et al., 2008). Costs and uncertainties are subject to discussion when internationalising due to differences in both formal and informal institutions (Kostova et al., 2020).

Strong formal institutions put pressure on upgrades of resources as they must comply with local norms (Cuervo-Cazurra & Genc, 2011). The extent to which a market is stable and efficient is dependent on several factors, such as law, the quality of regulations, and freedom (Kostova et al., 2020). Markets with underdeveloped institutions are less attractive as there is more bureaucracy, corruption, and weakly enforced contracts and less opportunities as a consequence (Mingo et al., 2018). Moreover, when these institutions are weak, informal institutions can substitute the formal ones as these are represented by cultural rules (Contractor et al., 2019; Puffer et al., 2013). These cultural differences might influence behaviour and preference of customers and business partners (Hong & Lee, 2015; Malhotra et al., 2016).

Furthermore, political institutions can be found in four dimensions, which describe a business network's institutional setting: political institutions, political actors, political activities of firms, and political resources (Johanson & Mattsson, 1991). Firstly, private actors have to play within a framework of rules and regulations provided by political institutions (Salmi, 1995). Secondly, political institutions might form new political and social values as there is an ideological dimension which is embodied in altered rules and regulations (Gemünden et al., 1997). Thirdly, political actors are actors with which firms may have connections including opposition parties, media, interest groups, members of parliament et cetera. These actors can influence business networks through facilitating disruptive activities and, therefore, help form or change the network (Hadjikhani & Håkansson, 1996). Hallén (1992) says that infrastructural networks often include political actors. An example of these political actors are government officials who perform the duties of vehicles for information and communication. These political actors even "may be as important as the business relationships" (Hallén, 1992, p. 79). Lastly, political resources such as licences and approvals, contracts, industry policies and regulations, funding for research and development, tariffs and other protectionist measures, and support in the form of tax concessions can be gained by these political activities (Hadjikhani & Håkansson, 1996).

Moreover, firms can be provided with market-specific information by governments and can attain legitimacy by acting politically (Jansson et al., 1995). Firms do not only have to be

legitimate in terms of business measures, such as profit and market share. A firm must be institutionally legitimate as well as political norms and values must be prevailed by justifying performance (Hadjikhani & Sharma, 1999; Jansson et al., 1995).

Banta (2009) mentions that the Health Technology Assessment (HTA) aims on synthesising information about health technologies with regard to economic, social, and ethical value. This body emphasises on the formulation of safe and effective health policies. These are reimbursements and coverage decisions, specifically. The focus lies predominantly on medical devices, clinical procedures, pharmaceuticals, and organisation systems. Regulatory practises of medical devices were researched, including the EU (European Commission Directorate-General for Health and Consumers, Health Technology and Cosmetics unit). Medical devices follow four categories as defined by the European Commission Medical Devices Directive 93/42/EEC. These are medical devices are assessed based on risks based on four dimensions: 1) duration of contact with patients 2) invasiveness 3) intended use and dependence on an external source of energy 4) location of anatomical area affected. These dimensions require evaluation and evidence to ensure safety and efficacy (Tarricone et al., 2014).

H8: Establishing a firm in a market with strong political and regulatory institutions has a positive influence on internationalisation efforts for the reason that improved contracts are being enforced and uncertainty is reduced.

2.4 Conceptual model

The proposed conceptual model displays the underlying structure of this research project (Riggan & Ravitch, 2017) and, thus, conceptualises the entire research (Kivunja, 2018). There are several business network related variables that have a direct relationship with the internationalisation performance of SMEs in the healthcare sector. This conceptual model poses that all independent variables have a direct and strong relationship with the dependent variable, i.e. SME internationalisation, as depicted in figure 1.

The model illustrates that business networks have a positive influence on the internationalisation of SMEs in the healthcare sector. This is due to the fact that business networks facilitate knowledge exchange and capabilities (Lechner et al., 2006). The position in a network aids in entering markets as well, according to the model. Barriers and challenges can be surmounted, resulting in enhanced SME internationalisation efforts. Market entry barriers are ground for failure (Hulbert et al., 2013). Therefore, the model suggests that local networks help overcome these barriers by means of networking (Boehe, 2013).

The model poses that network capabilities have a positive influence on the performance of SMEs when internationalising due to the built and maintained relationships with actors in the business network. These relationships can be utilised to gain access to other actors' resources due to their strong network capabilities (Walter et al., 2006). This allows a firm to obtain competitive advantage due to gained access to resources, such as information, human capital among other aspects and adapt to the market (Bell et al., 2003). As posited

by the model, the extent to which a healthcare SME engages in a network contributes to internationalisation performance. The development of these relationships are utilised to acquire knowledge and resources (Johanson & Mattsson, 2015), and enhance positions within business networks (Johanson & Vahlne, 2009). The contribution of the level of engagement in network activities to SME internationalisation performance regards to proactive engagement in networking, leading to meaningful connections, sharing collaborative opportunities, and support from partners in the network (Johanson & Mattsson, 2015).

The model argues that dynamics in a network affect SME internationalisation in the healthcare sector; characterised by mutual trust and strong ties affects internationalisation positively, whilst open communication leads to exchange knowledge between parties, resulting in opportunities (Håkansson & Snehota, 1989; Musteen et al., 2014). Insidership positively influences internationalisation as well for the reason that, as an insider, a firm gains access to various network resources. Overcoming the liability of outsidership is, therefore, imperative to gain market knowledge and legitimacy. Achieving insidership positively affects the internationalisation performance (Johanson & Vahlne, 2009; Schweizer, 2013). As a result, a firm is able to create new business opportunities (Lagerström & Lindholm, 2021). Lastly, the performance of SMEs internationalising is positively affected by strong or favourable political and regulatory institutions. Markets that contain strong institutions are stable and are more likely to succeed as there are more opportunities, less bureaucracy, and contracts that can be enforced (Kostova et al., 2020; Mingo et al., 2018).

In summary, this conceptual model depicts a comprehensive overview of the relation and interaction between the variables. The dynamics are illustrated as well, depicting how all variables jointly affect the SME internationalisation performance. Hence, this influences healthcare SMEs' internationalisation efforts as a result.

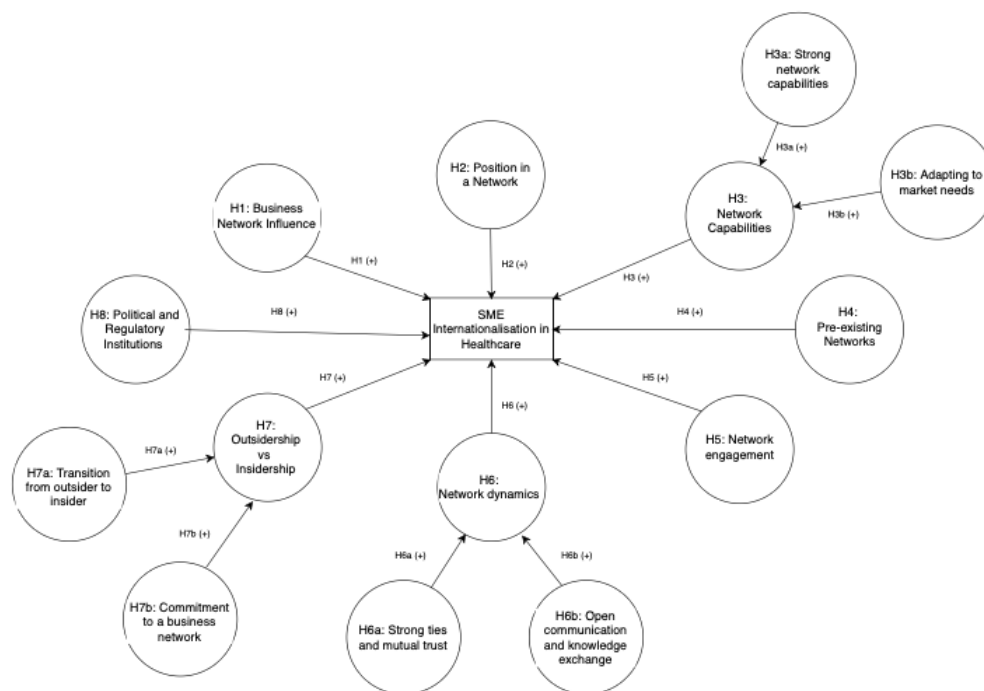


Figure 1: Conceptual model

3. Methodology

3.1 Research approach

The aim of this study is to understand how small and medium-sized enterprises in the healthcare industry can internationalise their business by developing a network in a foreign market. Extensive research has been conducted on the internationalisation processes of SMEs and how this leads to competitive advantage (e.g., Dutot et al., 2014; Schweizer, 2012). Especially, several studies highlight network behaviour with regard to internationalisation behaviour of SMEs as these are seen as determinants of internationalisation (Coviello & Munro, 1995; Coviello & Munro, 1997; Zain & Ng, 2006). In spite of numerous studies concerning internationalisation, limited research has been conducted in the field of internationalisation of SMEs in the healthcare sector with regard to networking specifically.

The case study that is conducted has a qualitative research design for the reason to understand how the German healthcare market operates and how networks are incorporated, leading to market entry essentially. The qualitative research design can include experiences of individuals by explaining how organisations function and relationships are formed in this context (Bogdan & Biklen, 2006; Corbin & Strauss, 2008). By doing so, the German healthcare market can be outlined as how one can become legitimate, gain market knowledge and, thus, overcome the liability of outsidership (Fiedler et al., 2017; Yamin & Kurt, 2018). Participants of this qualitative research give insights in their perceptions, experiences, meanings, and perspectives. Therefore, a semi-structured interview will help gain insights in this topic (Hammarberg et al., 2016). The study employs an explorative as well as a descriptive approach. Exploratory studies are used for finding insights by means of literature, conducting focus group interviews, and interviewing experts in the subject. A descriptive approach enables portraying an accurate profile of this situation, which may complement exploratory research, according to Saunders et al. (2009).

3.2 Research design – a multiple case study

The research design of this study is based on a case study strategy since this applies to both the exploratory and descriptive approach from a qualitative perspective (Bell et al., 2022; Yin, 2009). Robson (2002) states that a case study is a research strategy that incorporates an empirical investigation of a particular contemporary phenomenon within its real life context based on multiple sources of evidence. In this case, multiple semi-structured interviews with professionals are conducted within the context of SME internationalisation in the German healthcare market. Yin (2009) adds that understanding the context within the case study is imperative as the boundaries between the phenomenon and the context are not clearly evident in this study and, thus, align with the goal of understanding the entailing complexities of SME internationalisation. Case studies are able to answer *why* and *what* questions as well and are often used in both explanatory and exploratory research, which are fundamental to this research.

A form of triangulation is used as this study consists of qualitative data collected by semi-structured interviews and secondary data (Saunders et al., 2009). The semi-structured interviews are considered a qualitative method which enables to provide extensive information of the phenomenon that is investigated. The interviews provide information as answers are probed into follow-up questions when interviewees are needed to explain their answers (Silverman, 2013). Secondary data may involve documents and reports that support and complement the primary data source by means of historical background, additional context, or quantitative data in order to enhance both reliability and validity of the research (Saunders et al., 2009). According to Yin (2009), this study incorporates a multiple, holistic case study strategy. A multiple case study is preferable in this context as there is a need to generalise findings as findings occur in other cases as well, whereas the approach is considered holistic as solely the organisation is of interest.

3.3 Data collection

Multiple data sources are used and applied for this study. Most data sources are obtained via the primary data source i.e. semi-structured interviews, which either predicts similar or contrasting results (Yin, 2009). Secondary data are used to complement the interviews, such as governmental publications, annual reports, news articles, or research articles. The secondary data gathered functions as additional information to the primary data obtained in the interviews in order to complement and support the interviews. All sources of information function as one piece of a puzzle. Each piece of the puzzle enables the researcher to understand the phenomenon. The convergence strengthens the findings as it entwines all data, fostering a comprehensive understanding (Baxter & Jack, 2008).

3.3.1 Primary data collection

Fifteen semi-structured interviews are the primary data source of this study. All interviews were conducted either in person or via Microsoft Teams. These interviews are the basis for the empirical findings of this study. Prior to these interviews, I studied literature to get a comprehensive understanding of the concept of networking in the internationalisation of SMEs in the healthcare sector specifically. Participants of this study have to meet the criteria of working in the healthcare sector in Germany, or have worked in the German healthcare sector, whether this is a company focused on cardiovascularity, diabetes, or health insurance. All interviews are recorded and transcribed thereafter and were tailored in an inductive manner, involving abduction with the goal to obtain new perceptions as explained in the subchapter hereafter. The transcriptions were analysed, coded, and categorised in order to answer the hypotheses. Finally, all participants agreed to being recorded and the interview being transcribed. Both participant and company names will be omitted due to privacy. The overview of the interview sample is displayed in table 1.

Table 1: Overview of sample

TYPE OF COMPANY	INTERVIEW TYPE	LENGTH	INTERVIEWEE
HEALTHCARE MARKET RESEARCH	MS Teams	60 min	Consultant
HEALTHCARE MARKET RESEARCH DIABETICS	MS Teams	60 min	Consultant
DIABETICS	Personal	60 min	Chief Executive Officer (CEO)
DIABETICS	Personal	45 min	Chief Financial Officer (CFO)
DIABETICS	Personal	30 min	Key account manager
HEALTHCARE DISTRIBUTION	MS Teams	30 min	Commercial Director
HEALTHCARE DISTRIBUTION CARDIOVASCULAR	MS Teams	45 min	Category Manager
DIABETICS	MS Teams	60 min	Key Account Manager
CYTOLOGICS DISTRIBUTION	MS Teams	30 min	Managing Director
DIABETICS	MS Teams	30 min	Commercial Director
PHARMACEUTICAL	MS Teams	30 min	Director Market Access
HEALTH INSURANCE PHARMACEUTICAL	MS Teams	45 min	Contract manager
PHARMACEUTICAL DIABETICS	MS Teams	30 min	Senior area manager
DIABETICS	MS Teams	30 min	Key Account Manager
HEALTH INSURANCE	MS Teams	45 min	Medical Specialist

3.4 Data analysis

All data are obtained via semi-structured interviews and are transcribed and reviewed thoroughly. Every interview is transcribed and coded which permits the researcher to obtain a comprehensive review of the assembled data. The purpose of analysing qualitative data is characterised by highlighting meanings, themes, and patterns. This process usually emphasises on openness and conceptual flexibility to perceive patterns, being immersive towards the data collected, and processing information (Swanson & Holton III, 2005). Merriam (1998, p.178) states that the process of qualitative data analysis is, in essence, “the process of making sense out of the data”. This is a grounded theory approach as theories are ‘grounded’ in the data and can be generated subsequently (Glaser & Strauss, 2017; Strauss & Corbin, 1994).

This study adopts the Gioia Methodology (GM), a qualitative methodological approach to analyse data as rigorous standards of trustworthy research can be met. This holistic approach allows new concepts to be created inductively, whilst balancing conflicting developed concepts and meeting high standards (Corley & Gioia, 2011; Gioia, 2021; Gioia et

al., 2013). The GM is a systematic approach and is used as a guideline allowing creative theoretical developments whilst remaining rigorous and trustworthy (Gioia et al., 2022). Structuring data employing the GM is an inferential process, involving both induction as well as abduction. This analytical process diverges inferentially from inductive-reasoning towards a more abductive one, cultivated by combining empirical data with theory systematically (Magnani & Gioia, 2023). According to Magnani (2001), when involving abduction in such a process, either plausible hypotheses or inferences are generated to “the best explanation”. Dubois & Gadde (2002, p. 555) state that systematically combining the existing theory with empirical data results in “the ultimate objective of matching theory and reality” (p. 556). This enables the data to be structured in such a manner that it tends to accomplish: 1) existing concepts and interrelationships can be affirmed; 2) existing knowledge can be extended; and 3) new concepts can be initiated in order to understand the phenomenon (Magnani & Gioia, 2023).

The entire research process of the GM transitions from an inductive approach to an abductive approach. The abductive approach is inclined to produce novel theoretical insights as inferences are made by combining theory and empirical data, and can be seen as scientifically creative. The entire GM process is depicted in figure 2. Firstly, the GM considers 1st-order concepts to build upon interviewees’ words. Secondly, 2nd-order themes can be derived based on 1st-order concepts allowing for abduction and systematically combine data and theory. Lastly, the aggregate dimension comprises intertwining induction and abduction. The latter could be knowledge enriching as this dimension promotes the creative process of initiating new concepts for understanding the phenomenon (Magnani & Gioia, 2023). The three GM concepts are further expounded in the section hereafter. Notably, this study has been conducted using the researcher, notwithstanding the fact that the researcher concluded that some answers were overlapping. These coinciding answers were to be combined into the same dimensions, whereas other answers that merely occurred once were omitted as the researcher decided these codes were not noteworthy.

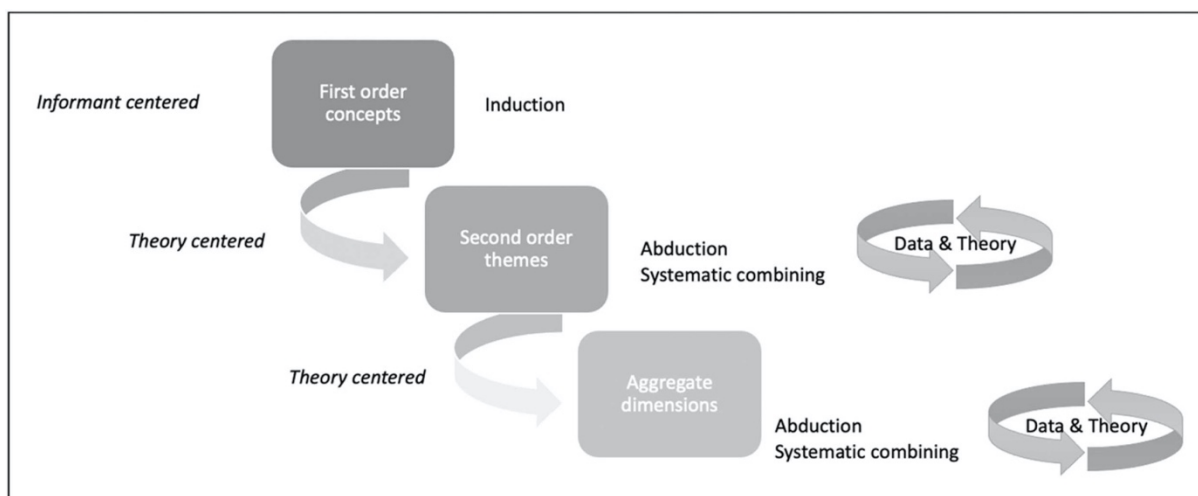


Figure 2: The inferential process in developing a data structure (Magnani & Gioia, 2023)

3.5 Data presentation

The empirical findings from the interviews will be reported in a manner where the overarching concept, 1st-order concept, and 2nd-order theme are supported by using appropriate verbatim quotes (Burnard et al., 2008). Grøgaard et al. (2022) used the GM for structuring their data in their research, scrutinising the organisational flexibility of MNEs to address multiple and shifting strategy pressures over time. During this research, they accumulated data from interviews and triangulated this with secondary data, such as internal documents and reports. Thereafter, the empirical data was reported utilising a precise coding protocol. The researcher will use this manner of reporting accordingly. The precise protocol in question is as follows:

1. 1st order concepts are to be analysed and the interviewees language should be adhered to, so that preeminent themes as well as certain expressions can be identified.
2. 2nd-order themes are to be formed on the basis of comparing the concepts uniformly. The empirical data discovered is to be compared with the literature to ensure the abductive approach, resulting in the eventual 2nd-order themes.
3. Overarching concepts are the product of 1st-order concepts and the 2nd-order themes. The empirical data-driven 1st-order concepts are to be combined with the theoretically substantiated 2nd-order themes forming overarching concepts as a consequence.

Furthermore, Polit & Beck (2004) stress that qualitative data should maintain its integrity and should not lose its narrative by compressing it too much. If the findings are merely summarised by the researcher, the data will be deprived of the new concepts we seek. Hence, the case findings will be presented in such a way that the overarching concepts will be presented as the subchapters, the 2nd-order themes as subsections, and the 1st-order concepts by bold subsections. Additionally, the findings will comprise several examples how categories are labelled and described, including the most relevant exemplary verbatim to elaborate and support the meanings of the categories (Thomas, 2003).

4. The Healthcare System

This chapter emphasises on insights in the healthcare industry in the European Union and Germany specifically. Themes that will be discussed in this chapter are the Medical Device Regulation, the procurement process, and coverage and reimbursement. Both the perspective from the European Union and Germany on these topics will be highlighted and expounded.

The health system in Germany finds health insurance compulsory via either statutory health insurance (SHI) or through substitutive private health insurance (PHI). The vast majority of the German population is covered by the SHI (90%), whereas the other 10% is covered by PHI or special schemes (Wenzl & Paris, 2018). The German health system is governed by federal, state levels, and corporatist bodies of self-governance and is, therefore, considered complex and decentralised. The decision-making power is divided between these three bodies as corporatist bodies have the most power within the SHI system. The federal government decides how the legal framework is set up, whereas the state governments' responsibility is hospital planning and public health services. Patients can freely choose their physicians, general practitioners, and specialists. This is due to the fact that the vast majority of health service providers are supported by the SHI and PHI (Blümel et al., 2022).

4.1 Medical Device Regulation

The Medical Device Regulation (MDR) was initiated by EU Member States in 2017 as the successor of the Medical Device Directive (MDD); a safety measure focusing on increasing both efficacy and safety of medical devices and, hence, the benefit-risk ratio. The European Medicine Agency (EMA) functions as regulatory endorsement, assessing specific categories of medical devices, including medicines used in combination with a medical device, 'In Vitro' diagnostics, medical devices with an ancillary medicinal substance, medical devices made of substances that are systemically absorbed, and high-risk medical devices⁵.

Medical devices must undergo and pass a conformity assessment to ensure safety, meet legal requirements, and perform as intended. To assess the conformity of a medical device, manufacturers are preconditioned to audit and review their device on the basis of technical documentation and the quality of the system. Manufacturers can place a Conformité Européenne (CE) mark on the product when the conformity is assessed successfully, as depicted in figure 3⁶. Products can be categorised into modules based on low risk class or high risk class based on the products intend or invasiveness, for instance. The categorisation includes quality management system, technical documentation, production quality assurance, individual type examination, and product conformity to a type of examination. Depending of the categorised risk of the product, the conformity assessment is performed by the manufacturer to certify conformity with legal requirements in order to obtain a certificate of conformity⁷. CE marking was instated by EU Member States to assess products

⁵ European Medicines Agency (2023), Medical devices. Retrieved on 18 October 2023.

⁶ European Medicines Agency (2023), Medical devices. Retrieved on 18 October 2023.

⁷ BfArM (2023), Conformity assessment. Retrieved on 23 October 2023.

on satisfying legislative requirements of the applicable regulations before placing them on the market. This mark is a prerequisite permitting products to be marketed within the EU and withdrawing products that do not conform (Hill et al., 2015).

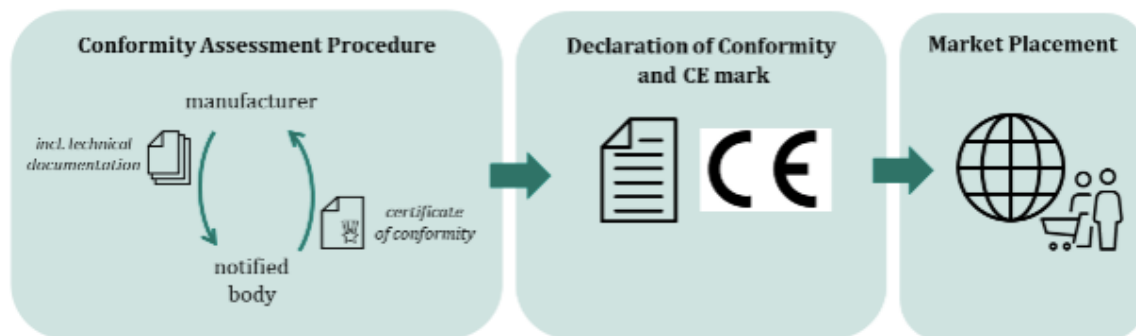


Figure 3: Conformity assessment procedure (BfArM, 2023)

Notably, Medical Device Regulations (EU 2017/745) were applied on 26 May 2021, repealing Directive 93/42/EEC on medical devices and Directive 90/385/EEC on active implantable medical devices. Correspondingly, In Vitro Diagnostic Devices (EU 2017/746) were applied on 26 May 2022, repealing Directive 98/79/EC (Kaule et al., 2020).

4.1.1 Implementation of MDR in Germany

Germany, as an EU Member State, adopted and implemented the MDR whilst incorporating nuances for its own particularly. The German legal framework is based on two sequential laws in this context: the Medical Devices Adaptation Act-EU (MPAnG-EU), and the Medical Devices Implementation Act (MPDG). The Federal Cabinet passed the former on 6 November 2019 and was amended by the Bundestag on 5 March 2020. The latter is described in Article 1 of the MPAnG-EU. Although, a detailed description of the legal changes will not be included, the MPDG is intended to repeal the Medical Devices Act (MPG), making this act binding for all operators and manufacturers in the medical device field. In other words, the most important modifications from MPG to MPDG are⁸:

- The number of paragraphs increases from 44 to 69 paragraphs
- More legal reasons for legal punishment, penalties remain the same
- Structure of document remains the same
- Prerequisites increase for the evaluation of clinical trials/performance
- Extended responsibilities for BfArM

The overseeing authority of the MDR/MPDG is the Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM). This authority is an independent federal party endorsing the German Federal Ministry of Health (BMG). BfArM is responsible for improving safety of medicinal products and detecting and evaluating medical device risks⁹, although the institute is not involved in conformity assessment. In order to contribute to German and EU standards, nationally accredited notified bodies

⁸ Johner Institut (18 January 2023), Medical Device Regulation MDR – Medizinprodukteverordnung (2017/745) Stand 2023. Retrieved on 19 October 2023.

⁹ BfArM (2023), About us. Retrieved on 19 October 2023.

assess conformity of products before they can be marketed. A list of notified bodies is published by the “Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten” (ZLG) according to EU regulations, as the ZLG is responsible for the monitoring as well as the designation of notified bodies¹⁰.

4.2 Procurement

In response to ever-increasing cost of healthcare, governments and healthcare organisations try to reduce the cost of medical care and medical devices. Access of patients is affected negatively by this procurement process; buyer power increases and procurement prices are driven down, notwithstanding the fact that the reduction of healthcare expenditure is failing (Graves, 2011). The procurement process remains a struggle for governments as patient access to healthcare and the economic sustainability of healthcare systems must be balanced; endeavours to get the lowest prices possible and cost-effective devices help to attain cost reduction. Finding an appropriate balance between patient access to innovation and cost containment have been the main goal for the Health Technology Assessment (HTA) using centralised procurement to introduce and diffuse medical devices (Sorenson & Kanavos, 2011). Centralised procurement that a cooperation is formed to leverage value added pricing, technology, and services as these are purchased collaboratively to meet their individual requirements of materials, services, and capital goods (Gobbi & Hsuan, 2015; Hendrick, 1996; Lega et al., 2013).

Manufacturers must become accustomed to the procurement process as this is vital for their business practices due to the complexity of the process for medical devices. Sorenson & Kanavos (2011) found that the German government control costs and influence coverage decisions by using reference pricing. Reference pricing is used to guide the procurement process, serving as a maximum price ceiling for tenders in essence. The German government also reformed hospital funding to a diagnostic-related groups (DRG)-based system.

4.3 Coverage and Reimbursement in healthcare

Other financial activities that align with procurement are coverage and reimbursement. Coverage and reimbursement are another method within the procurement landscape and are, therefore, tightly connected (Sorenson & Kanavos, 2011). New medical technologies and procedures can be offered by means of insurance coverage and the reimbursement it offers (Garber, 2001). Reimbursement systems are a funding mechanism enhancing quality of care, access to care, cost containment, and recruitment of physicians to underserved areas (Simoens & Giuffrida, 2004). Requirements for reimbursement evolve over time resulting in making and braking technology in healthcare. Prerequisites for reimbursement differ per insurance company in different ways for different technologies (Raab & Parr, 2006). Both private and statutory insurance companies incorporate reimbursement and coverage policies, which affect the availability of certain medicine and medical devices (Sorenson & Kanavos, 2011).

¹⁰ BfArM (2023), Notified Bodies. Retrieved on 19 October 2023.

4.3.1 The reimbursement landscape in Germany

The German reimbursement landscape distinguishes reimbursement pathways for medical devices based on whether the device will be used in a hospital (inpatient) or in an ambulatory setting (outpatient). Hereafter, the reimbursement system for patients with SHI is explained.

Inpatient setting

New medical services in the inpatient setting are reimbursed without prior assessment due to the Reservation of Prohibition (Article 137C of the Social Security Code V). In general, innovative medical devices can be applied to clinical practice quickly and allows new medical services to be provided with immediate provision and reimbursement as long as there is no violation of the quality and cost-effectiveness principles. Moreover, the German Diagnosis Related Groups (G-DRG) is the basis for a fee-per-case billing system for treatment of patients. All treatment and hospitalisation costs, of a patient is covered by the G-DRG, including medical devices. This DRG is revised on a yearly basis based on empirical data collected from German clinics by the Institute for the Hospital Remuneration System (InEK) (AiM, 2020).

New Methods of Treatment and Screening (NUB) payments can be applied for by hospitals as these are not yet part of the DRG programme. Technologies and procedures must be considered new in Germany before applying for this procedure. If the method at stake is already part of an existing DRG or is not considered innovative, the method is inclined to be rejected. In addition to the NUB procedure, additional charges can be applied for by hospitals and medical societies, i.e. invoicing an extra fee on top of the DRG. If considered appropriate by InEK, the patient is charged extra on InEK's initiative (AiM, 2020).

Outpatient setting

Private practitioners in the community mainly provide outpatient services, with an estimate of 146,000 physicians working in outpatient care. These practitioners are members of the Association of the Statutory Health Insurance Physicians (ASHIP) by law. They are paid by ASHIP, which is covered by SHIs. This is based on the Uniform Evaluation Scale (EBM) catalogue. This catalogue is compounded by representatives of ASHIP and SHIs, which form the Evaluation Committee. Physicians' invoices comprise the number of patients, services delivered, and a fixed budget distribution system. Although, this varies of the ASHIP's annual budget and the EBM amounts per doctor in certain cases as procedures are performed too frequently (AiM, 2020).

All ambulatory medical services are covered by the Authorisation Right (Article 135 §1 of the Social Security Code V). In other words, therapeutic procedures and novel diagnostics must be evaluated before reimbursement. A new procedure is covered nationwide if positively evaluated, and the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) ratifies this procedure. Albeit, new, innovative procedures with a high demand of clinical evidence are reimbursed based on contracts between providers and payers that require lower demands of clinical evidence. Individual Healthcare Services (Individuelle Gesundheitsleistungen, IGeL) is a service for procedures not considered 'necessary,

economic, or appropriate' by SHIs and, hence, have to be paid out of the patients pocket. (AiM, 2020).

5. Case findings

This chapter aims to unravel case findings with regard to the intricacy of the healthcare sector. This research implemented the Gioia methodology in order to ensure rigourness during the deconstructing and interpreting process of the qualitative data in a systematic order. The GM is apparent presenting the case findings as the subdivisions in this chapter give evidence to: overarching concepts, i.e. subchapters 5.1 Healthcare system and market dynamics and 5.2 Network and relationship management; 2nd-order themes, e.g. subsections 5.1.1 German healthcare sector and 5.2.1 The role of networking in collaborating; and 1st-order concepts, i.e. bold subsections such as Quality of healthcare, KOLs, or Relationship building. This writing style comprises a comprehensive structure, emphasising on the most important factors discovered during the interviews. Hereinafter, everything written in the case findings is based on the results of the interviews, incorporating exemplary verbatim as well to underpin the interpretations of the interviews.

5.1 Healthcare system and market dynamics

Entering the German healthcare market necessitates a comprehensive understanding of the healthcare system and market dynamics. The German healthcare sector is considered rigour and presents many complexities. Therefore, the healthcare system and market require extensive knowledge. Pivotal elements pertaining to the healthcare system are discussed, such as the quality and pricing of healthcare, how its many health insurance companies operate, and identifying the myriad of obstacles presented by political and regulatory institutions. The many components of the regulatory environment are expounded, including the medical device regulation, the approval procedure, and how to qualify for reimbursement. Finally, the dynamics of the German market are expounded; trends are identified, the role of KOLs during market entrance is explained, and pricing policies and competition are discussed.

5.1.1 German healthcare sector

German healthcare

The German healthcare sector is described as bureaucratic and fragmented due to the 96 health insurance companies and a wide range of healthcare practices incorporating policies varying across federal states and, hence, lacking unity and increasing complexity. One participant noted: *“That’s a significant challenge for policymakers in Germany, as achieving unity is quite difficult due to this lack of a unified system. It starts with education. I recall the nursing education curriculum had different contents in different regions. There is no uniformity; every state and province does its own thing.”* This complex system leads to policymakers facing significant challenges due to the absence of a unified system and regional differences. Also, the cases argue that there is a need for digitalisation in the German healthcare sector, although it faces reluctance among doctors as well, partly due to privacy and a lack of face-to-face consultation concerns. Steps toward digitalisation are considered too slow as well as for the implementation of laws in this context.

Quality of healthcare

The cases suggest that the German healthcare sector comprises high standards in terms of quality. Quality of healthcare is prioritised in Germany, although pricing policies are pressuring quality. Hospitals are often controlled by German organisations, leading to commercialisation, high-quality, and cost-effective healthcare. One interviewee highlights the perpetual dispute between quality of healthcare and pricing policies: *“The pricing policy in Germany is becoming sharper, demanding high-quality services and a modern healthcare system at an ever-lower price.”* This seems to be a challenge as another participant commented on the quality of healthcare in relation to the cost of it: *“The challenge is how we can provide the best care for the lowest possible price. Cost-efficiency in the context of therapy is, therefore, a crucial aspect.”* However, the German healthcare system allows patients to have direct access to medical specialists, whether this is a cardiologist or a diabetologist, without needing any referral from their general practitioner. Due to the direct access to medical specialists, a higher satisfaction rate can be attained. More specialised services are offered to patients, resulting in higher insurance premiums and increased healthcare costs, as a consequence.

Health insurance companies

Moreover, health insurance companies, or ‘Krankenkassen’, are pressuring prices for new medical products due to stringent contract negotiations. This is influenced by doctors as well because of the demand for medical technology. As noted by one participant: *“It all starts with doctors. If there is no demand, insurance companies will not be interested. If there is demand, insurance companies will be interested in the problem you are trying to solve.”* Another participant commented on price negotiations: *“Of course, health insurers are also trying to push down prices for new medical products in contract negotiations, trying to pay less, and increasingly assessing necessity.”* Health insurance companies must ensure comprehensive coverage whilst manoeuvring through a myriad of regulations, although they are constrained by their own medical expertise. Rather the lack of it. Due to this lack of expertise, they seek aid by outsourcing product assessment to external parties. Health insurance companies are open to foreign medical devices as long as they meet German standards and regulations. New innovative medical devices are often seen as expensive, albeit health insurers are often misinterpreted not being innovative due to cost-savings.

5.1.2 The regulatory environment

Medical regulations

First and foremost, medical devices must suffice to the MDR and must have all European approvals to enter the market. However, nuances of the German market must be navigated as well in order to ensure market entry, e.g. national regulations and reimbursement. They must be classified and labelled correctly, meet safety standards, and have the CE hallmark. The CE hallmark is the cornerstone for product introduction in the EU. A declaration of conformity, ISO standards, and directives underlie the CE hallmark. This means that a notified body checks and issues to the MDR accordingly. The MDR requires product performance to be tracked diligently and report and follow up on malfunctions of the

product throughout its lifecycle. As one participant noted: *“The product must have market approval, accompanied by all necessary certificates. These must be valid. We scrutinise these aspects meticulously, especially in light of the well-known MDR regulations. This serves as a prerequisite.”*

The complex regulatory environment in Germany is augmented as one participant said: *“Recently, the requirements have been reinforced as well, making the regulatory evaluation process quite substantial. These are closely tied to both the preceding evaluation process and subsequent understanding of the pricing process.”* Having a comprehensive understanding of the market and regulatory requirements are, therefore, imperative. One participant added: *“Political conditions are fixed and non-negotiable. There is no way around it as they are agreed upon at the European level.”* Federal states influence at the national level, depending on the party strength or influence of the respective state representative. One participant argued: *“Therefore, manufacturers need to engage with politicians and institutions that formulate guidelines to implement and depict billing practices, for instance.”*

Approval procedure

The approval procedure for getting a medical device on the German market is not a simple one as Germany is known for its rigorousness and stringentness. One participant argued it to be a long process and highly administrative as all studies have to be presented and evaluated. Thereafter, the Joint Federal Committee (Gemeinsame Bundesausschuss, GBA) or IQWiG (Institute for Quality and Efficiency in Healthcare) will decide. If it gets endorsed the GKV Spitzenverband writes how the device will be practically implemented in statutory health insurance. Albeit, market entrance involves submitting an application to the Federal Institute for Drugs and Medical Devices (BfArM) as well.

Furthermore, due to the rigorous approval procedure, admission studies need to be demonstrated in order to guarantee safety, efficacy, and the functionality of the product. One participant noted: *“Simply put, nothing happens without studies. Conducting a clinical trial under laboratory conditions is not sufficient for medical devices. Health insurance companies and the umbrella association demand real-time observations. These do not have to be based on formal studies, but they require observations and insights that are subsequently medically confirmed.”* However, the German market requires clinical trials to be in Germany. Other clinical trials, in other countries for instance, will not suffice.

Reimbursement

The requirements for reimbursement eligibility start by registering products with the GKV Spitzenverband, the National Association of Statutory Health Insurance Funds. Registering your product is vital for both market entry and success. This process incorporates having a strategic approach, including obtaining a ‘Hilfsmittelnummer’ (medical aid number) or ensuring the product to be included in the Lauer Fischer Taxe to name a few. One participant stated: *“The medical device must have a registration, the so-called Hilfsmittelnummer, in Germany. This is imperative and, ideally, it should also be listed in the Lauer Fischer Taxe with a so-called PZN (Pharmazentralnummer), which also regulates the AEP, because the PZN forms the basis for a possible billing. These are simply the formal requirements that must be met.”* Notwithstanding the lengthy process, once products are

accepted and classified into their respective product groups, health insurance companies are theoretically obliged to reimburse medical devices. Nevertheless, the initial reimbursement is often minimal and require a randomised controlled study for continued approval.

Regulatory hurdles

A participant elaborated on the regulatory hurdles: *“For medical devices, the regulatory hurdles are quite high due to the qualification as a medical device. It must be appropriately classified to enter the market. European approvals are required for pharmaceuticals. These are the regulatory aspects of products.”* Hence, having a comprehensive understanding of the market and regulatory requirements is critical. *“Recently, the requirements have been reinforced as well, making the regulatory evaluation process quite substantial. These are closely tied to both the preceding evaluation process and subsequent understanding of the pricing process”*, commented another participant. This makes the regulatory evaluation process in Germany strict, slow, and labour-intensive.

5.1.3 Market dynamics and pricing

Key Opinion Leaders

Several factors impact market dynamics, particularly in Germany, according to the cases. Key opinion leaders (KOLs) are the first focal point and their significance is not to be underestimated. KOLs need to be convinced, whether they are in Hamburg or Munich. Whenever you want to launch a product on the market, you need to convince the KOLs, first and foremost. Hence, reaching and convincing them is pivotal. Including KOLs in your network is of utter importance, partly for they are members of a council. Engaging with five KOLs can be an adequate amount since clinical needs and patient preferences can be met, for instance.

Product lifecycle

The product lifecycle needs to be considered as well since the journey of a product needs to be monitored. One participant responded: *“What you can do, for instance, when you look at the lifecycle management of a product, is that you have a certain product that is in the market and in use. But the development time in the medical technology field averages around five years. So, at the moment you introduce a product, and if your next product is already in development, you can maintain conversations with the right people to continually gather feedback on what is desirable. This ensures a good fit with those products.”* Scrutinising data and feedback is crucial in order to have a significant product.

Channels

According to the cases, you can keep being informed of market occurrences by subscribing to journals, newsletters, and platforms relevant to their niche market. You can find information about new products and product updates of medical devices. Such changes in the market are publicised by organisations like IQWiG and the GKV Spitzenverband as they disseminate relevant changes and updates. Attending conferences and trade fairs are vital information channels for organisational learning according to participants. *“It’s an opportunity to engage with stakeholders in the industry. These conferences provide an*

opportunity to check out the competition, see what is new in the market, and understand the landscape”, another participant adds. These channels provide you with new opportunities, let you grasp market trends, and keep you ahead of the competition. This underscores the importance of the dynamics of network capabilities in order to adapt to the market and innovate accordingly. Additionally, competition in the German healthcare market is often considered intense, and for medical technologies in particular. Market share is hard to gain due to already established players. “Little competition means stronger pricing and margin negotiations, whereas significant competition could mean more intensive negotiations as there are more alternatives”, one participant noted.

Digitalisation

The uprise of digitalisation in the German market is worth mentioning as, evidently, there is a need for a shift towards digitalisation. Although, doctors are facing challenges adopting such digital tools. The introduction of the digital health applications (DiGAs) is a complex process. One participant argued: *“Germany faces significant challenges in modernising its healthcare sector due to bureaucracy, resistance to digitalisation among doctors, and slow adoption of digital health applications. The system needs substantial improvements to meet the demands of an evolving healthcare landscape.”* There is a need for the development of digitalisation in healthcare organisations since this benefits the organisation’s interdependencies and to leverage successful internationalisation. The need for digitalisation rises due to shortage in personnel as well. *“For example, when I worked as managing director, we received around 150.000 physical prescriptions per month, which had to be sent in envelopes. Imagine the efficiency and costs.”*, added another participant emphasising on inefficiency and the lack of costs-effectiveness.

Pricing

Finally, pricing is imperative within this dynamic market. Pricing strategies and market dynamics are associated with engagement in networks during the internationalisation process, particularly navigating through the obstacles of market dynamics. The German healthcare market is price-driven, particularly the medical device market. Economic viability is a significant factor for healthcare providers for doing business as one participant noted: *“When I lead negotiations at a German insurance company and prices were already more expensive than the German average price, it was difficult to conclude a contract due to the economic viability.”* Furthermore, a product must ensure that it aligns with the pricing regulations. Hence, the approach towards pricing must be sophisticated and strategised in order to succeed in the German healthcare market. A participant argued: *“In a market involving prices, certain discussions, particularly those pertaining to pricing, must be handled carefully within the bounds of compliance.”* In order to do so, offers of the price and margin of a product must be ensured and documented, including payment terms, discounts, and bonuses to ensure smooth sailing with both your team and partner.

5.2 Network and relationship management

The role of networking and relationship management is discussed in this part of the results as these two are pillars of successful internationalisation. The benefits and importance of networking are discussed as well as how to maintain a network. The networking perspective

of the study's participants are expanded by elaborating on collaboration and its prerequisites. By managing relationships, mere connections in the network can be transcended to building actual relationships. Fostering relationships is an investment due to the reliability and longevity of the partnership. Cultural aspects are prone to challenge the relationship due to its international setting. Hence, the cultural context is critical for the survival of the relationship. All these facets are brought together by intermediaries. Successful internationalisation of SMEs into the German healthcare market requires knowledge and precision that can be provided by using an intermediary approach.

5.2.1 The role of networking in collaborating

Benefits and importance of networking

The role of networking is indispensable in the business environment, particularly when internationalising. *"When you have a network to your disposal, you can always enquire within your network. Everyone is willing to take your call"*, one participant commented. Another participant added: *"A strong connection with the key players, particularly those actively involved in the specific area within the German healthcare sector that we are discussing, is essential."* The aforementioned KOLs are not only important for market entrance, but also for networking as they are the gatekeepers to information. By joining such a network, all the right information channels can be addressed, challenges can be faced jointly, and they could assist in finding solutions. *"Establishing relationships and networks directly is always better than relying on intermediaries"*, one participant argued. There are certain platforms that exchange valuable information as well depending on the specific field; these are leading associations for suppliers, manufacturers, and distributors.

Network maintenance

In terms of networks, a partner that has a similar vision and mission is necessary to introduce you to a network, and their connections in particular. A corresponding network helps introduce your product into the market and provides access to customers. Within such a network, agendas can be set and specific topics can be discussed, whilst advisory board members can gain access to confidential information. Business relationships emerge based on advisory services, as a consequence. For these networks to be maintained, means to periodically reach out, introduce interesting topics, and stabilise the relationship, resulting in the ability for enquiries due to a stabilised relationship. For instance, diabetes specialty retailers operate much like manufacturers, introducing themselves to health insurance companies. Once a contract is formed with the parties involved, the contractual relationship is maintained, meaning that the health insurance companies are kept informed. One participant added: *"Maintaining a network, engaging in platform exchanges, and having close ties with associations are crucial."*

Manufacturers or suppliers actively approach their potential partners and engage in dialogues. If there is a potential partnership, the dialogue is being nurtured through regular meetings and sessions in order to collaboratively work on the same project. Additionally, networking actively is of utter importance. International exhibitions and congresses are ways to expand your network. This is a crucial step towards market access since initial

contacts can be established with influential stakeholders. *“It is an opportunity to engage with stakeholders in the industry”*, one participant added.

Collaboration

Networking capabilities outline the following case findings about collaboration in relation with dynamic capabilities as they discuss the capabilities of internal communication, relational skills, coordination, and partner knowledge. Companies are frankly always open to collaborate, albeit it depends on the offer and product. German health insurance companies are not reluctant toward foreign products as long as all German conditions are met. Companies predominantly engage in conversations, to iteratively explain and convey their position and added value, and how a win-win situation can be created through mutual benefit. A critical step prior to initiating contact with prospective partners, is a thorough preliminary screening process to identify the most compatible partners. Once initial contacts are made, the focus shifts towards fostering the partnership and collaborative projects. *“Thereafter, collaborations could be established within the framework of contracts”*, one participant added. However, certain factors have to be taken into consideration before entering a contract; pricing policies, economic considerations, and legal regulations are to be taken into account. This can only be attained in conjunction with communication and negotiation between parties, creating cooperation. Reliability and adherence to commitments are crucial when signing a contract as the contract must be honoured with all its rights and obligations. One participant argued: *“If you work with a distributor in Germany, you are obliged to offer the same contract. It is prohibited to have or offer exclusive contracts.”* Normally, there are no substantial disparities in terms of contractual agreements within the European Union.

Requirements for collaboration

Before establishing any form of collaboration, critical first steps are to identify key prerequisites for the reason that these are the foundation of any fruitful partnership. The prerequisites for considering collaboration are stringent. Innovative technology is often motive for collaborative projects. The German healthcare setting displays a willingness for collaboration when introducing innovative medical devices. These medical devices must suffice to the regulatory environment, whilst taking into account future collaborative projects and market trends. In addition, collaborative projects are often attractive due to financial considerations. A lower price and higher margins in combination with a significant product often result in a better economic viability. One participant said: *“The collaboration must be commercially attractive.”* Hence, there must be a balance between the financial attractiveness and competitive pricing as the partner’s margin could be a decisive factor, for instance.

Expertise and experience are valued competences in a partner. *“Partners must have market knowledge, understand the introducing of products domestically and internationally, and have experience in the market”*, one participant stated. Know-how in the market is, therefore, imperative as well as reputation. This ensures the credibility and reliability of a potential partner. Reliability does not only entail product reliability, but also business integrity and credibility, funding the foundation of long-term relationships.

5.2.2 Relationship management

Relationship building

The networking landscape is paramount for the internationalisation of SMEs, although it demands more than having mere connections. A cornerstone of the networking landscape is relationship management; building and maintaining strategic business relationships is essential within the art of networking as it can help cultivate alliances and collaborations. Investing time in actively building relationships is crucial for an organisation as these lead to market access. Leveraging established partners in an existing network helps gain traction in the market. A strong relationship between parties and open, honest communication leads to successfully accessing the German healthcare market, particularly with innovative products. Moreover, the cases show that personal relationships are imperative in strategic business relationships. The personal relationship strengthens the business relationship and allows to communicate candidly and adds value by not solely being transactional. Building and fostering such relationships require effort, particularly at industry events and through advisory board. Meetings, regular communication, and evaluations instrumentally nurture business relationships. The value of the established relationships is unmatched. One participant stressed: *“The relationships with healthcare professionals, hospitals, and other stakeholders are crucial. Mutual trust and collaboration are vital in the healthcare sector in Germany.”*

Cultural aspects

Partaking in international business means managing relationships with partners by means of steer through cultural differences, negotiation, business practices, and communication nuances. Language barriers present significant challenges as technical terms often cannot be translated, emphasising on the need for proficient communication and terminology. One participant argued: *“Mastering the language and knowing the system is really a must.”* English might be the business language in the case of some health insurance companies, but it is not universally used, indicating linguistic challenges in the German context, particularly when dealing with regulatory authorities. In addition, negotiations are affected due to the hierarchical system in Germany in terms of flexibility and the dynamic of business relationships, influencing communication channels and the decision-making process. One participant added: *“When dealing with foreign companies, it is essential that we can understand each other. No language barrier, and the partner is available for our enquiries.”* Moreover, characteristic to the German healthcare market is the hierarchic working culture. Negotiations are affected as well as everyday tasks and interactions. Hence, meticulously comprehending the cultural dimensions is critical to adapting to the market and ensuring regulatory compliance, reliability of supply, and successful integration into the German market.

Intermediaries

Crucial to a successful market integration are partners and distributors, i.e. intermediaries. Many German manufacturers distrust their products themselves, although this is not recommended for foreign SMEs new to the German market. One participant stressed: *“The supply chain plays an important role when introducing a new product on the market. Distributors and partners are crucial.”* Hence, the endorsement of third parties is instrumental for market access since they bridge gaps between the company and both

potential and established partners. Contemplating third parties is essential as they provide insights in the market, logistical support, and facilitate communication between parties. Finally, adoption of third parties help create opportunities for market growth whilst balancing risk diversification. Personnel need to be trained and educated so support services can be offered. A German-speaking support department is essential for succeeding in the German market, and often due to a lack of resources of SMEs, support has to be provided by engaging with third parties.

5.3 Empirical findings in relation to the conceptual model

The conceptual model developed for this study takes several facets of networking into consideration to seek interrelations within the context of the internationalisation of SMEs in the healthcare sector. Among these facets are network capabilities, insidership and outsidership, the influence of regulatory and political institutions, and engagement in networks. Several cases provide insights in this study, answering questions to study whether the hypotheses can be affirmed, refuted, or that slight nuanced perspectives can be introduced to the existing literature of multiple scholars.

5.3.1 Analysis and discussion of the conceptual model

The effect of business networks on internationalisation efforts of SMEs in the healthcare sector has been researched. The conceptual model is supported by the case findings, providing compelling evidence that there is a positive relationship. This is evident as the interviews indicate that active engagement in networking is positively related to both foreign market entry and expansion. Knowledge can be exchanged extensively by blending in a network, providing market insights, comprehending the regulatory landscape, and help navigate cultural nuances that are essential for integrating in the market. Thus, the findings suggest that business networks positively affect internationalisation efforts of SMEs, providing new angles towards market insights, regulatory requirements, and cultural nuances in complex international environments, underpinning its indispensable role.

The cases give evidence that strong positions within networks aid in surmounting network entry barriers and enhance internationalisation efforts. The cases support strong network positions as these help mitigate any challenges faced by SMEs. The empirical data show that integration in the market is enhanced vividly as these network connections can be leveraged to facilitate valuable insights and information. This results in a smoother market entry due to less hurdles that have to be jumped and risks and challenges that have to be mitigated. Therefore, the depth and strength of network ties significantly aid in crossing borders successfully.

The cases demonstrate that network capabilities are positively related to valuable resource acquiring, including the aforementioned market insights, guidance in the regulatory landscape, and navigating the healthcare sector across borders in general. The stronger the network capabilities, the better one can acquire valuable resources from within the network. Furthermore, adapting to market needs is positively correlated with the extent of

network capabilities of SMEs in the healthcare sector. This becomes evident from the cases as liabilities are addressed with less effort due to connections in the network, adapting to market needs easier. Extensive network capabilities are positively correlated to market adaptation as the cases validate that the influence of network capabilities are pivotal in international healthcare.

Moreover, pre-existing networks are paramount during the internationalisation stage of SMEs in the healthcare sector due to its cultural understanding and its obtained knowledge. These kind of relationships facilitate smoother entry and allows for prompt adaptation to the new business environment, showing a distinct advantage and its indispensable role during this process. Engaging in network activities actively is positively linked to acquiring valuable knowledge and strategic partnerships. Network engagement is the cornerstone for forming partnerships and knowledge acquisition, demonstrating enhanced internationalisation capabilities that elaborate on the dynamic interplay between valuable resources and engagement in networks activities.

The cases exhibit that network dynamics mutual trust and strong ties are the foundation for business networks. These characteristics of dynamics within a network enhance collaboration and the position within the network. Whilst open communication and knowledge exchange help identify opportunities that are to be exploited, facilitating market entry, growth, and opportunity exploitation.

Moreover, the transition from outsidership to insidership is positively correlated as indicated by the cases. Insidership in a business network can help gain knowledge about the market and access resources in the healthcare sector. By integrating this transition, SMEs are able to successfully enter a new market, underpinning the significance of credibility and trust to facilitate this transition. In addition, the commitment to a business network is positively correlated to the enhancement of the position within a business network, providing a stronger insider position as a consequence. Engagement is, therefore, correlated to the attainments within a business network.

Entering a market with strong political and regulatory institutions has a positive influence on internationalisation efforts of SMEs in the healthcare sector as indicated by the case findings. As initially hypothesised, contracts can be enforced and uncertainty is reduced due to a stable environment. Nonetheless, the case findings suggest that the influence of political and regulatory institutions is beyond the enforcement of contracts and uncertainty reduction and is, therefore, more nuanced. This is because the regulatory landscape is complex and provides both challenges and opportunities. The cases indicate that SMEs need to alter their strategies based on the institutional dynamics as well, emphasising to not only rely on them for enforcing contracts and reducing uncertainty.

5.3.2 A comprehensive evaluation of the conceptual model

The conceptual model in this study takes several facets of networking into consideration during the internationalisation process of SMEs in the healthcare sector. These facets are elaborated on as the empirical findings indicate that there are more elements to it than

initially thought. This study provided a meticulous analysis of the empirical data, the theoretical framework, and the author's conceptual model, unveiling concepts within the internationalisation picture and scrutinising all hypotheses hereafter.

Hypothesis 1: Business network influence on internationalisation efforts

The case findings strongly uphold the hypothesis posited as all fifteen interviews indicate that active engagement in networking is endorsed when entering foreign markets as this increases successful market entry and expansion. This relates to knowledge acquisition as well in terms of market insights, regulatory comprehension, and understanding cultural nuances. Hence, hypothesis 1 is accepted.

Hypothesis 2: Position in a network on market entry

Seven interviews indicate that strong network positions aid in surmounting market entry barriers and, therefore, lead to increased performance in internationalisation efforts. Market integration can be enhanced by leveraging connections in the network to exchange valuable knowledge, resulting in mitigated challenges when entering the market. This affirms hypothesis 2.

Hypotheses 3a and 3b: Network capabilities on resource acquisition

Network capabilities are positively related to resource acquisition as outlined by eight interviews. This corroborates both hypotheses 3a and 3b, aligning with the theoretical perspective of the conceptual model; the role of network dynamics on succeeding internationalisation.

Hypothesis 4: Pre-existing networks on successful internationalisation

The case findings showcase that pre-existing networks are positively related to the successful internationalisation of SMEs in the healthcare sector. This is pointed out since nine interviewees argued that pre-existing networks facilitate knowledge and guidance through the complex healthcare system, corroborating hypothesis 4.

Hypothesis 5: Network engagement on resource acquisition

The case findings indicate that network engagement has a positive effect on resource acquisition. Twelve interviews point out that the cornerstone in knowledge acquisition and strategic alliances, i.e. resource acquisition for crossing borders and international expansion is formed by the engagement in a network, as posited by hypothesis 5.

Hypotheses 6a and 6b: Network dynamics on market entry

Strong ties are instrumental for market entry due to enhanced collaboration, market entry, and opportunity identification and exploitation, as posed by eleven interviews. Hence, the characteristics of network dynamics validate hypothesis 6a and 6b on enhanced market entry.

Hypotheses 7a and 7b: Outsidership versus insidership

Hypotheses 7a and 7b are reinforced by six interviews, verifying that resources can be accessed much quicker and easier due to a stronger position in the business network. Committing to a business network tends to enhance a stronger insider position in the network, indicating that this affects the position positively.

Hypothesis 8: Institutions on internationalisation

The case findings indicate that there is more to the statement than initially hypothesised; not only enforcing contracts and uncertainty reduction are influenced by political and regulatory institutions as there is more nuance. Seven interviews substantiate the hypothesis, albeit two interviews outline that political and regulatory institutions are more shaped towards an industry wide influence, rather than internationalisation strategies of SMEs alone. Thus, hypothesis 8 is not provided with substantive support, rather mixed support.

5.3.3 Implications of the conceptual model

This study of the role of networking on the internationalisation process of SMEs in the healthcare sector resulted in the aforementioned hypotheses. The model can be largely implicated in real-time as almost all hypotheses are accepted, suggesting a consolidated networking approach for internationalising SMEs in the healthcare sector. This conceptual model argues for engagement and commitment to networks, emphasising on creating strategic alliances, enhancing the position within a network through engagement, and focusing on pre-existing networks, with the common goal of facilitating market entry, mitigating challenges and risks, and integrating and expanding into international markets. The conceptual model was developed to get a comprehensive understanding of the role of networking in relation to the internationalisation process of SMEs in the healthcare sector, advancing the current understanding of the concept.

This conceptual model elaborates on the roles of the aforementioned facets, explaining the interrelations of the facets discussed. The identified correlations provide a meticulous addition to the already existing literature, emphasising on the role of networking in the healthcare industry particularly. Moreover, practical implications can be derived from the conceptual model. First and foremost, fostering strategic network relationships can provide mutual benefits by means of trust building and resource exchange. Second, in order to navigate through the complex and rigour political and regulatory landscape, a more flexible approach is requisited to consider the market dynamics and broader context of institutions specifically. Another noteworthy facet is to implement a holistic approach toward the international market strategy. Network dynamics and institutional environment are to be taken into consideration uniformly when formulating a strategy.

Altogether, this conceptual model provides an extensive theoretical understanding as well as a comprehensive practical perception on the role of networking during the internationalisation process of SMEs in the healthcare sector, offering directions on how to leverage networks and exploit opportunities.

6. Conclusion

The purpose of this study was to investigate the role of networks in SME internationalisation in the healthcare sector with the aim to find out how SMEs can become an insider in a business network and enhance internationalisation efforts. There already is a considerable amount of studies focusing on the role of networks or similar to the network approach or in the SME internationalisation context. Nonetheless, previous research is scarce in the context of SME internationalisation in the healthcare sector in relation to networking in particular. Therefore, this study addresses internationalisation of SMEs in this industry in this context, creating a conceptual model based on literature in order to examine the model on an empirical level. The aim of this study is to complement literature in this field, providing meticulous insights for both scholars and SMEs in this sector and outlining potential opportunities and challenges. The aforementioned results of the case studies can be utilised to answer the central research question. The sub-questions need to be answered beforehand in order to be able to answer the central research question. Hereafter, the three subquestions are answered, followed by the central research question.

How do SMEs in the healthcare sector position themselves in foreign markets?

A prerequisite of entering a foreign market is taking the market and regulatory environment into consideration. Comprehending the dynamics of the market is critical with the aim to adapt to it, whilst exploring the regulatory landscape in order to manoeuvre through it. This includes KOLs and pricing policies since KOLs are paramount for entering and integrating in the market, whilst pricing policies are critical and need consideration as well. Incorporating high quality healthcare products in the market entry strategy enhances the position of newly entering SMEs, engaging with health insurance companies to highlight the product and the problem it is going to fix.

How do SMEs position themselves in business networks in foreign markets?

It is evident that business networks are fruitful for SMEs to position themselves in a foreign market. Entrance in a business network is evidently useful for leveraging the exchange of knowledge by actively participating. KOLs function as gatekeepers of information sources, which means that KOLs are to be leveraged in order to enter the market. Thereafter, forming and fostering strategic partnerships in business networks leverage strong positions in networks to obtain mutual benefit based on shared objectives and visions. Intermediaries can aid in establishing a position in a business network, which eases the market entry process.

How can an SME enter a business network and, consequently, enter a foreign market?

First and foremost, potential partners have to be identified in order to collaborate. Both firms must be like-minded, have a compatible vision, and perceive compatible goals. By engaging in dialogues and meetings regularly, fostering potential partnerships. To do so, international trade fairs and congresses are to be attended to increase engagement in such conversations with potential partners. Hence, networks are indispensable when entering a

foreign market, highlighting the need for intermediaries or other third parties such as distributors. This enhances market entry as intermediaries act as a network, providing entrance and knowledge of the market.

How do networking and collaborations with stakeholders influence the internationalisation efforts of small and medium-sized enterprises in the healthcare sector and how can these relationships be leveraged to enhance their market entry and growth in foreign markets?

We can now answer the central research question, taking the previous sub-questions into consideration. As previously discussed, networks strongly affect the extent of internationalisation efforts of SMEs. Joining networks and fostering collaborations are pivotal for enhancing internationalisation efforts. In essence, networks are required for manoeuvring the complex regulatory environment and apprehending market dynamics. Moreover, the sub-questions indicate that collaborations with stakeholders are paramount; knowing the environment with its most important stakeholders is essential. This includes KOLs as they are the focal point for market entry. Convincing KOLs will earn market entrance, whilst health insurance companies focus on reimbursement and pricing of the product. Smooth market entry can be ensured by active network engagement; mutual benefit can be attained due to knowledge sharing and resource acquisition. Active engagement in networks leads to strategic alliances as well. These alliances are cultivated through networks since they encourage a stronger position in the network and, thus, a better position in the market.

In conclusion, this study displays the intricate journey of SMEs in the healthcare sector and their process of crossing borders by means of networking. The aim of this study is to provide valuable insights for both academics and practitioners and to provide a conceptual model for theoreticising how to become an insider in a network.

7. Discussion

In this study, we investigated the role of networking on the internationalisation of SMEs in the healthcare sector. The results show that networking has a positive influence on the extent of internationalisation. The research questions are substantiated by the hypotheses as they focus on the influence of the role of networking on the extent of internationalisation, including efforts and aspects related to the concept. The first finding suggests that the importance of KOLs is underemphasised. KOLs seem to be underrepresented in the theory and appear to play a more significant role in the internationalisation of SMEs. Engagement with KOLs contributes to market entry as they are the cornerstone of succeeding in the healthcare market. The theory of Hohenthal et al. (2014) and Welter et al. (2016) mentions that the engagement with stakeholders is necessary to form collaborative partnerships, but does not mention anything about engaging with KOLs specifically. I found this finding noteworthy due to the difference between the study results and the theory, resulting in way more emphasis on KOLs in the empirical findings than initially hypothesised. Without the endorsement of KOLs, there is practically no chance of succeeding in the foreign market due to their paramount influence.

The second finding demonstrates the approach to manoeuvre through the complex regulatory landscape as this is more intricate than the theory suggests. The theory implies that political and regulatory activities can be governed in a rather simplified manner. On the contrary, the interviews argue that there is more than meets the eye as they unravel challenges such as fragmentation, non-unified federal states, and the rigorous and stringent approval procedure, for instance. The interviews indicate that the German healthcare market requires a separate clinical trial for its market as well. From my perspective, the main difference in stress put on the concept of navigating regulations was compelling. The interviews unraveled that the process of market entry by means of regulations is more prominent than initially hypothesised due to its stringent and rigorous government of regulations. This underscores the importance of comprehending the intricate regulatory environment, whilst the theory of Fuentelsaz et al. (2020) and Pogrebnyakov & Maitland (2011) is prompted to focus on the difference in institutions between the domestic and foreign market, rather than the institutions impact on the lengthy market entry process, for instance.

Previous studies have found that active networking facilitates market entry when internationalising as posited by Loane & Bell (2006). Johanson & Vahlne (2009) and Ojala (2009b) even stress the significance of networking during the internationalisation process, emphasising on nurturing business relationships with partners and other stakeholders. The results of this study consolidate these theories as evidence not only underscores the importance of networking during the internationalisation phase, but also demonstrates that contracts are imperative in this context; reliability and adherence to commitments accentuate the devotion to a network or relationship as per the results of the interviews. The importance of contracts adds another dimension to networking, that is not focused on in the theory. The process of concluding a contract, including the importance of negotiation and communication during this process, were discussed. However, the prominence of contracts for relationships is once more underscored during the interviews, albeit not extensively discussed in the theory. Additional evidence shows not only a positive

relationship between the extent of internationalisation and intermediaries, but explicitly focuses on a support department in the particular country. However, an own support department is often not feasible for SMEs, which means that intermediaries must bridge this gap; functioning as a support department requires product knowledge and, thus, training. Therefore, there are more perspectives on how an intermediary ought to bridge these gaps and facilitate market access. This complements the theory of Chetty & Blankenburg Holm (2000) and Oviatt & McDougall (2005), suggesting that intermediaries are crucial for market integration.

As a final thought, this study displays that the role of networking has a positive influence in on the internationalisation of SMEs in the healthcare sector. Since this study demonstrates to be a good addition to the literature, in the sections hereafter both academical and managerial implications are elaborated on since they can aid in developing new future research avenues and strategies in this context. This study has been conducted using ATLAS.ti for coding every interview and ChatGPT for the purpose of idea generation.

7.1 Research limitations and implications

Presenting limitations of this research is imperative as some areas are potentially excluded and unexplored, leading toward biases of conclusions and results (Greener, 2018). By providing limitations, the researcher adheres to the ethical element of scientific inquiry (Drotar, 2008), ensuring both the research' and the researchers' transparency (Annesley, 2010; Bunniss & Kelly, 2010; Chasan-Taber, 2014), transferability, reproducibility of methods, and endorsing the validity of the research (Ioannidis, 2007).

This thesis is predominantly focused on qualitative research and critical literature review i.e. desk research. Potential biases could arise as this thesis relies on fifteen interviews alone. Three of these cases were researched within the Dutch company I am doing this research for. These three cases are potentially biased as these interviewees have no particular knowledge of the German healthcare market, and currently do not have sufficient resources to their disposal. They merely hypothesised their expectations. Nonetheless, this leaves room for interpretation of the results. The sample size could be another limitation since a larger sample size, e.g. twenty interviews, would be more ideal as this would depict a more reliable projection of the German healthcare market in this case. Thus, we cannot exclude that the results would be different if we were to have a larger sample size. This could be an avenue for future research; upscaling the sample size and do a comparative study between the healthcare sector and other sectors in the context of the internationalisation of SMEs by means of networking, focusing on similarities and dissimilarities.

Although the results of this study appear to be aligned without many discrepancies, the quality of the study could be biased due to its subjective nature. Fifteen different professionals were interviewed, each presenting not only their own opinion on matters in this context, but also their perspective from their point of view. Conversely, these professionals look at the German healthcare market from different angles; there are some who view the market from a health insurance, cardiovascular, or diabetic point of view, resulting in an array of perspectives and opinions. This affects the results positively as lots of

angles on the market and networking are discussed. This could be a potential direction for future research, focusing on different subsectors, such as the cardiovascular or diabetic subsector, or pharmaceutical or medical devices particularly.

7.2 Managerial implications

This study delves into the effect of networking on the internationalisation process of healthcare SMEs, providing comprehensive insights into the healthcare market, particularly in Germany. Several facets in terms of networking have been highlighted in this study that have to be evaluated when entering a market abroad. From a managerial perspective, KOLs have to be taken into consideration. The findings not only suggest that KOLs are underemphasised in literature, but have to be taken into serious consideration as well for the reason that KOL endorsement is the cornerstone for entering a new, foreign market successfully. Engaging with KOLs can be accomplished by attending congresses and trade fairs, whereas active network engagement might lead to identifying KOLs as well.

Another managerial implication is engaging with intermediaries. Successful market entry is positively correlated with the use of intermediaries in the commencing stages. Distributors are said to be crucial when introducing a new product to a foreign market, for instance. Due to their market knowledge and know-how in the market, their role in the supply chain plays an important role. Other parties, that act as an intermediary, are crucial for market access as well since their insights in the market can assist in logistical support as well, but also facilitate communication between the parties involved, brokering relationships and aid in opportunity recognition and risk diversification. Finally, a third party that can provide support in the German market is necessary for successfully intergrating in the market, addressing the language and cultural barrier.

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