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The strategic determinants of choosing an inbound or outbound approach to Open Innovation. A practical application to Swedish and Italian pharmaceutical SMEs.

Master Thesis
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Abstract

In today's increasingly complex and competitive business landscape, SMEs face significant challenges in sustaining innovation with limited internal resources. Open innovation has emerged as the imperative from profiting in this environment, especially for a R&D intensive sector like the pharmaceutical one; yet little empirical evidence was found on how SMEs practically choose between the two main approaches of open innovation: whether an inbound or an outbound type. This study investigates the strategic factors guiding this choice by conducting six semi-structured interviews with pharmaceutical SMEs based in Italy and Sweden. Through the implementation of a qualitative, inductive approach and a subsequent cross-case thematic analysis, the following four key strategic factors were identified: strategic alignment, resource constraints, regulatory and cultural barriers, and the stage of the innovation lifecycle. The analysis of these findings exposes inbound open innovation as the preferred approach within the sample, particularly in early development phases and for knowledge and capabilities building, while outbound tends to be adopted for proprietary drugs and medicines closer to commercialization. Overall, this work attempts to extend the existing literature around open innovation by emphasizing the contextual, institutional and sectorial nature of open innovation in pharmaceutical SMEs. By doing so, this study also provides managers with actionable insights for navigating the innovation process in constrained SMEs.

1. Introduction

In an increasingly uncertain and competitive market, the growing globalization of economic activities has undoubtedly accelerated innovation demands. Therefore, innovation has become a pillar for achieving and sustaining long-term competitive advantage. According to Inauen & Schenker-Wicki (2012), firms need to remain competitive and continue growing by focusing on their innovation potential and on securing alternative commercialization options (Inauen & Schenker-Wicki, 2012). In this context, new models of innovation have emerged to enable the continuous technological advancement in organizations' offerings. Starting from the early 2000s there has been the rising concern that organisations are not able to innovate in isolation, having to engage with different types of partners to acquire new ideas and resources to become competitive (Leitão et al., 2020). This has been the first motivation behind Open Innovation that emerged as a new imperative for creating and profiting from technology (Chesbrough, 2003).

According to Chesbrough (2006), this model of innovation relies on the expansion of the organizational boundaries to benefit from externally and internally generated ideas and resources, ultimately leading to increasing the innovative potential of firms which might be constrained by singular efforts and limited resources (Chesbrough, 2006). In this context, organizations that want to exploit their resources to gain sustainable competitive advantage, often face the critical choice between two major open innovation practices: inbound open innovation, where external ideas and technologies are integrated into the firm's operations, and outbound open innovation, where the firm's internal ideas and technologies are shared with external parties (Leitão et al., 2020).

Since the foundation of Open Innovation, its adoption has varied across industries and firm sizes. Research indicates that firms in high-tech industries, where knowledge and technology evolve rapidly, tend to engage more

actively in open innovation strategies (Parida et al., 2012). Furthermore, among these industries, prior research has highlighted the strong R&D component of the pharmaceutical sector (Schuhmacher et al., 2013), as well as many other sectorial characteristics such as complexity in drug development and high failure rates that lead to the engagement in Open innovation (Gassmann et al., 2008). With these premises, the suitability of the pharmaceutical sector as the focus of this analysis appears to be highly relevant. Furthermore, open innovation was found to be highly diffused among SMES, given their lack of financial and human resources compared to big corporations, in order to remain competitive (K.V. & Hungund, 2022). This last information suggested the centrality of open innovation in SMEs, leading the focus of this work only on these types of firms.

1.1 Research problem

In a context where in order to remain competitive and ensure continuous growth without falling in the "valley of the death", organizations need to cooperate and engage in open innovation practices, it is often challenging to determine which is the most suitable course of action to pursue based on a firm's strategy. According to Wikhamn et al. (2019), the extensive research around open innovation seem to lack an empirical investigation of how companies practically perform open innovation activities. What this entails is that the existing literature lacks a thorough investigation regarding the factors, the inner thoughts and crucial determinants that shape the decision making regarding the open innovation strategy – whether inbound or outbound – to pursue. The absence of a guidance in understanding which are the strategic implications of both open innovation approaches, their specific challenges, and their suitability to different firms, leaves a gap in the literature and in managerial practice (Wikhamn et al., 2019).

1.2 Research purpose and research question

The aim of this research is to explore the strategic determinants of adopting an inbound or an outbound open innovation practice. The focus will be on

unveiling the strategic factors that underpin the decision behind the open innovation approach to adopt. Therefore, the outcome of the analysis aims to guide decision-making in pharmaceutical SMEs and their innovation strategy. Thus, to investigate the mentioned objective, a systematic and relevant research question (RQ) has been formulated:

RQ: What are the main strategic factors influencing the choice between an inbound or an outbound approach to open innovation?

With the use of "strategic factors" within the chosen RQ, there is the clear purpose of investigating the main drivers that make managers choose between an inbound or an outbound approach to open innovation. In simple terms, what are the decision-making drivers that make them prefer one open innovation strategy over the other? What are the motivations that shape the logic behind their choice?

Furthermore, the choice behind the formulation of this research question derives from the unavoidable awareness that, in today's business scenario, a closed innovation model is not possible anymore. That's because globalization, the transfer of knowledge and experience between organizations, the presence of many venture capitals and startups and an increasing competition are threatening the economic feasibility of organizations that innovate in isolation (Chesbrough, 2003). Thus, in such a context, there is the need of reading and understanding the real world through the lenses of the Open innovation Model applied to a highly innovative and research-driven sector like the pharmaceutical one. Having recognized the shift to this innovation approach, this work aims to study and empirically derive, through a qualitative research design, the main strategic determinants behind the choice between an inbound and an outbound open innovation mindset. With the attempt of achieving this result, this research aims to serve as a practical example for managers on how to choose the best approach to open innovation applied to their specific firm.

1.3 Delimitations of the study

Before delving into the following sections of this work, it is important to clarify its scope. In order to do so three main points need to be highlighted to draw the borders of the vast literature found around the topic of Open innovation. Firstly, as previously mentioned, this work will only focus on two main types of open innovation: the inbound and outbound type. A third type existing in previous research, referred to as: "coupled open innovation" (Gassmann & Enkel, 2004), being a combination of the first two, lies beyond the scope of this work as it is not considered to be a relevant and interesting parameter to explore. That's because the analysis of this third mixed approach might be seen as an overlap of inbound and outbound open innovation and a repetition of some characteristics of these two other types, therefore not adding any real contribution to this research. Thus, by focusing only on inbound and outbound open innovation this work aims to study and investigate the two extreme versions of open innovation.

Secondly, another point that needs clarification relates to the choice of the industry of interest for this research. As a matter of fact, this thesis is only focused on the pharmaceutical sector, thus not concerning other industries where open innovation might also play an important role. As previously mentioned, Open innovation not only strongly characterizes high-tech sectors, but is also related to R&D intensive industries like the pharmaceutical one where both the technological and the research component are highly present. Furthermore, this work delimitates once more the investigation by interviewing firms located only in Sweden and Italy. This choice derived from personal connections and network ties of the researcher to these two countries, making the search of sample's respondents a smoother process.

Lastly, the interviewed companies, from which the results were analysed, were restricted only to SMEs. The definition of SMEs employed for this research followed the European guidelines contained in the Article 2 of the Annex to

recommendation 2003/ 361/ EC of the European Commission. Thus, in line with the standard criteria emitted by the European commission, the interviewed companies in this research were chosen only after meeting the following eligibility criteria:

- Number of employers not higher than 250 people and,
- An annual turnover not exceeding EUR 500 million or an annual balance sheet not exceeding EUR 43 million.

The choice behind the delimitation only to enterprises which configurate as SMEs, derived from the interest in analysing the implementation of Open innovation in resource-constrained contexts where the need of collaborating with other entities to innovate is more relevant (K.V. & Hungund, 2022).

2. Literature review

In order to address the research question, the following section will present the most relevant research around Open Innovation (OI) as an alternative to the traditional model of "Closed Innovation". Furthermore, the focus will shift to the three existing types of Open innovation, namely inbound, outbound and a combination of the two referred to as "coupled". However, as previously mentioned, this work and the revised literature, will focus only on studies regarding inbound and outbound open innovation and on their strategic determinants. Following, this chapter will outline the main literature on these two approaches to Open Innovation applied to the pharmaceutical industry. Lastly, the main takeaways as well as key concepts will be summarized in a conclusive table.

2.1 Literature Review Methodology

Given the extensive literature found on Open innovation, this methodology section explains the criteria that were used for narrowing it down only to the most relevant studies, the databases and sources consulted, and the employed search keywords.

Firstly, to narrow down the research, inclusion and exclusion criteria were fixed to ensure the quality and relevance of the literature review. Regarding the former type, inclusion criteria were peer-reviewed journal articles and academic books. Furthermore, the chosen studies were those published from 2003 onwards, after the formalization of the Open Innovation concept by Chesbrough; the only exception relates to the use of concepts (e.g. absorptive capacity, etc…) developed in a context prior to the formulation of open innovation but which were used in the writing to support the explanation of certain theories. On the other hand, regarding the exclusion criteria, studies were excluded if they were not available in full text, derived from non-academic sources such as blogs or magazines, or dealt with innovation processes in big pharma without reference to SMEs.

Secondly, to gather the relevant literature, searches were conducted across reliable academic databases such as Scopus, Web of Science, ScienceDirect, Emerald Insight, Wiley Online Library, ResearchGate and Sage Journals.

As for the utilized search strategies, a range of keywords and search strings were used to include only relevant studies. These included keywords such as "Open Innovation" AND "pharmaceutical industry," "Inbound Open Innovation" OR "Outbound Open Innovation," "Strategic factors" OR "determinants" AND "open innovation," "Inbound vs outbound innovation" AND "small pharmaceutical firms" OR "SMEs," "pharmaceutical SMEs. These searches were conducted more than once, thereby with an iterative approach, since the employed keywords were continuously adjusted based on the quality and relevance of the screened material. This methodology aims to reach the most comprehensive coverage of the topic.

Lastly, after utilizing the mentioned strategies to gather the relevant material, the chosen academic sources were initially screened by reading their titles and abstracts. Furthermore, only the publications meeting the inclusion criteria were then subject to full-text analysis and later included in the literature review. Overall, this structured methodology ensured that the literature review remained consistent and focused, acting as a strong basis for the subsequent analysis and discussion of the strategic drivers behind inbound and outbound open innovation choices in pharmaceutical SMEs.

2.2 The Open Innovation paradigm

The concept of Open Innovation was first thought and introduced by its father Chesbrough (2003) that defined it as "the purposive inflows and outflows of knowledge to accelerate internal innovation, and expand the markets for external use of innovation, respectively" (Chesbrough, 2003). Through this definition, open innovation challenges the traditional closed innovation model by emphasizing the importance of external knowledge flows in the innovation

process. Indeed, in contrast to the conventional model, where firms rely solely on internal R&D, open innovation encourages firms to engage in inbound and outbound knowledge exchanges to enhance their innovation capabilities and market competitiveness (Chesbrough, 2012). The idea behind Chesbrough's intuition, according to Wikhamn et al. (2019), was meant to act as a critique to the traditional vertical integration model characterized by an incumbent firm closed in its organizational boundaries in order to actively protect its Intellectual property rights (IPRs) from external exploitation, preserving the internal resources, time and energy utilized in developing a particular product or technology (Wikhamn et al., 2019). Furthermore, differently from the previous approach, Open Innovation allows firms to enhance their innovative capabilities by collaborating with external stakeholders such as customers, suppliers, research institutions, and even competitors (Bogers et al., 2019). This view is also shared by Mortara & Minshall (2011), who agree that the implementation of OI as a paradigm is considered to boost the innovation potential of firms (Mortara & Minshall, 2011).

While the "closed model" to innovation relies on rigidity and individualism, the approach under study is characterized by the permeability of firm boundaries, facilitating the exchange of ideas, technologies, and knowledge between a company and its external environment (Chesbrough, 2017). As previously mentioned, in this context firms can decide which type of open innovation to pursue, namely: "Outside-In (inbound), Inside-Out (outbound) and the combined "Coupled type" (Chesbrough & Bogers, 2014). Even if three different types of approaches to open innovation are present in literature, this work will only focus on understanding whether to follow an inbound approach to innovation, which refers to acquiring external knowledge to enhance internal innovation processes, or and outbound one, which involves firms leveraging their internal knowledge, expertise and extensive research by sharing it with external actors (Gentile-Lüdecke et al., 2020). This model has proven to be particularly beneficial for SMEs, which often lack resource and can thus benefit from external partnerships (Lee et al., 2010).

2.2.1 Why is it a "paradigm shift"?

While it is important to introduce and define Open Innovation as a new paradigm for Innovation within firms, it is crucial to understand in which way we can define it as a shift from the previous established model of innovation. Firstly, it was Chesbrough (2003) that referred to the old paradigm as "Closed Innovation" since the whole innovation process happened inside a firm making organizations strongly self-reliant and internally focused on their R&D processes. This logic can be extensively explained by *Figure 1*.

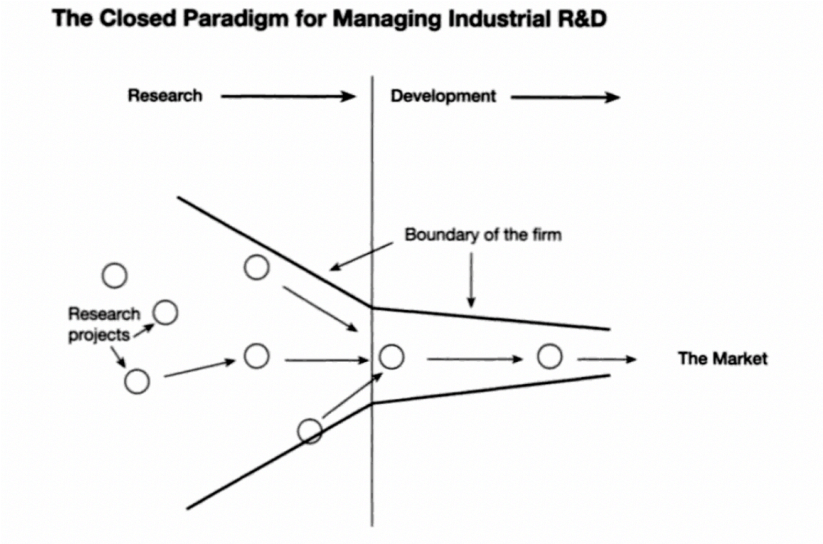

Figure 1 – Closed Innovation paradigm

Source: Chesbrough, 2003.

The above figure mainly describes how projects following the "Closed Innovation" paradigm work; they start from the left of the figure and their research and development is entirely conducted inside the firm before delivering the products or services to the market. Therefore, utilizing Chesbrough's words, firms that engage in this model: "generate their own ideas and then develop them, build them, market them, distribute them, finance them, and support them on their own" (Chesbrough, 2003). This logic enabled firms to be present in the entire value chain of their products, directly realizing more sales, earning higher margins from them and benefitting from non-disclosing their Intellectual properties (IP). As a matter of fact, in this model

IP was seen as an important tool used as a barrier to protect firms' innovations and provide freedom in utilizing their own products or technologies (Chesbrough, 2017).

While this way of delivering value has proven to be efficient for a long time, as mentioned before, today's business landscape has changed and, in order to thrive and grow in it, a new approach is needed (*Figure 2*).

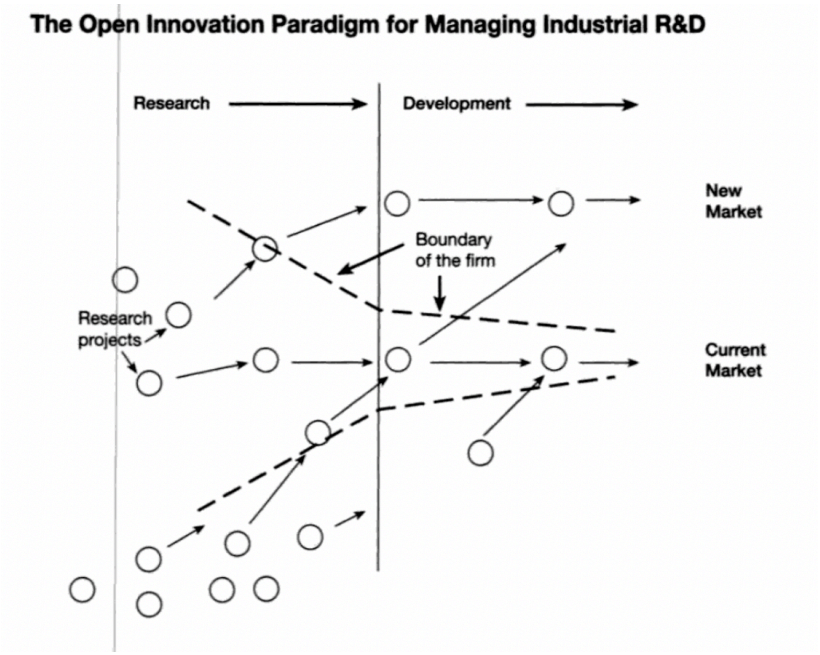

Figure 2 – Open Innovation paradigm

Source: Chesbrough, 2003.

According to Chesbrough (2003), there have been certain "eroding factors" that contributed to disrupt the business environment. Firstly, the increasing trend of changing job performed by highly skilled people transferred the acquired knowledge and experience between organizations. Furthermore, knowledge spillovers from universities to organizations increased as well as the higher presence of venture capitals that gave rise to startups, which started challenging large established organizations and contributed to increasing competition. Therefore, as can be seen from *Figure 2*, the new awareness that outside options existed, completely broke the whole idea of the "Closed Innovation paradigm" and introduced the possibility that the research and

development of products and services can be derived both internally and externally to the organizational boundaries (Chesbrough, 2003).

2.3 Types of Open Innovation

As previously mentioned, there are three main Open Innovation process archetypes that can be found in literature. By conducting a case study on IBM Industry Solution Lab Zurich, Gassmann & Enkel (2004) were able to derive an extensive framework for Open Innovation that identified three main open innovation core processes (*Figure 3*):

- *Outside-in process:* firms can improve their innovation potential by integrating their own knowledge with external sources such as suppliers and customers.
- *Inside-out process:* firms can profit from their innovations by sharing their ideas and technology to the external environment and by selling their IP.
- *Coupled process:* firms can combine outside-in and inside-out processes by engaging in giving and taking with complementary partners.

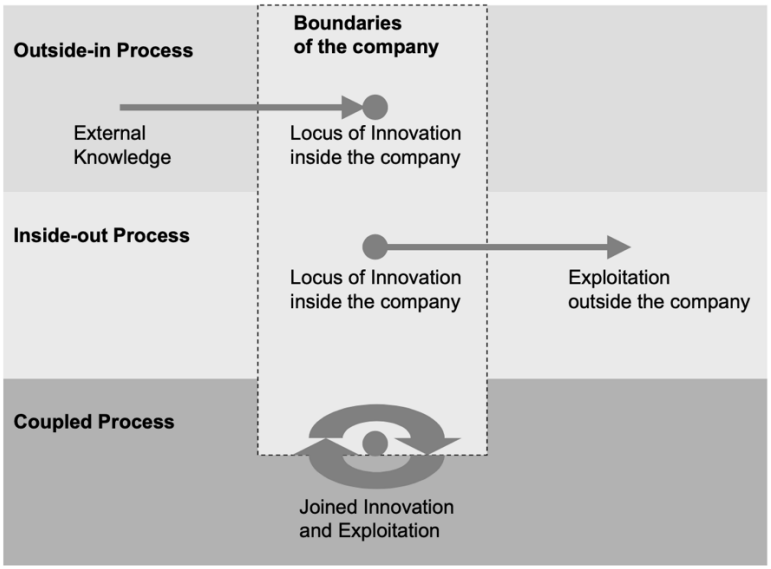

Figure 3 – Three Open Innovation Process Archetypes

Source: Gassmann & Enkel, 2004.

2.3.1 The two main approaches to Open Innovation

After having defined Open Innovation and introduced its three main declinations, it is important to focus the revision of the existing literature only around the two central approaches of this work: outside-in (inbound) and inside-out (outbound) Open Innovation.

According to Chesbrough & Crowther (2006), a first definition of "inbound" Open innovation can be expressed as "the practice of leveraging the discoveries of others". This implies that firms need to shift from the Closed innovation mindset and choose not to rely only on their internal R&D efforts. On the other hand, with the term "outbound" Open Innovation, the same authors refer to the possibility of organizations to look for other companies that can better commercialize a certain innovation or technology. Furthermore, while these authors have focused their research on "inbound" practices, they agree that both approaches are reciprocal in the sense that an organization's "inbound" effort triggers automatically an "outbound" one (Chesbrough and Crowther, 2006). Also, in an attempt to explain the big amount of literature around Open innovation, Chesbrough & Bogers (2014) highlight that most of the research is conducted around the inbound type of open innovation (Chesbrough & Bogers, 2014). This is also shown by research conducted by West & Bogers (2014) that reviewed 165 publications around open innovation and found out that the majority of the reviewed material addressed inbound open innovation *(Table 1)*. In particular, 118 publications out of the total number of reviewed documents regarded inbound open innovation, while only 50 addressed the outbound type (West & Bogers, 2014).

Count of open innovation articles by mode

Open Innovation Mode(s)†	Outbound	No Outbound	Total	Remarks
Inbound only	24	57	81	
Inbound and Coupled	11	26	37	All Inbound: **118**
Coupled only	1	32	33	All Coupled: **70**
Total corpus	36	115	**151**	
Neither inbound nor outbound	14	0	14	
Total open innovation	**50**	115	**165**	

Table 1 – Count of Open Innovation articles by mode

Source: West & Bogers, 2014.

However, regarding the outbound type, it has been recorded an increasing interest towards IP, licensing and many other expressions of this approach to Open innovation (Chesbrough & Bogers, 2014). Furthermore, differently from the majority of the authors, Chesbrough (2021) considers the outbound type of open innovation not less relevant than the inbound one. In fact, through the concession of licenses, the creation of new ventures (spinoffs) or by creating a joint venture with external parties, the outbound type of innovation is the approach that enables to discover new business models for underused internal technologies or innovations (Chesbrough, 2021).

While further researching around these two topics, it appeared clear that there are different ways commonly used to refer to "inbound" and "outbound". According to Mortara & Minshall (2011), the literature appears to have distinguished two directions around which OI processes create, and which are the "outside-in" and the "inside-out" directions of knowledge flows. While the expression "outside-in" refers to exploration activities, the phrase "inside-out" is associated to exploitation practices (Mortara & Minshall, 2011). Inauen & Schenker-Wicki (2012), agree that, with the establishment of the paradigm of Open Innovation, also two different approaches have been identified: "outside-in" and "inside-out". While the former approach focuses on the collection of ideas from outside the firm, the latter approach gives importance on how to commercialize innovations and make them enter new markets (Inauen & Schenker-Wicki, 2012).

1. Inbound

As mentioned before, by revising the existing literature on the two main approaches to Open Innovation – inbound and outbound – the vast academic research present on the topic has paid more attention to the "outside in" type (Chesbrough & Bogers, 2014). According to these authors, when defining Open Innovation paraphrasing Chesbrough's words (2003), there is the idea of a distributed innovation process based on knowledge flows which are deliberately directed across organizational boundaries (Chesbrough, 2003). In the context of inbound OI, these knowledge flows are directed towards the focal organization by exploiting external knowledge and technological sources, to boost the innovative degree of a firm.

Given that outside-in open innovation focuses on external sources of information to implement internal R&D, it is of paramount importance to understand which types of actors are eligible for this role. According to Inauen & Schenker-Wicki (2012), different examples of sources outside the organizational boundaries can be considered customers, suppliers, competitors, cross-sector companies and universities (Inauen & Schenker-Wicki, 2012). These external actors can take part to the R&D activities through technology in-licensing, acquisition or joint venture, ultimately leading to an increased innovative potential for the firm (Spithoven et al., 2010). Since firms need to find these external parties with which engage in inbound OI activities, it is crucial for them to present the appropriate search processes within the firm that would allow them to scan the environment and source the required technologies and innovations. The mentioned "search processes" make up the ability of "absorptive capacity" that should be present within the firm's boundaries. According to Cohen & Levinthal (1990), absorptive capacity can be defined as: "the ability of a firm to recognise the value of new, external information, assimilate it, and apply it to commercial ends'' (Cohen and Levinthal, 1990: 128). This implies that organisations need to be able to detect valuable external information and absorb it within their own organizational structure. In other words, firms need to generate this absorptive capacity to be

able to benefit from inbound open innovation and successfully manage it (Spithoven et al., 2010). Furthermore, according to Cohen & Levinthal (1990), this ability could be encouraged by increasing in-house R&D as well as stimulated in the production process or generated by enhancing the technical training of employees. These three options suggest that companies which intensively engage in R&D activities might have a higher probability to generate "absorptive capacity" and, consequently, engage in inbound open innovation practices; this would leave less space for SMEs, which often lack resources, to perform this type of open innovation activity (Cohen & Levinthal, 1990). However, despite the low level of absorptive capacity of small and medium enterprises, the literature on the topic states that companies of these sizes in traditional sectors do not refrain from engaging in inbound open innovation (Muscio, 2007; Spithoven et al., 2010).

It was previously mentioned that stimulating in-house R&D is crucial to generate absorptive capacity in firms. On this matter, Bogers et al. (2019) believe that starting from the 1990s internal R&D has drastically decreased in firms, leaving space for Open innovation to grow as the imperative. However, the authors underline the fact that in-house R&D and open innovation need to be seen by managers as complementary and affirm that: "the one without the other is unlikely to succeed" (Bogers et al., 2019: 79). As a matter of fact, the required absorptive capacity that enables the transfer from external sources of technologies or innovations is strongly linked to internal resources. This clarifies how important internal research is in generating absorptive capacity, which in turn is crucial for inbound open innovation to happen.

Common characteristics of outside-in open innovation

According to Gassmann & Enkel (2004), If companies decide to adopt the "outside-in" process as their core open innovation approach, they choose to cooperate with suppliers and customers and to integrate the acquired external knowledge. These types of cooperations can take different forms such as customer and supplier integration, listening posts at innovation clusters,

applying innovation across industries, buying intellectual property and investing in global knowledge creation (Gassmann & Enkel, 2004). Furthermore, depending on the level of organizational integration, firms might choose to engage in inbound open innovation by technology sourcing and acquisition, strategic alliances with external suppliers or a collaborative joint venture (West & Bogers, 2014).

While the forms that outside-in process can take are clear, it is important to understand which characteristics are typical in firms that undertake these practices. Firstly, it needs to be underlined that companies that choose this approach to innovation as their core process, need to present competencies and abilities in managing other supply chain members like customers and suppliers and in integrating knowledge and resources coming from these external sources (Fritsch & Lukas, 2001; Gassmann & Enkel, 2004). Evidence from a supplier integration can be seen in enhanced products, fewer technical problems, optimized use of internal resources, easier access to new products and technologies, improved projects' success and ability to innovate (Gassmann & Enkel, 2004).

Moreover, as it can be seen in *Figure 3,* the "outside-in" open innovation type represents a situation where the "locus of knowledge creation", which is external to the organizational boundaries, doesn't coincide with the "locus of innovation", internal to the firm. Gassmann & Enkel (2004) try to explain this situation by summarizing *(Table 2)* the main characteristics and determinants that encourage certain firms to engage in these activities.

Characteristics	Outside-in process
Low tech industry for similar technology acquisition	Earlier supplier integration
Act as knowledge brokers and/or knowledge creators	Customer co-development
Highly modular products	External knowledge sourcing and integration
High knowledge intensity	In-licensing and buying patents

Table 2 – Characteristics of the outside-in process

Source: Gassmann & Enkel, 2004.

Firstly, a common trait between these types of companies is that they are often involved in low tech industries or typically configurate as companies that leverage technologies spillovers from higher tech industries. Another characteristic is the engagement of these firms in knowledge brokerage activities and/or knowledge creation ones for bigger companies. In addition, the high modularity of their products was also found to be a relevant element (Gassmann & Enkel, 2004). That's why, according to Vickery et al. (2015), modularity is the attribute of a product or process of being made of smaller "subsystems" that can be originated independently and work together (Vickery et al., 2015). This definition shows how companies detaining such products in their portfolio might be encouraged to engage in co-development as well as any other external partnership. Lastly, firms involved in high-knowledge intensity industries might have the need to get out of their organizational boundaries to acquire knowledge and, thus, engage in inbound open innovation.

2. Outbound

According to Inauen & Schenker-Wicki (2012), the term "inside-out" Open Innovation is used to address the commercialization of internal ideas as well as technologies through external means (Inauen & Schenker-Wicki, 2012). The rationale behind companies that engage in this practice is to externalize their

internal knowledge, innovation or technology to decrease the time-to market that would be needed if the innovation was internally developed (Gassmann & Enkel, 2004). Some examples of this approach are given by Enkel et al., with the practices of profiting through selling intellectual property (IP) and contributing to technology sharing through the transfer of ideas to the outside environment (Enkel et al., 2009). In this context, by going outside the organizational boundaries, profits are generated by transferring ideas and technologies to other companies (Inauen & Schenker-Wicki, 2012). For instance, it is a common outbound open innovation practice to commercialize ideas between different industries, therefore generating a *cross-industry innovation*. This practice is well known to happen in the pharmaceutical industry, where drugs initially formulated for one purpose, later become popular for other applications. This is the story behind the development of successful drugs such as Viagra, which went from a blood pressure controller to a sexual aid, and Botox, which was first introduced as a nerve toxin but then used as a beauty tool (Gassmann & Enkel, 2004).

As mentioned before, while extensive research is present around inbound open innovation, in the case of outbound there is generally less focus (West & Bogers, 2014; Gentile-Lüdecke et al., 2020). However, a growing interest in this approach is shown by the research present around IP and licensing (Bogers et al., 2019). The connection between the outbound type and licensing might be explained by the fact that, according to Spithoven et. al (2010), certain companies might find other firms better suited to commercialise their technology or innovation in the form of IP or brand-out licensing (Spithoven et al., 2010). Furthermore, licensing is considered to be one of the most important expressions of "inside-out" open innovation (Inauen & Schenker-Wicki, 2012). According to Chesbrough & Bogers (2014), licensing allows "unused and underused" ideas and resources of one firm to get out of the organizational boundaries and be used by other firms in their own business models (Chesbrough & Bogers, 2014). As a matter of fact, this outbound form of open innovation encourages a wider adoption of a company's technology since it

gives the opportunity for other firms to access these innovations through licenses and consequent royalties, which are sufficient to scale-up the investment (Bogers et al., 2019). However, the benefits deriving from the "outward technology transfer", which is how Lichtenthaler (2009) refers to outbound open innovation, are not merely the financial ones. In fact, when undertaking outbound open innovation, firms aim to generate monetary as well as strategic outcomes (Lichtenthaler, 2009). Examples of firms making hundreds of millions of dollars from annual licensing are Texas Instruments (Rivette and Kline, 2000; Inauen & Schenker-Wicki, 2012) or IBM from licensing and selling its intellectual property rights (IBM, 2010; Inauen & Schenker-Wicki, 2012). On the other hand, regarding the strategic advantages of outbound practices and, in particularly, licensing, firms might manage to set their technologies as industry standards (Lichtenthaler, 2009) or improve their brand reputation on the market (Inauen & Schenker-Wicki, 2012).

Common characteristics of inside-out open innovation

The open innovation paradigm and especially the inside-out process, as shown in the previous *Figure 3*, illustrate a situation in which the "locus of innovation" is not necessarily equal to the locus of exploitation. As explained before, with outbound practices, companies decide to externally transfer and commercialize their innovations and technologies.

In order to understand which are the key characteristics of companies that engage in these practices, Gassman & Enkel (2004) visually summarize them *(Table 3)* and point out that these firms are often research driven.

Characteristics	Inside-out process
Research driven company	Bringing ideas to the market
Objectives: ● Decreasing R&D fixed costs ● Branding ● Setting standards via spillovers	Out-licensing and/or selling IP

Table 3 – Characteristics of the inside-out process

Source: Gassmann & Enkel, 2004.

These companies have the common goal of decreasing their R&D fixed costs and sharing the associated risks; this is how pharmaceutical companies like Novartis act when they outsource parts of their development processes. Moreover, another common trait of firms involved in outbound open innovation, might be a lower brand recognition since many organizations might have developed the right technology without having the needed presence to commercialize it in certain markets (Gassmann & Enkel, 2004). Indeed, firms with these attributes might benefit from partnering with firms with a higher brand recognition, exploiting their strategic position on the market, ultimately increasing their reputation (Inauen & Schenker-Wicki, 2012). Lastly, as mentioned before, another popular motivation behind these open innovation practices, relies on trying to set a technological standard. This is also achieved by partnering with other companies with their own proprietary technology only to expand their innovation on the market as a standard (Gassmann & Enkel, 2004),

2.4 Open innovation in the pharmaceutical industry

2.4.1 Relevance of the pharmaceutical industry

After examining the literature on the general topic of open innovation, the focus will now be on open innovation applied to the pharmaceutical industry. The choice behind this sector is linked to the high relevance of Research and development for breakthroughs in this field. Indeed, according to

Schuhmacher et al., (2013), pharmaceutical companies, like Novartis and Roche, are positioned among the top-spenders in R&D. Furthermore, the increasing cost in clinical research fundings as well as the need for more R&D personnel, have contributed to increasing the overall complexity of the sector and stimulated the diffusion of Open innovation (Schuhmacher et al., 2013). Additionally, some characteristics of the pharmaceutical industry such as the complexity of drug development, high failure rates, and strict regulations made open innovation suitable for this sector (Gassmann et al., 2008).

Researching on the sectors of implementation of open innovation, according to Inauen & Schenker-Wicki (2012), some of the first industries to gradually further develop in the innovation process were the high tech, electronics, telecommunications, pharmaceutical and biotechnology ones (Inauen & Schenker-Wicki, 2012). This is backed up by Chesbrough and Crowther's prior research (2006) that tried to find evidence of Open innovation practices in industries different from the so-called high-technology ones, namely computers, information technology, and pharmaceuticals, which showed the highest adoption of open innovation practices (Chesbrough & Crowther, 2006). These authors also went beyond these "early adopters" industries and extended the evidence of the application of open innovation also to other linked medical areas such as medical devices, chemicals, and bioscience tools and services (Yeung et al., 2021).

Moreover, other than the technological driver that was common to the early-adopters industries involved in open innovation, therefore also the pharmaceutical industry, also the need for decreased fixed R&D costs and their associated risks became crucial motivations behind the origin of OI within this industry. In fact, risk-sharing collaborations, co-creation and knowledge transfer agreements with partners, competitors or research institutions represent popular forms of open innovation collaborations in the pharmaceutical and biotechnological industry. An example of this type of collaboration is the well-established partnership between Novartis and the

Massachusetts Institute of Technology (MIT), which represents a real-world example of knowledge transfer from a university to the business world (Inauen & Schenker-Wicki, 2012). According to Yeung et al. (2021), another example of collaboration in the healthcare industry is crowdsourcing, which leverages on the use of large groups of people to find innovative solutions in medical research (Yeung et al., 2021). Examples of this approach are innovation challenges (e.g. prize competitions, contests, open contests), hackathons, which are short events that encourage different individuals to work for a common goal, and online systems for collaboration (Tucker et al., 2019). Furthermore, Wikhamn et al. (2019), further specifies that the last mentioned crowdsourcing activities as well as the mentioned innovation contests often opt for inbound open innovation (Wikhamn et al., 2019).

These forms and examples of collaborations, that can be found in the existing literature, refer mainly to established firms in high-tech and consumer goods industries. However, few studies have empirically analysed how large pharmaceutical firms partner with smaller firms for knowledge sharing. In these cases, these collaborations of ten take place in the form of bilateral, contract-based agreements, where issues related to intellectual property rights and appropriability concerns become crucial (Wikhamn et al., 2019).

1. Inbound Open innovation

Evidence of the application of inbound open innovation to the pharmaceutical industry comes from an in-depth analysis of the existing literature conducted by Wass & Vimarlund (2016) that showed that this type of open innovation was the most popular approach (Wass & Vimarlund, 2016; Yeung et al., 2021). Regarding the technical aspects of Inbound open innovation in the pharmaceutical industry, this practice primarily involves sourcing external knowledge to complement internal capabilities. This strategy enables firms to integrate new scientific discoveries, access novel drug candidates, and leverage specialized expertise that may not be available in-

house (Chesbrough & Crowther, 2006). According to Schuhmacher et al. (2013), accessing external know-how might also stem from the need for shorter development times and costs, as well as from the strategic move of outsourcing specific knowledge, which is deliberately kept out of organizational boundaries, to external parties (Schuhmacher et al., 2013). Examples of different forms of inbound OI in this industry are collaborative agreements with biotech firms, research institutions, and universities in order to enable a smoother access to last generations technologies and reduce R&D costs (West & Bogers, 2014).

According to Schuhmacher et al. (2022), there are various drivers behind the internal use of external knowledge. For instance, as already mentioned, some companies increasingly invest in close partnerships with universities and other research institutions to access complementary skills and competencies. In addition, companies create innovation incubators, regional hubs or networks to aid collaboration between the academic world and external scientists to enable the rapid start-up of new business ideas. Furthermore, another inbound practice named "outcubation" was mentioned in the literature. While it was found to be another process aimed at linking academic and corporate world, this practice is not reserved to top-notch universities but gives access to a broader group of people to take part to the innovation process (Schuhmacher et al., 2022).

Regarding the positive aspects that were previously mentioned on inbound open innovation, these include a reduction in the costs, a quicker innovation process, and the opportunity of accessing diverse knowledge sources (Gassmann & Enkel, 2004). However, challenges such as property of intellectual property (IP), and regulatory and integration barriers between entities, need to be considered to benefit from engaging in inbound open innovation. In this direction, companies must establish solid governance and control structures to perform open innovation while protecting their proprietary technologies (Lichtenthaler, 2011).

2. Outbound Open innovation

Regarding the second investigated type of OI, outbound open innovation in the pharmaceutical industry leverages on externalizing internal knowledge and technologies. This approach enables firms to deliberately externalize and monetize from non-core innovation, maximise their market presence, and create alternative sources of profit (Lichtenthaler, 2011). What happens in practice is that large pharmaceutical firms frequently out-license patents and technologies to smaller biotech companies, enabling the latter to further develop and commercialize innovations that may not align with the strategic objective of the focal firm (Gassmann & Enkel, 2004). Furthermore, by studying inside-out open innovation in the bio-pharmaceutical industry, Bianchi et al. (2011) found out that some activities undertaken mainly during earlier stages, such as clinical tests and post-approval processes, have the purpose of securing a better and more rapid market access (Bianchi et al., 2011).

Furthermore, also strategic motivations play a significant role in outbound innovation decisions. Indeed, by engaging in this practice, firms must strike a balance between the potential short-term financial gains and the prospect of their long-term competitive position, ensuring that the externalization of proprietary knowledge does not reduce their market presence (Enkel et al., 2009). As a matter of fact, examples of challenges derived from engaging in outbound open innovation are IP leakage, misalignment of incentives between partners, and regulatory constraints in the pharmaceutical industry (Gassmann et al., 2008). Given the evidence of these threats to outbound OI, effective governance mechanisms need to be established to preserve internal knowledge.

In conclusion, Open innovation has become a crucial strategy in the pharmaceutical industry, enabling firms to speed up the drug development process, reduce costs and externalize non-crucial activities. Both inbound and

outbound approaches come with unique benefits and challenges which will be described in the following paragraph.

2.5 Critiques and Limitations of the Open innovation model

In the previous sections the main characteristics of Open innovation have been highlighted, and they've mainly configured as benefits that this model generates for firms. Firstly, according to the father of Open innovation Henry Chesbrough, this innovation approach enables companies to reduce fix costs for R&D and acts as a new source of research funding (Chesbrough, 2006). Another benefit of this model is represented by the possibility of sharing risks of R&D projects, products or technologies with partners or competitors (Herzog, 2008; Inauen & Schenker-Wicki, 2012). This implies that the emergence of the mentioned risk-sharing collaborations is especially suitable for the pharmaceutical and biotechnological industry, where high-risk R&D projects and significant costs are involved (Reepmeyer, 2006; Inauen & Schenker-Wicki, 2012).

However, as every approach, while many studies have often demonstrated the success of open innovation practices, especially in large firms, few publications have shown also the failures, obstacles and underperforming or interrupted projects implemented with open innovation (Chesbrough, 2021). According to Inauen & Schenker-Wicki (2012), there are barriers associated to the proper functioning of knowledge and technology markets that needs to be taken into account when adopting an innovation strategy. This concept traces back to what Arrow (1962) describes as the recurring problems of technology markets, namely uncertainty, indivisibility and appropriability. The last-mentioned issue is strongly related to the fact that ideas are unbreakable and can only be transferred once and, especially in the "inside-out" or outbound open innovation practices, this represents an issue (Arrow, 1962). As a matter of fact, firms that engage in this type of innovation strategy, bringing ideas from the inside to the outside of their organization, might incur in loss of profit from their revealed innovation or impossibility of capturing its associated

value. Furthermore, the value of a new idea or technology is not known until it is at least partially disclosed. That's why, having strong intellectual property rights is essential to limit the appropriability concern (Kim and Vonortas, 2006; Inauen & Schenker-Wicki, 2012).

Another limitation of the open innovation model is the fear of private investors to proceed with R&D investments for a new technology or innovation. This is because any innovation entails exciting opportunities as well as many risks since there is still no proof of concept behind the early development of a new technology. Indeed, while a promising new discovery aims to solve different issues and revolutionize customers' needs, in practice it may fail to generate its initial purpose and application, ultimately falling into the "Valley of death". In this context, no discovery can be further developed and successfully exploited, discouraging private investors to spend money in the R&D for new products or services (Chesbrough, 2021).

Moreover, according to Chesbrough (2021), in the end open innovation "is all about generating, disseminating and assimilating knowledge inflows and outflows" (Chesbrough, 2021). This relates to the concept of "absorptive capacity" already mentioned in the previous sections, which affirms that is not enough to discover new ideas or technologies; what's important is to transfer them to the right people and in the right places within firms. What this implies for firms is the need to have educated and highly skilled employees that can engage in job rotations and in high job mobility in order to share and transfer new acquired knowledge between organizations. Furthermore, job rotations within firms avoid the risk that business units might block the diffusion of innovation and hinder open innovation. Following on the human aspect of open innovation, an important contribution on this topic was given by research conducted by Hila Lifshitz-Assaf (2017) on the Johnson Space Center, a NASA infrastructure. In this context, NASA used Open innovation, in the form of crowdsourcing, as the tool to address the estimation of the occurrence of solar storms. What this initiative highlighted was the fact that NASA's brilliant

engineers, physicists and researchers were having issues in facing the contribution of external parties, through crowdsourcing, to the resolution of their technical task. As a matter of fact, despite the skills and top-notch academic background of these figures, NASA's employees found themselves unable to recognize the "distributed" value of open innovation and were failing to accept that, in accordance with the model, knowledge and innovation can happen without clear boundaries and that any individual can take part to it. The conducted study shows that individual identity is crucial in adopting innovation since opening organizational boundaries' questions professionals' roles within the organization (Lifshitz-Assaf, 2017). Therefore, this example sheds light on the importance for employees of regaining their identity, when engaging in open innovation, and in accepting knowledge and ideas coming from external sources. Furthermore, this relates to a frequent phenomenon that happens in R&D's departments, and which is referred to as the" Not Invented Here" (NIH) syndrome (Katz and Allen, 1982). This concept can be best explained as a negative attitude-based bias towards any kind of external knowledge. It consists of a rejection and devaluation of an external idea even when it might bring positive outcomes to the innovating organization. For these companies this tendency becomes economically damaging when knowledge is rejected despite being potentially very valuable (Antons and Piller, 2015). This is a recurrent characteristic of technology-based firms where R&D employees tend to discard everything that wasn't invented in their firm, ultimately hindering open innovation (Chesbrough, 2021).

Overall, despite the frequent negligence of academics in mentioning the obstacles and problems of Open innovation, the above section aimed at exposing also the failure and limitations of this model.

2.6 Conclusions

The following section will summarize the main takeaways and themes around Open Innovation. Furthermore, in order to aid the comprehension, a visual

table *(Table 4)* was included to gather the main pieces of relevant information from each section of the literature and their relative references.

The literature review started from acknowledging the occurrence of a shift from the closed innovation model to the Open innovation paradigm. The latter approach consists of a drastic change in how firms innovate. Indeed, Open innovation consists of enlarging the traditional closed organizational boundaries to allow firms to collaborate with partners to exchange knowledge, resources, and competencies. In this context, two main approaches were highlighted in the literature: the inbound and outbound ones. While the former approach is based on exploiting external knowledge to enhance internal capabilities, the latter focuses on externalizing internal innovations. Furthermore, some companies might employ a combination of these two approaches, utilizing the so-called "coupled" type of open innovation.

Moving on to the literature found around OI applied to the pharmaceutical industry, inbound open innovation is fundamental in accelerating drug discovery and development. By engaging this type of innovation strategy, firms can reduce R&D costs and increase the probability of discovering breakthrough innovations. On the other hand, outbound open innovation enables firms to monetize by externalizing secondary internal innovations and expand their market reach.

As suggested, the existing literature has supported the positive value of open innovation practices, especially in pharmaceutical firms. However, it also needs to be developed the so-called "absorptive capacity", a concept that was found to be present in the literature prior to the emergence of open innovation. Ultimately, the literature suggests that especially for outbound OI, small pharmaceutical firms should carefully protect the externalization of their proprietary technologies in order to avoid incurring in loss of control and misalignments between the focal firm and their partners.

Lastly, a conclusive section on the main critiques and limitations of Open innovation emphasized the crucial need of assimilation and integration of external sources of knowledge, especially in the case of "inside-out" open innovation.

Section	Concept	References
The Open Innovation Paradigm	Open innovation represents a shift from closed innovation models, emphasizing knowledge exchange beyond firm boundaries.	(Chesbrough, 2003; West & Bogers, 2014)
The Two Main Approaches to Open Innovation	Inbound innovation enhances firm knowledge by integrating external research, while outbound innovation leverages firm-created knowledge for commercialization.	(Gassman & Enkel, 2004; Chesbrough & Crowther, 2006; Mortara & Minshall, 2011; Inauen & Schenker-Wicki, 2012)
Open Innovation in Pharmaceutical industry	Open innovation is crucial for pharmaceutical firms due to the high costs and risks of drug development, driving collaboration with external partners.	(Gassmann et al., 2008; Wikhamn et al., 2019)
Inbound Open Innovation in the Pharmaceutical Industry	External collaborations, strategic alliances, and licensing agreements accelerate drug discovery and reduce R&D costs.	(Schuhmacher et al., 2022)
Outbound Open Innovation in the Pharmaceutical Industry	Firms commercialize internally developed technologies through licensing and partnerships to maximize market reach and profitability.	(Lichtenthaler, 2011; Bianchi et al., 2011)
Critiques and limitations of the model	Open innovation presents criticalities that are often overlooked by academia and mainly relate to the need for assimilation, integration and emergence of NIH syndrome.	(Lifshitz-Assaf, 2017; Bogers et al., 2019; Chesbrough, 2021)

Table 4 – Summary of Literature review

3. Methodology

This section analyses the methodological approach that has been followed to answer the research question and the whole purpose of this study.

3.1 Research design

When choosing the kind of research approach that best suited this research, the first thing that was addressed was the way by which knowledge was acquired. The induction approach was considered to be the most fitting option since it focuses on discovering patterns and associations derived from observations of the world, rather than starting from a previously stated theory (Ritchie et al., 2013). According to Patel & Davidson (2019), an inductive approach consists of moving from a particular data to a general theory (Patel & Davidson, 2019), meaning that the inductive logic utilizes evidence as the basis for a conclusion (Ritchie et al., 2013).

To address the research purpose and answer the research question, a qualitative approach has been chosen for this study. The rationale behind this research design is that it primarily emphasizes words rather than numbers, which is necessary to gain in-depth, real-world knowledge by various experts involved in the pharmaceutical industry. Furthermore, qualitative research has been chosen for its explanatory nature as it provides, according to Richie et al. (2013): "an essential tool for studying what lies behind, or underpins, a decision, attitude, behaviour or other phenomena" (Ritchie et al., 2013: 28). This is particularly fitting to the research purpose since this study seeks to explore the strategic underpinnings behind pursuing an inbound or outbound open innovation approach in pharmaceutical SMEs.

Furthermore, as for the chosen research design, qualitative research is well-suited for gaining deep insights into decision-making processes, motivations, and strategic considerations, which cannot be easily quantified (Ritchie et al., 2013). This aligns with previous research on open innovation in SMEs, which

often employs a qualitative research design to capture nuanced strategic decisions (Spithoven et al., 2010). By conducting semi-structured interviews with managerial figures in pharmaceutical SMEs, this study aims to uncover the main strategic factors that influence the complex decision-making that lie behind the choice between pursuing an inbound or an outbound open innovation strategy.

3.2. Data Collection

After having chosen the research design, it is of paramount importance to establish the chosen data collection methods. In order to understand whether natural occurring data – observations, documentary analysis, etc… – or generated data – interview and focus groups – are more appropriate for this research, it must be taken into account the type of data that best responds to the research question (Ritchie et al., 2013). In other words, the choice behind the nature of the collected data should be based on the type of data that best meets the research requirements. In this context, generated data has been chosen since it enables participants to share their own meanings, perspectives and interpretation of a topic. Thus, in order to investigate the main strategic determinants behind the open innovation approach to pursue, semi-structured interviews have been chosen as the type of data to further analyse and derive conclusions from.

3.2.1 Primary data collection

As it was previously mentioned, data for this study was collected through six semi-structured interviews. Regarding the choice behind the study's format, semi-structured interviews provide flexibility, allowing for the exploration of key themes while enabling respondents to elaborate on their experiences and perspectives (Ritchie et al., 2013). Furthermore, semi-structured interviews are consistent with the choices made so far regarding the methodology. As a matter of fact, qualitative analysis prefers words rather than numbers,

therefore, in-depth information is necessary to fill the literature gap and fit the purpose of an inductive approach.

This form of primary data was chosen since it gave the possibility of obtaining detailed information from experts and professionals in the pharmaceutical field, ultimately leading to a deeper understanding of the topic. Furthermore, semi-structured interviews provide a structure by which key questions are asked in the same way each time, ensuring consistency across the interviewees, while the interviewer does some probing for specific information; the probing is way less present than in unstructured interviews (Ritchie et al., 2013). These methodological characteristics assured the coverage of all arguments relevant to the research question while giving freedom to the interviewee on how to reply. The use of an interview guide, visible in *Appendix A*, provided consistency and structure to the interviews.

Search of respondents

In terms of identifying an appropriate sample to address the research question, there was a thorough and systematic research of the most suitable organizations to interview. As a matter of fact, the search process has been conducted through the use of the wide network of innovation hubs and university incubators both in Sweden – such as GU ventures, Vinnova and AstraZeneca Bioventurehub – and in Italy – Lazio Innova and Egualia. Thanks to the diverse ecosystems that these networks create, the chosen companies, while all being active in the pharmaceutical sector, they are specialized in the production and commercialization of different as well as complementary drugs, providing unique perspectives and heterogenous contributions to this research. The specifics about the chosen companies will be described more thoroughly later in this section.

After having utilized the mentioned means to get in touch with potential companies to interview, this research opted for the use of a non-probability and purposive sample. Being a purposive or criterion-based sample, the

selected companies were involved in the study only if possessing key criteria. In this context, the selection of participants was based on three main criteria: a) their status as pharmaceutical firms, restricting the scope only to firms involved and operating in the pharmaceutical industry, b) the evidence of their previous engagement in open innovation practices, and c) the configuration as SMEs. While the adhesion to criterion a) was easily found on companies' websites, the suitability of potential pharmaceutical firms to criterion b) was assessed only after a direct contact with the firm. Lastly, regarding criterion c), the configuration of the potential candidates as SMEs was assessed by following the definition of small and medium enterprises which was introduced by the European commission in 2003. The specifics of this definition were already addressed in the delimitations of the study included in the introduction of this work. In order to aid the respondents' search, a snowball sampling was used. In other words, prior interviewees have been asked to identify other people who perfectly responded to the fixed criteria. This approach facilitated the identification of potential interviewees involved in pharmaceutical SMEs. However, given that some sample members were generated through prior ones, the use of this technique could compromise the diversity of the sample. Therefore, in an attempt to mitigate this risk, some of the new respondents that had been identified by existing sample members were treated only as "link people" used to find other individuals who might fit the criteria and not as potential interviewees (Ritchie et al., 2013).

Selected companies

As previously mentioned, the use of innovation hubs and their networks ensured the creation of a heterogenous and diverse sample. In *Table 5*, there are the specifics about the selected companies' core businesses and locations.

Company	Core Business of the Company	Size of the company	Location
Company A	Commercialization of biopharmaceuticals specialized in rare diseases	150 employees	Sweden and Italy
Company B	Distribution and specialized training for aortic prostheses and CT imaging	20 employees	Italy
Company C	Production and commercialization of pharmaceuticals (primary care, specialty care, immunology)	100 employees	Italy (affiliates of US companies)
Company D	Production of Pharmaceuticals specialized in iron deficiency, dialysis, nephrology & rare disease	200 employees	Italy
Company E	Commercialization of Pharmaceuticals specialized in rare diseases and hemophilia	200 employees	Sweden and Italy
Company F	Development of drug specialized in the non-surgical treatment of LDH	10 employees	Sweden

Table 5– Companies' information

As it can be easily seen from *Table 5,* all the selected companies are involved in the pharmaceutical sector. Their core businesses range from the specialization in the production and/or commercialization of pharmaceuticals related to rare diseases as well as to diseases and conditions such as iron deficiency, dialysis and haemophilia (Company A, Company C, Company D, Company E). Other firms included in the sample are involved in the distribution of aortic prostheses (Company B) or in the development of a drug aiming at treating Lumbar disc herniation (LDH) with a non-surgical option (Company F). Therefore, given the vast variety of the selected companies' offerings, the use of a snowballing technique in this sample undoubtedly ensured diversity. Furthermore, what can be noticed by analysing the mentioned core businesses is the presence of R&D intensive companies (e.g. Company C, Company D, Company F) as well as firms that only commercialize and

distribute products whose development was outsourced (Company A, Company B, Company E), or companies that do both (Company C). This distinction was clarified in order to prove once more the heterogenous nature of this sample with firms that can share their unique experiences and perspectives – whether coming from a R&D or a commercial experience, or both – on the topic of Open innovation.

Regarding the location of the selected companies, the interviewed firms are located only in Sweden and in Italy. Regarding this choice, the existence of networking connections and ties with innovation hubs and platforms in these two countries enabled the researcher to have access to a wider and more relevant number of alternative companies to interview. Therefore, the choice behind the two countries doesn't relate to a structural suitability of the two geographies in relation to the concept of open innovation. Indeed, it was never in the purpose of the researcher to investigate the diffusion of inbound and outbound open innovation in Italy and in Sweden. However, the choice between the two countries was only the consequence of a personal choice of the researcher.

Selected respondents

Lastly, regarding the configuration of the sample, in *Table 6*, there are the details regarding the interviewees, their roles, and the technical information regarding the conducted interviews (e.g. medium, date and length).

Respondent	Company	Role	Medium	Date	Length
Respondent A	Company A	Market access director	Audio call	8/04/2025	28 min.
Respondent B	Company B	Founder & CEO	Zoom	14/04/2025	41 min.
Respondent C	Company C	Medical Manager	Written interview	14/04/2025	N/A
Respondent D	Company D	Sales Director	Audio call	9/04/2025	30 min.
Respondent E	Company E	General Manager of the Italian branch	Audio call	9/04/2025	29 min.
Respondent F	Company F	Founder & CEO	Zoom	3/04/2025	25 min.

Table 6 – Interviews' overview

As it can be seen in the above *Table 6*, the respondents' roles vary a lot across the companies. For instance, some of the chosen respondents were the founders and/or the CEOs of their companies (Respondent B, Respondent F), or at least the CEOs of one regional branch (Respondent E). Behind these choices, there was the awareness that the insights gathered from their point of views could provide an overall vision of the company, specifically focused on the strategic direction of the organization. Therefore, in connection to the research question, the choice of these respondents appeared to be in line with the whole research purpose. On the other hand, while the remaining interviewees had completely different roles, the choice behind these people was still directed to ensure consistency across the sample and relevance between the respondents and the research goals. For instance, the sample also includes a Market Access Director (Respondent A) and a Sales' Director (Respondent D) to provide the perspective of individuals specialized in the commercialization of pharmaceuticals to expand the market presence of their companies in other segments or geographies. All the selected respondents were chosen for their unique contribution to answering the research question. In particularly, thanks to their closeness to the firm's strategy and to the commercialization options of their core businesses, they all provided valuable

insights for understanding the strategic factors that shape their approach to open innovation.

Regarding the organization of the Interviews, they were first scheduled via email and then conducted through formal online meetings or telephone calls, depending on participant availability and preferences. Moreover, as for the structure of the interviews, they all started with a brief introduction of the research purpose, the interviewees' own presentation and the recognition of their contribution to the research. The focus on the interviews then moved towards the formulation of eight questions that can be found in the Interview guide *(Appendix A)*. All interviews were recorded with the consent of the participants and subsequently transcribed verbatim for analysis and to ensure a complete and reliable gathering of data.

3.3 Data Analysis

Moving on towards the handling of the collected data, its analysis was conducted using a process based on preparing the obtained data for a successive thematic analysis, as formulated by Braun and Clarke (2006) (Braun & Clarke, 2006). In order to condense and breakdown data, this process leveraged on the coding process which, according to Strauss (1987): "fractures the data and exempts the researcher from description, ultimately forcing interpretation to higher levels of abstraction" (Strauss, 1987: 55). As a matter of fact, this process started in Word where "open codes" or phrases of the transcribed interviews were highlighted using different colours depending on the specific topic. Following open coding, an axial coding process was conducted to group related codes into broader thematic categories. The third step consisted of the further condensation of concepts in broader topics, called "selective codes". This three-step process enabled the identification of four main themes: (1) strategic alignment, (2) resource constraints, (3) regulatory and cultural barriers and (4) innovation stage lifecycle. These

themes represented the key strategic factors influencing firms' preferences for inbound or outbound open innovation. A coding table is visible in *Appendix B.*

After conducting the coding process, to synthesize and compare results across the six different companies that were interviewed, a cross-case thematic matrix was developed. This matrix shows the representation of each theme in every company, enabling the identification of shared patterns as well as opposite ones for every emerged category. The matrix not only acted as a visual aid for the following findings but also served to ensure analytical rigor by translating raw data into thematic findings. The mentioned matrix is illustrated in *Table 7*.

Theme	Company A	Company B	Company C	Company D	Company E	Company F
Strategic Alignment	Innovation is assessed for long-term fit and guided by governance.	Driven by values and continuous feedback from clients.	Strategy evolves quickly in response to market and therapeutic needs.	Coherence is ensured across departments through planning.	Vision cascades from leadership to all teams globally.	Innovation is filtered through the core goal of market entry.
Resource Constraints	Keeps lean through pilots and avoids heavy internal investment.	Faced early turnover; now values team stability and capacity.	Resources depend on strategic choices and market context.	Constraints in staff and skills lead to outsourcing.	Limited R&D capacity drives reliance on deals and partnerships.	Funding and staffing limit internal efforts; partnerships fill gaps.
Regulatory and cultural and Barriers	M&A brings cultural challenges; regulation adds complexity.	Change is resisted; innovation requires mindset shifts.	Global shifts and compliance issues complicate innovation.	Strict rules limit communication and require outsourcing.	Mergers demand cultural alignment across functions.	Outbound deals face control risks; inbound limited by systems.
Stage in Innovation lifecycle	Inbound is preferred; piloting reduces risk and tests feasibility.	Inbound is dominant, supported by external knowledge intake.	Choice depends on opportunity and organization context.	Inbound is chosen when lacking skills or blocked by regulation.	Inbound is the core model after ending internal R&D.	Outbound is prioritized to support product launch and scaling.

Table 7 – Cross-case thematic matrix

This data analysis approach was chosen since it allowed an easier interpretation of the collected information from the interviews. This enabled the emergence of theory from qualitative data by representing a connection between the codes and the induction of a new concept. Therefore, this

structured data collection and thematic analysis provided a robust foundation for the findings presented in the next section.

3.4 Research quality

To ensure the quality of the research, the study followed key criteria for its qualitative rigor, namely credibility, transferability, dependability, and confirmability (Lincoln & Guba, 1985).

Credibility

Credibility is considered to be the qualitative equivalent of the reliability of research findings in quantitative studies which, in few words, is the extent to which a study can be replicated. Because of the uniqueness of qualitative studies, their replicability is often questioned, and it is substituted with terms like "trustworthiness" (Glaser & Strauss, 1967), or credibility (Ritchie et al., 2013). According to Lincoln & Guba (1985), credibility refers to how respondents individually perceive the relation between research findings and their own individual contribution (Lincoln & Guba, 1985). This characteristic of the study was enhanced through methodical data collection, verbatim transcription, and systematic coding. Furthermore, member checks to the selected respondents were employed where possible, allowing interviewees to validate the accuracy and the summary of their research interpretations. As a matter of fact, member checking is a tool that allows to negotiate research conclusions together with participants, ultimately leading to reduce the error in the validity of the research. This further validation of the respondents' answers was ensured through the conduction of conclusive and follow-up questions, as shown in the Interview guide *(Appendix A)*.

Transferability

Transferability was considered in order to ensure academic rigor. This characteristic concerns the replicability and generalisation of the research findings to other contexts. As previously mentioned, the generalisation of qualitative data appears to be more difficult since it lacks the objectivity of

quantitative analysis (Lincoln & Guba, 1985; Ritchie et al., 2013). In order to strengthen this feature, purposive sampling was used to represent variation among pharmaceutical SMEs, enabling patterns to emerge among firms involved in the same industry but with diverse core businesses.

Dependability

Regarding the characteristic of dependability, this concerns the extent to which the same research findings could be reproduced by a different researcher. In order to increase this feature, all the e-mail conversations with chosen respondents, interviews' records, and transcripts were kept and stored throughout every research phase. Furthermore, the coding table resulted from the coding process is visible in *Appendix B.* This high level of documentation, allows all the generated information to be available when required.

Confirmability

As for the confirmability issue, this addresses the extent to which the research findings are affected by the researcher's own biases, motivations, interests or perspectives (Lincoln & Guba, 1985). Especially in qualitative research there is the risk that the findings might be highly subjective and clouded by the researcher's judgement and interpretation. In order to minimize this issue, the potential level of subjectivity was reduced by presenting follow-up questions to respondents in order to find additional information about a topic that didn't emerge from the semi-structured interviews. Furthermore, a more transparent documentation of the findings was conducted by using a certain level of reflexitivity in the writing, especially in the current section of the methodology. The inclusion of reflexivity was chosen to ensure neutrality and objectivity of the research by showing to potential readers the key steps of the followed procedures that lead to the research conclusions.

3.5 Ethical Considerations

This study followed ethical research guidelines to ensure the respect of participants' rights, privacy and confidentiality. As a matter of fact, before

conducting each interview, participants were given the Interview guide *(Appendix A)* and a consent form outlining the purpose of the research, and they were reminded their right to withdraw at any time. All questions regarded only publicly available information about the interviewed companies and were anonymized, under request, to protect participants' identities. As it was visible in the previous tables, all the interviewees chose to keep their information anonymous. Therefore, the names of the selected respondents were substituted with the names: "Respondent A…, Respondent F", whereas their respective companies with names: "Company A…Company F".

4. Findings

This chapter presents the results deriving from the data analysis. By effectively displaying the results of this analysis, the chosen research design would hopefully emerge as the most suitable research project and the employed methods as the appropriate ones.

By conducting qualitative research in the form of semi-structured interviews, it was possible to draw results from comparing six different pharmaceutical SMEs and their respective respondents' perspectives. This process was carried out by arranging a coding structure *(Appendix B)* that allowed to fracture data in order to identify common strategic determinants behind the choice between an inbound or an outbound open innovation approach and, subsequently, compare them to arrive at our results. In order to display the findings more clearly, the current section will be broken down into the main themes and patterns that emerged from the previous coding and that were believed to be the most representative of the collected data. The selected themes will be treated as categories against which all the interviewed companies will be compared with the use of direct quotes, words and perspectives obtained through the transcribed interviews. Lastly, visual illustrations of the summarized findings will be included to ensure a more rigorous analysis.

4.1 Cross-case comparison of the concept of Open innovation

Firstly, before analysing in-depth the emerged main strategic drivers, it is important to reflect on the individual meaning given to the concept of Open innovation by the sample members. As a matter of fact, while following the Interview guide, one of the first questions regarded the personal definition and interpretation of open innovation within each firm and how they dealt with it in practice. Although all companies employ open innovation to varying degrees, the different meanings given to this concept differ significantly across firms. This emerged to be highly affected by the specific context, internal structure, strategic orientation and industry environment. *Table 8* illustrates

each company's own perception regarding open innovation and the practical implementation of this practice within the firms. In addition, the findings below present each firm's interpretation of the concept of open innovation based on their own descriptions and show similarities as well as contrasts across cases.

Company	**Companies' perceptions of Open Innovation**	**Example of Open Innovation Practice**
Company A	Accessing external competencies and resources	Uses consultants and partners to complement technical gaps
Company B	Learning-driven internal capability building	Transfers external learning (books, courses) into internal training programs
Company C	Strategic flexibility and unmet need response	Collaborates with universities and KOLs to co-develop treatments
Company D	Regulation-driven external reliance	Outsources data collection and collaborates in clinical research with universities due to compliance restrictions
Company E	Core inbound strategy via acquisitions	In-licenses assets and builds joint ventures instead of in-house R&D
Company F	Informal practice, partnership-driven	Seeks licensing or co-development deals to launch its proprietary injection

Table 8 – Different meanings attributed to Open innovation

Firstly, Company A perceives open innovation as a practical tool to acquire external competencies that are not internally developed. As noted by the interviewee:

"*Open innovation is an essential tool for us to access competencies and resources we don't have internally*" (Respondent A). The firm engages in open innovation by collaborating with external consultants to address technical issues as needed. This provides an example of project-based, inbound open innovation used to enhance efficiency.

Another view is shared by Company B which describes open innovation in terms of continuous self-learning and internal knowledge building. In this context, rather than focusing on external acquisitions, the firm absorbs outside knowledge and translates it into cultural and professional development. The CEO stated:

"*From the moment I opened the company, I began training myself… These learnings generate inbound innovation.* By reading books, attending advanced training, and analyzing external models, I gather insights that I then translate into our daily operations." (Respondent B). *Examples of these continuous learning and training initiatives involved* coaching, exploring AI, public speaking and even on practicing mindfulness. What these examples provide is the proof of a high level of embeddedness between open innovation and organizational learning routines.

In addition, Company C points out that strategic adaptability plays a crucial role in its innovation approach. In particular, the company sees open innovation as the ability to continuously adapt to new needs in the market or therapeutic areas. As the CEO explained:

"*The primary element of innovation is a company's ability to rapidly redesign its strategies*" (Respondent C). The ways by which this company engages in open innovation is through collaborations with universities and KOLs to co-develop drugs and medicines. Therefore, in this case there is the use of both inbound and outbound activities depending on the market opportunity and product maturity.

Company D shares a completely different experience by engaging in open innovation mainly because of regulatory structural constraints. Given that internal development is limited by compliance to sectorial regulations, the firm relies on outsourcing for research and data. According to the interviewee:

"We rely on an external resource... this can be seen as a feature of the pharmaceutical sector" (Respondent D). Examples of these are collaborations with universities for epidemiological studies and outsourcing activities involving patient contact. The approach is largely inbound, and compliance driven.

Furthermore, with no internal R&D pipeline, Company E relies entirely on acquisitions, licensing, and partnerships to innovate. As affirmed by the company's Italian General manager:

"We completely shut down our internal research and development line… we seek business development opportunities based on acquiring assets, partnerships, or joint ventures" (Respondent E). This makes open innovation a core business activity since no internal innovations are developed. Thus, the utilized model is inbound, using external sources to enrich their rare disease portfolio.

Lastly, while open innovation is not formally defined internally, Company F engages in similar practices such as outbound licensing and collaboration with academic institutions. The CEO mentioned:

"We haven't formally adopted open innovation in a wide sense, but we do engage in practices that reflect that approach" (Respondent F). As a matter of fact, the company is currently preparing its proprietary drug for commercialization and is exploring co-development and licensing opportunities to bring their product to market.

Overall, while some firms (e.g. E and A) use open innovation as a business model, others (e.g. B and D) use it to fill learning or regulatory gaps. Outbound innovation, instead, tends to appear in firms that are closer to the commercialization stage (e.g. Company F).

4.2 The identified strategic determinants behind Open innovation

This section will present the four identified themes which emerged from the previous coding process, and which correspond to the main strategic factors that shape the decision-making of firms between an inbound or an outbound approach to open innovation.

1. Strategic Alignment

Firstly, the coding process highlighted the importance of "strategic alignment" in choosing between inbound and outbound open innovation. This theme emerged from different representative codes found in the text that concerned the importance of alignment between innovation and commercialization goals as well as their internal structures and the long-term value orientation of the interviewed firms.

Furthermore, by displaying this theme across all six companies, it emerged that strategic alignment is a primary common determinant in the selection of innovation initiatives. However, as it is shown in *Table 9*, this feature takes different forms depending on the company, its characteristic and the specific therapeutic area it works in.

Company	**Strategic Alignment**
Company A	Innovation is assessed for long-term fit and guided by governance.
Company B	Driven by values and continuous feedback from clients.
Company C	Strategy evolves quickly in response to market and therapeutic needs.
Company D	Coherence is ensured across departments through planning.
Company E	Vision cascades from leadership to all teams globally.
Company F	Innovation is filtered through the core goal of market entry.

Table 9 – Strategic alignment across all interviews

By utilizing the above table, Company A affirms that: "Every innovation initiative is assessed for its long-term sustainability and alignment with the company's overall vision and is ensured through solid governance" (Respondent A), clearly showing that innovation is not seen as a standalone initiative, but it must fit within corporate priorities. As a matter of fact, thanks to a strong leadership and the use of piloting, this company ensures that the chosen contractual agreements are consistent with the company's overall direction. This perspective is shared by Company F, which states that: "We're cautious about entering partnerships that might dilute our value or distract us from our core mission" (Respondent F), underlining the role of commercialization goals in shaping the innovation strategy.

While the mentioned companies take a more business-oriented perspective, Company B takes a more human-centric approach, with the CEO highlighting that: "Client feedback is our compass" (Respondent B), suggesting that strategic direction is defined through market responsiveness and customer closeness. Company C, following this direction, takes a market-oriented strategic stance, stating that: "Innovation begins with a careful study of the need for treatments in therapeutic areas that are insufficiently covered" (Respondent C), linking innovation choices to gaps in clinical research. Meanwhile, Company D stresses the importance of internal planning and coherence across departments, affirming that: "Every innovation project is assessed for coherence with our long-term vision" (Respondent D). Finally, Company E addresses this concern as a matter of "consistency". In fact, starting from the top of their company with a cascade of communication based on clarity, transparency and alignment, a whole internal mobilization is activated to ensure that the whole organization is headed towards a common goal.

Across all cases, innovation is strategically filtered and decisions about whether to pursue an inbound or outbound innovation are evaluated based on how closely they align with long-term business objectives, confirming the idea that

strategic alignment is a crucial factor influencing the choice of the open innovation model.

2. Resource Constraints

The coding procedure highlighted "resource constraints" as another essential driver behind the decision of pursuing an inbound or an outbound open innovation strategy. This theme emerged from different representative codes found in the text that concerned the weight of financial limitations, human resources constraints, limits in the operational capacity of firms and organizational fragility as a common feature of SMEs. *Table 10* illustrates the different perspectives offered by each firm on this relevant theme.

Company	Resource constraints
Company A	Keeps lean through pilots and avoids heavy internal investment.
Company B	Faced early turnover; now values team stability and capacity.
Company C	Resources depend on strategic choices and market context.
Company D	Constraints in staff and skills lead to outsourcing.
Company E	Limited R&D capacity drives reliance on deals and partnerships.
Company F	Funding and staffing limit internal efforts; partnerships fill gaps.

Table 10 – Resource constraints across all interviews

Another central strategic factor influencing the choice is the availability of internal resources. All firms reported limitations in terms of funding, personnel, and internal R&D capabilities. Thus, limited internal capabilities emerged as another major factor pushing firms toward inbound innovation. In this regard, Company A maintains a deliberately lean structure, stating: "Inbound innovation is generally more advantageous... it allows us to keep a lean structure" (Respondent A), which leads them to rely on partners to compensate for technical gaps. Company B similarly refers to the limitations of its small team: "Losing two people means losing 30% of operational capacity" (Respondent B). This situation leads to a strong dependence on external

expertise in acquiring additional training and development of specific technical capabilities that, because of lack of resources, can't be externally sourced hiring new professionals but need to be developed internally. This is somewhat shared by Company D that underlines the challenge of internal bandwidth: "We bring in external doctors to educate us on diseases we don't specialize in" (Respondent D). For Company E, inbound innovation is not just strategic—it is structural since, as mentioned in the previous paragraph, they completely dismantled the internal R&D and, therefore, they're looking for business opportunities. Company F confirms that funding constraints are an issue, leading them to prioritize outbound innovation only when necessary and feasible. That's because Company F owns a proprietary drug protected by a patent, therefore making commercialization options through external parties the driver behind their open innovation strategy.

As a result, inbound innovation emerged as the predominant approach, particularly in Companies A, B, D, and E. These firms use external partnerships, knowledge outsourcing, and pilot collaborations to innovate without leveraging on internal resources. Furthermore, what these findings show is that resource limitations are not only operational barriers but act as fundamental strategic factors that shape the innovation model.

3. Regulatory and Cultural Barriers

By conducting a three-level coding process, the research findings show that also "regulatory and cultural barriers" are relevant in shaping the decision making behind Open innovation. This theme emerged from different representative codes found in the text that concerned the existence of compliance and due-diligence issues when undertaking partnerships and cultural and integration challenges with external entities when engaging in open innovation practices.

Company	Cultural and Regulatory Barriers
Company A	M&A brings cultural challenges; regulation adds complexity.
Company B	Change is resisted; innovation requires mindset shifts.
Company C	Global shifts and compliance issues complicate innovation.
Company D	Strict rules limit communication and require outsourcing.
Company E	Mergers demand cultural alignment across functions.
Company F	Outbound deals face control risks; inbound limited by systems.

Table 11– Regulatory and Cultural barriers across all interviews

Table 11 indicates the diverse regulatory and cultural barriers found by the interviewed companies when choosing between an inbound or outbound open innovation practice. For instance, Companies D and F emphasized the difficulty of engaging in outbound activities due to strict rules regarding patient interaction and promotional communication. On one hand, Company D is especially constrained by compliance stating that: "due to strict regulations, we outsource patient contact and drug production" (Respondent D). As a matter of fact, the interviewed company stressed the issue that the healthcare sector is strongly affected by regulation and laws that prohibit companies from directly inviting opinion leaders – doctors and medical staff – to corporate events or research-driven conventions, in order to avoid conflict of interests in advertising a certain drug or medicine. On the other hand, Company F remarks that cultural or institutional barriers when working with academia or larger firms can limit collaboration effectiveness. Similarly, cultural misalignment was cited by Companies A and E as a challenge during post-acquisition integration, limiting the scope of knowledge sharing and joint innovation. For example, Company A has experienced the difficulty of merging different operational logics: "Acquiring or integrating new products... is about building a bridge between two company cultures" (Respondent A). This is also shared by Company E which compares integration between companies involved in open innovation to a marriage: "You must build a

shared vision, otherwise it ends in a divorce between the two entities" (Respondent E). Regarding internal resistance in open innovation practices, Company B also mentions internal resistance, noting that: "The biggest challenge is cultural resistance... people fear change" (Respondent B).

Overall, these findings show that also non-technical factors like regulation and culture significantly influence innovation behaviour and serve as practical limitations of the implementation of open innovation, suggesting that also context plays a role in shaping open innovation.

4. Stage of Innovation Lifecycle

The lifecycle stage of an innovative drug or medicine emerged as a critical temporal factor that influences the innovation strategy. *Table 12 clearly* shows a clear dominance of inbound practices since only one company out of six was found to engage in outbound open innovation practices.

Company	Stage of Lifecycle
Company A	Uses inbound innovation during early-stage development to pilot ideas and limit internal investment.
Company B	Applies inbound innovation in the early phase, with learning and adaptation as a central goal.
Company C	Adopts both inbound and outbound strategies, depending on maturity and market conditions.
Company D	Relies on inbound methods in early pipeline phases, supported by external expertise.
Company E	No internal R&D; uses inbound innovation through acquisitions of late-stage assets.
Company F	Employs outbound innovation in the late clinical stage to support commercialization and scaling.

Table 12 – Stage of Innovation Lifecycle across all interviews

Company F, which has in-house developed a singular injection to cure LDH, is the only firm actively pursuing outbound innovation (e.g., licensing and co-development deals). In contrast, firms treating the development or

commercialization of early-stage innovations (A, B, D) generally opt for inbound models to acquire knowledge and capabilities. For instance, Company A uses piloting to try out ideas as a risk-adverse strategy during the earlier development stages. Similarly, Company B relies on continuous learning and training through external sources in order to gather insights for its internal operations. Therefore, this firm relies consistently in inbound learning. Company C, instead, prefers shifting between models based on the practical case, size and context of the opportunity. Following this logic, Company D often brings in external stakeholders in order to forecast potential therapeutic shifts and future trends. Finally, differently from the other firms, Company E, completely lacking an internal R&D pipeline, limits its role to inbound innovation through acquisitions.

4.3 Summary of findings

Linking back to the research question, the findings show that the choice between an inbound or outbound approach to open innovation is shaped by four interrelated strategic factors: (1) strategic alignment with long-term business goals, (2) Internal resource constraints, (3) Regulatory and cultural barriers and (4) Stage in the innovation lifecycle. The emerged themes are visually summarized in a table (*Table 13)* which includes a holistic and an aggregated view of all the main findings and presents how each strategic factor influenced the choice behind the open innovation approach, whether choosing an inbound or an outbound open innovation strategy.

Identified theme	Description	Impact on OI Choice	Commonality Across Firms
Strategic Alignment	Degree to which OI initiatives align with the firm's vision, goals, and mission	Gatekeeper for both inbound and outbound	Strongly present in all
Resource Constraints	Limits in funding, internal skills, or R&D capacity	Pushes toward inbound (to acquire knowledge externally)	Very common in SMEs
Regulatory & Cultural Barriers	External regulations and internal resistance or cultural mismatch	Often discourages outbound; shapes inbound choices	Sector-specific but frequent
Innovation Lifecycle Stage	Maturity of the innovation or product under development	Inbound used in early stages, outbound in later ones	Observed across most cases

Table 13– Summary of the findings

After an in-depth analysis of each theme, it emerged that inbound innovation is the preferred strategy across the investigated sample. On the other hand, outbound open innovation is less common and occurs primarily at later stages of development for commercialization purposes. In this way, the research question is answered through a nuanced, evidence-based understanding of how strategy, context, and capabilities interact to shape open innovation decisions in pharmaceutical SMEs.

5. Discussion

This section aims to summarize the obtained findings from the previous chapter and link them back to the research question. This would provide evidence of whether the sample, the collected data and the conducted analysis proved to be relevant and accurate to the research purpose or not. In addition, the acquired findings will be compared against the revised existing literature to further validate the quality of the conducted research and then analysed on a more abstract note compared to the previous section. Lastly, implications of this study for further research and other fields will be included as well as limitations that could be objected to this research.

According to the findings of the previous section, the information coming from the six semi structured interviews was extremely varied and provided meaningful and diverse perspectives. Starting from the definition of open innovation, the main theme of this work, the variation in how this concept is understood and used suggests that this approach is flexibly adapted by SMEs according to their structure, goals, and constraints. In order to discuss the main themes emerged in the findings, this chapter will follow the same structure as before, therefore dividing the text in paraphs associated to each main theme.

5.1 The identified strategic determinants behind Open innovation

As previously stated, this section traces back to the core research question of this thesis:

What are the main strategic factors influencing the choice between an inbound or an outbound approach to open innovation?

By analysing the interviews conducted with six different representatives of pharmaceutical SMEs and organizing the insights through thematic and cross-case analysis, several strategic patterns emerged in the findings' section. In this chapter, the same strategic determinants will be clearly linked to the central

inquiry and reflect the real-world trade-offs and decision-making processes shaping innovation strategies in pharmaceutical SMEs.

1. Strategic alignment

Reflecting more in-depth on the first theme that emerged from the coding process, the level of alignment between the interviewed companies' innovation strategies and their long-term business goals emerged as crucial. This suggests that innovation is not pursued as a stand-alone function, but as an extension of a company's long-term goals, mission, and commercial objectives. Therefore, this implies how important it is for managers or innovation managers to opt for an open innovation approach – inbound or outbound – which better fits their initial objectives. This piece of relevant information strongly supports the idea that open innovation should be aligned with a firm's internal strategy in order to be effective (Chesbrough & Bogers, 2014). As a matter of fact, supporting what Chesbrough (2021) researched, firms that adopt open innovation should have or at least have had a prior experience in internal R&D (Chesbrough, 2021). This would allow them to internalize the innovations or technologies brought in from the external market, especially in the case of inbound open innovation. While this aspect was found to be true in literature, the case of Company E, fully dismantling its own R&D department, prove otherwise and offer a different view on how to approach open innovation. However, going back to what Company's E General Manager noted in the interview, having a whole department within the organization devoted to R&D, wasn't leading to achieve the long-term objectives of scaling its company to being a leader in the rare disease sector; ultimately confirming once more the importance of the alignment between the innovation approach and the overall business direction. Furthermore, the correspondence between the literature and this theme was found to be present also on outbound open innovation. As a matter of fact, this follows what Gassmann & Enkel (2004) researched about firms which develop a proprietary technology but might lack in brand recognition and, therefore, commonly engage in outbound open innovation (Gassmann & Enkel, 2004).

This implies that less established firms, by selling or licensing-out innovations that don't fully align with their main strategic goals, can still make profit from them while focusing on other technologies which are in line with their main objectives.

Overall, according to previous studies and reflecting on the insights gathered from the interviews, the findings highlight two main practical considerations. Firstly, they show that open innovation in pharmaceutical SMEs acts as a strategic filter where innovation activities – whether inbound or outbound –are only pursued if they serve clearly defined business priorities. Furthermore, building on this premise, the theme "strategic alignment" doesn't serve only as a simple filter but works as a strategic cut-off condition. In other terms, this theme regulates what is considered as a suitable innovation practice and what is not. This suggests that open innovation shouldn't be seen as a generalizable model, but it should be treated as a context-based approach affected by each firm's long-term vision.

2. Resource Constraints

The second theme highlights the structural constraints typical of SMEs, namely lack of human capital, funding, and technical competencies. Consistent with the previously mentioned literature, this research confirms that limited internal resources push firms toward inbound open innovation. Indeed, inbound open innovation allows companies to access external knowledge without incurring in heavy R&D investments. This is particularly aligned with the research of Spithoven et al. (2010) and Bianchi et al. (2010), who found in inbound open innovation a suitable model for resource-constrained SMEs. Furthermore, as already discussed in the literature review, in order to be able to internalize external technologies and innovations, therefore engaging in inbound open innovation, firms need to generate absorptive capacity (Cohen & Levinthal, 1990). This concept needs in turn an internal R&D experience in order to be developed. However, in relation to this logic that was found in the literature, the findings have shown that many of the interviewed companies have

preferred building absorptive capacity via outsourcing critical innovative functions rather than by building them internally. For instance, company A has avoided internal building by using piloting while company B, due to shortage in the personnel, has made external trainings of essential knowledge-intensive activities a vital feature of its business.

Overall, reflecting on this theme, while the criticality of resource constraints has been found to be aligned between the findings and the existing literature on the topic, the same can't be said for the concept of absorptive capacity. As a matter of fact, while the literature assumes that absorptive capacity is an essential prerequisite for inbound open innovation, the findings shed light on an opposite mechanism which involves the externalization of core innovation activities. Indeed, some of the examples provided by the interviewed firms show that in real-life firms tend to outsource even core innovative activities that, according to the theory around absorptive capacity, should be at least partially developed internally. This suggests that firm which engage in OI practices should simultaneously continue being involved also in R&D activities. However, the case represented by Company E shows otherwise by dismantling completely its own R&D department. This contradiction between the literature found on absorptive capacity and a real-life application of open innovation suggests that there might be some differences between theory and practice. Lastly, the emerged misalignments around the topic of absorptive capacity might set the basis for a deeper understanding of the role of resource constraints and real-life pressure on open innovation in pharmaceutical SMEs.

3. Regulatory and Cultural Barriers

The third theme that emerged from the interviewed companies, further extends the resource constraints that SMEs have when engaging in open innovation strategies to regulatory and cultural barriers. In particular, the main challenges that were mentioned by the interviewees related to strict healthcare regulations and the need for compliance with healthcare

institutions, and cultural barriers that stress the difficulty of integrating with partners.

What the findings seem to be leading to is the raising awareness that regulatory factors reinforce the preference towards inbound open innovation over the outbound type. This key insight supports Gassmann and Enkel's (2004) argue about SMEs engaging in inbound open innovation for their limited internal resources and also shows the influence that regulatory constraints have in the pharmaceutical sector. For instance, as emerged from the interviews, these constraints might force pharmaceutical SMEs to outsource key areas such as health economics and discourage them from pursuing outbound open innovation strategies which involves direct patient contact or commercialization. This implies that inbound innovation, particularly in highly regulated industries like the pharmaceutical one, doesn't serve only as a means of accessing external ideas but also as a strategic tool to elude external limitations. This conclusion might also raise future discussion on whether pharmaceutical SMEs might ever be able to overcome these sectoral barriers and engage in outbound open innovation autonomously.

Regarding internal constraints posed to open innovation, the findings emerged from the interviews point to internal resistance and integration difficulties as the main examples of cultural barriers. These limitations to the approach of open innovation support the issues of appropriability, uncertainty, and indivisibility raised by Inauen & Schenker-Wicki (2012) and Chesbrough (2021), especially when dealing with outbound open innovation. As a matter of fact, concerns around the difficulty in capturing the value of the innovative idea and in retaining its control might discourage from engaging in this type of practice. On another note, the issue of internal resistance might characterize not only outbound open innovation but also the inbound type. For instance, among the interviewed firms, company's B testimony serves as an example of a firm that engages in inbound open innovation trainings while experiencing internal resistance to change and cultural friction. This example might be explained by

the previously referenced "Not Invented here" (NIH) syndrome that might have characterized company's B employees when trying to adapt to acquired external trainings and expertise.

Overall, the discussed findings on this theme have important implications. Firstly, the emergence of regulatory constraints as a crucial strategic driver of open innovation suggests how this approach is not only a strategic or operational choice, but it also somewhat an institutionally constrained practice. This is because, in the pharmaceutical sector, pursuing an inbound open innovation approach rather than an outbound one sometimes is not only a choice, but it is a matter of complying to sectorial regulations. Therefore, it could be implied that regulatory compliance is a key structural factor encouraging inbound open innovation. This might raise the future need for pharmaceutical SMEs of specific support to overcome institutional barriers to outbound open innovation.

4. Stage of Innovation Lifecycle

The fourth and last theme showed that the choice behind the open innovation approach also depends on the stage of the innovation lifecycle of an innovation or technology and its intended use. In particular, inbound open innovation is preferred for early-stage development, while outbound practices are more common towards a stage closer to commercialization.

These findings could be related to Enkel et al.'s (2009) argument that outbound open innovation is more frequent in later phases of development, especially when the innovative technology is closer to being commercialized, allowing it to be sold or licensed-out. Moreover, Enkel et al.'s (2009) suggest that the inbound approach is preferable for capability building, while the outbound one allows for monetization of underused technologies or market expansion in later stages. According to the interviewed companies, especially Company A and B rely on inbound open innovation to acquire knowledge and build competencies. This could be explained by the fact that pharmaceutical SMEs,

which are often in lack of resources, might choose to engage in inbound open innovation in order to obtain those capabilities and know-how that are missing within their organization or to partner with other firms, universities and other entities to further develop a promising new drug. On the contrary, Company F, a firm owning a late-stage proprietary drug, was the only company across the sample to engage in outbound open innovation, actively seeking for partnerships and collaborations.

Overall, the discussed findings suggest that the stage of the innovation lifecycle of a technology influences the type of open innovation approach to follow, namely inbound or outbound, and is in turn determined by the intended use given to the innovation. Therefore, this implies the importance played by timing in shaping the chosen open innovation approach, leaving space for the assumption that innovation openness is not static; on the contrary, it is in continuous evolution, and this should encourage managers to develop dynamic capabilities to adapt to change.

5.2 The links between the identified themes

In order to bring the analysis a step further, some connections between the four identified themes were found to be present. *Figure 4* illustrates the visual ties between each of the identified themes and, by using colourful arrows, it shows the different and diverse connections that each theme has with all the others.

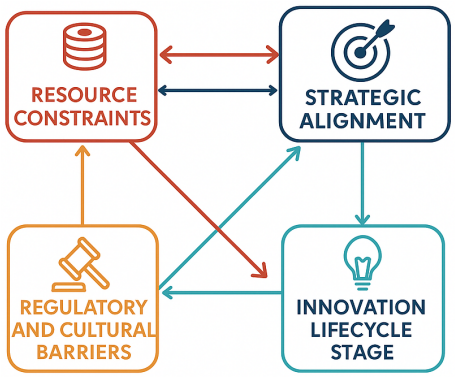

Figure 4– Links between the four identified themes

The four identified strategic factors, namely strategic alignment, resource constraints, regulatory and cultural barriers, and innovation lifecycle stage, were found to be closely intertwined, leading to a decision-making framework for pharmaceutical SMEs adopting open innovation. Starting from the higher factor on the left, "resource constraints" determines and defines which types of innovation activities are feasible, often pushing firms toward external collaboration and inbound open innovation. Furthermore, as it can be seen by the direction of the arrows in *Figure 4*, these constraints also influence how firms define their strategic priorities, thereby affecting strategic alignment. This is easily understandable since lacking funding or human resources in a firm could shape the long-term vision of a company in terms of prioritizing certain objectives over others. Moving on towards the lower factor on the left, "regulatory and cultural barriers" determine the kinds of partnerships that are legally feasible and how innovation is perceived internally. These barriers often encourage risk-aversion and preference for more controlled, inbound modes, shaping in this way also the alignment between the open innovation strategy and the long-term vision of the business. Lastly, the lower factor on the right, the "stage of the innovation lifecycle" determines not just timing but also the direction of innovation flows—early stages tend towards inbound solutions, whereas later stages may prefer outbound strategies. By acting as a temporal factor which directly determines the approach to open innovation, the stage of the innovation lifecycle also influences the firm's overall direction and the consequent regulatory and cultural barriers applicable to the chosen open innovation strategy.

Overall, all the three determinants that were described here link back to "strategic alignment", which acts as a guiding factor for evaluating whether an inbound or an outbound open innovation strategy best supports the firm's goals and long-term direction. This confirms once more, as it was discussed previously in this section, the value of "strategic alignment" as a crucial cut-off condition in choosing the most suitable open innovation approach.

6. Conclusions

6.1 Summary of the obtained answers to the RQ

This work started from the ambition of exploring the main strategic factors that shape a firm's choice on the approach – whether inbound or outbound – to Open innovation. This purpose stemmed from the recognition of a general undeniable truth: the impossibility for a firm to survive without continuing to innovate. In this context, the closed innovation model is not appropriate anymore, and a shift to the open innovation approach was found to be a well-established solution. After a careful revision of the existing literature on this topic, open innovation emerged to be highly relevant in the pharmaceutical filed where, especially SMEs, often lack the necessary resources and internal capabilities that would allow them to innovate in autonomy. However, this is not what happens in real-life and pharmaceutical SMEs frequently engage in different forms of Open innovation activities.

By analysing the six semi-structured interviews conducted to Swedish and Italian pharmaceutical SMEs, this research identified four main interrelated themes that drive the decision-making behind open innovation. By analysing these findings, the answers to the research question were found. Firstly, the following main strategic factors – strategic alignment, resource constraints, regulatory and cultural barriers, and stage of innovation lifecycle – were found to be determinant in shaping the decision between an inbound and an outbound open innovation approach. While deriving these factors, inbound open innovation emerged as the dominant approach among the interviewed companies; especially because the chosen firms were SMEs, thereby being resource constrained and utilizing this approach to build knowledge base and capabilities. On the other hand, outbound open innovation was a singular example within the sample and was implemented by a firm holding a late-stage proprietary drug, close to its commercialization. Furthermore, moving away from strictly technical factors, also regulatory and cultural barriers were found to be responsible in shaping the innovation strategy.

Building on the emerged findings, this work was able to show how open innovation is not treated as a general or universally applicable model, but as a flexible and context-sensitive approach, influenced by regulation, availability of resources and maturity of the technology.

In conclusion, while this work is only applied to a single industry, it serves as general example of the current need for innovation and for ways to navigate around its governance. By questioning the main strategic drivers behind the type of open innovation to pursue, this work attempted to act as an initial basis for managers to understand how to tackle the future and current challenges of this world. If empirical examples like this research continue to be conducted, then a deeper knowledge of the tool that is Open innovation would continue to spread also in many other fields.

6.2 Theoretical contribution

After having widely discussed the main findings coming from the interviews, it is important to draw the theoretical contributions of this work to the existing literature on Open innovation. As a matter of fact, this study contributes to the open innovation literature by offering empirically grounded evidence of how pharmaceutical SMEs strategically decide between inbound and outbound open innovation. While prior research lacks practical examples of how open innovation works in practice (Wikhamn et al., 2019), this thesis expands the discussion by exposing the four main strategic determinants that drive this choice in resource-constrained and highly regulated environments.

By summarizing the key discussed findings, this work provides a crucial contribution by explaining how the strategic alignment between the open innovation approach and the company's long-term goals not only acts as a filter but also as a boundary condition. Furthermore, in exposing the importance of resource constrains in determining the open innovation approach, this study challenges the traditional view of absorptive capacity (Cohen & Levinthal, 1990) as an enabler of inbound open innovation; it does

so by showing that some pharmaceutical SMEs might choose to outsource even crucial core innovation activities, instead of internally developing and assimilating them, and prefer to source them externally. Furthermore, regulatory constraints have been found to be structural drivers leading towards inbound open innovation. Together with this, also cultural barriers have emerged to be strategic determinants behind the open innovation approach and once again confirm how also structural drivers, not only strategic ones, affect the innovation strategy of firms. Finally, the work contributes to stressing the importance of the timing of the innovation lifecycle of technologies in shaping the open innovation approach.

6.3 Implications for future research

Given the theoretical contributions of this work, this study could provide a strong qualitative foundation for future quantitative investigations on open innovation in pharmaceutical SMEs, trying to derive also numerical evidence of the emerged themes. Further work could also extend this study to other adjacent sectors in continuous evolution such as the med-tech and biotech ones, to see if these findings can be generalized also to similarly structured fields. Furthermore, regarding the choice of the sectors, the research inquiry that was investigated in this study could be applied to other highly innovative fields where cases of open innovation are frequent and supported by strong literature. Lastly, given the higher evidence of inbound open innovation practices over outbound ones in the sample, this work could also be repeated, following the same methodological approach, to test if the probability of including more examples of outbound open innovation increases or not.

6.4 Managerial implications

Regarding the practical takeaways of this research, especially given the strategic nature of the research inquiry, this study might also present interesting managerial implications. For instance, practitioners could implement strong governance and control mechanisms that ensure the alignment between

innovation strategies and the firm's overall direction before undertaking open innovation initiatives. Furthermore, by making use of the findings coming from this research, managers would be advantaged by knowing that inbound open innovation could be a good choice for building capabilities and knowledge base, while outbound open innovation could be more appropriate for proprietary technologies that are ready for commercialization. Lastly, given the weight of regulatory and cultural barriers on the choice of the open innovation approach, managers should plan in advance a risk-assessment of these constraints, structure a suitable monitoring of these elements, and develop integrating mechanisms to reduce cultural misalignments.

6.5 Research Limitations

As for any qualitative research project, this study presents certain limitations that need to be acknowledged to provide a basis for future refinements and investigations.

Regarding the chosen methodology, the sample size was limited to six firms operating in the pharmaceutical sector both in Italy and in Sweden. This wasn't a chosen number, on the contrary, the initial aim was to interview eight or ten people. However, given the unpredictability of potential interviewees, a typical feature of qualitative research design, the initial number of selected respondents was in the end subject to reduction. Furthermore, while the purposive sampling served as a main criterion in ensuring a high relevance to the research question, it might have affected the diversity of the sampled respondents. On this note, also the use of snowball sampling may have limited the randomness of the sample. Despite this possibility, diversity of the sample was still guaranteed by using some referred respondents not as direct interviewees but as intermediaries to get in touch with other people. In addition, another limitation could be objected to the exclusive use of primary data in the form of semi-structured interviews. While this was true, the flexible and open format followed during the interviews allowed for additional information related to the industry specifics to be obtained. Although this

method enabled rich data collection, it still may present a high degree of subjective interpretation. That's why, future studies may include additional data sources such as company documentation or quantitative performance metrics.

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Appendix

Appendix A – Interview guide

Appendix A.1. Introduction

- *Introducing the researcher and the research purpose*
- *Asking permission for recording and utilizing the name of the company in the study. This was not granted; therefore, all the companies' and interviewees' names were anonymised.*

Appendix A.2. Questions

Introductory questions	Could you provide information about your company's core business? Could you describe your role within your company?
Question Number	**Questions**
1	How would you define open innovation within the context of your company? And how does open innovation align with your strategic goals?
2	What factors drive your firm's decision to pursue inbound vs. outbound open innovation? Can you provide specific examples of strategic key drivers that influence your choice?
3	Do you perceive one approach (inbound or outbound) as more beneficial to small pharmaceutical firms? Why?
4	Can you share examples of successful inbound or outbound innovation initiatives in your firm?
5	What are the main challenges your company faces when engaging in inbound innovation and outbound innovation? (e.g., regulatory barriers, financial constraints, cultural resistance, partner selection, etc.)
6	How do resource constraints (e.g., funding, expertise, partnerships) influence your firm's innovation approach?
7	How does your company ensure that its open innovation strategy aligns with its long-term business goals?
8	Looking ahead, do you foresee any shifts in your firm's approach to open innovation? Are there specific trends or challenges that may drive this change?

Appendix A.3. Concluding questions

- Could I send you the transcribed interview so that you could validate it?
- Would you like to receive the final interview and results of this study?

Appendix B – Coding table

Open Code	*Axial Category*	*Selective Theme*
1st theme: Strategic alignment		
Innovation assessed for long-term fit and governance.	Strategic evaluation mechanisms	**Strategic Alignment**
Values and continuous feedback from clients.	Market-responsive alignment	**Strategic Alignment**
Strategy evolves in response to market and therapeutic needs.	Adaptive strategy design	**Strategic Alignment**
Coherence is ensured through planning.	Internal coherence and planning	**Strategic Alignment**
Vision cascades from leadership to all teams.	Leadership-driven alignment	**Strategic Alignment**
Innovation is filtered through market entry.	Commercialization-driven focus	**Strategic Alignment**
2nd theme: Resource constraints		
Keeps lean through pilots and avoids heavy internal investment.	Financial efficiency	**Resource Constraints**
Values team stability and capacity.	Human capital constraints	**Resource Constraints**
Resources depend on strategic choices and market context.	Context-driven resource prioritization	**Resource Constraints**
Constraints in staff and skills.	Skills and expertise limitations	**Resource Constraints**
Limited R&D capacity.	Structural R&D limitations	**Resource Constraints**
Funding and staffing limit internal efforts	Operational reliance on external support	**Resource Constraints**
3rd theme: Regulatory and Cultural barriers		
M&A brings cultural challenges; regulation adds complexity.	Post-integration cultural challenges	**Regulatory and Cultural Barriers**
Change is resisted; requires mindset shifts.	Internal resistance to change	**Regulatory and Cultural Barriers**
Global shifts and compliance issues.	Global compliance complexity	**Regulatory and Cultural Barriers**
Strict rules limit communication	Regulatory constraints on communication	**Regulatory and Cultural Barriers**

. *Mergers demand cultural alignment across functions*	Cross-functional cultural integration	**Regulatory and Cultural Barriers**
. *Outbound deals face control risks; inbound limited by systems.*	Legal and institutional bottlenecks	**Regulatory and Cultural Barriers**

4th theme: Innovation lifecycle stage

Uses inbound innovation during early-stage development to pilot ideas and limit internal investment.	Early-phase experimentation	**Innovation Lifecycle Stage**
Applies inbound innovation in the early phase, with learning and adaptation as a central goal.	Knowledge-building in early stages	**Innovation Lifecycle Stage**
Adopts both inbound and outbound strategies based on maturity and market conditions .	Strategy shifts by maturity level	**Innovation Lifecycle Stage**
Relies on inbound methods in early pipeline phases .	Inbound dominance in early development	**Innovation Lifecycle Stage**
No internal R&D; uses inbound innovation through acquisitions of late-stage assets .	External sourcing at later development stage	**Innovation Lifecycle Stage**
Employs outbound innovation in the late clinical stage to support commercialization and scaling.	Outbound strategy for commercialization	**Innovation Lifecycle Stage**