CONTRACT RESEARCH ORGANIZATIONS FOR OUTSOURCING PHARMACEUTICAL RESEARCH IN IRELAND: AN INDUSTRIAL INSIGHT.

By

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Abstract

This study analysed the evolving landscape of pharmaceutical research outsourcing, with a specific focus on contract research organizations (CROs) in Ireland. By investigating the motivations, factors, challenges, and implications of pharmaceutical research outsourcing, this study contributes to an understanding of outsourcing practice within the Irish pharmaceutical industry. The research objectives consisted of exploring the drivers for outsourcing, identifying commonly outsourced research areas, investigating the criteria for selecting CRO partners, and examining challenges and future directions.

The research methodology adopted was qualitative research, wherein semi-structured interviews with professionals directly involved in decision-making processes within pharmaceutical companies based in Ireland were conducted over zoom calls. Thematic analysis was employed, unveiling significant themes such as motivations for outsourcing, commonly outsourced areas, key factors in CRO selection, challenges, and emerging trends.

Findings indicated that while cost reduction is a driving factor, smaller pharmaceutical firms are motivated by budget constraints. Pharmacovigilance and clinical trials were most commonly outsourced areas according to the interviewees. Collaborative abilities and expertise emerged as pivotal with respect to CRO selection criteria. Challenges included staying updated with regulatory guidelines and managing staff turnover in outsourced projects. The study also helps to forecast future trends, highlighting the growing need for management-based expertise within the pharmaceutical industry.

This research provides insights for stakeholders in the Irish pharmaceutical landscape, both contract research organizations and pharmaceutical firms, encouraging collaboration, addressing skill gaps, and optimizing outsourcing strategies. Furthermore, it culminates in the realization that industry's dynamics are dependent on the constituting it.

Keywords: Pharmaceutical research outsourcing, Contract Research Organizations, motivations, Outsourcing trends, CRO selection, qualitative research, thematic analysis, future trends, industry stakeholders.

Abbreviations and definitions

CRO: Contract Research Organization. A company that provides specialized research services to pharmaceutical and biotechnology companies.

R& D: Research and Development. It refers to the process of creating and improving products or processes through systematic investigation and experimentation.

POS: Probability of success of a clinical trial. This is the likelihood that a clinical trial will achieve its intended outcomes.

LIMS: Laboratory information management system. A software-based tool used for tracking, managing, and storing laboratory data and information.

FTE: Full time equivalent rates. This represent the number of hours worked by one full-time employee on a specific task or project.

MSA: Master services agreement. A contract that outlines the terms and conditions of a working relationship between two parties.

GSK: GlaxoSmithKline. A pharmaceutical company that researches, develops, and manufactures a wide range of medical products.

AHP: Analytical hierarchy process. This is a decision-making methodology that involves structuring complex problems into a hierarchy of criteria and alternatives to make informed choices.

CHAPTER 1: INTRODUCTION

The global pharmaceutical industry is constantly seeking novel themes and concepts to streamline research and development processes while ensuring compliance of strict regulatory frameworks. In this context, the practice of research outsourcing has emerged as an essential tool to optimize resource allocation and achieve operational excellence through efficient collaboration between pharmaceutical companies and specialized service providers. This dissertation delves into the evolving landscape of contract research organizations (CROs) in Ireland, by understanding the motivations, factors, challenges, and implications that underlie pharmaceutical research outsourcing in this region.

1.1 Research background

The pharmaceutical industry in Ireland has recently observed an increase in outsourcing activities to research organizations (O'Dwyer *et al.*, 2023). This can be attributed to several factors. One of the main reasons have been the pace at which pharmaceutical sector has been evolving worldwide. This has necessitated pharmaceutical companies to allocate their resources to research and development to maintain a stronghold in the industry. In addition, the increasingly complex and high cost nature of drug development activities often prompt the companies to depend on external expertise. Ireland is particularly vulnerable to the changes in the current trends due to its strong presence of pharmaceutical sector. Many multinational companies have set up their bases in Ireland thus playing a vital role in the country's economy. With increasing presence of external factors influencing the landscape of pharmaceutical industry, research analysing the extent of their effect is necessary in order for the industry to grow and develop in the right direction.

1.2 Significance of the study

The pharmaceutical industry's reliance on outsourcing has been observed to have intensified over the years, significantly reshaping the ways in which research and development are conducted. The importance of understanding the landscape of pharmaceutical research outsourcing is not just a logistical decision, rather it is of paramount importance with respect to its influence of strategic decisions, resource allocation, and collaborative partnerships. Most literature observed the outsourcing relationships between Irish pharmaceutical industries and academic research organizations (Deasy *et al.*, 2015), (O'Dwyer *et al.*, 2023). The current study helps to address the literature gap and thus provides the much needed focus on the Irish context.

By analysing the motivations behind outsourcing to contract research organizations and delving further into the domains of research outsourcing the study contributes to the existing knowledge. The study also helps to further explore the criteria which pharmaceutical companies would use to guide CRO partner selection and thus identify various challenges inherent in these practices. By examining these facets, the current research aims to provide practical insights for industry stakeholders to optimize outsourcing strategies and ultimately enhance research outcomes.

1.3 Research Objectives

The main objective of this dissertation is to provide an industrial insight into contract research organizations in Ireland. This study seeks to:

a) Explore the motivations that drive pharmaceutical companies to outsource their research and development activities to CROs.

b) Identify and analyse the areas of pharmaceutical research that are most commonly outsourced within the Irish pharmaceutical industry.

c) Investigate the key factors that pharmaceutical companies consider when selecting CRO partners.

d) Examine the challenges and risks associated with pharmaceutical research outsourcing in Ireland as well as future directions of outsourcing practices.

1.4 Research Methodology

This study is implemented through qualitative research which serves the purpose of exploring various dimensions of pharmaceutical research outsourcing in Ireland. This methodology is specifically appropriate as it enables the researcher to delve into the subjective experiences, perspectives, and motivations of industry stakeholders. Through qualitative research, the study aims to extract in-depth data that originates from the unique professional experiences and viewpoints of key players in the pharmaceutical landscape.

The study interviewed 3 professionals currently involved in decision making process in pharmaceutical companies based in Ireland and each individual had previous experience working in various other pharmaceutical companies in similar roles prior to their current position. By engaging in these interviews with key decision makers, the perspectives gained enabled the researcher to capture their knowledge and experience over the years as well as

current practice in these 3 pharmaceutical companies and further translate them to motivations, and challenges that shape outsourcing decisions within the Irish pharmaceutical context.

The qualitative research process consisted of several stages:

Research Design: The research design was aimed towards uncovering the elements of outsourcing dynamics and motivations within the Irish pharmaceutical industry. An exploratory qualitative research design was adopted to gain an in depth insight into the industry in a flexible manner.

Data Collection: In this study, semi structured interviews served as the primary method for data collection, providing a base of opinions from industry experts through their perspectives and experiences.

Data Analysis: The collected data, in the form of transcribed interviews, underwent thematic analysis which entailed systematic coding of the data through identifying patterns, contrasts, and associations within the data.

Reporting: The findings derived from the analysis of qualitative data was synthesized and presented in a comprehensive report..

1.5 Overview of Dissertation Structure

This dissertation is structured to address the research objective and explore the multifaceted dimensions of pharmaceutical research outsourcing in Ireland. Following this introductory chapter, the subsequent chapters are organized as follows:

Chapter 2: Literature Review

This chapter provides an in-depth exploration of the existing body of knowledge surrounding pharmaceutical research outsourcing, including its historical context, theoretical frameworks, and best practices. This chapter also lays the foundation for the specialized terms and concepts used throughout the dissertation.

Chapter 3: Methodology

This chapter outlines the research design, methodology, and data collection procedures employed to gather insights into pharmaceutical research outsourcing in Ireland. It elaborates on the research approach and philosophy, data sources, and analysis methods of the said data to achieve the research objectives.

Chapter 4: Findings and Analysis

This chapter presents a detailed synthesis of the data obtained from interviews conducted with key industry stakeholders. This chapter also critically examines the motivations, trends, challenges, and selection criteria underlying pharmaceutical research outsourcing in Ireland under various themes formed from the data collected with respect to the literature analysed in chapter 2.

Chapter 5: Conclusion and Recommendations

This chapter explores the implications of the findings, deriving practical recommendations for enhancing the outsourcing landscape in the pharmaceutical industry of Ireland. These recommendations are intended to guide decision-making and strategic planning for industry stakeholders.

In conclusion, this introductory chapter provides the base for an in-depth exploration of pharmaceutical research outsourcing within the context of Ireland. The subsequent chapters of this dissertation explores the practice, motivations, trends, challenges, and implications that shape the industry's outsourcing landscape. Through analysis of findings, this research further aims to provide practical insights for stakeholders to navigate the complexities of outsourcing.

CHAPTER 2: LITERATURE REVIEW

2.1Introduction

Strategic outsourcing wherein core skills and competencies of a company are shared to add value to a firm and its partners have been met with success in other industries over the course of time (Wit, 2017). The pharmaceutical industry has always been characterized by a thriving research and development field wherein a continuous demand for expertise and an appropriate distribution of resources have been necessary for its improvement. Outsourcing has been increasingly used as a strategy to improve efficiency and reduce expenditure by the pharmaceutical companies. Utilization of external organizations excelling in research like Contract Research organizations and educational institutions enables pharmaceutical companies to access latest knowledge, processes and facilities for more efficient outcomes in pharmaceutical research.

While the primary research objective has been to identify the drivers for outsourcing pharmaceutical research in Ireland, this review would help analyse the existing literature and recognize patterns and themes not only with respect to selection of contract research organizations and outsourcing research but also understand a perspective of outsourcing involved at various stages of pharmaceutical research. The researcher aims to understand key drivers such as drug development costs, efficiency, expertise and accessibility to resources along with identifying challenges associated with outsourcing of research with respect to current trends in practice. This review seeks to identify gap in existing literature with regards to the selection of appropriate outsourcing partners. While all parts of pharmaceutical research can be outsourced to appropriate partners, this review narrows the focus to specific stages like drug development process, clinical trial processes, post marketing surveillance and regulatory affairs.

2.2 Motivations for outsourcing pharmaceutical research.

Pharmaceutical companies have had different motives over time to outsource their research activities. Various case studies on the nature of business strategy adopted by Merck & Co. has outlined how the company has been historically averse to partnering externally and has had various losses as a result (Rothaermel and McKay, 2015) (Beer and Fagan, 1999). Outsourcing strategy they later developed to complement their own research pipeline enabled them to

maintain competitiveness in the industry. Another pharmaceutical company, Pfizer, often formed partnerships with which allowed them access to a varied research portfolio helping them focus their resources in other fields like marketing (Collis and Smith, 2006). This implies how various different pharmaceutical companies have had various causes to outsource their research over tie and further become successful. Howells *et al.*, (2008) categorized the factors which prompted the pharmaceutical industry to outsource research into two main classifications as initiating factors and framing factors (Figure 1).

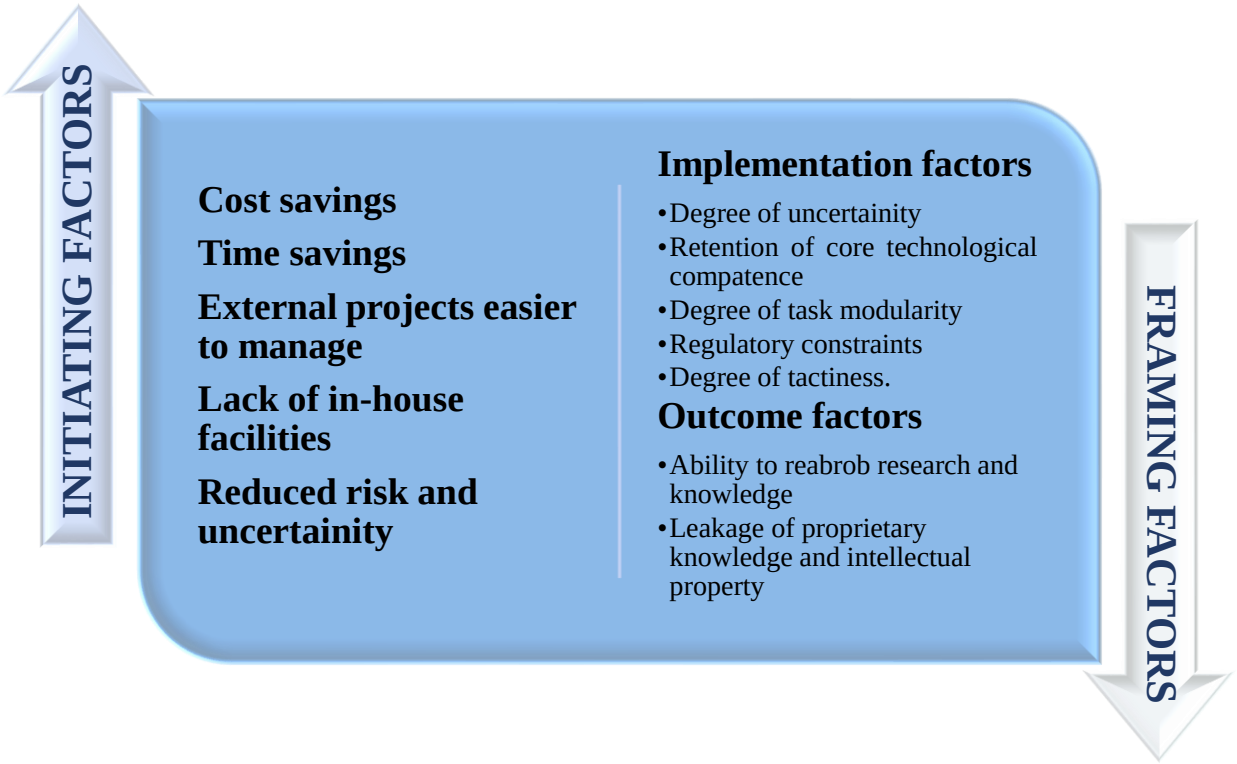

Figure 1: Factors behind outsourcing pharmaceutical research (Howells et al., 2008).

2.2.1 Analysing the influence of research and development costs.

A systematic review of articles from 1980 to 2009 estimate the cost of new drug development as anywhere from around 100 million to 900 million US dollars in the beginning of 21st century (Morgan *et al.*, 2011). On the other hand, an analysis of research and development investment cost for a single drug by Rennane *et al.*, (2021) estimated the amount to be anywhere between 113 billion to 6 billion US dollars in 2018. The wide range of this estimate in the literature from 1980 to 2018 can be ascribed to various factors within the industry which involved trade-off between price and quality as well as innovation incentives involved in the effort. While the

previous research entailed both new molecular entities as well as research into already established drugs, Simoens and Huys, (2021) further estimated the cost of research and development per new medicine to be anywhere between 944 million to 2826 million US dollars. They contributed 50-58% of these costs to clinical drug development and suggested that rest of the costs were attributed to pre- clinical development and profile maintenance of the company and the product. These studies identify the trend of increasing research and development costs in the pharmaceutical industry over the years further stressing the need to understand and allocate efficiently the costs involved. However, a vast majority of these drugs never make it to the market. According to Wong *et al.*, (2019), of the clinical trials involved in development of new oncology drugs, the success rates were estimated to be 8.3% in 2015. They also emphasized that probability of success (POS) of a clinical trial was often crucial to the investors and shareholders to determine the capital involved. In addition, a study on the causes of drug failures estimated that 90% of market withdrawals happen due to drug toxicity at various stages of clinical trial (Schuster *et al.*, 2005).

There has been a substantial gap in literature from the past decade or so comparing the advantages of in-house research and outsourced research. However, previous models by Cardinal and Hatfield, (2000) suggests how diversified firms benefit from separate research spaces rather than incorporating research under the corporate management. Since pharmaceutical industry is ultimately driven by economic benefits, the challenges faced by the industry during product development need to be addressed in the most cost effective way due to the huge capital involved in the process. Outsourcing of certain stages involved in the research and development can help reduce the costs incurred by the company and further enable them to focus their resources in key capabilities. Outsourcing the research to contract research organizations, particularly offshoring has risen as a remedy to this issue. While McCoy and Sarx, (2008) suggested that India was preferred as a destination for offshoring due to the country's thriving information technology sector, recent literature emphasized how use of state of art technologies like laboratory information management systems (LIMS) influences the position of the contract research organization in the research industry of their home country (Sayed and Agndal, 2021). Apart from these, Kermanimojarad, (2020) suggested the most common factor for outsourcing research to countries like India and China were the cheaper cost of labour in these countries.

2.2.2 Leveraging access to specialized experts and resources.

Wong *et al.*, (2019) discussed the success rates of clinical trials in various therapeutic areas like oncology. While they concluded higher success rates of about 5% from the years 2012 to 2015, the success of these clinical trials were attributed to specialized focus on patient selection and recruitment with the use of biomarkers specifically in oncology. This implies the importance of specialized expertise with respect to successful drug development in each therapeutic areas while investing capital for research and development. Yu and Gusev, (2019) had discussed the trend of outsourcing of research activities that involved clinical biomarker analysis to contract research organizations due to their increased focus on large molecule research. Hence, availability of expertise in the specific field of research can be one of the driving factors in pharmaceutical companies deciding to outsource such research activities.

During initial stages of research and development, like drug discovery and molecule analysis, recent trend in decrease of in house lab capacity was observed in pharmaceutical companies by Yu and Gusev, (2019). They further describe how this prompts the migration of experienced research scientists to organizations with specialized equipments. Along with this, the knowledge management strategies adopted by various CROs as described by (Wu *et al.*, 2022) has resulted in a culture of knowledge accumulation and protection on a regular basis which is often enticing for skilled researchers in the field. The adoption of such practices by the CROs prompts pharmaceutical companies to outsource their research for access of not only state of art technologies but also highly specialized researchers in a therapeutic field outside the company's core competencies.

With respect to regulatory reporting, Wasan *et al.*, (2022), suggested that contract research organizations often hire skilled professionals with expertise in the local regulatory process which enables the sponsor to gain access to generic drug market in the particular country upon completion of Phase 3 trials in line with the regulatory requirements of the region. The ability of the contract research organizations to maintain strict quality control and assurance with the help of these expertise has been one of the key drivers to outsourcing of regulatory affairs to these organizations.

Apart from regulatory affairs, pharmacovigilance (PV) has been a field which requires high quality data monitoring and regular submissions. It is imperative to maintain this quality while detecting new signals and to prevent hazards to patients. Hence outsourcing of PV activities

rise as a solution to gain access to the required expertise in order to handle the surveillance appropriately (Price, 2018).

2.2.3 Focusing of core competencies through outsourcing

While outsourcing research to partners with expertise in desired therapeutic field is the practice to enhance a company's research portfolio, various companies also adopt a strategy where in low priority procedures were outsourced and companies in turn are free to pursue research in their own area of expertise (Steadman, 2018). This was further observed by Gummerus *et al.*, (2016) in their analysis of outsourcing of regulatory affairs activities. In the survey, 69 % of pharmaceutical companies aimed to focus their resources on core competencies and marketing approvals of drugs in their area of specialization. As a result other activities like translations and variations were outsourced to contract research organizations. This helped ensure timely market entry of their high priority products and further maximize potential success. It is important to note that in these studies, faster completion of regulatory processes were not favoured by pharmaceutical companies. This was a result of the pharmaceutical companies wanting to undertake the more significant tasks themselves with fixed deadlines themselves. However, in case of clinical development of the drug, which would potentially take years to complete due to slow recruitment rate outsourced research work was observed to cut the time required for approval by 4-5 months which is a huge in terms of getting the drug to the market (Temkar, 2015).

2.3 Trends in outsourced research activities.

The type of research a pharmaceutical company decides to outsource has been analysed in various studies. Clinical trial work closely followed by technology used in research and development seemed to be the most common types of research that were outsourced (Howells *et al.*, 2008). Outsourcing during drug development can be specialized to different stages (Figure 2). Pharmaceutical companies often undertake research in medicinal chemistry within their own organizations while a CRO may be involved in design of delivery mechanism. This process ensures design rights of the pharmaceutical or biotech company. The shift in tangible deliverables of outsourced research from compounds which were manufactured and later transported to the data on biological compounds were earlier analysed by Mistry *et al.*, (2012) with respect to the pharmaceutical giant GlaxoSmithKline (GSK).

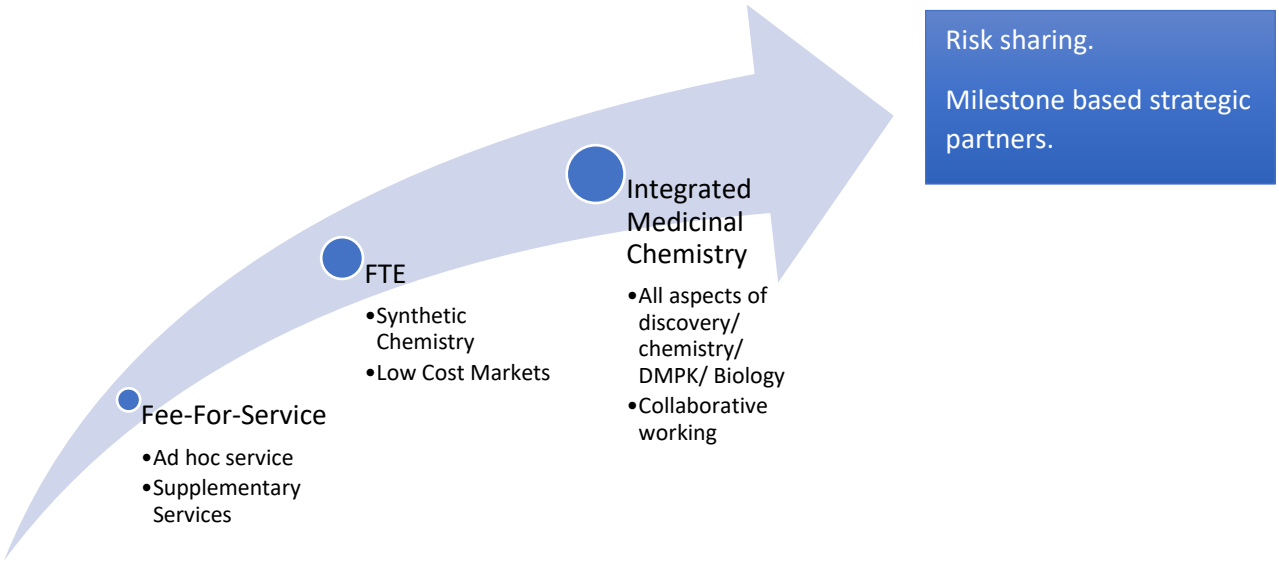

Figure 2: Evolution of drug discovery outsourcing (Mistry et al., 2012).

Furthermore, contemporary shifts and patterns have been identified wherein contractual agreements between outsourcing firms and pharmaceutical companies include molecule design which would be closely monitored with constant input from the client. This ensures that the pharmaceutical company utilizes only its intellect as a resource while the CRO would handle all other aspects (Steadman, 2018).

Pharmacovigilance activities have been increasingly outsourced to contract research organizations as this allows pharmaceutical companies to focus their resources on core competencies. Organizations with good skills and expertise in the area rather than cost efficiency are being increasingly considered for partnerships as the data from safety monitoring have high regulatory implications (Furlan *et al.*, 2017). Similarly regulatory affairs tasks have been increasingly outsourced across the world. A survey conducted on European pharmaceutical companies on the rationales and determinants behind outsourcing of regulatory affairs tasks to contract research organizations demonstrated that all aspects of regulatory reporting could be outsourced (Gummerus *et al.*, 2016). Recent literature by Wasan *et al.*, (2022), also suggests that pharmaceutical companies often outsource regulatory filing to the CROs based in the region with potential market for the drug further enabling easy approval of the drug in the particular country.

2.4 Factors influencing selection of Contract Research Organization (CROs).

Hussein *et al.*, (2022) suggests that the practice of outsourcing should aim to form a stakeholder perspective of improved quality and at the same time ensure that it enhances profitability and creates a stronger market position for the company. Contract research organizations often set specific targets and deliverables to assess quality of research they deliver to the pharmaceutical companies (Shih, 2015) (Grady Rainville, 2002). Since companies often look to outsource research as an increased capacity to pursue parallel research in core competencies, cost savings along with convenience and efficiency has been some of the factors in selection of a contract research organisation.

2.4.1 Evaluating the criteria considered for CRO selection.

While outsourcing decisions may depend on a contract research organization's capability to deliver outstanding results with its expertise, only CRO's with high dynamic capabilities were favoured for forming longstanding contracts according to an analysis of a multinational pharmaceutical company with headquarters in Europe (Zhang *et al.*, 2013). Many pharmaceutical companies base their selection of right organization for outsourcing research by prioritizing factors they would consider essential to their research. Research by Chen and Goh, (2019) suggest that selection of a partner for cooperative partner should focus on their collaborative ability up to a certain threshold before taking into consideration their individual achievements of the company. They defined a dual factor theory perspective to acknowledge the importance of partner ability and co-operation factors as ignoring one or the other could lead to failure in the process. While this particular model comes highly recommended as a versatile solution for encouraging collaboration and providing a standardized approach across diverse industries it is crucial to emphasize the need for meticulous customization and adjustment during its implementation with respect to choosing the right partner for outsourcing research in pharmaceutical industries.

Song (2019) analysed strategic priorities in outsourcing partner selection of Korean pharmaceutical firms by developing an analytical hierarchy process (AHP) for assessment. This method integrated both task related factors like capabilities and partner related factors like organizational fit to be considered while outsourcing research. It specifically explored outsourcing partner selection factors within two stages of research and development, namely early stages of drug development and regulatory affairs. While the article does provide a valid

evaluation criteria for assessing future partners, its reliance on 34 responses from Korean pharmaceutical industry in the specific research fields raises concern on the model's generalisability. It does however help in acknowledging the shifting focus on research based outlook on outsourcing decisions of pharmaceutical companies.

2.4.2 Identifying key decision-making factors for partnering with CROs.

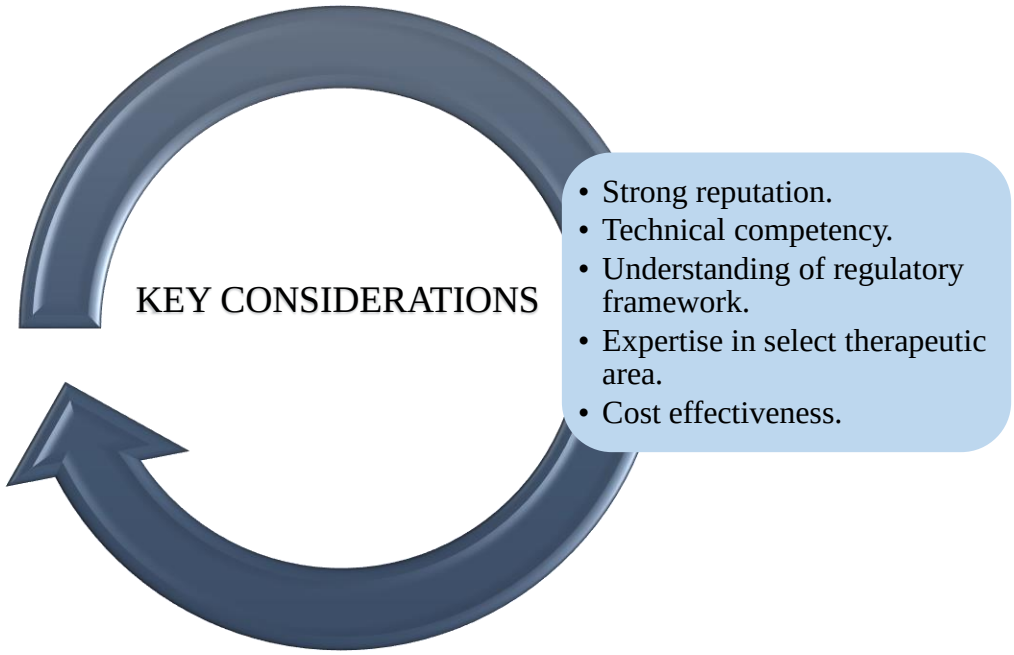

Figure 3: Key considerations in selecting contract research organization according to Wasan et al., (2022)

Cost effective solutions and financial considerations

There has been an increasing trend of outsourcing drug development process to low cost areas like India and China. This was analysed in a study by Lampert and Kim, (2019) wherein they stated that offshoring of pharmaceutical research is often considered due to its cost leveraging potential. Further, Mistry *et al.*, (2012) concluded that the selection of a contract research organization for early drug discovery were often based on various financial factors. CROs offering standardized full time equivalent (FTE) rates at best costs as well as savings on repeated contracts on an annual basis were very lucrative for the pharmaceutical industry while selecting the right partner for collaboration. Full time equivalent (FTE) business models are based on the contract research organization paying for the scientists time rather than the service

as a whole. Cost effective solutions that would not compromise on data quality and reliability is often the most attractive attribute to a pharmaceutical companies.

Expertise, Reputation and technical stability

The technical expertise of an organization is often considered as the key factor while selecting the same for outsourcing research (Howells *et al.*, 2008). With respect to clinical trials there is an increased demand for more complex and long term studies as data is being more accessible throughout the world. Hence clinical trials have been outsourced to contract research organizations that would have better expertise in the field and risk management strategies (Valdes and McGuire, 2004). In addition, recent research also suggest experience as a factor while considering an appropriate CRO. This was analysed by Dombernowsky *et al.*, (2019) who suggested that pharmaceutical companies often chose to conduct clinical trials at site which offered experienced personnel in both early phase and phase III trials. Contract research organizations able to recommend appropriate trial sites to the sponsor who would be preferred while outsourcing clinical trials. Further, Wasan *et al.*, (2022), also suggested that access to expertise in the specific therapeutic field can directly influence the time taken to complete targeted task with high efficiency. This implies that experience in a particular field of therapy can often influence a multitude of other factors that can be pivotal in selection of the contract research organization for outsourcing. This can perhaps be attributed to the thought that specialized knowledge and expertise in the particular field would assure the pharmaceutical companies that their projects will be handled by experts in the domain.

Integrated approach and multidisciplinary teams.

Dolman *et al.*, (2020) analysed a few CROs involved in molecule development activities on the basis of biomarker assay expertise each could provide. In this comparison, they concluded that organizations with more developed tests for assay validation often had a higher performance than with those with lesser operational facilities. It goes to show that in order to develop a successful CRO- sponsor relationship, it is necessary for the organization to excel in the field they are involved in as the pharmaceutical companies often have a wide variety of vendor selections based on just the cost savings and other capabilities. The ability of contract research organization to be the right technical and scientific fit for the sponsor with respect to their competencies is often prioritized while evaluating their performance for selection.

Steadman, (2018), identified the benefit of opting for a contract research organization that would provide a different teams with expertise in different phases of research like drug

development and post marketing surveillance. To further enhance an integrated approach, contracts such as Master services agreement (MSA) were found to be effective with reduced the need for multiple project management teams. These collaborations work towards a more inclusive and multidisciplinary approach to drug discovery. As such they are described as 'one stop shops' for research.

Apart from cheap labour, outsourcing to offshore CROs often allows the access to local Information Technology (IT) sector. This was analysed by Subramaniam and Dugar, (2012) to imply that CROs in India and China have developed an integrated approach to research wherein the contract research organization would provide systems needed for implementation of research along with deliverables necessary for the research.

Effective communication and collaboration

With respect to outsourcing of research to Indian contract research organizations, Sayed and Agndal, (2021) concluded that more efficient information systems were often preferred by western pharmaceutical industries while selecting a CRO. They particularly emphasized on the use of LIMS (Laboratory information management system) within the industry which helps real time analysis and surveillance of the research work outsourced by the pharmaceutical company in another country. While this would eliminate concerns over quality of research outsourced with continuous update, it could also result in predictable and repetitive modules in regards to innovation as evidenced by decreased work satisfaction observed among the scientists.

An analysis of relationship between GSK and the contract research organizations involved by Mistry *et al.*, (2012) describes the need for efficient communication and relationships between the scientists of the two parties involved for a smooth data transfer. Standardized contracts with risk mitigation clauses as well as ensuring consistent deliverables over longer term were the basis of CRO selection. Contract research organizations with lesser turnaround time and faster response rates along with other factors were found to be more favourable in terms of performance in comparison to others with lower scores in a study conducted by Dolman *et al.*, (2020). The communication of data involving bioanalytical method validation and sample analysis are required to be communicated to sponsors in a timely manner.

Timely completion and efficiency in clinical trials.

The time taken for completion of clinical trial can proportionally affect the cost involved in the drug development as mentioned in Messersmith, (2012). Timely completion of clinical trials is often beneficial for various stakeholders involved in the drug development as it ensures that the drug reaches the market at the correct time. Dombernowsky *et al.*, (2019) concluded that while outsourcing clinical trials to contract research organizations, partners with trial sites which enabled timely patient recruitment as well as efficient management of timely data entry and reporting were preferred. In trial phases requiring a large number of patients to be enrolled, this would be particularly beneficial for its faster completion would ensure faster entry of drug into the market. This further supports the analysis by the authors that pharmaceutical companies would opt for contract research organizations which prioritized timely completion of trial over cost of services.

2.5 Challenges associated with outsourcing research activities.

With increasing shift towards outsourcing research activities to contract research organizations, there have been many risks and challenges associated with selection of the same. One of the main disadvantages seem to be the contractual nature of research work, meaning research is viewed as a commodity and hence the pharmaceutical company is dependent on the supplier for its deliverance (Piachaud, 2002). This eventually leads to knowledge gap and decline of in-house expertise ultimately affecting the culture of innovation necessary for the growth of pharmaceutical industry.

Wasan *et al.*, (2022) further suggested that offshoring of research activities may have regulatory ramifications if compliance with regards to conduct of clinical trials and the quality of data produced is not acceptable to regulatory agencies. The accessibility of data and confidentiality constraints were also observed to be common challenges faced while outsourcing the research. The article further examines the need for closely monitoring the process of selecting as well as overseeing and further optimizing services obtained from contract research organization to ensure that any challenges faced are tackled.

2.6 Pharmaceutical industry in Ireland: Insights into research outsourcing.

The assessment of research development of the Irish pharmaceutical industry over the period of 2000 to 2010 (Egeraat and Barry, 2009) (van Egeraat, 2010) demonstrates that while firms

have been increasingly involved in research activities, the focus has been on 'lower value generating' components from a global perspective. On the other hand, a case study by (Deasy *et al.*, 2015) on research partnership between pharmaceutical firms and academic institutions suggests an increasing trend towards outsourcing of further research by these firms.

O'Dwyer *et al.*, (2023) explored collaborations between research institutions and pharmaceutical companies in Ireland through understanding enablers and barriers of the process. They suggested that the pharmaceutical industry in Ireland was increasingly depending on external sources to increase their research and innovation. However, the authors primarily explored the dynamics of research outsourcing by the Irish pharmaceutical industry to universities and other educational institutions. A similar perspective with respect to contract research organizations would need to be further analysed.

2.7 Summary of literature review

The literature analysed was found to contribute to understanding drivers of outsourcing research and the factors which influence selection of a contract research organization. They can be summarized in the following table (Table 1).

S.No	Literature	Key findings
1.	The growth and management of R&D outsourcing: evidence from UK pharmaceuticals.	Outlines various drivers and factors that can influence outsourcing of pharmaceutical research.
2.	Estimation of clinical trial success rates and related parameters	Expertise and specialization in specific therapeutic area leads increased success rates of clinical trials.
3.	CRO benchmarking for clinical biomarker analysis outsourcing.	Contract research organizations are assessed on their ability to provide top notch research expertise in specific therapeutic area.
4.	Drug Discovery: Collaborations between Contract Research Organizations and the Pharmaceutical Industry.	Drug development process are being increasingly outsourced enabling companies to strategically manage their resources.
5.	Offshore outsourcing of R&D to emerging markets: information	Superior information management systems of contract research organizations act as a driver for

	systems as tools of neo-colonial control.	outsourcing research and also as a factor selecting contract research organization.
6.	Investigating Knowledge Management Activities and Influential Factors of Contract Research Organizations (CRO)	Superior knowledge management activities by contract research organizations increase their efficiency.
7.	Drug development process and COVID-19 pandemic: Flourishing era of outsourcing.	Pharmaceutical companies outsource regulatory activities to CROs with expert local regulatory knowledge.
8.	Outsourcing in early drug discovery: Evolution and opportunities.	Outsourcing model of full time equivalent (FTE) views expertise as the resource.
9.	Criteria for site selection in industry-sponsored clinical trials: a survey among decision-makers in biopharmaceutical companies and clinical research organizations.	Timely completion of clinical trials is the most essential factor during site selection.
10.	Data driven CRO benchmarking for biomarker analysis.	Faster turnaround time of research data are indicative of higher CRO performance.

Table 1: Key findings of literature review.

2.8 Identifying research gaps and future directions

While the above sections examines the key drivers, factors and trends with respect to pharmaceutical research outsourcing, current literature was not available on comparison of in-house research versus outsourced research with respect to quality. The published data often focussed on how outsourced research enabled pharmaceutical companies to strategically succeed in the field of drug development. However, long term impacts on research and innovation in the pharmaceutical industry have not been assessed. Further, impacts on intellectual property rights as well as labour practices have not been observed on analysis of available literature. The current focus on state of outsourcing has been on operational and financial capabilities of contract research organizations. Recent literature on contract research organizations with respect to Irish pharmaceutical industry was also found to be lacking.

Articles assessing the competency of CROs often considered offshoring aspect of outsourcing and hence were based in Asia. This can be further explored through analysing a European and particularly Irish perspective on outsourcing of pharmaceutical research.

2.9 Conclusion

The process of drug development and the capital involved has been keenly documented throughout various decades. This literature review enabled the researcher to explore key works which emphasized the need for outsourcing. The main drivers identified included cost of research and development, the expertise needed to conduct research and the need to allocate resources to core competencies internally. Most research pointed out to the how the need for expertise in a particular field and efficiency during drug development was eventually contributing to outsourcing of research. While cost was often a factor, most of the literature relayed the statement that it was not priority in outsourcing decisions.

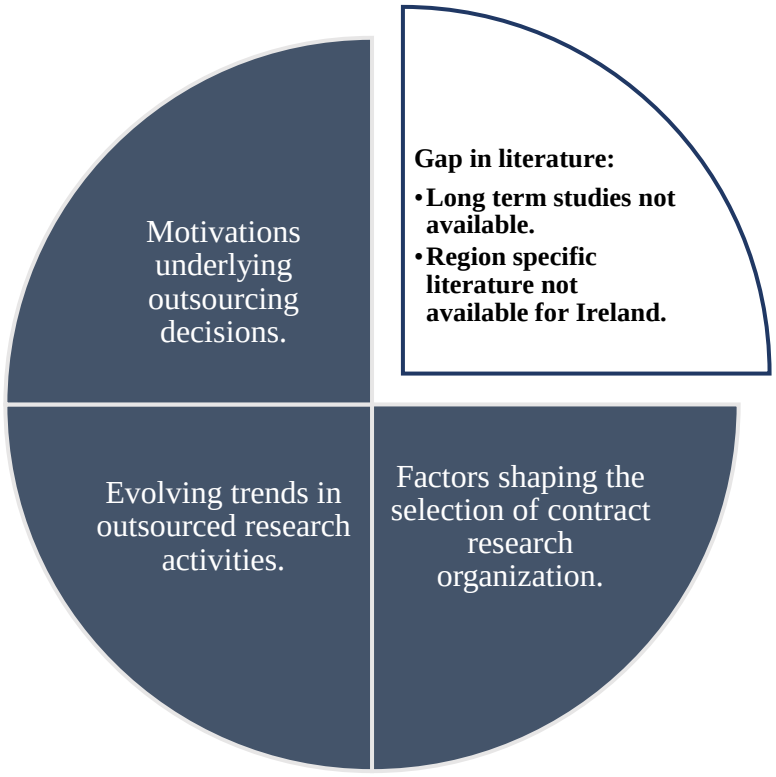

Figure 4: Components of the literature review (Researcher's own).

The evolving trends of prioritising data driven deliverables in outsourcing have been explored in this review with respect to various stages of pharmaceutical research. This implies the adaptability of pharmaceutical industry. On the other hand, analysis of literature on evaluation

criteria indicate a shift towards need for balancing expertise and collaborations. The key factors involved in selection of contract research organization have also been critically examined in this review which further helped to understand the challenges presented while outsourcing research. Significant gaps in literature with respect lack of recent research on outcome of integrating outsourcing in the pharmaceutical industry was also analysed especially a perspective on Irish pharmaceutical firms. Overall, the review helps develop a foundation for further research to understand this ever evolving practice. This can begin by addressing the gaps in literature on the impact of outsourcing on pharmaceutical firms and form a path for further scientific advancements.

CHAPTER 3: RESEARCH METHODOLOGY

This chapter provides a brief idea on the research design, methodology, and data collection procedures employed to gather insights into pharmaceutical research outsourcing in Ireland. It explores the research approach and philosophy as well as defines data sources, and analysis methods of the said data to achieve the research objectives.

3.1 Research philosophy and approach

Outsourcing of pharmaceutical research activities presents a significant and complex landscape (Billette de Villemeur *et al.*, 2022). Furthermore, this landscape cannot solely be defined by quantifiable metrics. Hence a purely positivist approach would not be suitable for current research. Rather, to understand the current scenario, deeper insight into the practice of outsourcing is imperative. The research problem lies in understanding the varied landscape and effectively identifying the drivers, emerging trends and pivotal factors in selection of contract research organizations for outsourcing research. This necessitates understanding the perspectives of those closely involved in the process of research outsourcing. Hence, in order to gain an industrial perspective on this, an interpretivist approach was undertaken by the researcher.

The factors affecting the selection of contract research organization as well as the key drivers for outsourcing research has often been subjective to the people executing the decisions in the pharmaceutical industry (DeCorte, 2020). Interpretivism helps to acknowledge that various stakeholders within the industry hold different opinions and hence can provide diverse perspectives. This essentially enables the researcher to understand the research subjects from their point of view (Saunders *et al.*, 2019). The influence of organizational culture, surrounding factors and individual values that affect the outsourcing practices in the industry can be assessed through this method.

The interpretivist approach does have its limitation when undertaken as a singular method. The acknowledgement of subjectivity as a core value in interpretivism enables the possibility for multiple valid perspectives to co-exist. Hence, the choice of this research philosophy, while enhancing the depth of understanding, can also introduce a degree of subjectivity throughout data collection, analysis and conclusions.

3.2 Research Approach

An inductive approach to the primary research further complements the interpretivism by allowing a more flexible structure of research emphasis. The outsourcing industry in itself has been constantly evolving (Mederos, 2021). Given this dynamic nature of the industry, an inductive approach ensures fluidity in identifying insights. In addition, it allows the researcher to capture emerging trends, patterns and interrelationships that would not be possible through a preconceived deductive approach. This would in turn impart more authenticity to this research. In conclusion, this research aims to form a detailed understanding of the current elements that are associated with outsourcing and at the same time understand the future directions of outsourcing landscape.

3.3 Research design

An exploratory qualitative research design is adopted for this study. While the main themes with respect to key drivers and factors associated with outsourcing of research and selection of contract research organization have been recurrent, they also vary across contexts (Wasan *et al.*, 2022) (Chen and Goh, 2019). An exploratory research design ensures a flexible and adaptable approach to the topic to gain an in depth insights into the industry. This aligns with the objective of analysing the outsourcing practice in pharmaceutical industry and would allow the researcher to assess the field in a new light.

The adoption of a qualitative method of data collection would enhance the research's capacity to understand the outlook on decision-making process of outsourcing. Qualitative research, by nature is used to unravel the research question based on human behaviours, perceptions and rationales. In current study, the main purpose has been linked to understanding the "why" rather than "what" of outsourcing. This is reflected in objectives wherein, major drivers as well as current trends are focussed. A subjective outlook provided by qualitative research would delve into the motivations and factors for the decision making process.

The application of above research design is done through semi structured interviews. This ensures balance between predefined enquiry structure and the opportunity to explore any emergent areas that might arise during the process of interview. The researcher interacts with key stakeholders who are individuals with experience in decision making process related to Outsourcing using open ended questions in the interview and this helps in generating valuable perspectives and for the participants to share their experiences freely which would further be analysed to uncover new themes and a deeper understanding of the pharmaceutical industry.

3.4 Time horizon

This is a cross sectional study as the research is conducted in the present time period. The current industrial perspective is analysed through interviewing key decision makers involved in strategic outsourcing decisions.

Primary data approach	Qualitative analysis
Philosophy	Interpretivist
Source	Semi structured interviews
Subjects	Individuals involved in decision making process of pharmaceutical research outsourcing.
Location	Ireland

Table 2: Summary of research methodology (Researcher's own).

3.5 Sampling strategy

The primary research is conducted through purposive sampling. Participants are individuals involved in decision making in the outsourcing of research activities in the pharmaceutical companies. This includes professionals holding the position of Chief scientific officers, Procurement managers, Directors or Vice presidents. The intentional selection of participants with significant level of experience and knowledge about outsourcing process in pharmaceutical industry enables the researcher to obtain valuable insight into the industry. This in turn ensures that the research objectives are addressed effectively.

The use of social media platforms like LinkedIn enables the researcher to identify and approach the participants for voluntary participation. Key words including the above mentioned positions

and hashtags related to pharmaceutical industry were used to generate list of potential participants and the profiles were screened on the basis of relevant experience and job descriptions. A total of 13 candidates of desirable experience and involvement in the industry were identified and selected candidates were further approached with short semi formal introductory message requesting participation in the study. Response was received from 5 candidates of which 3 agreed to be interviewed. Overall, the sampling strategy allows a deliberate and thoughtful selection of individuals which enhances the study's ability to contribute to the existing knowledge on outsourcing decisions.

3.6 Data collection method

The data collection method chosen for this research is semi structured interviews conducted through zoom calls. This was chosen to complement the exploratory nature of research adopted. The interview questions are open ended to allow the participants to explain and build on their responses and further invite discussion on themes that might emerge from the interview. This is in line with the interpretivist approach taken for the research. The questions in the interview are designed with focus on research objectives by understanding the perspectives and views of the participants.

The interviews are scheduled at a convenient time for the participant through zoom calls. The whole process is conducted with assurance of safety and comfort of the participants. The interviews are also audio recorded with participants consent. This is to transcribe them later for a thorough data analysis.

Before conducting the main interviews, a pilot testing was conducted on 1 participant of similar profile involved in the pharmaceutical industry. The purpose of the pilot test was to understand the flow and clarity of interview questions, as well as any possible ethical concerns that may arise. The participant was an individual with 12 years of experience in pharmaceutical industry of India and was involved in outsourcing decisions of their company. The pilot study enabled to weed out repetitiveness and restrictions in the original set of questions. The pilot study also enabled the researcher to frame the final questions (*Appendix 1 Pg 58*) in a manner that ensured minimum breach of confidentiality. Few questions were added and possible areas for probing were identified and marked in the questionnaire for actual interviews.

The interview consisted of open ended questions which enabled further probing if needed. The participants were informed of the purpose of the research and the advantages of participating

in the interview. Estimated time taken for the interview was also communicated. Various areas pertaining to the objectives were discussed systematically. In the end, answers were analysed with main points noted during the interview for clarifying the content obtained.

3.7 Ethical considerations.

Prior to the interview, the researcher elaborately explained full research as well as the basic information on the purpose of the study with the help of patient information leaflet (PIL). This was to ensure transparency of the research being conducted by explaining the use of collected data. Further, explicit informed consent was obtained for recording the interviews as well. It was also explained that the participants may withdraw their consent at any time in the study without any repercussions.

The questions asked were strictly to facilitate the requirements of the study which was for academic purposes and only focussed on understating an industrial perspective on outsourcing of pharmaceutical research. Hence, there were no questions on demographics of the participants. Furthermore, all the questions were formulated with focus on understanding the landscape with the participants expert and experience and not specific company information. The interviewees also had the option to skip any question that they felt uncomfortable answering or if they believed any of their responses would breach company confidentiality.

Any sensitive or personally identifiable data was securely handled and stored throughout the research with respect to GDPR guidelines (Health Research Board Ireland, 2023). All the participants confidentiality and anonymity were protected throughout the process.

3.8 Data analysis

The interviews were transcribed verbatim using Microsoft word transcribe tool and further cross checked with the audio to avoid any errors. Thematic analysis approach was employed to analyse the data in line with the inductive nature of the research. From the transcribed interviews, codes were initially identified and similar codes were grouped under focussed groups. Within this framework, overarching themes emerged which represented repetitive concepts across the interviews. This method enabled the researcher to obtain an in depth understanding in line with the initial objectives set out for this research.

3.9 Conclusion

In conclusion, this chapter explains the thoughtful and deliberate choices made to navigate the landscape of pharmaceutical research outsourcing. The selection of an interpretivist approach serves as the foundation and this further aligns with the complex and subjective nature of current research. This methodological decision is underscored by the recognition that understanding the motivations, contexts, and values underlying outsourcing decisions requires the researcher to go beyond quantifiable metrics. An inductive research design further complements the interpretivist approach empowering the researcher to uncover emergent themes and novel connections within the dynamic industry, thus imparting authenticity and relevance to the findings. Anchoring this approach in qualitative research methods further provides the means to understand the depths of human experiences and rationales. Semi-structured interviews as the data collection method further facilitates direct engagement with industry stakeholders, allowing the researcher to shed light on the multifaceted dimensions of outsourcing decisions. The researcher's ability to interact with these experienced decision-makers allows the emergence of valuable perspectives, which, in turn, contribute to the identification of novel themes and deeper insights into the industry dynamics. Overall, the research methodology chapter consists of a meticulously considered approach that captures the essence of the research journey. The alignment of interpretivism and inductive exploration supported by qualitative methods and semi-structured interviews, constitutes a holistic framework for unravelling the complexities of pharmaceutical research outsourcing. Hence this chapter sets the stage for subsequent analysis, discussion, and conclusion of insights for this study.

CHAPTER 4: FINDINGS AND ANALYSIS

4.1 Introduction

This chapter presents and analyses the data obtained from the interviews conducted according to the method described in the previous chapter. It explores the insights and perspectives gathered from interviews capturing the essence of the acquired information. The findings were carefully analysed to draw conclusions through interpretation. The researcher also examines the validity, reliability and trustworthiness of these findings shedding light on how raw data from the interviews transformed into identifiable patterns and themes. Moreover this chapter evaluates the implications and practical applications that arise from this research considering the evolving landscape of research outsourcing in Ireland. By synthesizing deductions and which help offer recommendations listed in the next chapter, it not only provides an industrial insight into the pharmaceutical industry in Ireland but also paves the way for future explorations in this field. Ultimately this chapter serves to understand the dimensions of pharmaceutical research outsourcing and its impact in Ireland.

4.2 Summary of Interview process.

There were 3 Interviewees who were interviewed virtually. The interviews took place between 31 July 2023 to 14 August 2023 and ranged from 30 minutes to 90 minutes based on the respondent's schedule. All respondents were experts from Ireland in the field of pharmaceutical research outsourcing and participated in the in-depth interview to share their insights and opinion on the topic. The Interviewees were part of 3 global pharmaceutical and biopharmaceutical firms based in Ireland and had prior experience working for a contract research organizations. They were all currently involved directly in decisions with regards to selection of contract research organizations for research in their respective firms. The interview consisted of probing questions under 6 sections (*Appendix 1 Pg 58*) covering the research outsourcing landscape of Irish pharmaceutical industry. The following table explains the profile of interview Interviewees with respect to their experience.

Interviewee	Role	Years of experience
Interviewee 1	Head of Operations	17 years
Interviewee 2	Vice- President	35 years

Interviewee 3	Senior Global Procurement Manager	14 years

Table 3: Summary of interviewees.

4.3 Thematic framework of results.

Figure 5: Thematic framework of the results.

The main themes observed over the interviews included:

1) Motivations for outsourcing research
2) Commonly outsourced research areas
3) Key factors in selection of contract research organizations.
4) Risks and challenges associated with outsourcing of research.
5) Emerging trends and future directions in outsourcing.

The themes were each derived from set of codes formed from the transcribed interview excerpts. Some of the codes were grouped further into focused codes while others were individual and directly contributed to the formation of the theme.

4.4 Research findings and analysis

4.4.1 Theme 1: Motivations for outsourcing research

Overview of findings

This theme "Motivations for Outsourcing Research" analyses the driving factors that lead pharmaceutical companies to outsource their research activities. This theme emerged from four focused codes identified from the interview: "Cost Barrier in Conducting Research", "Lack of expertise", " Lack of resources" and "Need for increased efficiency of the company". These

sub themes were uncovered by grouping the codes identified like Cost of manufacturing, Downsizing of companies, Lack of expertise, Lack of in house and specialized expertise, Lack of access to sites for clinical research, Lack of access to clinical trial patients. This theme hence offers a valuable insight into the strategic rationale behind outsourcing research including financial need and the quest for specialized skills. By using external resources, pharmaceutical companies can increase resource allocation and ultimately achieve superior research outcomes. Figure 1 represents the framework of the theme with number of times each code was mentioned in brackets to corresponding code.

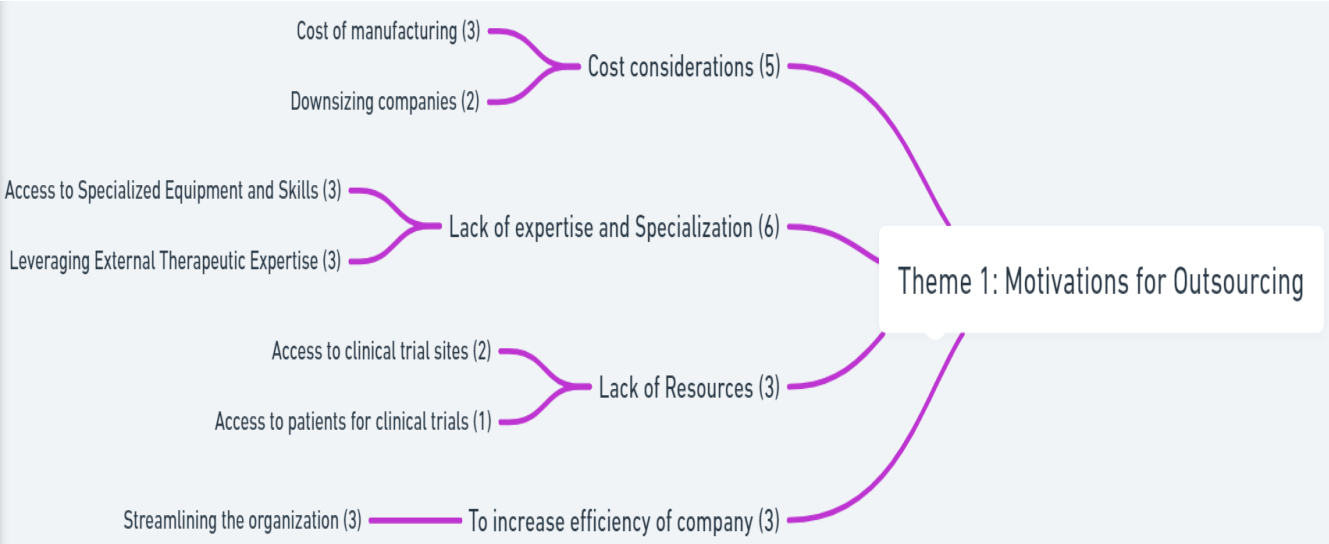

Figure 6: Framework of theme 1.

Description and evidence

1) Cost considerations

According to Interviewee 1 (P1), the main driver for outsourcing research was often costs involved in research. Interviewee 2 (P2) also stated the cost considerations while outsourcing research in the following statement:

P2: "So they have fixed costs, smaller and then when they need to do a big study, they contract out so they don't have to increase the headcount only to have to decrease it later."

Interviewee 2 also mentioned how most pharmaceutical companies have been downsizing in the recent economy and this has led to further budget constraints driving the need for outsourcing research. The statement was as follows:

P2: "The other thing which I think has changed as well is a lot of pharmaceutical companies now have been forced to downsize. …..So as a result, pharmaceutical companies often don't

have the resources themselves now. To be able to undertake these projects so that necessitates them to have to outsource."

2) Lack of expertise and specialization

Interviewee 1 expressed their view that smaller firms lacked individuals with expertise for carrying specialized research and hence it often motivated the companies to outsource research. The statement was as follows:

P1: "Most Irish pharmaceutical companies as compared to big multinationals, are still quite light with respect to the staff that they're carrying as well and also the expertise that you can get in Ireland. And so it just makes it makes sense to outsource and not just from a cost point of view, from an expertise point of view as well."

This view was further resonated by Interviewee 2 who commented on the impracticability of having extensive in house expertise in the following statement:

P2: "You can't be an expert in everything, so sometimes it's better to outsource to people who are experts."

Interviewee 3 (P3) was also of the opinion that research was often outsourced due to availability of more expertise from contract research organizations. The statement was as follows:

P3: "It helps with de risking the clinical trial to ensure that they have the resources and expertise to run the clinical trial as opposed to trying to run it in-house".

In addition, the interviewees also emphasized on lack of specialized expertise which was identified as another code in interviews 1 and 2. Interviewee 1 mentioned how preclinical work and gene therapy often needed access to specialized individuals in the following statement:

P1: "Generally a lot of the preclinical work can require a lot of high tech equipment and also high tech people as well. So a lot of big Pharmaceutical companies don't have this technology or have these people available to them a lot of times, especially if you're looking into, you know, gene therapy as well."

Interviewee 2 commented that the presence of contract research organizations that specialize in post marketing and post approval safety studies often provided expertise necessary for these studies to pharmaceutical companies.

3) Lack of resources

Interviewee 1 stated that during the conduct of clinical trials, pharmaceutical companies often do not have access to sites which would provide them with specific cohort. The statement was as follows:

P1: "If it's a healthy volunteer study it's easier. But for a patient study you won't have access to those sites, those doctors, to those that comes with building a business where you get access to those sites and you won't have that."

Similarly, interviewee 2 was also of the view that in order to develop more efficient projects, the pharmaceutical firms need to "go global". They also emphasized on the importance of access to enough patients during a clinical trial which was a driver for outsourcing the research to contract research organization. The statement was:

P2: "Patients sometimes take three or four other medications, they have arthritis, they have high cholesterol. So also being able to pick up maybe those rarer drug interaction which you don't see again in your in your clinical trials unless you have access to a larger population."

4) To increase efficiency of organization

During the interviews, all the Interviewees separately concluded that outsourcing of research was often a way to increase the efficiency of the organization. Interviewee 1 emphasized how utilizing external efficiency through outsourcing helped in streamlining the organization with respect to its research function.

P1: "You don't have to hold those expertise in-house then once you contract out you can have a management function and you can streamline your organization much more."

Interviewee 2 stated that organizations are often looking to become "more lean" and outsourcing of research has been a strategy they adopted for the same in the following statement:

P2: "Most pharma companies now are much leaner. So they have fixed costs, smaller and then when they need to do a big study, they contract out so they don't have to increase the headcount only to have to decrease it later".

Discussion

The first theme of understanding motivation for pharmaceutical research outsourcing corresponds to the objective of analysing the drivers for outsourcing pharmaceutical research. While outsourcing as a cost cutting strategy was not evident in literature, all the Interviewees agreed that outsourcing was indeed beneficial for reducing the costs incurred during research and development. However, while the literature suggests the companies aim to reduce costs by outsourcing to areas providing cost effective labour solutions (Kermanimojarad, 2020), suggesting cost as an opportunistic driver, the insight from the interviews unveils a different narrative. Despite cost considerations being a leading cause of outsourcing research, their impact varied on the basis of size and financial capacity of the pharmaceutical companies. Specifically for smaller pharmaceutical companies, cost was a predominant driver due to budget constraints. However, bigger firms often had a myriad of factors interplaying their decision to outsource rather than budget limitations.

The Interviewees all agreed that lack of in house expertise was one of the drivers for outsourcing research. While P1 identified the lack of expertise due to smaller size of the pharmaceutical companies, both P2 and P3 were of the opinion that specialization of research area and specialized equipments was more available in contract research organizations. This can be explained by Yu and Gusev, (2019), which identifies the migration of expertise to contract research organization due to their availability of high tech equipment. Further, the statement by Interviewee 2 on outsourcing of post marketing research to organizations that specialize in the area corresponds to findings by Wasan *et al.*, (2022) which state that pharmaceutical companies outsource regulatory reporting to organizations with expertise in regulatory framework of the particular region.

Another observation was the necessity for outsourcing to assist core competencies of the organization. This was reflected in two different opinions. While Interviewee 2 emphasized how outsourcing of non-priority functions was a declining trend, Interviewee 3 stated that organizations outsourced research to allocate individual resources more efficiently. The opinion by Interviewee 2 can be interpreted as an advancement to the research by Steadman, (2018)

which identified a prevailing trend within pharmaceutical companies to externalize lower-priority processes.

4.4.2 Theme 2: Commonly outsourced research areas.

Overview of findings

This theme, "Types and Areas of Outsourcing," explores the landscape of outsourcing practices within the pharmaceutical sector systematically. It was formed by codes identified from the second section of questioning which explored current research areas which were being outsourced by pharmaceutical firms in Ireland. These included post marketing testing, analytical and formulation development outsourcing, clinical research outsourcing and health economics outsourcing. These findings further underscore the industry's dynamic approach to resource allocation and the optimization of core competencies, ultimately contributing to enhanced research outcomes and operational efficiency. Figure 2 represents the framework of theme 2 with number of times each code was mentioned in brackets to corresponding code.

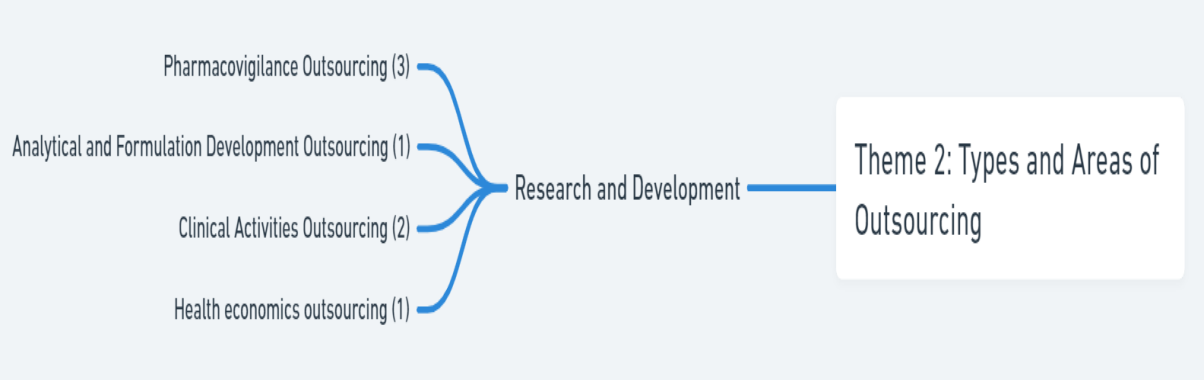

Figure 7: Framework of theme 2.

Description and evidence

1) Pharmacovigilance outsourcing

   All the Interviewees agreed that pharmacovigilance was most likely to be outsourced by Irish pharmaceutical firms. However, each Interviewee had unique perspective on the reason for this perspective.

   Interviewee 1 stated cost efficiency to be the reason for outsourcing of pharmaceutical research in the following quote:

   P1: “We outsource pharmacovigilance just because it isn't a big function….Also then the systems that are needed for pharmacovigilance as well……..systems are quite expensive.“

On the other hand Interviewee 2 emphasized that pharmacovigilance was most likely to be outsourced particularly by smaller companies. They affiliated the trend to requirement of specific expertise for pharmacovigilance as well as resources needed to maintain them in the following statement:

P2: "Pharmacovigilance, I think that's also outsourced, particularly by smaller companies who perhaps don't have the infrastructure to be able to manage things like you know Adverse event reporting and signal detection. So a lot of that now kind of what I would call more specialized Pharmacovigilance and risk monitoring is outsourced."

Interviewee 3 expressed the view that pharmacovigilance was most commonly outsourced due to increasing complexity in demand for more safety data by government organizations. In other words, pharmacovigilance was considered as a bigger function which could not be handled by small and upcoming pharmaceutical firms.

2) Analytical and formulation development outsourcing.

Interviewee 1 was of the opinion that second field to be outsourced most likely was formulation development especially in Ireland's context due to large number to small pharmaceutical firms. They stated:

P1: "The next biggest things though would be Analytical method development, formulation development and just well especially with startups." This was also interpreted as an outsourcing of contract manufacturing.

3) Clinical activities outsourcing

Interviewees 1 and 3 both expressed their opinion that clinical activities was often commonly outsourced in Ireland. Interviewee 1 expressed their opinion that clinical research was often outsourced due to decreased frequency of trials to be conducted every years and the fact that it needs to be specialized. The statement was:

P1: "Another very common function to be outsourced is your clinical activities as well which are outsourced to CRO. Because it's quiet a niche area and very few companies, especially small companies, can afford to keep on a clinical team as well and you know when you might be doing one study every few years."

Interviewee 3 stated how they had observed more of outsourcing in clinical trial specific services over the years.

P3: "I suppose it's (*most common outsourced area)* the clinical trials, but so I've done some pretty much clinical outsourcing but majority of what I've seen in Ireland is at a clinical outsourcing."

4) Health economics outsourcing

While this area was only mentioned by Interviewee 3, they emphasized the need for real world evidence through health economic outsourcing in the following statement:

P3: "Another area which I think is very common, health economics……in a clinical trial you may want a patient to take your medication for a month. But in the real world, maybe to save money, they only take it for two Weeks. So how does that two week data compare with your 28 day data."

Discussion

This theme corresponds to the objective of understanding commonly outsourced areas of research in Ireland's pharmaceutical industry. While this theme could not be analysed separately without considering the motivations for outsourcing these areas and taking into account the current trends in outsourcing, it was important to assess the industrial perspective on commonly outsourced areas to further explore the current state of Irish pharmaceutical industry.

While assessment of outsourcing landscape of UK pharmaceuticals by Howells *et al.*, (2008) revealed clinical research to be most outsourced function in that region. Based on the insights gathered from interviews, there is a predominant trend towards outsourcing of pharmacovigilance as the most common field in Ireland. However, this does not mean that clinical activities were less outsourced within Irish pharmaceutical industry. The opinion of post marketing surveillance being more frequently outsourced can be considered as the perspective by the interviewees who have observed the presence of large number of pharmaceutical start ups in the country. On the other hand, this can also be a reflection on research by O'Dwyer *et al.*, (2023) on increasing collaborations between research firms like universities and the pharmaceutical companies in Ireland. The increased partnerships indicated outsourcing of molecular development and such activities to academic firms due to their culture of innovation and the expertise they carry. Hence it can be implied that research at a stage like pharmacovigilance which would require less innovation and more quality control would be outsourced on a contract basis to large organizations.

4.4.3 Theme 3: Key factors in selection of contract research organizations.

Overview

The theme "Key factors in selection of contract research organization" examines the main considerations that guide pharmaceutical companies in their choice of Contract Research Organizations (CROs) for outsourcing research. This theme emerged from combination of two focussed codes namely evaluation criteria and selection factors. These were further derived from codes observed in the interview like "Resource Optimization through Outsourcing," "Strategic Planning for Outsourcing,", "Access to Expertise and Resources," "Access to Location,", "CRO Reputation and Track Record" and "Guideline adaptation". Interviewees emphasized the significance of a systematic CRO selection models that can be tailored to fit specific company requirements. This theme further highlights the process of allocating resources strategically and aligning them with the best value proposition. It also helps to understand the decision-making involved in selecting CROs, showcasing the importance of aligning expertise, resources, location, reputation, and regulatory adaptability. Figure 3 represents the framework of theme 3 with number of times each code was mentioned in brackets to corresponding code.

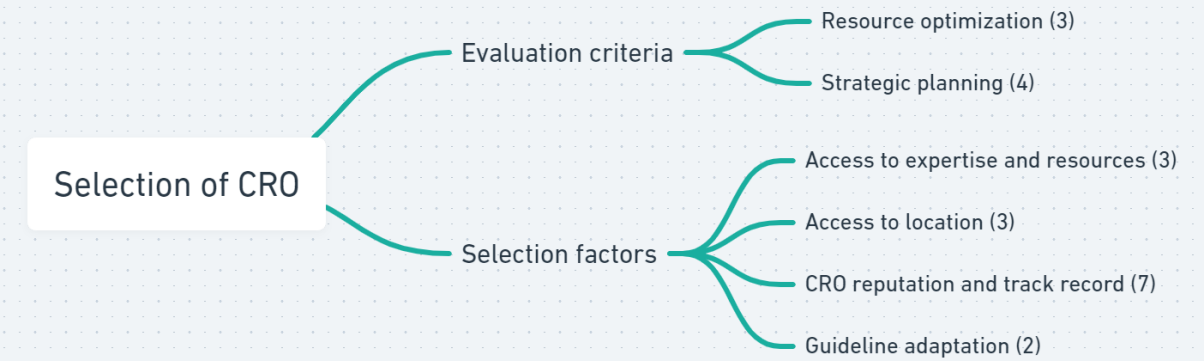

Figure 8: Framework of theme 3.

Description and evidence.

1) Evaluation criteria

   Interviewee 1 and Interviewee 2 had both stated the use of a CRO selection model based on few common criteria while selecting a contract research organization for research. While P1 ascribed a tweakable model which pharmaceutical companies transform according to their needs, P2 described the use of a checklist within the model to analyse CROs prior to outsourcing research.

Resource optimization was identified as one evaluation criteria in several conversations. Interviewee 3 stated that make "…companies would ensure to make most use of your resources. So like, that's what we did..".

Interviewee 2 summarized the selection of CRO in the following statement.

P2: "If you have a good product, a good protocol and a good set of investigators, 90% of the time, your study will be successful"

All the Interviewees emphasized the importance of forming a strategic plan for outsourcing to enable optimum resource allocation. Interviewee 1 stated the importance of the strategic allocation in the following statement:

P1: "You have to have a strategic plan. You also have to look at where your expertise are, make most use of your resources, where you want to spend your money and where you'll get the best value for your money."

2) Selection factors

When asked about what factors they think would come into play on the basis of the evaluation criteria while selecting a contract research organization, all the Interviewees emphasized the reputation and track record of the company to be of utmost importance. In fact, this code was mentioned most times in all the conversations.

The reputation and track record of the company was implied through various elements by the 3 Interviewees. For example, the size of the company was one theme mentioned by both interviewee 1 and interviewee 2. Both agreed that size of the company was a very important function to consider, P1 preferred smaller, more focussed CROs as they felt bigger organizations would not be suitable for small scale organizations. They stated:

P1: "For small companies you don't want to go into *(naming a few big scale CROs)* where you're going to be lost"

On the other hand, P2 specifically stated the advantage of smaller firms with regards to accessibility of management of the company and ease of forming personal connections with these organizations. Hence trust was the utmost factor that P2 emphasized while selecting a CRO.

P2: " So if I'm happy with the CRO I'll go to them for another project. Because I've already built that trust, the relationship. I understand the procedures, the systems, and perhaps I know the CEO. So if I have a problem I can just bring the CEO and say there's an issue

here. I need you to jump in and sort it. If I'm working with *(naming a big scale CRO)*, you know I have to go through probably 10 layers of management to get to that CEO."

The reputation of a CRO was often considered by measuring various factors like "financial stability", time taken for completion of a study, the "systems and platforms they have in place" and which team the outsourced project would be assigned to according to participant 2.

Interviewee 3 voiced similar opinion with respect to track record of the organization. The statement was:

P3: "…and the quality as well, that is high priority and any interactions in the past with the CRO would be taken into account how their quality organization set up and if there has been any quality issues in the past with the company."

Therapeutic expertise and access to location as well as resources were second most common factors mentioned in the interviews. Interviewee 1 was of the opinion that therapeutic expertise was least important while considering a CRO as in the current age expertise could be easily accessed. They stated:

P1: "Then finally, probably less important these days, is therapeutic expertise".

On the other hand, Interviewee 1 was of the opinion that experience in therapeutic areas was important "especially when you're doing trials". The expertise was also preferred in specific regions by interviewee 3 in the statement "…..where you want to run your clinical trials and does the CRO have expertise in these regions."

With respect to the location, Interviewee 2 stated that companies with global reach was preferred while outsourcing certain areas of research for convenience.

P2: "Companies prefer not to go to three different CRO's, you know, one for America, one for Europe, one for Asia PAC."

On the subject of location of the CRO, Interviewee 1 commented on the growing trend of globalization of contract research organization. They emphasized that base of the company did not matter as long as they had access to other factors while evaluating the company for outsourcing. P1: "So I suppose, we just found this recently, where (*where the CRO HQ is located*) does not really come into play since all companies are going global nowadays."

Discussion

This theme corresponds to the objective of identifying various factors which come into play while selecting a contract research organization for outsourcing. The emphasis on collaborative ability of contract research organization by interviewee 2 aligns with the perspective provided by Chen and Goh, (2019) which suggested the need for outsourcing partner assessment using dual factor theory which assessed the ability of contract research organization to be strategic partners to the pharmaceutical firm along with their individual capabilities.

Analysis of literature had provided cost effectiveness as one of the desired factors in various organizations. However, no participants in this interview had suggested cost as a factor in this particular line of questioning. This was surprising considering the mention of cost as a motivation for outsourcing research multiple times during the answers corresponding to the first theme. The response can be attributed to respondents view that while cost constraints may drive pharmaceutical companies to outsource their research, selection of said partners would solely be based on other factors which are essential to the quality of research.

Access to therapeutic expertise and resources was often a common theme observed in the literature (Steadman, 2018), (Dolman *et al.*, 2020). This was also resonated in the data from the interviews. Interviewee 2's opinion on reasonably faster completion of clinical trials by the CRO as a desirable attribute while assessing the reputation of the company can be further explained through research by Wasan *et al.*, (2022) who observed that access to specialized expertise had direct influence on reducing time taken for trial completion.

4.4.4 Theme 4: Risks and Challenges associated with outsourcing research

Overview

This theme delves into the challenges and risks that pharmaceutical companies in Ireland encounter when attempting to navigate the landscape of research outsourcing. This theme emerged from the patterns identified in the interview with regards to regulatory challenges as well as impact of staff turnover in contract research organizations. Since the question was direct to assess the challenges and risks without specifically providing any prompts to the participants, three separate views were obtained from the interviewees. The assessment of this theme allows to explore future trends in outsourcing of research as well as provide recommendations for current strategies to pharmaceutical firms in the selection of contract

research organizations. Figure 4 represents the framework of theme 4 with number of times each code was mentioned in brackets to corresponding code.

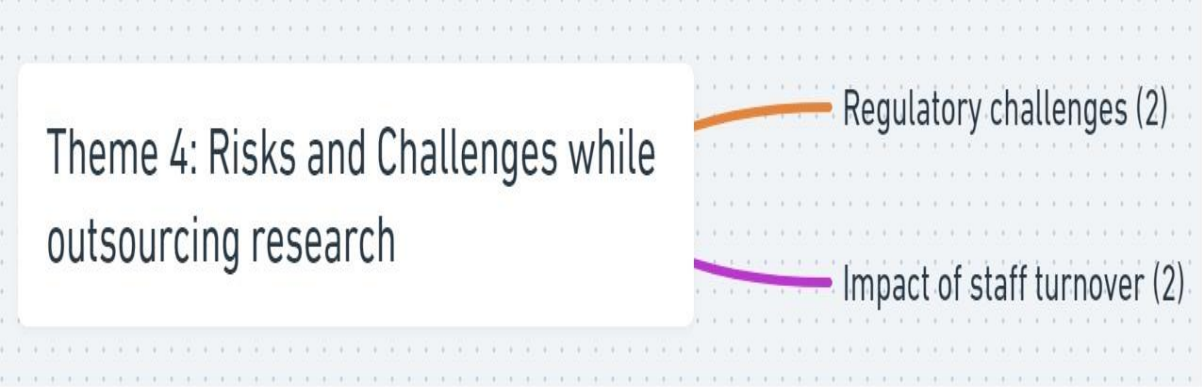

Figure 9:Framework of theme 4

Description and evidence.

1) Regulatory challenges

   The view of regulatory ramifications due to inappropriate outsourcing practices was provided only by participant 1. This was assessed as a separate theme since two separate challenges were identified by the interviewee with respect to the question.

   P1 emphasized the importance of having a contract research organization that was up to date in changing regulations of the industry. With respect to clinical trials, they mentioned that "timelines have changed" and experience dealing with the new timelines is a necessity in the following statement:

   P1: "So I suppose with the new guidelines that have come into place and if the company hasn't previously used these guidelines, it would be a risk."

   Another risk with respect to changing regulations were observed in the field of contract manufacturing. They implied that it was necessary to closely monitor the performance of contract research organizations with respect to these changes as they could be possible risks encountered while outsourcing research.

   P1: "The stability requirements have also changed from the old regulations to the new regulations as well."

2) Impact of staff turnover.

The impact of staff turnover while outsourcing to contract research organization was the challenge mentioned by interviewee 2 as well as interviewee 3. While discussing the risks they observed in the practice of outsourcing interviewee 1 stated:

P2: "People leaving so staff turnover in the CRO I think is also important. So I would always check turnover data and perhaps even speak to people you know how long have you been at the company?",

Interviewee 3 further delved into the reasons for considering staff turnover as one of the main risks while outsourcing in the following statement:

P3: "You're getting consistency on the team members when there isn't high turnover and you're not losing experienced team members that need to be retrained."

Discussion

This theme corresponds to the objective of identifying the challenges and risks to be considered while outsourcing pharmaceutical research. Analysis of this theme enables the researcher to provide further recommendations to the pharmaceutical industry with respect to outsourcing of research.

Wasan *et al.*, (2022) had commented on the risk of contract research organizations not having sufficient expertise in the regulatory field of the particular region which might result in unacceptable data quality for submission. The findings of the present research align parallel to the literature, they do not mirror the exact same outcomes. The response from the interviews suggest the need for up to date knowledge on the FDA and EMA guidelines as well as previous experience working with it.

With respect to the impact of staff turnover on research outsourcing, statements by interviewee 2 and interviewee 3 compliment each other. Interviewee 2 follows the same pattern as the previous theme, with focus on amicability of the organization to be outsourced. This ultimately leads to the view that outsourcing should be considered with respect to the individuals involved in it rather than relying on the corporation as a whole entity.

4.4.5 Theme 5: Future directions in outsourcing

Overview

This theme explores the trends gaining traction in the pharmaceutical industry with respect to outsourcing. The question was asked as a closing remark during the interview to obtain an insight into the practices as well as factors needed to be monitored for further research in the industry. This theme was formed by various codes identified in the interviews like Risk based approach, Integration of technology and other future trends. The last category of codes comprised of interview statements which were future possibilities as well as changes in management outlook due to outsourcing. Figure 5 represents the framework of theme 5 with number of times each code was mentioned in brackets to corresponding code.

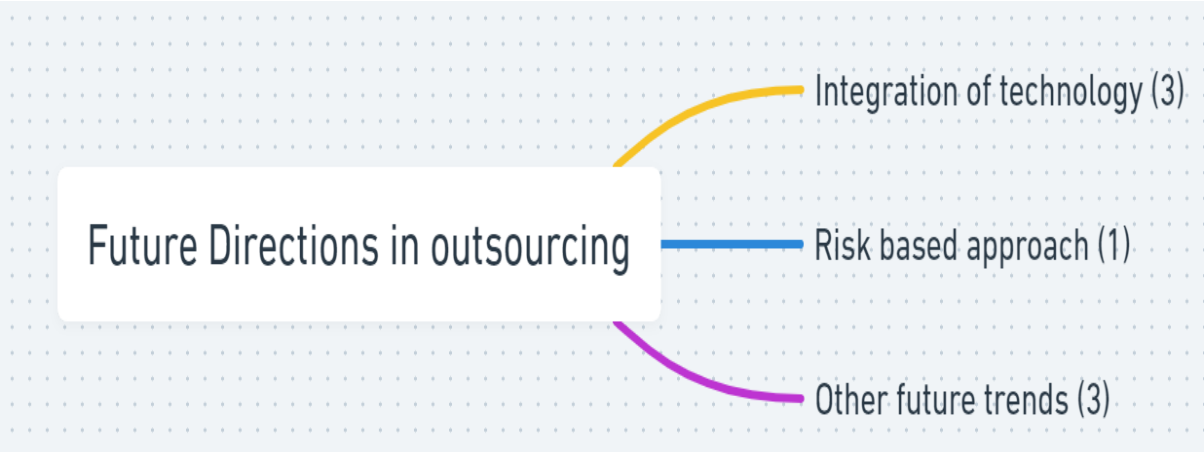

Figure 10: Framework of theme 5

Description and evidence

1) Risk based approach

   Interviewee 2 stated the growing trend of regulatory agencies adopting a risk based approach which would have a heavy impact on the pharmaceutical industry. They further explained that there has been a shift in quality monitoring process by regulatory bodies of United stated and Europe, wherein, instead of constant real time data analysis, data monitoring was prioritised on the basis of risk assessment in clinical trials. Hence integration of risk assessment has been observed.

   P2:"Now FDA and EMA are moving to what they call a risk based approach, so only having to check important data points. You know key efficacy, key safety. So now this risk based monitoring means you have to do less work out in the field, but more work in house."

2) Integration of technology.

   Both interviewee 1 and interviewee 2 expressed that future of outsourcing would be more specialized and advanced technology use by the CROs. Participant 1 stated: "Some of the

cutting edge therapies now, gene therapy, stem cell therapy, there are CRO's now that are kind of setting themselves up as having the expertise." While participant 2 stated "And what the future holds is probably more technology, artificial intelligence." In addition, participant 2 also mentioned the use of artificial intelligence with respect to pharmacovigilance outsourcing specifically.

3) Other future trends.

Participant 3 stated that the future of outsourcing was connected to efficient partnership formation between the CRO s and pharmaceutical firms enabling CROs to take on more responsibilities.

P3: Yeah, it's more moving for (*company name)* anyway, to a partnership model where we would kind of give more responsibility to the CRO and get more, out of full service where we kind of get them to do the early activities and be involved decision making at the start."

Participant 2 had similar opinions with regard to the changing management scenarios of the pharmaceutical industry. In addition, importance on faster market approvals of drugs were observed in the industry by participant 2.

P2: "And the other thing as well is we're going to have more time driven contracts. So if you have a drug and you want to get that on the market as quickly as possible."

Discussion

The findings from the interview illuminate key trends in pharmaceutical outsourcing, shaping the industry's future trajectory. These trends, signify transformative shifts and strategic directions that are redefining outsourcing practices. Regulatory agencies' adoption of risk-based approaches can help optimize resource allocation and thus focuses on key efficacy as well as safety indicators. This in turn helps maintain regulatory compliance. The shift towards risk based approach and selection of milestone based strategic partners were predicted in models for outsourcing of drug development process by Mistry *et al.*, (2012).

CROs are aligning with cutting-edge therapies such as gene and stem cell therapies, and further integration with artificial intelligence aimed at streamlining operations, especially in pharmacovigilance can be linked to the necessity of industrial evolution to Pharma 4.0.

Efficient partnerships between CROs and pharmaceutical firms are gaining importance as evident from the interviews. This view was also shared by the participants during their initial

introduction where all of them had mentioned how contract research organizations are no longer seen as a service provider, rather they are being recognized as strategic partners. In conclusion, these trends signal towards a new era in pharmaceutical outsourcing, characterized by strategic adaptation, innovation, collaboration and agility.

Through this chapter, the interviews conducted and data analysis performed provided a detailed understanding of the complex landscape of pharmaceutical research outsourcing in Ireland. The insights gathered from the interviews were examined carefully to extract meaningful conclusions and discernible patterns. Through this process, the researcher has ensured the credibility and reliability of the findings, ultimately forming distinguishable themes from the raw data. The synthesis of findings from this chapter serves as a foundation for the conclusion as well as future recommendations from this research to further guide the industry practices and decision-making.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.1 Introduction

The exploration and analysis of the data obtained from interviews provide valuable insights into the dimensions of pharmaceutical research outsourcing within the context of Ireland. The findings shed light on critical factors that motivate pharmaceutical companies to outsource, the commonly outsourced areas, the selection criteria for contract research organizations (CROs), as well as the challenges and risks associated with outsourcing. This chapter is based on the synthesis of findings and subsequent implications lead to recommendations for the industry's stakeholders.

5.2 Conclusion

Motivations for outsourcing research.

The first theme delves into the motivations driving pharmaceutical research outsourcing. While cost reduction emerged as a prominent factor, it was found that smaller pharmaceutical firms primarily considered budget constraints as a driving force. Lack of in-house expertise and the need to enhance core competencies were also identified as significant drivers. The findings emphasize the concepts from the literature that cost-saving strategies and the need for efficient resource allocation shape outsourcing decisions (Kermanimojarad, 2020). However, a new perspective on cost as a driver was obtained through this research, as the industry insight was based on the growing presence of startups in the Irish pharmaceutical industry.

Commonly outsourced research areas.

The analysis of the second theme highlighted that pharmacovigilance is the most commonly outsourced field within the Irish pharmaceutical industry. However, this doesn't diminish the outsourcing of clinical activities, which are deeply influenced by the presence of pharmaceutical start-ups and the trend of collaborative partnerships between research institutions and companies. Hence with respect to outsourcing to contract research organizations pharmacovigilance seemed to be more preferred field due to need for quality in regulatory submissions of safety reports.

Key factors in selection of contract research organizations.

The theme focusing on CRO selection criteria emphasized the significance of collaborative abilities and expertise. The growing trend towards collaborative partnerships was underscored.

The importance of considering the contract research organization with respect to the individuals they provide rather than the reputation of the company as whole needs to be taken into account for outsourcing decisions. In addition, the absence of cost as a factor taken in to consideration suggest a growing trend of contract research organizations providing more or less a unifying rate for research services. This makes the theories on Full time equivalent rates (FTE) explored in the literature less significant redundant. (Mistry *et al.*, 2012).

Challenges and risks associated with outsourcing.

The challenges and risks associated with outsourcing were highlighted in the fourth theme. The necessity for up-to-date knowledge of regulatory guidelines, particularly those of the FDA and EMA, emerged as a crucial factor. The impact of staff turnover within outsourced projects was often linked to the reputation of the CRO and hence was one of the main scenarios to be considered during risk assessment. These insights provide the importance of continuity and interpersonal relations in outsourcing decisions.

Emerging trends and future directions in outsourcing.

On the exploration of future direction of pharmaceutical outsourcing, the results enable us to understand not only the pharmaceutical outsourcing industry but also the future opportunities for individuals looking to form a career in the field. The interviewees opinion on hiring trends with respect to the current industry is particularly important as it emphasizes the need for more management based expertise within the pharmaceutical industry.

5.3 Limitations of the study

While this dissertation aims to provide an understanding of pharmaceutical research outsourcing in Ireland, it is essential to acknowledge certain limitations in the research process. These limitations enable identification of potential gaps which can be explored with further research.

The sample size and process of selection of participants engaged in interviews might be one of the limitations to this study. While the insights were garnered from a select group of highly experienced individuals, this will still not represent the entire spectrum of outsourcing experiences and perspectives within the Irish pharmaceutical landscape. Furthermore, there is a possibility of selection bias, as the willingness of participants to engage in interviews could be influenced by their specific viewpoints or experiences. Even though every effort has been taken during the design of the methodology to exclude any personal bias, the qualitative nature

of research explores the researcher's and participants subjective point of view and hence would need further quantitative data to support the themes.

The findings of this research are with respect to the unique context of the Irish pharmaceutical industry. The dynamics identified from this research may not necessarily be same for other geographical regions or industries. The specific challenges as well as trends observed in the Irish pharmaceutical landscape will limit the generalizability of the study's outcomes. In addition, this study captures the essence of industrial insight in this specific age and time. As mentioned before, the pharmaceutical industry is ever evolving and as this continues, factors influencing outsourcing decisions and practices observed now may be redundant in the future.

In conclusion, while this research strives to provide an understanding of pharmaceutical research outsourcing in Ireland, it is important to understand the findings with limitations outlined above in mind. These limitations also serve as signposts for future research and further refinement of knowledge within the realm of pharmaceutical research outsourcing.

5.4 Recommendations

Based on the analysis of findings, several recommendations are proposed to enhance the pharmaceutical outsourcing landscape in Ireland for both pharmaceutical firms and CROs.

For pharmaceutical firms: Fostering of collaborative culture between pharmaceutical firms and CROs can help further embrace the shift from CROs a service provider to a strategic partner for mutual growth and innovation. At the same time a need for investment in in-house expertise development to address skill gaps, can help reduce the reliance on outsourcing solely due to lack of specialized skill set. The prioritization of knowledge on regulatory frameworks can lead ultimately lead to high-quality data submission an lesser chance of rejections.

For contract research organizations: Based on primary data from current study, development of strategies to mitigate the high staff turnover need to be implemented due to the growing importance of reputation of the work culture of the company. This would help pharmaceutical firms choose organizations that maintains consistent and effective collaboration. Tailoring outsourcing strategies based on the size and capabilities of pharmaceutical companies, would help to balance cost considerations with strategic needs specifically for Irish pharmaceutical industry where the presence of small scale startups have been increasing.

In conclusion, this dissertation's findings provide an improved understanding of pharmaceutical research outsourcing in Ireland. The identified motivations, trends, challenges,

and recommendations collectively contribute to shaping an adaptive approach to outsourcing in the rapidly evolving pharmaceutical landscape. Further, quantifiable research can be performed on the comparison of specific variables involved in the outsourcing landscape.

This research not only enabled an in-depth analysis of the industrial perspective, resulting in actionable suggestion for stakeholders, but it also helped the researcher reach a profound realization. This revelation was that, at its core, the entire industry's dynamics were inherently intertwined with the individuals who constitute it. More specifically the employees of the organization. This insight emerged throughout the interviews, wherein individuals possessing extensive years of experience, consistently emphasized the pivotal role of a company's treatment of its employees. This factor held great significance, implying that ethical and human values ought to be precedent even in the realm of technicalities.

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APPENDIX 1: Sample Interview Questions

Introduction

- To begin, could you please introduce yourself and provide an overview of your experience in the pharmaceutical industry, particularly in research outsourcing?
- How do you perceive the current state of pharmaceutical research outsourcing in Ireland, and what trends have you observed in recent years?

Understanding common drivers for outsourcing research

- In your opinion, what are some key factors that prompt pharmaceutical companies to outsource research activities to contract research organizations (CROs)? Could you share some specific examples of successful partnership between CROs and pharmaceutical companies that highlight the key drivers behind the decision to outsource.

Exploring the type of research outsourced in Ireland.

- Based on industry trends, which specific types of research activities do pharmaceutical companies commonly outsource to CROs in Ireland?
- In your opinion, how would pharmaceutical companies determine which research activities are best suited for outsourcing and which ones they prefer to keep in-house?
- Could you comment on how these outsourcing strategies impacted their progress in the pharmaceutical industry?

Discussion of factors influencing CRO selection.

- In your experience, what general factors do pharmaceutical companies take into consideration when selecting a contract research organization for research outsourcing in Ireland?
- From your experience, how would pharmaceutical companies assess the CROs before finalizing a partnership? Are there any specific evaluation criteria they use?

Understanding challenges and risks associated with outsourcing practices

- In your view, what are some of the challenges or risks associated with outsourcing pharmaceutical research to CROs?
- How can these challenges be dealt with to ensure a successful collaboration between pharmaceutical companies and CROs?

Exploring the future of outsourcing.

- How do you see the landscape of pharmaceutical research outsourcing evolving in the coming years, and what implications would it have for the industry as a whole?

- What are some of the emerging trends or innovative approaches in pharmaceutical research outsourcing that are gaining traction in Ireland's pharmaceutical industry?
- Based on your experiences, what recommendations would you make to pharmaceutical companies in Ireland regarding their outsourcing strategies and partnerships with CROs?

APPENDIX 2: Informed consent form.

Contract Research Organizations for Outsourcing Pharmaceutical Research in Ireland: An Industrial Insight.

The researcher retains one copy signed by both themselves and the participant. The participant should also receive a copy of consent form as a record of what they have signed up to.

- I (*participant's name*) voluntarily agree to participate in this research study.
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind .
- I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study.
- I understand that participation involves answering questions by the researcher about the nature of outsourcing pharmaceutical research as described in the information leaflet.
- I understand that I will not benefit directly from participating in this research.
- I understand that all information I provide for this study will be treated confidentially.
- I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.
- I agree to my interview being audio-recorded.
- I understand that disguised extracts from my interview may be quoted in dissertation, published papers, ejournals, library etc.
- I understand that I will adhere to all of the codes of conduct and employee confidentiality for company XXX and there is no expectation to breach these by partaking in this research.
- I understand that if I inform the researcher that myself or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission
- I understand that signed consent forms and original audio recordings will be retained in researcher's personal computer until the exam board confirms the results of the dissertation.
- I understand that a transcript of my interview in which all identifying information has been removed will be retained for two years.

- I understand that under freedom of information legalisation I am entitled to access the information I have provided at any time while it is in storage as specified above.
- I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

Researcher Details

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Signature of participant

……..

Date:

Signature of researcher

I believe the participant is giving informed consent to participate in this study.

……

Date: