DISSERTATION

How can Ireland Improve Access to Clinical Trials for Patients? A Policy and Strategy Perspective

Module Title: Capstone Project

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Project Submission Sheet

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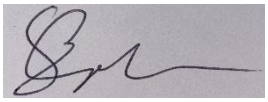
Signature: 

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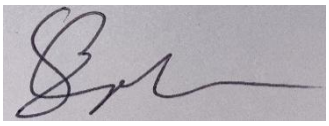
Signature of research student: 

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Abstract

Clinical trials are essential for evaluating the safety and effectiveness of new therapies, improving patient outcomes, and contributing to economic growth. Yet, Ireland has consistently underperformed in this area compared to international best practice. This dissertation explores the question: 'How Can Ireland Improve Access to Clinical Trials for Patients? A Policy and Strategy Perspective.'

Using a mixed-methods approach, the study combines 14 semi-structured interviews with key stakeholders in the Irish clinical trials ecosystem and quantitative analysis of Ireland's performance relative to benchmark countries. This dual approach provides a more comprehensive understanding than either method alone, revealing both systemic challenges and practical opportunities for improvement. This comprehensive analysis reveals systemic barriers and underutilised opportunities that hinder Ireland's clinical trial potential. From this, the study proposes a set of evidence-based recommendations focused on five key domains:

1. **Policy & Advocacy** – Strengthening national direction and visibility.
2. **Funding** – Enhancing investment in trial infrastructure and capacity.
3. **Integration** – Improving coordination across health, research, and regulatory systems.
4. **Strategic Partnerships** – Leveraging public-private and academic collaborations.
5. **Legislative Interpretation** – Clarifying and streamlining the clinical trials regulatory environment

These findings highlight the need for a cohesive national strategy that aligns policy with operational realities, ensuring patients in Ireland have greater and more equitable access to clinical trials.

While the study provides a robust foundation for policy development, certain limitations are acknowledged, including time constraints and a non-representative sample of stakeholders. As such, findings may not fully capture the breadth of perspectives across the sector. Future research should delve deeper into national infrastructure, expand stakeholder engagement, and build on this work to create an enhanced base for meaningful reform in Ireland's clinical trial landscape.

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1. Introduction

Clinical trials are research studies conducted in humans to evaluate the safety and effectiveness of medical interventions such as new medicines, treatments, devices, diagnostics or procedures (WHO, 2023). As well as providing vital information on the impact of treatments on patient outcomes, clinical trials are also the mechanism through which regulators approve medicines for public use and reimbursement.

A strong clinical trial infrastructure gives patients access to sometimes life-saving treatments (IPHA, 2024). Clinical trials span all interventions from medical devices to cell and gene therapies and are critical for advancing healthcare.

Clinical trials are massively important to patients for a range of reasons, including allowing patients to “play an active role in their own healthcare, gain access to new treatments, increase the options for treatment when standard therapy has failed, and helping others by contributing to the advancement of medical knowledge” (Novitzke, 2008). In addition to the direct benefits of clinical trials, it is widely recognised that patients who are cared for in research active environments have better healthcare outcomes, with one study highlighting improvements (reductions) in mortality rates across National Health Service (NHS) England hospitals which were more research active (Ozdemir et al., 2015). This speaks to the important impact of trials, as engines of innovation in healthcare, promoting a culture of enquiry where outcomes are best.

Clinical trials also drive economic growth, with the global clinical trials market valued at $64.94 billion in 2025, and projected to grow to $104.41 billion by 2032 (Fortune Business Insights, 2025). The life sciences sector in Ireland spans pharmaceuticals, biopharmaceuticals, medical devices and diagnostics, and is a major contributor to Ireland’s economy, with over €45 billion exported in 2022, and 50,000 people directly employed within the sector (The Irish Times, 2022). Ireland is uniquely placed for research and innovation as a global hub with a thriving life sciences sector, as well as being home to 16 of the top 20 technology companies globally, and the three largest enterprise software organisations (IDA, 2025).

Ireland has a well-developed collaborative landscape which supports clinical trials, providing expertise in protocol development, site management, data management and more. In addition to this, Ireland’s educated and skilled workforce and the substantial

pharmaceutical presence further solidify its attractiveness for conducting clinical trials (InnoPharma Education, 2024). Key features of this landscape which can enable Ireland's clinical trial activity include well-established regulatory frameworks, international collaborations, academic research centres, clinical trial networks, and funding agencies.

The regulatory framework within Ireland for conducting clinical trials is made up of national bodies with responsibility for regulatory and ethical compliance. The Health Products Regulatory Authority (HPRA) are the national competent authority and alongside the National Research Ethics Committees (NREC) provide rigorous oversight and streamlined approval processes, ensuring data security and patient safety in line with EU standards such as the EU Clinical Trials Regulation (HPRA, 2025).

Ireland's clinical trial activity is primarily driven by a network of six clinical research facilities/centres (CRF/Cs) which conduct clinical trials with hospital and industry partners (HRB NCTO, 2022). In addition to the CRF/Cs funded by the Health Research Board (HRB), the HRB also fund 9 clinical trial networks (CTNs) which focus on disease specific trials, including in areas such as cancer, critical care, and rare diseases (HRB NCTO, 2022). These CRF/Cs and CTNs bring together researchers, clinicians, patients, and industry partners to collaborate on clinical trials.

One of the most important enablers of clinical trials in any country, is funding. The HRB provides significant funding and support for clinical trial initiatives, including infrastructure development and trial specific funding, with over €155 million invested by the HRB to 2022, and additional funding ongoing (HRB, 2023). The maturity of Ireland's clinical trials ecosystem to date is largely due to the HRB, which has developed a strong base and primed the system for expansion. This investment has allowed Ireland to occupy key positions within Europe and beyond for coordinating and leading international efforts such as the BOOSTAVAC vaccine trial, evaluating the efficacy of booster vaccines for SARS-CoV-2 (COVID-19) which was sponsored in Ireland by UCD and led by UCD Principal Investigators (UCD School of Medicine, 2023).

Despite Ireland's growing clinical trial capabilities, there are significant challenges within the system which inhibit its full potential. A study conducted by the Irish Pharmaceutical Healthcare Association (IPHA) found that Ireland significantly

underperforms compared to other benchmark countries, with Ireland initiating 35% of the number of trials initiated in Denmark, and 69% of the number initiated in Finland from 2014 to 2023 (IPHA, 2024). Considering the scale of the pharmaceutical and biopharmaceutical industry footprint in Ireland, Ireland should be performing at least in line with its European counterparts.

There has been limited similar research undertaken on Ireland's clinical trial system to date. In 2019, the HRB published a review of all clinical research infrastructure in Ireland, focused specifically on infrastructure rather than a system wide view. The review found some key issues across the infrastructural system including a lack of integration of clinical research into healthcare, difficulties in collaboration, duplication of skills and knowledge and substantial variability across HRB funded infrastructures (HRB, 2019). While this review is nearly six years old at the time of this research being prepared, many of the issues identified remain prominent in the clinical trials, and broader clinical research ecosystem.

Leddy et al. highlight that many of the factors which have a detrimental effect on the initiation of clinical trials in Ireland are typically outside of the control of singular infrastructures. For example, it is highlighted that the most common issues experienced by the sample within the study include areas such as contracting, ethical approval, staff availability, and site identification, selection and activation (Leddy et al. 2020). This study emphasises that the system in Ireland does not make it easy to perform clinical trials through timeline issues and the lack of suitably trained professionals in areas such as biostatistics, which are core to enabling the conduct of clinical trials.

In 2024, the Minister for Health established the National Clinical Trials Oversight Group (NCTOG), "tasked with developing recommendations to increase the number of commercial and non-commercial clinical trials taking place in Ireland" (gov.ie, 2024). While the work of the group is still ongoing, interim recommendations have been published to improve areas of the trials ecosystem in Ireland and enable the completion of more clinical trials.

These areas include contracting, costings and data protection (gov.ie, 2024). As evidenced by the interim recommendations published by the Group and the published guidelines, the Group is primarily focusing on legislative areas and frameworks.

The purpose of this dissertation is to identify challenges and opportunities for Ireland to improve its clinical trial performance, thus providing better access for patients. The outputs of the research will be evidence-based recommendations, based on findings derived from literature, from interviews with key stakeholders in the Irish system, and from a quantitative analysis of Ireland's clinical trial performance and the factors affecting this.

The position of this research is that Ireland can undoubtedly increase its clinical trial performance. Patients accessing health services in Ireland deserve the best care, and clinical trials are a vital ingredient of providing the best care. There is appetite in this area, from the ongoing efforts of academic institutions and the HRB, to the establishment of the NCTOG. Thus, this research is timely to identify actionable recommendations to increase Ireland's trial performance.

While the current system is better than nothing, it would be nonsensical to continue on this path while expecting an improvement in results.

2. Literature Review

Introduction

This literature review will provide insight and background into the clinical trial environment within Ireland. Ireland has a substantial strategic position as a global hub for both technology, with 16 out of the top 20 tech companies headquartered in Ireland (IDA Ireland, 2025) and a thriving life sciences sector. The intersection of emerging technologies such as artificial intelligence (AI)/analytics, hardware and software in the Irish technology sector presents significant opportunities to leverage these technologies to develop life sciences capabilities.

Ireland's system is further supported through key elements such as a skilled workforce, strong pharmaceutical & medical device presence and well-established regulatory environment, which will be explored through the lenses of infrastructure, funding and policy. However, Ireland has historically lagged behind similarly sized European counterparts in terms of clinical trials performance.

The 2024 Irish Pharmaceutical Healthcare Association (IPHA) Clinical Trials Performance Report compared Ireland's performance with that of Finland and Denmark across the period 2014 – 2023 (IPHA, 2024). The report found that Ireland initiated 460 clinical trials in the 10-year period, compared to 661 in Finland and 1,290 in Denmark in the same time period.

This relative underperformance in such a critical area emphasises that Ireland must improve in its conduct of clinical trials to deliver the best outcomes possible for patients.

2.1. Infrastructure

Introduction

Well-developed infrastructure is key to enable the startup, completion and reporting associated with clinical trials. In the context of this research, infrastructure refers to physical infrastructure such as labs, equipment and freezers, staffing, as well as digital infrastructure such as data and material sharing agreements.

Investment in Infrastructure

Clinical trial infrastructure in Ireland is largely centred around Clinical Research Facilities/Centres (CRF/Cs) which are in academic institutions, to generate trial designs, methodologies and investigators and partnered with either a hospital or hospital group to enable the operational elements of clinical trials such as patient visits, sample collection and therapeutic administration.

Ireland has increased its clinical trial performance in recent years through infrastructural investment delivered largely through the Health Research Board (HRB), Ireland's health research funding agency (HRB, 2019).

Opportunities for Further Infrastructure Development

Leddy et al. (2023) have emphasised that while this additional investment in infrastructure has been positive it has not been enough to act as a catalyst for additional trial activity. In addition, Leddy et al. highlight significant infrastructural roadblocks which affect access to clinical trials for patients such as access to infrastructure, relationships between clinical trial sites and reporting (Leddy et al., 2023).

These roadblocks can limit the cooperation and coordination between clinical trial sites and can make participating in trials difficult for patient. For example, if a patient based in Galway has a rare disease for which there is a trial ongoing in Dublin – the patient will have to travel across the country to gain access to the trial. Innovative trial methodologies such as decentralised trials have the potential to solve these issues but are not commonly seen across the infrastructural system yet.

WhyzeHealth highlight the opportunity for the Irish system to utilise the heavy inbound investment from the large amount of pharmaceutical and med-tech multinational

corporations (MNCs) which are in Ireland, and heavily clustered around Galway, with foreign direct investment (FDI) in Ireland growing to over €1.2 billion in 2021 and a "large proportion of that coming from the pharmaceutical and med tech sectors" (WhyzeHealth, 2023).

Another key element of clinical trial infrastructure in Ireland is the move towards an academic health sciences system (AHSS). This move towards an AHSS can be enabled through Sláintecare, Ireland's policy for health care reform. Key stakeholders from Irish Universities have emphasised the opportunity to fully leverage existing infrastructures to create a more efficient clinical trials system (UCD, 2021).

Infrastructure for Enablement

An element of the infrastructural system which is often overlooked is that of 'enabling infrastructure', which is required to enable the start-up and initiation of clinical trials. The HRB National Clinical Trials Office (NCTO) (2019) highlighted issues across areas such as biobanking, systematic reviews and registries – important areas which are required to generate the necessary evidence for a trial to take place.

A survey found pharmaceutical companies felt that a national biobank network (NBN) would benefit their company and would facilitate an expansion of their current R&D activities (Flavin et al., 2016). In addition, the same survey found that "an NBN would make Ireland more competitive for new clinical trials".

While the survey conducted by Flavin et al. (2016) was highlighted as a pilot study and as such is not completely representative of pharmaceutical companies it does highlight the needs for these systems to be put into place.

Regulation

The European clinical trials system has seen regulatory changes in recent time, with the introduction of the Clinical Trials Regulation (CTR) in 2022, replacing the previous Clinical Trials Directive (CTD) which came into force in 2004 (European Commission, 2023). The European Commission (2023) outlined that the introduction of the regulation will "make it easier for pharmaceutical companies and non-commercial sponsors to conduct multinational clinical trials, which should increase the number of studies conducted within the EU (European Commission, 2023).

In theory, this should streamline the process for registering, initiating and executing clinical trials within Ireland and all EU jurisdictions – eventually increasing the number of clinical trials ongoing in Ireland and providing better access to new therapeutics for Irish patients.

2.2. Funding

Introduction

Funding is vital for any system, but this is even more pronounced in the Irish system which is funded predominantly through public money.

To 2022, the HRB had invested €155 million in clinical trials (HRB 2022) through various mechanisms such as infrastructure funding, disease specific funding such as cancer clusters which operate geographically and specialising in cancer trials.

Public vs. Private Funding

Despite the significant investment from the HRB, industry remains the largest funder of clinical research[1] in HRB-funded and associated clinical research infrastructures. 58% of all active trials are being supported by industry and 27% supported by national funding agencies (HRB, 2019).

This presents a significant downfall in the clinical trials system, through which public funding is being used to develop infrastructure – building the 'architecture' for clinical trials to take place. This often involves multiannual investment, for example, in 2021 the HRB invested €5.3 million in the University College Dublin Clinical Research Centre (UCD CRC) to enhance research over a five-year period (HRB, 2021).

Once this infrastructure is in place, industry organisations will then fund specific trials or develop partnerships with infrastructure to focus on developing therapeutics which are of most interest to their organisation.

Systemic Funding Gaps

Literature has highlighted the overall lack of investment in research and development (R&D) in Ireland, which in turn narrows the pool of available funding for health research and clinical trials (Silicon Republic, 2024).

Ireland's Strategy for Science, Technology and Innovation 2006 – 2013 committed to delivering an investment of 2.5% of Ireland's GNP in R&D by 2013 (Department of Enterprise, Trade and Employment, 2006), however as of 2022 this figure was reported at between 0.96% and 1.34% depending on the definition of R&D (Government of Ireland, 2022).

[1] Clinical research refers to all clinical research (observational studies, registry studies, biobanks etc.), not just clinical trials

The lack of delivery on this target, 9 years after the date for the commitment highlights the dysfunctionality of the Irish R&D system.

Flexibility and Sustainability of Funding

Another key critique of the Irish funding system for clinical trials highlighted through the literature is issues regarding the application of funding. Leddy et al. (2020) highlighted issues with external environmental changes effecting the use of the limited funding which is received.

For example – unexpected increases in salary bands for health service staff from the Government and public sector unions which had not been factored into budgets created for the use of funding.

The HRB (2019) also emphasise that the hubs at which clinical trials take place "have not found a way to be fully self-sustainable and most feel that they could not exist without a degree of core supports", further illustrating the weaknesses of the current funding system.

Further to the availability of funding, a core issue with funding for clinical trials in Ireland is that of the sustainability of funding. It is most common for funding to be made available for a defined period, typically ranging from 12 – 60 months (HRB, 2025).

This means that staff who are hired through specific funding mechanisms lack long-term job security and as such, institutions risk losing the knowledge, skills and expertise which staff have built up over the period for which they are funded. It is not difficult to see why staff such as research nurses seek to move to permanent roles, particularly when increasing in seniority.

2.3. Policy

Introduction

A supportive and effective policy environment is crucial to support the initiation of clinical trials. A strong policy environment builds the 'tracks' for which clinical trials can take place and can provide knock on benefits such as incentivising private sector companies to support and conduct clinical trials in Ireland.

The literature which was reviewed highlighted that the Irish policy environment when it comes to clinical trials, and broader health research has traditionally not been supportive. Leddy et al. (2020) outline several major issues which have hindered access to trials (Leddy et al., 2023). These issues include the complex regulatory environment and increasingly rigorous monitoring requirements as well as an increase in the demand for insurance and indemnification when conducting trials.

Data Policy and Regulations

The policy environment surrounding the use, governance and access to patient data for clinical trials was cited as another significant consideration. Staunton et al. (2023) emphasise the variability of interpretations across patients, investigators and regulators regarding the use of patient clinical data (Staunton et al., 2023).

In addition, Kirwan et al. (2021) states that elements of Ireland's Health Research Regulations which was enacted to provide for "suitable and specific measures for the processing of personal data for the purpose of health research" (HRB 2021) are having a "significantly negative and far-reaching impact on the conduct of health research in Ireland" (Kirwan et al., 2021).

Gaps in Existing Policy

The HRB's policy when it comes to assessment criteria for grant applications has been noted though a self-audit of the HRB as "lacking strength". In simple terms, the policy of the HRB is not to inform investigators who are writing grant applications around what is seen as 'strong' or as 'best practice' (Cody 2021).

While the policy environment has typically not been supportive of clinical trials, and providing access to trials for patients, the literature highlights some more recent developments which indicate that the policy environment may be improving.

Positive Changes to the Policy Environment

The SARS CoV-2 (COVID-19) pandemic put pressure on the government to relax some stringent regulations when it comes to broader health research as well as clinical trials. Shiely et al. (2021) highlight experiencing an increased level of flexibility around existing policies which in turn enabled the rapid start-up of clinical trials to develop therapies for COVID-19, which were a national priority in 2020 and 2021 (Shiely et al., 2021).

A major recent development which has the potential to significantly improve the policy environment is the National Clinical Trials Oversight Group (NCTOG). The NCTOG was established by the Minister for Health in July 2024, made up of clinical trialists, patient representatives, industry stakeholders and government officials to provide strategic recommendations to improve the policy environment (gov.ie, 2024).

The NCTOG published interim recommendations in October 2024, and while it is still too early for these recommendations to be implemented it is clear that if implemented this would be a significant improvement to the Irish policy environment (gov.ie, 2024).

The Irish Pharmaceutical Healthcare Association (IPHA), State Claims Agency (SCA) and the HSE have recently collaborated to introduce a model Clinical Trial Agreement (CTA) (IPHA, 2024). Which aim to improve the efficiency of the process around starting up clinical trials.

While this CTA appears as a step in the right direction, it is unclear if this model CTA will be substantially adopted across the wider system. The CTA is mandatory for all HSE hospitals; however, it is merely recommended for other organisations such as voluntary hospitals. Voluntary hospitals are mainly state funded but operated privately and contracted by the HSE to deliver services (Citizens Information, 2024).

The lack of any mandated CTA across all clinical trial performing organisations threatens to widen an already present rift in the provision of both health services and health research across hospital types. While this may be detrimental to the entire health system, it is patients who will suffer from the effects of this rift most substantially.

3. Research Question and Objectives

The research question for this study is: “How can Ireland Expand Access to Clinical Trials for Patients? A Policy and Strategy Perspective”.

3.1 Importance of This Research Question

Given the substantial importance of providing access to clinical trials for patients in terms of improving health outcomes, advancing scientific knowledge as well as clinical trials as a mechanism for economic output this research question is directly relevant to provide evidence based, realist recommendations and insight to improve the system.

There is a lack of published literature relating to this topic in Ireland. There has been research conducted into specific areas of the Irish system, such as the HRB review of clinical trials infrastructure in Ireland (HRB, 2019) as well as similar reviews conducted in other jurisdictions such as the such as the Lord O’ Shaughnessy review of commercial clinical trials in the United Kingdom (Gov.UK, 2023).

This research question seeks to bridge this gap and to provide an evidence base concerning the clinical trials ecosystem in Ireland, recognising its importance of contributing to better patient outcomes, heightened economic activity and quality within our broader healthcare system.

The research question has been framed in such a way that it will provide a holistic view of the Irish clinical trials system while maintaining a focus on the most important factor in the system – the patients for which clinical trials are designed, initiated and completed.

3.2 Research Objectives

The successful completion of this research project will be demonstrated through the achievement of the following research objectives:

Objective 1: To understand the current policy environment in Ireland and approaches which are used to provide access to clinical trials for patients.

Objective 2: To successfully benchmark the policy environment and strategic approaches used in comparator countries, that provide far more access to clinical trials for patients, such as Denmark, Spain, and New Zealand.

Objective 3: To garner the views of key stakeholders in the Irish system through primary research and understand major issues within the system, which have not been highlighted through secondary research as well as potential changes to the system to improve trial participation.

Objective 4: To propose a set of actions or recommendations which the Irish system could adopt to bring trial participation in line with best practice and improve the level of access to clinical trials for patients.

4. Methodology

4.1. Philosophical Assumptions

In devising and delivering this mixed methods research project, a critical component of design has been a consideration of the philosophical stance or paradigm, which has influenced the researchers approach to integrating the qualitative and quantitative approaches. Among the major paradigms in mixed methods research are pragmatism and dialectical pluralism.

In simple terms, pragmatism is a philosophy guided by the principle that the best method is the one that works. The view of this approach is that knowledge is created using different methods to solve problems where reality is both objective (quantitative) and constructed (qualitative) (Gobo, 2023).

Dialectical pluralism is a philosophy guided by the idea that different perspectives exist, and researchers should embrace and explore this complexity. This approach is useful when multiple stakeholders who may have different viewpoints are to be included within the research (Onwuegbuzie and Abrams, 2025).

Given the complexity of the clinical trial landscape, a pragmatic design, which is also strongly influenced by pluralism has been chosen by the researcher, given the different types of stakeholders involved, from academics to policymakers and funders.

Having selected pragmatism as the philosophical framework, multiple options for the design of this study were explored for suitability and relevance. Principle among mixed methods approaches are:

Convergent Parallel Design: When qualitative and quantitative data are collected and analysed separately but merged for interpretation to allow for a greater understanding of the subject matter (Creswell and Clark, 2018)

Explanatory Sequential Design: When quantitative results guide qualitative exploration (Creswell and Clark, 2018)

Exploratory Sequential Design: When qualitative findings inform the development of a quantitative instrument (Creswell and Clark, 2018)

Embedded Design: When one method plays a supporting role within a dominant method, for example using qualitative research to supplement a primarily quantitative piece of research (Creswell and Clark, 2018)

Having considered these varying approaches. A convergent parallel design was selected by the researcher as the primary basis for the research design as both the qualitative insights and the quantitative data are crucial to developing and understanding a clear picture for the clinical trial landscape in Ireland.

In addition, the experience of the researcher in working in fields adjacent to and supporting clinical trials in Ireland has contributed to the approach to this study. While this existing knowledge was beneficial to this study it has undoubtedly influenced the primary and secondary research contributing to this research project.

4.2. Research Design

As outlined above, this research has been designed and completed using a mixed methods approach. A mixed methods approach has been chosen in order to gain a more holistic view of the Irish clinical trials system with the ultimate view being to propose a set of actions to improve clinical trial access for patients. Recognising the complexity of the necessary data, and the differing viewpoints of the participants, this approach is best suited to achieving the desired outcome of discovering actionable, realistic ways in which the Irish clinical trials system can improve.

Literature highlights a mixed methods approach as being able to “give a better understanding of the problem and yield more complete evidence – the investigator gains both depth and breadth” (Emerald Publishing, 2021).

This research examines the Irish clinical trials system through three primary lenses, infrastructure, funding, and policy. These three lenses have been identified as areas which can have major supportive or detrimental effects on the timely, appropriate and effective access to clinical trials for patients. These areas also have significant effects on the number of trials which a country can initiate and support from initiation to ultimate completion.

The qualitative component of this research involves the gathering of primary data through the completion of semi-structured, qualitative interviews with key stakeholders from the Irish clinical trials system. In addition, further qualitative research has been

competed through a review of relevant literature which provided the necessary context to design the topics and questions used within the semi-structured interviews.

Semi-structured interviews were chosen by the researcher as the most appropriate style for this research to allow for flexibility and adaptability regarding the questions which were asked, depending on the direction of the conversation (Mashuri et al., 2022).

An important consideration in the selection of this approach has been the recognition of the differing viewpoints and priorities of the stakeholders. If the Irish clinical trial landscape is considered, its challenges and opportunities will be viewed differently by discrete stakeholder groups. For example, investigators are likely to be focused on completing trials, to better understand disease, improve treatment and to develop their own careers.

Policy makers are likely to be focused on how trials can improve the efficiency and productivity of the healthcare system and how they can enable the recruitment and retention of best staff. Funders are likely to be focused on how to maximise the return on their investment, ensuring they can demonstrate the effectiveness of their supports. Industry will likely be focused on how to enable trials by speeding up processes, making trials more efficient and more cost effective. Patients and (patient representative groups) will likely be more focused on gaining access to trials, particularly in those with life limiting conditions, in turn making newer medicines an option for treatment.

Recognising this broad range of viewpoints, the chosen semi-structured interview approach balances flexibility with comparability, enabling exploration of key topics which form the basis of this research, while also structuring the conversation around the key topics of focus.

Specific considerations which were key to the design of interviews which were performed include:

Flexibility in Exploration: Using a semi structured approach, the researcher had the ability to adapt questions based on responses and thus was able to probe topics which were unexpected but were relevant to the research.

Balancing Structure and Depth: A core set of questions maintains consistency across the interviews, regardless of stakeholder type, but the inclusion of open-ended

questions enabled the collection of richer data than a purely structured approach would.

Encouraging Reporting: A key objective during the interviews was to extract honest information from interviewees of the challenges in the clinical trial landscape in Ireland. The semi structured approach enables this by encouraging conversation and detail, reducing participant anxiety and bias.

Clarifications: Recognising the complexity of the research topic and having adopted a semi-structured approach – the researcher had flexibility to seek clarifications on interviewee responses if needed. A strictly structured approach or the use of a survey for data collection would not have allowed for this and possibly have led to incorrect interpretations.

Due to the time constraints in place during the period of this research, all interviews were conducted via Microsoft Teams, and each lasted between 30 and 55 minutes. On average, each interview lasted approximately 38 minutes which provided enough time for discussion around the key topics being explored, but did not constrain individuals too much. While it would have been preferable to conduct interviews in person, it would not have been practical in this instance due to the busy schedules of the individuals who agreed to partake in interviews, and the short timeframe of this study.

The quantitative component of this study involves the benchmarking of Ireland against comparator countries in areas such as clinical trial initiation statistics, healthcare expenditure data, and investment in research and development (R&D). This data for quantitative analysis has been gathered from sources such as clinicaltrials.gov, OECD health research reports and government funding reports on R&D spend.

The use of mixed methods within this research has allowed the researcher to gather a more complete picture of the Irish clinical trials system, a deeper understanding of the problems affecting it and a more realistic evidence base to develop recommendations for improvement than one method would provide when executed in isolation.

This approach has allowed the researcher to understand the thoughts and opinions of key stakeholders working in Ireland's clinical trial system and baseline these data points against raw quantitative data which cannot reasonably be interpreted. In other words, the quantitative data provides a more objective assessment of Ireland's position while the qualitative data gathered provides a more subjective assessment.

4.3. Sampling

Sampling within this research project involved selecting participants for the qualitative interview component of the research. Participants were initially identified for invitation to interview based on their level of expertise and involvement in clinical trials in Ireland.

The researcher performed background research into the key stakeholders in the system to identify suitable individuals who would be able to provide relevant information and opinions.

As will be discussed later, in the analysis and findings section, 14 interviewees were recruited and were divided broadly into two groups: trial conduct and trial enablement. Trial conduct participants are individuals who actually design and perform clinical trials, while trial enablement individuals enable clinical trials, through strategy, funding, policy etc.

Six of the 14 interviewees recruited were defined as trial conduct, with the remaining 8 defined as trial enablement. It was important during sampling and contacting these individuals to have a relatively balanced split so that the views of key stakeholder groups within the system were gathered to fully inform this study.

A total of 18 potential interviewees were initially contacted to take part in the study, however due to the busy schedules of many of the stakeholders, four of these individuals did not agree to participate, or were not available during the interview period. However, the 14 recruited was deemed sufficient by the researcher, mindful of the need for a somewhat even split between the two participant groupings.

4.4. Pilot

Due to the complex nature of the research topic as well as the broad range of questions which were being asked by the interviewer to the interview participants, a pilot interview was conducted.

This pilot interview was conducted by the researcher, interviewing a stakeholder in the Irish clinical trials system who is both knowledgeable in the area and known by the researcher, ensuring that constructive feedback and criticism could be given on the interview questions, structure and style in advance of the remaining interviewees.

After the pilot interview had taken place, a number of the original interview questions were rephrased to improve the general flow of the interview as well as to make the questions more 'open-ended', ensuring that participants were given more of an opportunity to discuss key topics.

4.5. Data Analysis

The semi-structured interviews were recorded and subsequently transcribed by the researcher. Once transcripts of each interview were produced, a thematic analysis approach was used to analyse the transcripts in isolation at first and then collated across all 14 interviews.

Thematic analysis is "the process of identifying patterns or themes within qualitative data" and as such, is highly relevant for this research (Maguire and Delahunt, 2017). Braun and Clarke (2006) identify a six-step guide which can be utilised as a framework when conducting thematic analysis, a framework which the researcher has followed when completing data analysis for this project.

These six-steps are (Braun and Clarke, 2006):

1. Become familiar with the data
2. Generate initial codes
3. Search for themes
4. Review themes
5. Define themes
6. Write-up

Once the themes arising from interviews were coded and defined for each individual interview, the themes were collated across all interviewees, within each question to identify areas of commonality. Themes were then reviewed and defined, with quotes evidencing each theme collected to be used within the write up, and to provide additional context for analysis.

Interview themes were selected with little interpretation, with each instance of each theme notes as a '1' when coding, and the lack of a theme within an interviewee response coded as a '0'. This allowed the analysis approach to be more objective and to reduce potential bias on behalf of the researcher. Interpretation of codes was then completed when writing up the analysis and was evidenced by a quote as an example of what was being discussed by interviewees.

The quantitative analysis element was performed after gathering publicly accessible data from sources such as Eurostat, the EU Clinical Trial Register, and the OECD Health at a Glance Report. Data was gathered for Ireland, Denmark and Finland to allow comparability and to identify areas in which countries which perform more clinical trials than Ireland focus activity, such as R&D.

4.6. Ethics

Ethical considerations within this research have primarily centred around three key aspects of informed consent, confidentiality & data protection and results.

Regarding informed consent, all stakeholders who took part in the semi-structured interviews were presented with a clear explanation of the project, its purposes and methods as well as an explanation of what their involvement would entail.

It was made clear to interviewees that their participation was completely voluntary, and they could withdraw from the process at any stage, or request that the information garnered from their interview be erased at any stage after the interview had taken place.

All interviewees were given a consent form outlining the purposes and parameters of the research which interviewees had to sign and return to the researcher before an interview could take place.

In terms of confidentiality and data protection, all interviews were audio recorded and then transcribed by the researcher, with the recording destroyed once the transcription was complete. All interview outputs were stored securely and password protected, in accordance with NCI regulations.

During analysis and reporting, all data was anonymised to ensure that no individual was identifiable. The details of interview participants were not made known to anyone other than the researcher, to fully protect participant anonymity.

In terms of analysing data and reporting results, the researcher respected all stakeholder voices and opinions expressed during interviews, eliminating bias. In addition, the semi-structured approach allowed the researcher to ask follow up questions, avoiding misinterpretation of interviewee statements.

All stakeholders were weighted equally when performing analysis to ensure that views across the cohort were accurately represented. Finally, the researcher offered all

interview participants a copy of the completed dissertation to return the findings as well as a gesture of thanks for their participation in the process.

4.7. Limitations

There are a variety of limitations which must be considered within the context of this research, to ensure that the analysis and findings of this study are interpreted appropriately.

This research was conducted over a relatively short timeline, with the bulk of the research completed between February and May 2025. This resulted in some sections of this dissertation being relatively 'light touch' as there was not enough time to fully delve into the infrastructure, funding, and policy systems which support and enable clinical trials in Ireland.

The sample of stakeholders is not fully representative of all infrastructures, clinical trial performing or supporting organisations, or geographies and as such does not encompass the vast array of views that is likely present across the entire system.

There is a lack of prior research available on this specific topic in Ireland. However, there have been similar reviews completed in other jurisdictions, such as the Lord O' Shaughnessy review of commercial clinical trials in the United Kingdom (Gov.UK, 2023).

The lack of previous research on this topic has meant that this study has not been able to build on directly comparable research and as such, there is a lack of a defined framework or previously used approach to follow.

Outside of the quantity of clinical trials themselves, which institutions must report to the European Medicines Agency, there is a lack of clear, representative data pertaining to clinical trials in Ireland which is readily accessible. This includes activity data of specific clinical trial sites, detailed funding information from funders, the scale & state of infrastructures as well as overall levels of investment in clinical trials in Ireland.

Due to the potential sensitivity which would have been involved and possible ethical issues arising, the researcher did not interview or seek to interview any patients who have tried to or indeed taken part in a clinical trial. As such, it is important to remember that this study focuses on improving access to clinical trials and there is not a significant

focus on the patient experience or perspective – which is a significant limitation of this research.

The final important limitation that must be acknowledged is potential bias on behalf of the researcher when selecting participants to invite to interview based on ease of access and the availability of participants to participate in an interview within the needed timeframe.

5. Analysis and Findings

5.1. Qualitative Analysis

5.1.1 Introduction

The results and main themes arising from the semi-structured qualitative interviews are presented below, with a bar chart and associated narrative for each question to provide some context, the prominence of each theme arising from each question and a quote extracted from interviews.

All themes extracted from the interview transcripts are recorded below, however not all are reported. Instead, the researcher has chosen to report themes which were highlighted by 40% or more of the interviewees who were asked each question. The rationale for this was to prioritise common themes across interviewees and avoid potentially identifying any interviewees if only one interviewee discussed a theme, and a quote was used to provide an example of this.

As outlined previously, there were a total of 14 interviewees who took part in this research. Not all interviewees were asked all questions to ensure that the questions were relevant to the participant. For example, there would be little benefit to asking an interviewee from a pharmaceutical company about the sustainability of funding in academic clinical trial infrastructures. For reference, a list of all interviewee questions used is available in Appendix 1: Interview Question List.

To provide further context to the points raised by specific interviewees, while maintaining anonymity, a ‘labelling’ approach has been used to assign an anonymous, non-identifiable code to each participant. As outlined previously, participants have been split into trial conduct or trial enablement.

Trial conduct participants are individuals who develop and implement clinical trials themselves and may be Professors, Academic Consultants or Clinicians. Trial enablement participants are individuals who enable the conduct of clinical trials, for example individuals working in the areas of research strategy, funding, or policy.

For example, the first trial conduct interviewee would be noted as TC1. The codes assigned to each interviewee can be seen below in Figure 1.

No.	Interviewee Role	Code Assigned
1	Trial Conduct	TC1
2	Trial Conduct	TC2
3	Trial Conduct	TC3
4	Trial Enablement	TE1
5	Trial Enablement	TE2
6	Trial Conduct	TC4
7	Trial Conduct	TC5
8	Trial Enablement	TE3
9	Trial Enablement	TE4
10	Trial Enablement	TE5
11	Trial Enablement	TE6
12	Trial Enablement	TE7
13	Trial Conduct	TC6
14	Trial Enablement	TE8

Figure 1: Interviewee Categories and Codes Assigned

Question 1

The first question, which was asked to all participants during the semi-structured interviews was "In overview, what is your general opinion on Ireland's current position with regards to clinical trials?". A total of 12 themes were extracted from this question, with 4 of these 12 themes deemed reportable, based on these 4 themes being mentioned by at least 40% of interviewees.

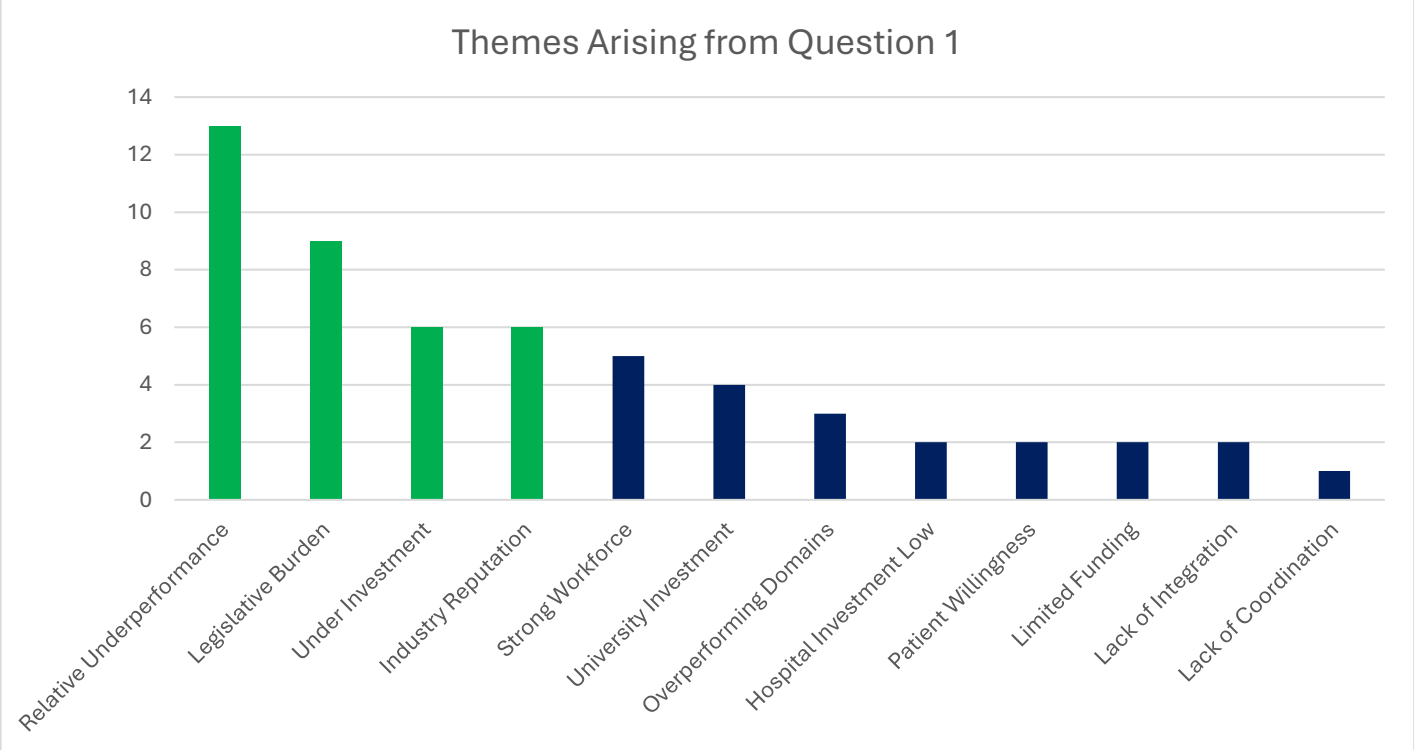

Figure 2: Themes Arising from Question 1

As can be seen in Figure 2 above, the most dominant theme within the question, highlighted by 13 out of 14 interviewees, or 93% was that Ireland underperforms relevant to benchmarks when it comes to clinical trials. These benchmarks highlighted by interviewees included Denmark, Norway, Finland and New Zealand. Interviewee TC1 mentioned "*But in truth, Ireland is significantly underperforming in terms of both industry led clinical trials and investigator led clinical trials*"

The second most common theme discussed within this question was the high legislative burden, which is present in Ireland around conducting clinical trials, discussed by 9 interviewees, or 64% of the total. Interviewee TE8 noted "*…the pace at which we get trials open is far slower than other jurisdictions*"

The third most frequent theme, highlighted by 6 interviewees, or 43% of the total was that Ireland overperforms relative to the investment or funding delivered to the clinical trials ecosystem. This was highlighted by interviewee TE4 who said "*I think we are successful despite ourselves in some ways*"

Finally, interviewees highlighted that Ireland has a generally poor relationship with industry when it comes to the conduct of clinical trials, with this mentioned by 6 interviewees, or 43% of the total. Interviewee TC3 noted *"….we have also developed a reputation with industry for not delivering the patient numbers for trials*".

Question 2

The second question overall and the first infrastructure focused question asked to all interviewees was “What do you see as the primary deficits within the clinical trials ecosystem in Ireland?”. As can be seen below in Figure 3, a total of 10 themes were extracted from the question, and four of themes were deemed reportable as 40% or more interviewees had mentioned them.

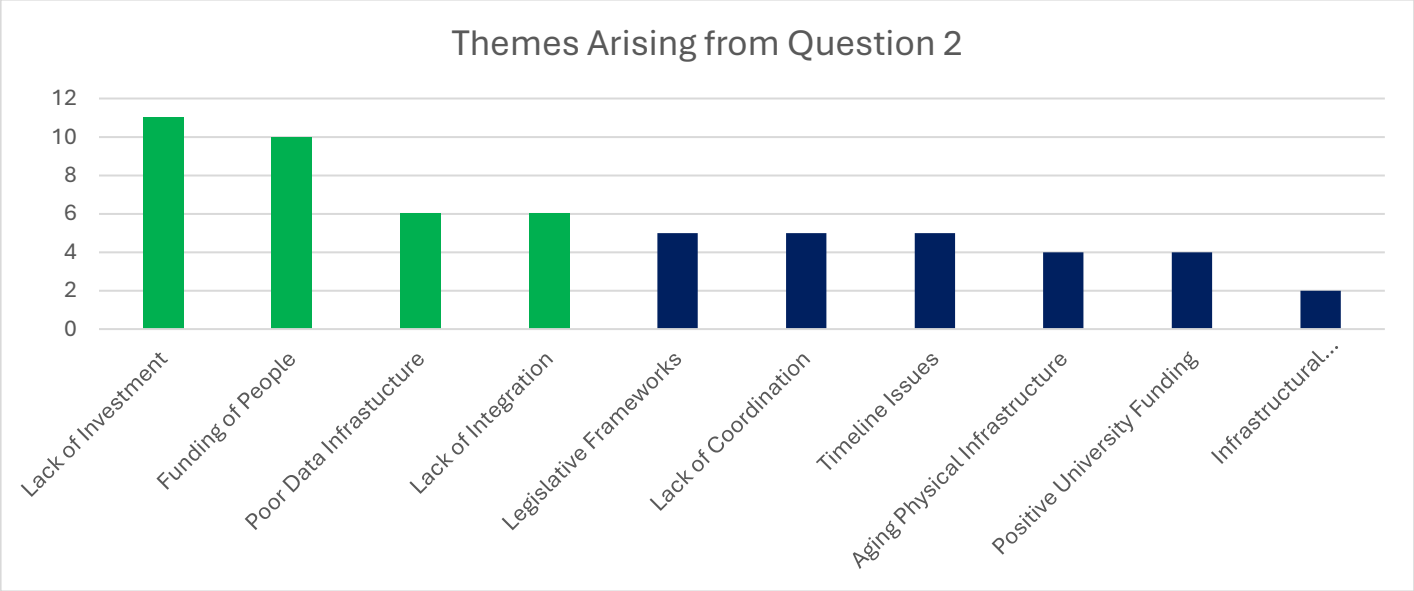

Figure 3: Themes Arising from Question 2

The most commonly discussed theme was a lack of investment in clinical trials infrastructure in Ireland, with 11 interviewees, or 79% discussing this topic. Interviewee TC5 said, “*We find it very difficult to fund posts, and keep posts funded over time*”.

The second most prominent theme highlighted by interviewees was issues with funding people, specifically in terms of short term, programmatic funding which is typically available for five years and leads to a lack of a solid career structure for many staff members. Interviewee TE5 outlined “*Funding is all five-year cycles. No trial is done and dusted in five years, so it is a very insecure environment to work in.”*

The third most prominent theme within this question, noted by 6 interviewees, or 43% of the total was Ireland’s poorly developed data infrastructure, encompassing issues such as a lack of a national electronic health record (EHR). This was highlighted by interviewee TE1 who outlined “*There is no infrastructure for patient cohort management, we have no national EHR. We have tried it a few times, but it has never happened.*”

Finally, the lack of integration of clinical trials into the health system and into routine healthcare was discussed by 6 interviewees, or 43% of the total interviewees. Interviewee TE3 noted "*There is a cultural aspect around recognising that clinical trials should be the norm. We don't have that and as a result, there is a disconnect between our health system and research system*".

Question 3

The third question which was asked to 13 of 14 interviewees was "Could you solve any 'low hanging fruit' that could solve infrastructure problems?". Figure 4 below illustrates that a total of seven themes were extracted from this question. Three of the seven themes were deemed reportable.

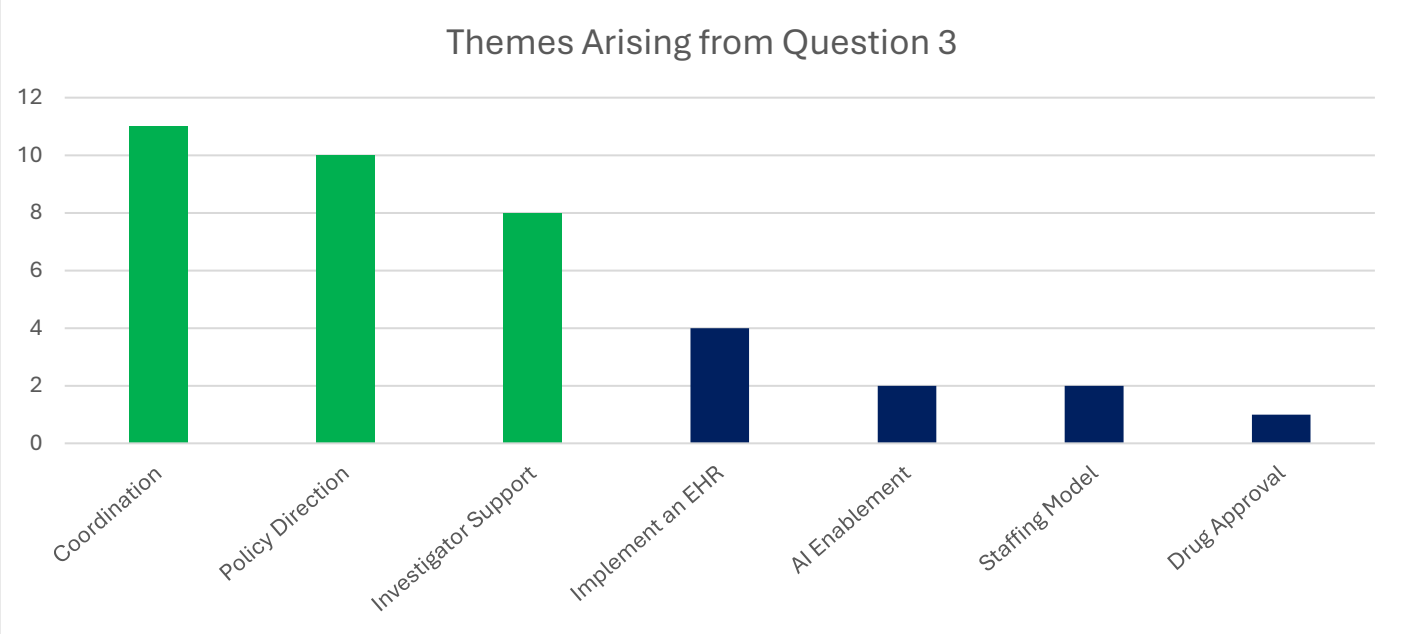

Figure 4: Themes Arising from Question 3

The theme most commonly highlighted by interviewees was the need for coordination. This theme was mentioned by 11 interviewees, or 85% of the total interviewees who answered this question. This theme was discussed in the context of establishing an effective coordination function within the system, and this being relatively easy to do. For example, interviewee TE8 outlined "*We need everyone talking to each other. We need people working together more collaboratively and in a properly coordinated way*"

The second most prominent theme within this question was the need for policy direction surrounding infrastructure. This was highlighted by 10 of 13 interviewees, or 71%. Interviewee TE6 noted "*You need that national clear signal around policy*

direction and of what's happening at a national level, and then that's reflected at the regional level."

The final reportable theme arising from this question was the need for investigator supports such as data management and grant writing to be built into the infrastructure system. This theme was discussed by 8 of 13 interviewees, or 57%. This was highlighted by interviewee TE4, who said "*We need to facilitate access to expertise, not only in the running of trials but in areas like grant applications, because a lot of clinicians wouldn't have that expertise*"

Question 4

The fourth question, asked to 8 of 14 interviewees was "How might the adoption of innovative clinical trial designs such as decentralised trials affect ecosystem requirements to perform trials?". As can be seen below, in Figure 5, six themes were note by interviewees, with four of these themes deemed reportable.

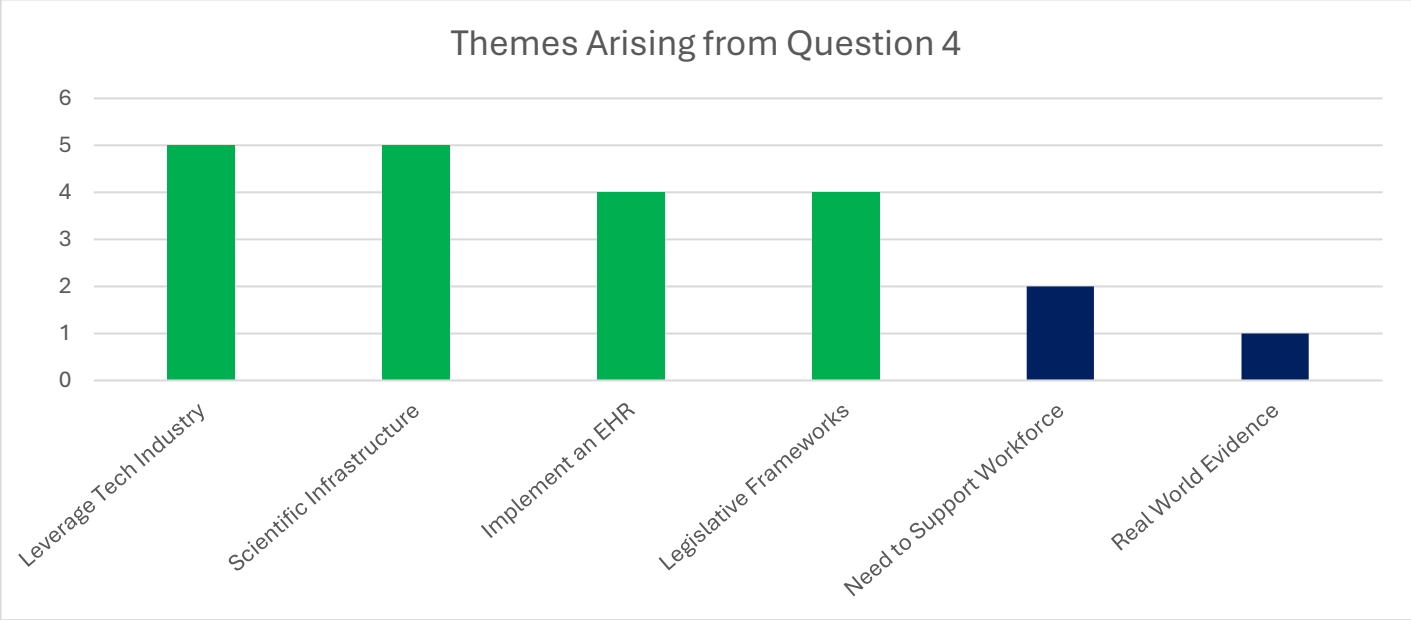

Figure 5: Themes Arising from Question 4

The most commonly mentioned theme by interviewees within this question was the need for the infrastructure system to better leverage technology to enable new innovations. This theme was discussed by five of 8, or 63% of interviewees. For example, interviewee TC1 outlined "*We have a fantastic opportunity in this area, the vast majority of the world's biggest tech companies are located here – we need to leverage that fact.*".

The second most prominent theme within this question was the requirement for further developments in scientific infrastructure such as biobanking. This was also mentioned by five of 8, or 63% of interviewees. In particular, interviewee TC5 highlighted "*We aren't really geared up for doing anything experimental – we are constantly shipping bloods for experimental testing off to biobanks, it's not efficient*.".

The third reportable theme within question four which was mentioned by 4 of 8, or 50% of interviewees was the importance of Ireland implementing a national electronic health record (EHR) to support innovative trial designs. In relation to this, interviewee TC4 outlined "I think the single biggest thing we need to do in Ireland is implement an electronic health record.".

The fourth and final theme which was deemed reportable from this question was the requirement for proper consideration, interpretation and application of legislative frameworks. This was generally discussed in the context of legislation such as GDPR or the Health Research Regulation, which interviewees noted had been ineffectively interpreted by Ireland as a system. For example, interviewee TE5 mentioned "*Work needs to be done to ensure that data is available and it's available for secondary use through a very secure environment, to maintain trust*.".

Question 5

Question number 5, and the final infrastructure focused question which was asked to 10 of the 14 interviewees was “How can Ireland better integrate clinical trials into routine healthcare?”. Figure 6 below shows that six themes were extracted from this question, with thee of these being reportable.

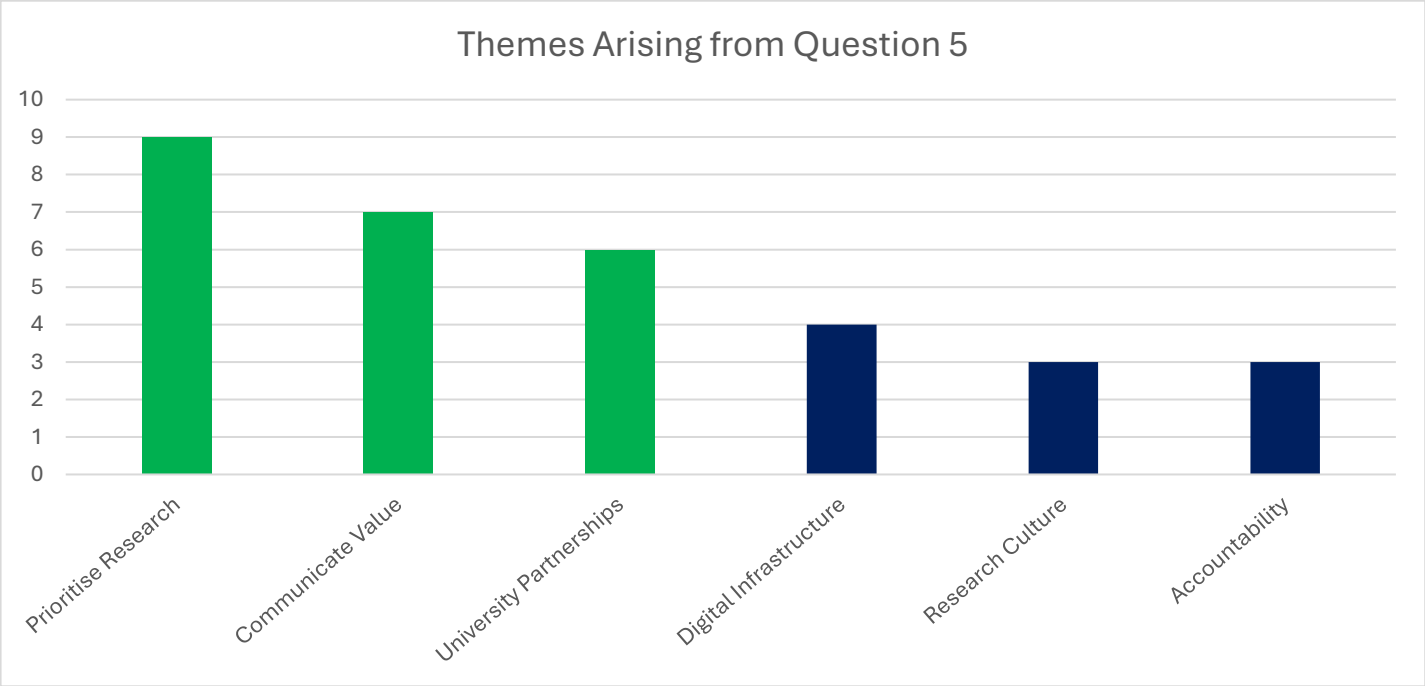

Figure 6: Themes Arising from Question 5

The most prominent theme mentioned by interviewees within this question was the importance of prioritising research to support integration into routine healthcare. This theme was highlighted by 9 of 10 interviewees who were asked this question, or 90%. For example, interviewee TE2 outlined “*There need to be a mandate from a high level, and an overall mindset change*.”.

The second most common theme arising from this question was the importance of communicating the value of clinical trials and highlighting why they are needed. This theme was discussed by 7 of the 10, or 70% of interviewees. Interviewee TC1 noted “*All of the data that we have shows that patients that are cared for in a research active environment have better outcomes. I don’t want to say that it is ignored, but it’s not even on the agenda*.”.

The final reportable theme from this interview question was the need to leverage partnerships with universities to ingrain clinical trials into the health system. This theme was outlined by 60% or six of the 10 interviewees. Interviewee TE8 mentioned “*We need to ensure the health system is closer aligned to our universities to access the expertise and resources needed to push trials forward*”

Question 6

The sixth question, and the first funding focused question was “What is the largest issue in terms of funding for clinical trials, infrastructure supports, and staff”. This question was asked to 11 of the 14 interviewees who took part. As illustrated in Figure 7, seven themes were present within this question, and three of these were deemed reportable.

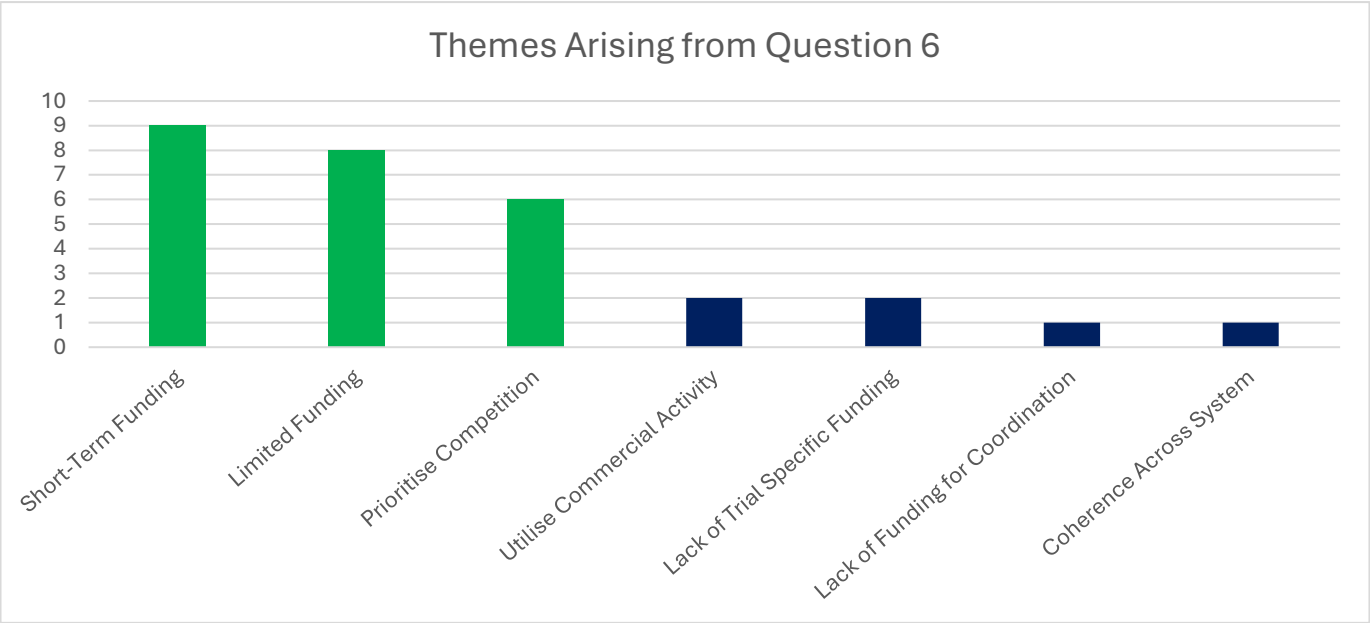

Figure 7: Themes Arising from Question 6

The most commonly discussed theme within this question was the problematic nature of short-term funding when it comes to infrastructure. This theme was highlighted by 9 of 11, or 82% of interviewees who were asked this question. For example, interviewee TC2 noted “*The funding maybe needs to be reconsidered in terms of the longer goal, instead of looking at what we can achieve in five years. Most trials wouldn’t even be finished in five years*”

The second most prominent theme arising from this question was the issue regarding the overall amount of funding which is available for infrastructures, directly to fund clinical trials, and staff funding. 8 of 11 interviewees, or 73% highlighted this point, with interviewee TC3 noting “*Although the HRB funds clinical trials, it’s a very limited resource. A lot of the other funders tend to not fund any clinical work*”.

The final reportable theme from this question, which was highlighted by 6, or 55% of the interviewees who were asked this question was the important of prioritising

competition within our infrastructure system. For example, interviewee TE6 mentioned "A key part of this is competition. People often forget that competitive funding is in place to drive quality and innovation – this needs to be retained and expanded in my view.".

Question 7

The seventh question which was asked to 7 of the 14 interviewees was "Has sustainability of funding become more of an issue in recent years?". Five themes were extracted from this question, as can be seen below in Figure 8. Three of these five themes were reportable.

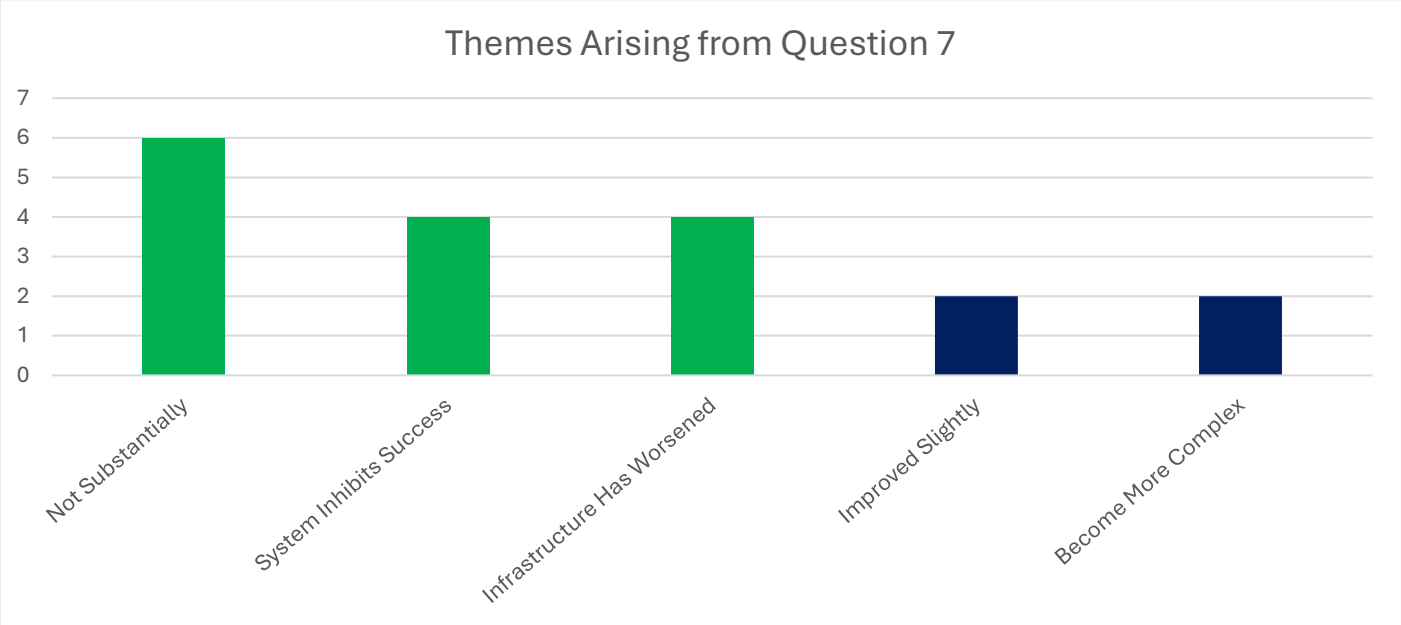

Figure 8: Themes Arising from Question 7

The most prominent theme within this question was that sustainability of funding has not substantially become more of an issue in recent years. This was discussed by six of the seven interviewees, or 86%. Interviewees instead highlighted other, more substantial issues within the system. For example, interviewee TE3 noted "*Money has gone into the system, but the demands of the infrastructure have simultaneously outpaced that.*".

The second most commonly highlighted theme, mentioned by four or 57% of interviewees was that the system generally inhibits success. Interviewee TC1 mentioned "*The way that the system is set up, like securing contracts and getting things in place has been notoriously difficult. It is a difficult environment, with lots of things actually inhibiting success*".

The final reportable theme arising from this question was that instead of the sustainability of funding, it is actually the infrastructure itself which has worsened in recent years. This theme was mentioned by 4 of the 7 interviewees, or 57%. Interviewee TE5 outlined "*The fact that it has been a big thing for long now means that infrastructures are starting to suffer. But definitely some more than others*.".

Question 8

The eight question, and final funding focused question was "What incentives could encourage CROs, pharmaceutical, and biotech companies to conduct more clinical trials in Ireland. This was asked to 8 of the 14 total interviewees. As can be seen below in Figure 9, a total of six themes were extracted from this question, with three of these themes deemed reportable.

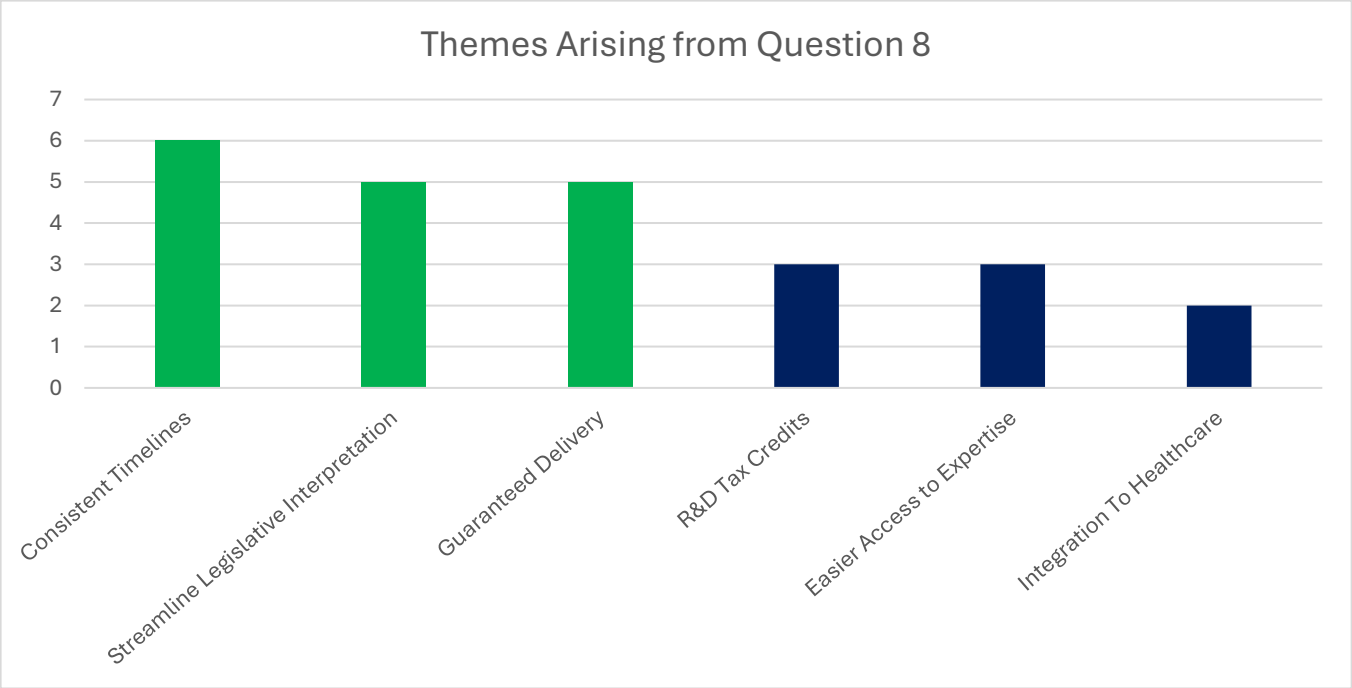

Figure 9: Themes Arising from Question 8

The most commonly discussed theme from this question was the importance of consistent timelines for industry organisations to operate in Ireland. Effectively, organisations want to know exactly how long it will take to complete elements of trial set up and organisation. This point was outlined by six of the 8 interviewees, or 75%. Interviewee TE2 outlined "Without a doubt consistent timelines – we need to be able to leverage this.".

The second most prominent theme within this question was the need for streamlined legislative interpretation. This was mentioned by 5, or 63% of the interviewees who

were asked the question and primarily in the context of stringent rules and regulations which relate to efficiently starting clinical trials. Interviewee TE7 noted "*Need to grease the heels of bureaucracy – there are so many things required to reduce the time for trials to start up*.".

The final theme which was deemed reportable from this question was the need for the guaranteed delivery of clinical trials. In particular, interviewees outlined that once an industry organisation decided to sponsor a trial in Ireland, this commitment must be delivered. This theme was also mentioned by 63% or 5 of the 8 interviewees, with interviewee TE2 saying "*There is little point in promising to enrol n patients into a trial and then only enrolling a fraction of that. It contributed to a view within industry of 'Ireland will let us down'*. "

Question 9

The ninth question, and first policy focused question, which was asked to 13 of the 14 total interviewees was "What organisation has policy responsibility for increasing the number of clinical trials in Ireland?". As can be seen in Figure 10 below, five themes were extracted from this question, with three of these five themes deemed reportable.

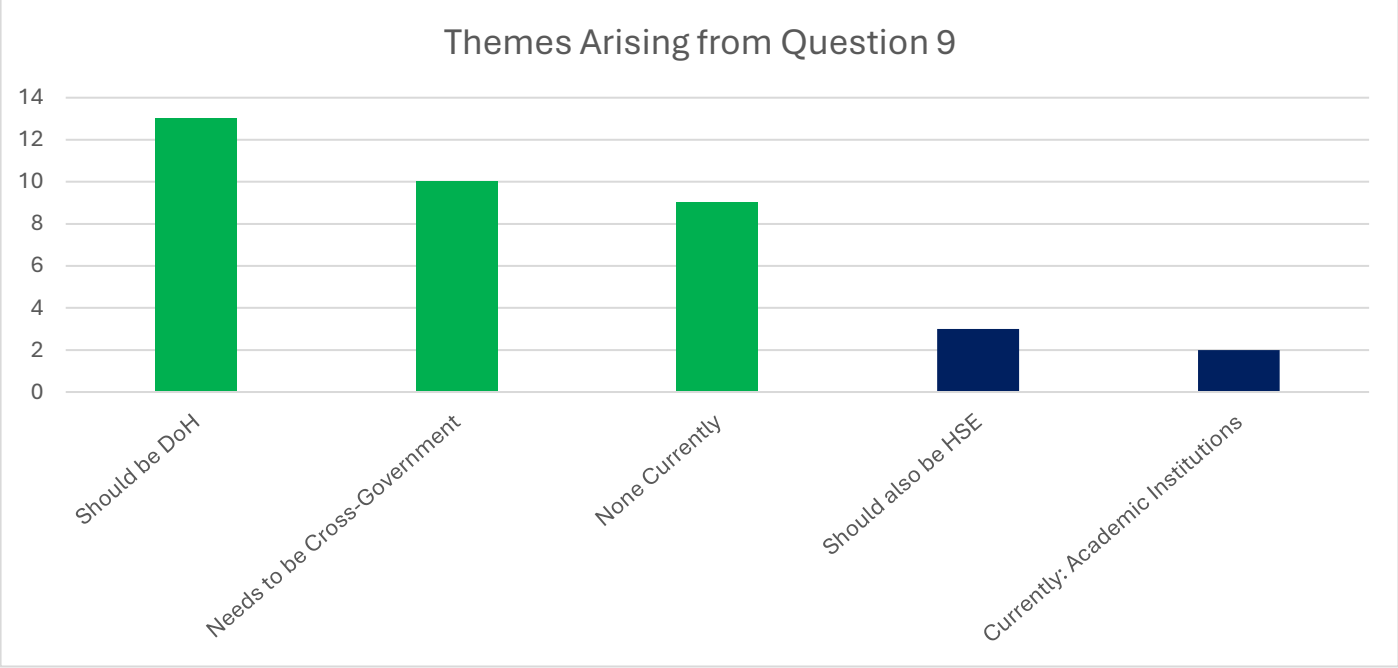

Figure 10: Themes Arising from Question 9

The most commonly highlighted theme arising from this question was that the Department of Health who should own policy responsibility for clinical trials in Ireland. This theme was mentioned by 13 of the 13 interviewees who were asked this question.

Interviewee TC6 outlined "*Considering it is policy, I think it would have to come from the Department of Health in particular*".

The second most prominent theme within this question was the importance of cross-governmental policy responsibility, with interviewees noting that the Department of Health, Department of Enterprise, Trade & Employment and the Department of Further & Higher Education, Research, Innovation and Science, amongst other departments are all crucial. This theme was highlighted by 10 of 13 interviewees, or 77%, including by interviewee TC4 who mentioned "*The Department of Health definitely, but it should also include the Department of Further & Higher Education, Research, Innovation and Science, Department of Enterprise and Trade and their agencies like the IDA, Research Ireland etc*."

The final reportable theme extracted from this question was that there is no organisation currently with policy responsibility in this area. 69% or 9 of 13 interviewees discussed this during their interview. Interviewee TE5 noted " *It's not really clear. I don't think there is one organisation putting their hands up for it right now*".

Question 10

Question number 10 was "Have there been any policy successes in recent years?". This question was asked to 9 of 14 interviewees. As shown in Figure 11 below, there were five themes extracted from this question, with four themes deemed reportable.

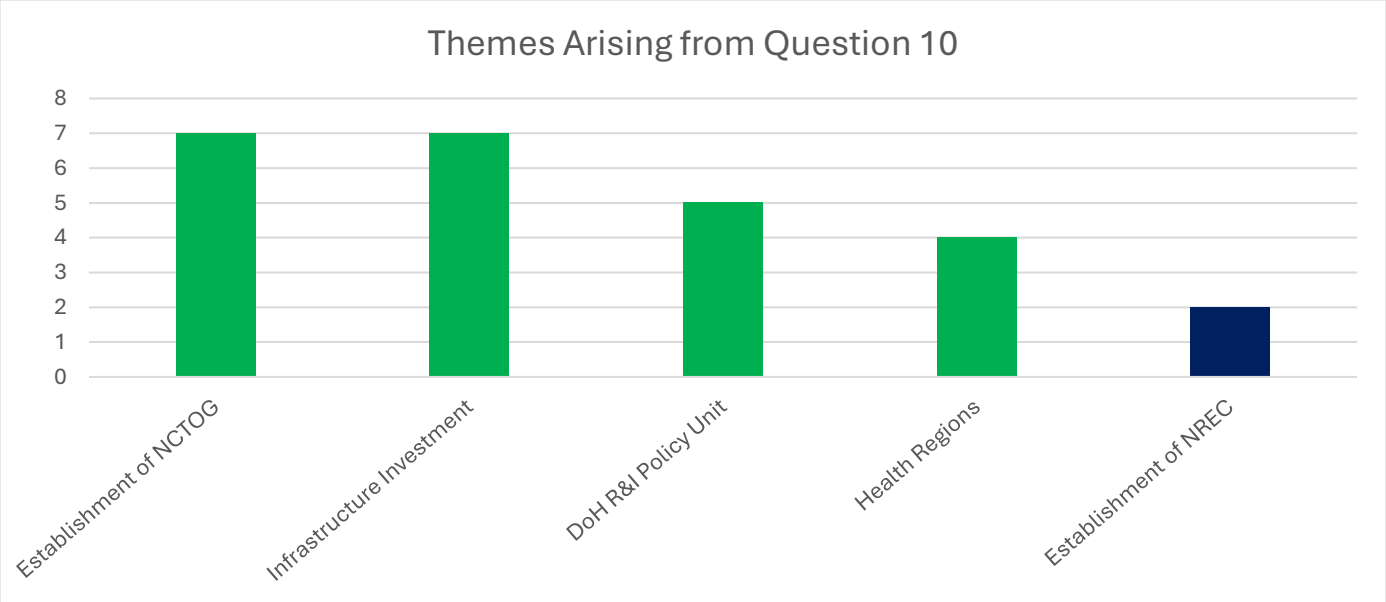

Figure 11: Themes Arising from Question 10

The most prominent theme from this question, mentioned by seven of the 9, or 78% of the interviewees who were asked this question was commandment around the establishment of the NCTOG by the Department of Health. For example, interviewee TC1 mentioned " *I think the best evidence of success for recent years is the establishment of the National Clinical Trials Oversight Group by the Department of Health*".

The second most common theme within this question was the positives which have arising from the HRB's investment into funding clinical trial infrastructures over the last 15 years. This was seen as a major positive by 78% or 7 of the 9 interviewees who responded to this question. Interviewee TC3 noted "*The fact the HRB has been funding for years is the biggest one coming to mind. It's better than it not being done at all, but that is just one agency really*"

The third theme which was deemed reportable from this question was that the establishment of the Research and Innovation Policy Unit within the Department is seen as a policy success by stakeholders. This was discussed by five of the 9 interviewees, or 56%. Interviewee TE7 said, " *I also think that the establishment of the relatively new unit around Research and Innovation policy in the Department has been a big success so far and is an attitude shift*."

The fourth and final reportable theme from this question was the establishment of the HSE Health Regions, which is seen as something that can enable research, depending on how research is implemented into the structures arising from the reorganisation. This theme was mentioned by 44%, or for of 9 interviewees, including interviewee TE4 who outlined "*I also think the Health Regions could be a success, I think in theory it looks really good, but again, it comes down to how they're actually implemented*".

Question 11

The final question asked to interviewees was “What would a ‘best practice’ policy which enables clinical trials look like?”. This question was asked to 13 of 14 interviewees and as can be seen below in Figure 12, 8 themes were highlighted by interviewees, with four of these themes deemed reportable.

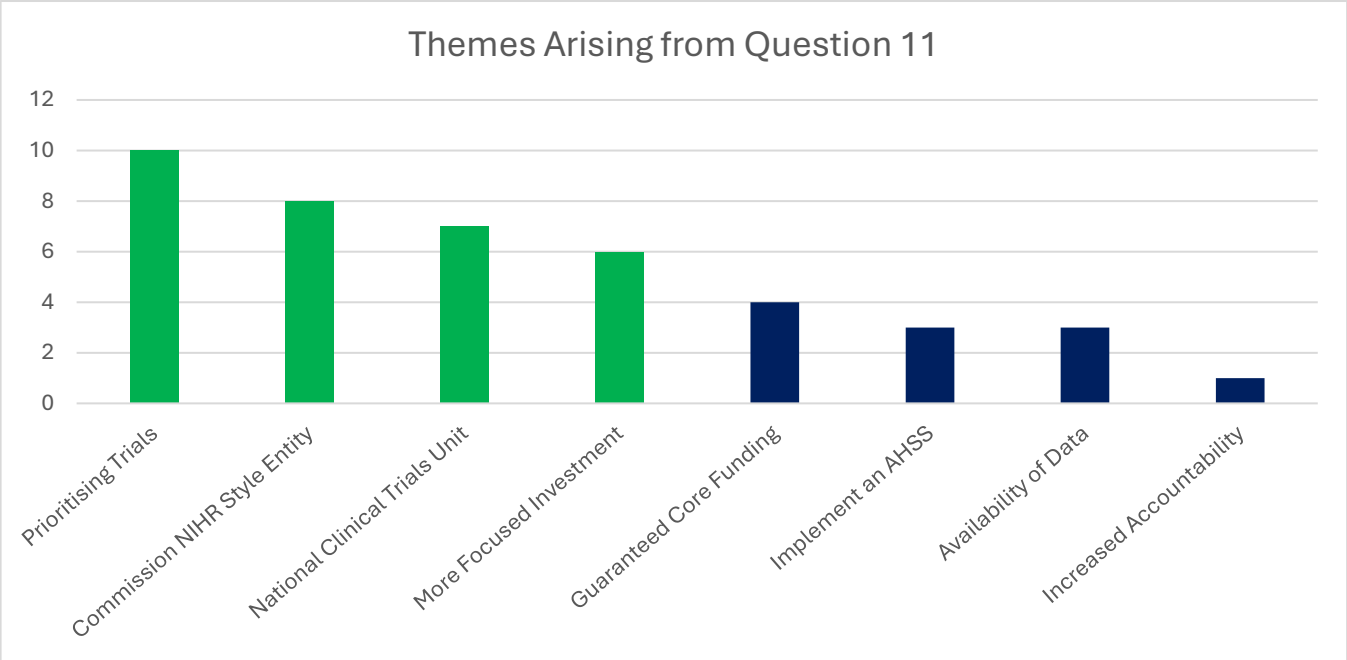

Figure 12: Themes Arising from Question 11

The most commonly mentioned theme by interviewees within this question, which was discussed by 10 of 13, or 77% of interviewees was the need to prioritise clinical trials within a future life sciences policy or strategy. Interviewee TC6 said “ *A real prioritisation of clinical trials specifically but broader clinical research and a focus on bringing that into our health system as the gold standard*”.

The second most prominent theme arising from this question, was the need within the system for the presence of an entity like the NIHR within the UK system to provide core funding for clinical trial infrastructures. This would allow the HRB to focus on funding actual clinical trials. This theme was discussed by 62% or 8 of 13 interviews, including interviewee TC1 who mentioned “*What I would really like to see is I would really like to see us commissioning to creating a national entity. Perhaps like NIHR, or perhaps an evolution of the NIHR model, but a central identity for clinical research activity in this country*.”.

The third reportable theme from this question, which was brought up by seven of 13 interviewee, or 54% was the need within the system for a national Clinical Trials Unit (CTU) to provide leadership and direction across the system. Interviewee TE1 mentioned "*There needs to be a centralised, national CTU which should be hosted at the most productive and effective site in the country*".

The final theme from this question, which was mentioned by six of 13 interviewees, or 46% was the requirement of future policy to have more focused funding and investment for clinical trials to focus on key, priority areas – rather than funding a 'small bit of everything'. Interviewee TE6 outlined "*I would like to see areas of excellence in certain disease or therapeutic areas to become global leaders in a small number of areas. We are a small country, so there is no reason why that can't be achievable*".

5.2. Quantitative Analysis

5.2.1 Introduction

The quantitative analysis within this study is primarily focused on establishing baseline activity benchmarks for Ireland against a selection of countries previously highlighted as high performing countries through either the literature or interviews conducted. To ensure robustness, Ireland will be compared with Denmark and Finland due to the similar size and population of the three countries, to ensure that any findings are relevant and are not skewed.

The areas analysed within this section are population, clinical trial initiation, healthcare expenditure per capita, and gross domestic expenditure on R&D (GERD).

5.2.2 Population

As outlined previously, Denmark and Finland were chosen as countries for this benchmarking due to their comparability with Ireland in terms of population. This metric provides important context for the other areas analysed as there would be little value in comparing the number of clinical trials initiated in Ireland with a country such as the United States, as the data would be completely skewed and would not be reliable. This is mainly due to the impact of population size on clinical trial enrolment, where countries with large populations can be seen as attractive, by having a single regulatory regime covering large populations. Figure 13 below shows the populations of the three countries from 2000 to 2025, at 5-year intervals.

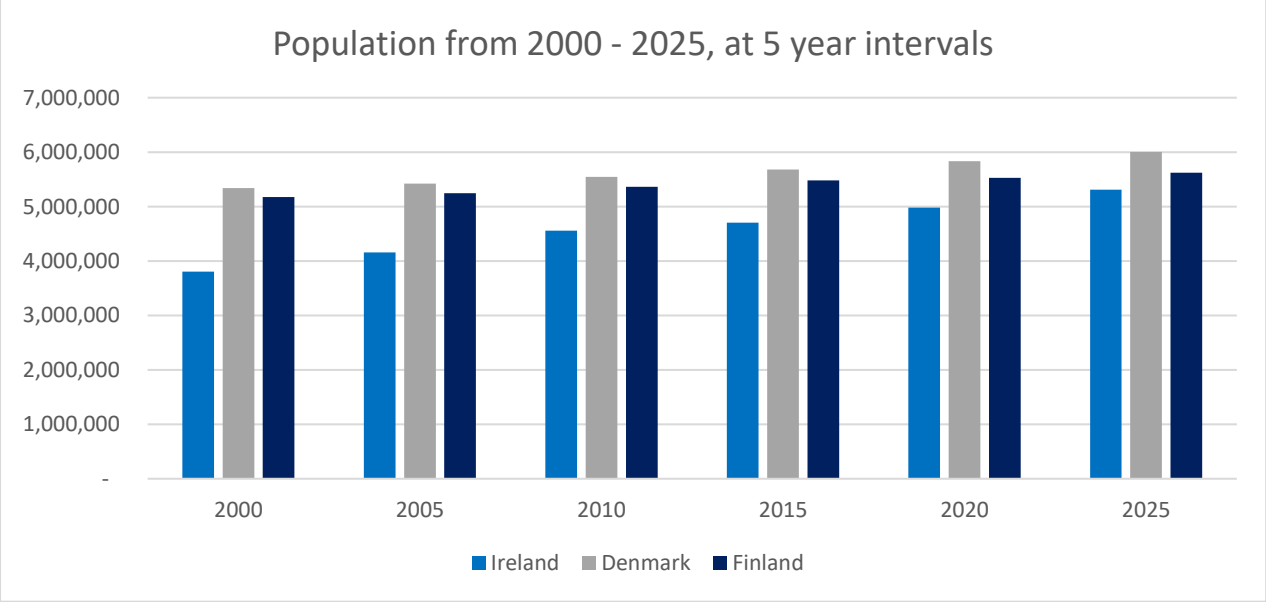

Figure 13: Ireland, Denmark, and Finland Population from 2000 - 2025, at 5-year intervals (Worldometer, 2025)

As can be seen above, Denmark and Finland both have a slightly larger population than Ireland with a delta of approximately 315,000 between Ireland and Finland, and a delta of approximately 700,000 between Ireland and Denmark. Whilst recognising the population size differences between Ireland, Denmark and Finland, the researcher maintains confidence that these still represent useful comparator countries. However, it is important that the following statistics presented, which are not determined per capita are interpreted in the context of the population variance.

5.2.3 Clinical Trial Initiation

Clinical trial initiation refers to the start of a clinical trial, once a trial has been approved by the relevant authority (the national competent authorities, being the HPRA in Ireland, the DKMA in Denmark, and FIMEA in Finland) and patent recruitment begins. Figure 14 below shows the numbers of clinical trials initiated across the three countries between 2015 – 2024. The data for 2015 – 2023 is sources from the EU Clinical Trials Register, while the 2024 data is sources from CTIS as this is when trial registration officially transferred to the new system.

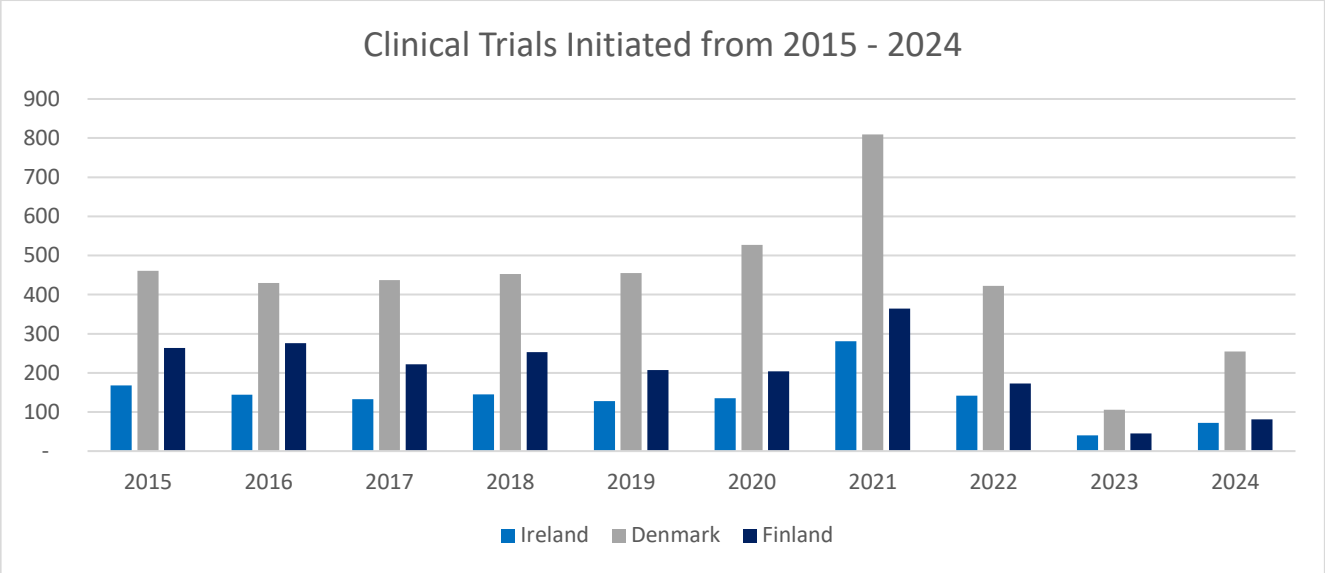

Figure 14: Number of clinical trials initiated in Ireland, Denmark, and Finland from 2015 - 2024 (European Union, 2024) (European Union, 2025)

Figure 14 highlights drastic differences across the three countries in terms of the startup of clinical trials. Denmark is a clear leader across the dataset and the country sample selected, averaging 316% of the number of trials initiated, that Ireland initiates. While Finland lags behind Denmark, it is still consistently outperforming Ireland, initiating 147% of the number of trials that Ireland have across the timeframe examined This would indicate that in future research, Finland may be a better short to medium

term benchmark, while Denmark should be viewed as best practice, and a longer-term goal in terms of performance.

5.2.4 Healthcare Expenditure per Capita

This metric looks to measure the total healthcare expenditure of Ireland, Denmark and Finland per capita so as to develop a solid baseline. This is an important measure as clinical trials do fit into the broader healthcare systems within these countries and are not exclusively delivered. As highlighted during the literature review, clinical trials as care or as a part of business as usual is increasingly recognised as the standard which should be attained, if we are to deliver best outcomes for patients

In 2022 (the most recently published healthcare expenditure data for the three countries sampled), Ireland spent €6,218 per capita on healthcare, with Denmark spending €6,185 per capita, and Finland €6,699 per capita (Eurostat, 2024). This is particularly noteworthy, given it is clear that whilst Irelands health expenditure is strong, its trial underperformance further points to a large and increasing gap with health system funding.

5.2.5 GERD

GERD refers to gross domestic expenditure on R&D, expressed as a percentage of gross domestic product. GERD is a useful metric in this context to evaluate the focus of different countries or jurisdictions on broader R&D. However, it is not a perfect measure in most cases, including for this research as it includes all R&D spend, from clinical trials and health research to R&D spend on semiconductors, agriculture and robotics. Whilst not specific to health and trials, it is however a useful measure of the innovation, research and development readiness and priority of the state

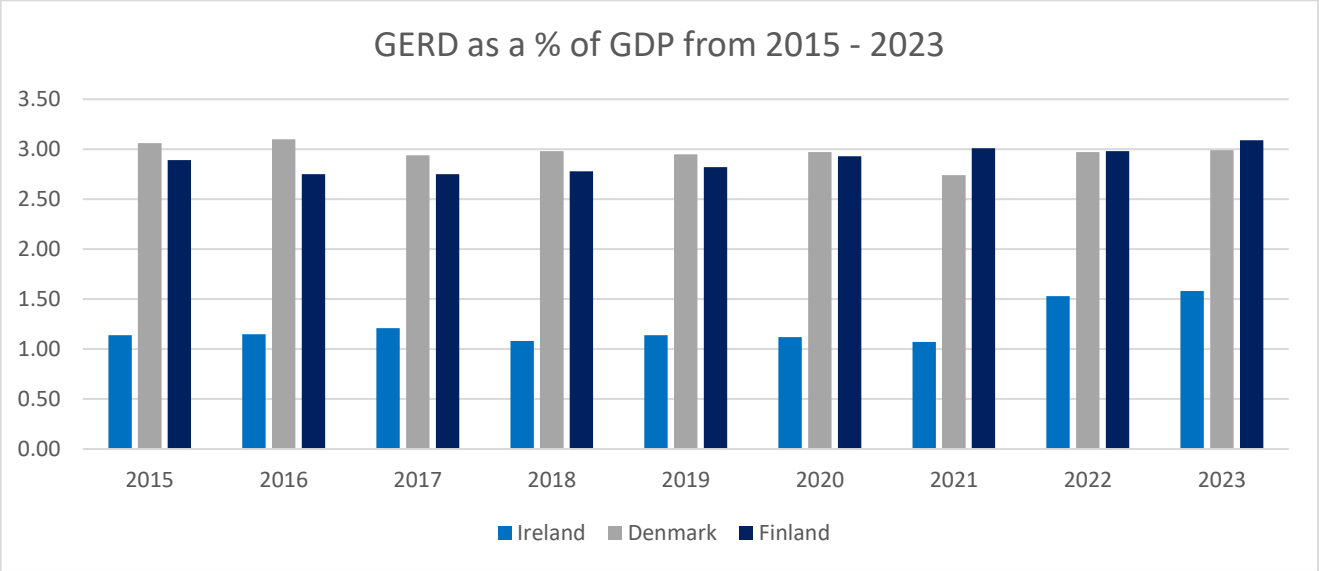

Figure 15: GERD as a percentage of gross domestic product in Ireland, Denmark, and Finland from 2015 - 2023 (Eurostat, 2024)

Nonetheless, it is an interesting measure, and as highlighted in Figure 15 above, Ireland falls significantly behind Denmark and Finland in this area. While there have been some increases in Ireland's GERD in 2022, and 2023, Ireland remains at half of the investment of the benchmark countries. This outlines a lack of focus across Irish sectors on long-term thinking to advance and evolve medicines, technologies and approaches, particularly when compared to the benchmarks utilised in this example.

5.3. Findings

This section collates the findings from the literature reviewed, the qualitative analysis of interviews completed, and quantitative analysis of data accessed. Herein the large amount of both quantitative and qualitative data, generated through a number of approaches are synthesised to describe an accurate picture of the state of the art and provide a foundation for policy initiatives. For ease of reading, the most prominent themes, as determined by their cumulative frequency, collected across all interview questions are presented below in Figure 16.

No.	Theme	*n*
1	Lack of Policy and Advocacy	44
2	Funding Issues	33
3	Lack of Integration and Focus on Trials	25
4	Not Properly Leveraging Partnerships	16
5	High Legislative Burden	14

Figure 16: Main Findings of This Study

It is important to note that the themes presented above are focused on issues within the system, and areas where respondents are strongly of the view that improvement is needed. As outlined previously, one of the primary objectives of this study is to develop recommendations which can be implemented to address some of the most prominent issues within the system. To deliver this, for each finding outlined below, a recommendation is proposed which, if implemented, can solve the issue identified.

Finding 1: Ireland has a lack of policy direction and 'advocacy'. There is no one entity designated to lead clinical trials in Ireland, and to communicate the value of clinical trials. There is no entity to represent Ireland on the global stage and attract investment from industry, or to attract excellent researchers to work in our system, rather we have a fragmented system of well intentioned, but not designated individuals.

Recommendation 1: An entity should be established and funded to provide leadership for clinical trials in Ireland. This entity should be independent of any government department but should work across many and should have the autonomy to work to improve Ireland's performance of clinical trials. This model has been proven to work, for example, Trial Nation in Denmark which has contributed significantly to the high numbers of trials in place, and is an independent organisation founded by various Danish government departments, life sciences organisations and the health service (Trial Nation, 2024).

Finding 2: As with many things, there is never enough funding for clinical trials, and the manner in which the available funding is administered is considered neither satisfactory nor optimal. The HRB act as the national funding agency for health research, however, a large portion of the HRB's budget primarily funds infrastructures to complete trials. These are not one and the same. Due to a lack of other funding available, the HRB have continued to fund trial infrastructures, as if the HRB did not fund this, it appears that they would not be funded whatsoever. Interviewees expressed a desire for 'core' funding to come from another source, allowing the HRB to specifically fund actual clinical trials.

Recommendation 2: A pathway should be established to properly resource the core trial infrastructures which enable the conduct of clinical trials. It is vital that this pathway retains the competitive funding element, which is crucial to drive quality and innovation, ensuring that funding goes to the units which will translate it into the biggest impact on patient outcomes possible.

Finding 3: There is a lack of integration and focus on clinical trials within our health system. Clinical trials, and clinical research more broadly are seen as a 'nice to have' rather than a core component of providing the best patient focused care. This is due in part to the fact that the value of trials is not communicated appropriately, and also due in part to Ireland's core health service being seen as quite 'messy', and as such it is focused on firefighting day to day. In one of the wealthiest and most well-educated countries in the world, this is not good enough.

Recommendation 3: Clinical trials should be appropriately integrated within the responsibilities of the HSE. It should be mandated that all HSE hospitals, as well as voluntary hospitals with which the HSE have contractual relationships must measure and report on their clinical trials activity in the same manner that other healthcare metrics are reported. Mandating and measuring clinical trial activity is the only way to hold these organisations accountable to deliver the best possible patient care, which has been clearly shown to benefit from enhanced trial activity.

Finding 4: At present, Ireland is not leveraging partnerships to the degree which it is possible and advantageous to do. The strong pharmaceutical and technology base in Ireland presents opportunities for collaboration and Innovation, however there not many areas in which this is currently being utilised.

Recommendation 4: Due to the limited funding available within the system and the significant opportunities to increase this through partnerships, partnerships with industry organisations, regardless of sector should be encouraged and the friction to establishing these partnerships should be reduced. A core ambition of the national coordinating entity described at recommendation 1 above should be to mobilise and create partnerships, integrating healthcare, enterprise and innovation to achieve collaborations of scale and of impact.

Finding 5: As seen across the literature and interviews, Ireland performs poorly when it comes to interpreting legislation. Particular example of this includes Ireland's interpretation of GDPR, which one interviewee described as "a uniquely Irish way to overcomplicate things". In simple terms, it takes too long to initiate trials in Ireland, and this dissuades industry from wanting to collaborate with Ireland on clinical trials.

Recommendation 5: The recommendations stemming from the work of the NCTOG should be fully implemented, and supported, both from a political standpoint but arguably more importantly – the financial perspective. Promising results can already be seen from the interim recommendations delivered from this group, but it is key that the recommendations are appropriately implemented in a timely manner.

6. Discussion and Conclusion

6.1. Discussion

The catalyst for the research question examined throughout this study arose from the recognised importance of clinical trials in an appropriately functioning health system, the relative underperformance of Ireland in this area, and the researchers own experience of working in the area. This lived experience has aided the analysis and interpretation of the available literature, and the thoughts and opinions of knowledgeable stakeholders in the area of clinical trials in Ireland. The importance of this research and the research question underpinning it has been made evident through the willingness of stakeholders to take part and contribute to this study, recognising the importance of the topic in general, and the lack of similar research previously undertaken.

Across the data gathered, there are significant correlations between the opinions of interviewees. The sample of stakeholders which took part in the interviews outlined key themes ranging from the high legislative burden around conducting clinical trials, to a lack of policy direction, to a lack of integration and prioritisation of clinical trials within the health system. There were a total of 76 themes identified across 14 interviewees and 11 interview questions, with 38 of these themes mentioned by 40% or more of the total sample. This approach has added a layer of rigour to the study to ensure that the most common themes were discussed, rather than the findings skewed by a minority of individuals with varying opinions.

Amongst the most commonly occurring themes were funding difficulties, lack of clear policy, lack of recognition of the importance of clinical trials, and the need to make trials easier to conduct from a legislative interpretation point of view. These themes were all identified through the literature as important and in the case of funding, this was particularly emphasised by Leddy et al. in terms of the current level of funding not being great enough to stimulate significantly enhanced trial activity (Leddy et al. 2023). However, there were also themes arising from the interviews which were not identified from the literature, such as the need for an entity, similar to Trial Nation in Denmark to provide leadership and advocacy for the clinical trials ecosystem. The critical importance of cross governmental support for clinical trials featured prominently in the interviews, recognising that there are areas of synergy which can be leveraged when taking more of a long term, strategic view on clinical trial performance. However, the

need for cross governmental support, rather than a single government department approach was not observed by the researcher in previously published literature.

Interestingly, there were some contradictory themes identified by different interviewees. For example, some interviewees said that there is sufficient funding for clinical trials within the system, while some said that the mechanisms for administering the funding were the problem, and others said that there is nowhere near enough funding for clinical trials.

This aligns with research previously conducted by the HRB, which found that different stakeholders may view the flexibility of funding as more important than the amount of funding and vice versa, depending on their viewpoints (HRB, 2019). These varying views were anticipated by the researcher, but interestingly – some interviewees from the same organisation conveyed these differing views, suggesting that some themes identified are very person-specific, and may not relate to the entire population of clinical trials stakeholders in Ireland.

There are some areas of commonality in the major findings from this study, particularly regarding the legislative burden and the need to appropriately interpret legislation. This is particularly in line with the work of the NCTOG, reviewing elements of the system such as contracts, as well as issues around governance and access to data highlighted by Staunton et al. (Staunton et al. 2023).

This study fills a gap in previously identified literature and may be useful as an evidence base for researchers, policymakers, patients, or other stakeholders in the system. While the research is relatively ‘high level’, the number and range of stakeholders who were interviewed make this study very relevant and important within the system, particularly considering the lack of similar research previously conducted in an Irish context.

As outlined previously, there are a range of limitations to this study, which are important to keep in mind when reading and interpreting this research. Firstly, the research was completed in a very short timeframe. The result of this was that not all factors were explored in depth due to the size and complexity of the clinical trials ecosystem in Ireland.

The 14 stakeholders who participated in interviews is a very small portion of people working in the area of clinical trials in Ireland. In addition to this, not all stakeholders

who were originally identified were interviewed due to scheduling restraints, and the need to complete the study in the short time frame.

The researcher did not contact or see to interview any patients who have taken part or considered taking part in clinical trial for this research. This was due to the complexity of interviewing these populations and the need for a high degree of sensitivity. While this approach was initially considered by the researcher, it was not deemed appropriate for a study like this which is more of a scoping nature. Regardless, this is an important consideration

Considering these limitations and the findings already discussed, if the researcher was to conduct this study again, on a larger scale it would be very valuable to conduct a more detailed examination of Ireland's clinical trial infrastructure such as the performance of individual sites, in the context of the funding that each site receives. In addition, future research on the economic value of clinical trials in Ireland would be a very valuable topic, to assess the amount of money that is generated by €1 of investment in clinical trials.

Future research should consider these points as well as recruiting a larger group to the study. Ideally, the interviewees would represent each organisation in the system, from each of the CRF/Cs, the HRB, the DoH, the HPRA, NREC, other funders and government departments. While there were stakeholders interviewed from many of these organisations, a larger and more cohesive sample would make the findings of future research more impactful.

Finally, the lack of a patient voice in this study is a major gap, and in a future study with the appropriate time and resources, it would be crucial to hear from patients. It would be particularly informative in future research to recruit patients who have taken part in a trial, patients who have declined to take part in a trial, patients who wanted to take part in a trial but couldn't, and patients with no knowledge of clinical trials. This would paint a far more complete picture of the system as a whole.

6.2. Conclusion

In conclusion, the mixed methods nature of this study has allowed this research to be based in reality, underscored by the literature and quantitative clinical trial data, and informed by the views and opinions of key stakeholders across the ecosystem. The combination of the qualitative and quantitative elements of this study has allowed the researcher to paint a broader, more informed picture of the clinical trials system in Ireland.

As discussed previously, there were a total of 76 themes extracted from the semi structured interviews conducted. These themes have been discussed in detail in the analysis, and discussion sections, but in summary, the key findings of the study are:

Finding 1: Ireland has a lack of policy direction and 'advocacy'. There is no one entity designed to lead clinical trials in Ireland, and to communicate the value of clinical trials.

Finding 2: As with many things, there is never enough funding for clinical trials, and the manner in which the available funding is administered is not satisfactory or optimal.

Finding 3: There is a lack of integration and a focus on clinical trials within our health system. Clinical trials, and clinical research more broadly are seen as a 'nice to have' rather than a core component of providing the best patient focused care.

Finding 4: At present, Ireland is not leveraging partnerships to the degree which it is possible and advantageous to do. The strong pharmaceutical and technology base in Ireland presented opportunities for collaboration and Innovation, however there not many areas in which this is currently being utilised.

Finding 5: As seen across the literature and interviews, Ireland performs poorly when it comes to interpreting legislation.

These findings are significant as the findings themselves, and the associated recommendations which propose solutions to address each finding, present an evidence-based roadmap to increase the number of clinical trials conducted in Ireland, increasing patient access to new medicines, increasing innovation, and driving economic growth.

This study has been grounded in reality, recognising that no system is perfect, and that there is no 'quick win' to solve all of the issues identified. However, these findings and

associated recommendations answer the research question for this study and are all implementable.

As outlined previously, there is already work ongoing through the NCTOG to solve some of the most common issues affecting the start-up of clinical trials. However, the Department of Health has yet to outline and funding arrangements in place to support the implementation of the final recommendations, due to be published in the coming months. It is difficult to see value in this activity without any commitment to follow through, outlining the potential for the work of the Group to be finished, with few concrete changes made to the trials ecosystem in Ireland.

In conclusion, this dissertation has outlined that there are a range of avenues to pursue to deliver increased access to clinical trials for patients, and in turn, better treatments and care, highlighting the vital importance of clinical trials within Ireland. The findings outlined contribute to the current understanding and research surrounding clinical trials in Ireland and can act as an evidence base for stakeholders within the system. The findings suggest that future research into the barriers and enablers of clinical trials of a wider scale than this study could yield even more valuable insights into the functionalities of the system. Ultimately, this study lays the foundation for future research, and presents practical, implementable recommendations to improve Ireland's clinical trials ecosystem, and to deliver better access to clinical trials for patients.

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Appendices

Appendix 1: Interview Question List

Opening Questions

1. Can you tell me a little bit about your role in [interviewee organisation]?
2. In overview, what is your general opinion on Ireland's current position with regards to clinical trials?

Infrastructure Questions

3. What do you see as primary deficits within the clinical trials ecosystem in Ireland?
4. Could you describe any 'low hanging fruit' that could solve infrastructure problems?
5. How might the adoption of innovative clinical trial designs such as decentralised trials affect ecosystem requirements to perform trials?
6. How can Ireland better integrate clinical trials into routine healthcare?

Funding Questions

7. What is the largest issue in terms of funding for clinical trials, infrastructure supports, staff etc?
8. Has sustainability of funding become more of an issue in recent years?
9. What incentives could encourage CROs, pharmaceutical, and biotech companies to conduct more trials in Ireland?

Policy Questions

10. What organisation has policy responsibility for increasing the number of clinical trials in Ireland?
11. Have there been any policy 'successes' in recent years?
12. What would a 'best practice' policy which enables clinical trials look like?