Irish Cancer Society

Cancer Clinical Trials in Ireland Scoping Report

July 2024

Irish Cancer Society

forvis mazars

Limitations

The work on which the observations and recommendations in this report have been made was undertaken in the period January 2024 – July 2024 and should be considered in that context. The review was conducted by means of independent analysis of information requested, observations, stakeholder meetings and consultations, and benchmarking. Forvis Mazars has relied on data provided and explanations provided without having sought to validate these with independent sources in all cases. We have however, satisfied ourselves that explanations received are consistent with other information furnished. The data presented in this report were gathered at a specific point in time (January to July 2024). It is possible that some of this information from public sources (e.g. trial numbers, trial stage) has since been updated by trial sponsors. Finally, whilst the report is informed by evidence, the interpretation and opinion of the authors, based on their experience, is applied and the report should be read in the context of the short timeframe and scoping nature of the review.

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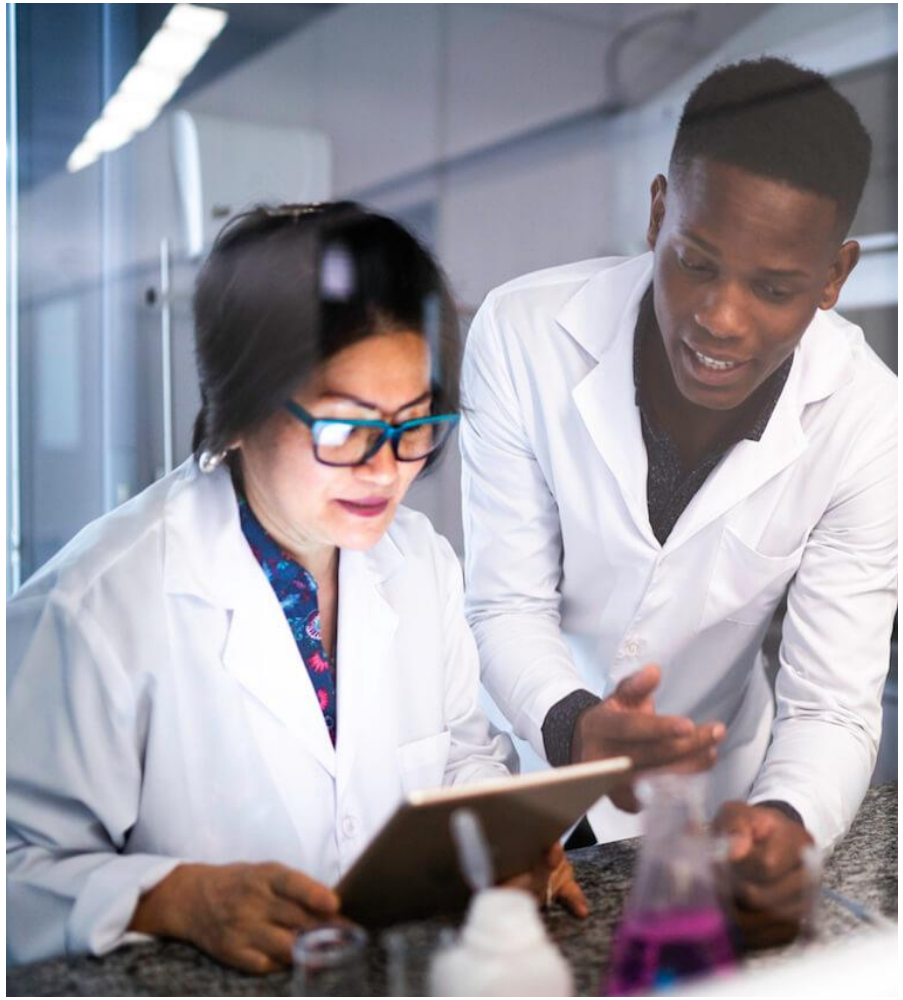


EXECUTIVE SUMMARY

What were we asked to do?

- To develop, within the limitations of a brief scoping exercise, a knowledge and evidence base that will help to inform The Society, clinical researchers, the pharmaceutical industry, healthcare practitioners and people affected by cancer regarding the cancer clinical trials landscape in Ireland.

Why were we asked to do it?

- Since the onset of COVID-19, many clinical trials have been suspended or discontinued
- This has resulted in significant ongoing knock-on impacts on Clinical Cancer Trial (CCT) activity and patient accrual rates.
- This report provides relevant information to allow The Society and other stakeholders across the Irish system to assess the situation, to be informed regarding access to trials, to support cancer trials and to take steps to increase patient accrual rates to deliver better outcomes for cancer patients.

How did we do it?

- We completed a desk-based review of documentation that was internal and external to The Society and deemed relevant to the scoping project (see Appendix 3)
- We performed consultations with key stakeholders from organisations within the wider clinical trial and research ecosystem (see Appendix 2)
- We completed a high-level international scan of a selection of comparator countries (see Section 3) to establish elements of best practice internationally
- We prepared a report on the current Irish system, as well as elements of good practice internationally, to establish a set of observations and recommendations to contribute to the improvement of the state of cancer clinical trials in Ireland.

When did we do it?

- Over the January – July 2024 period

EXECUTIVE SUMMARY (CONTD.)

What did we find and what do we recommend?

Due to the scoping nature of this review, its relatively limited timeline and dataset, the Findings & Recommendations following are pitched at a high level. Further work would be required to define them more granularly and to allocate responsibility for implementation accurately. Notwithstanding the above, it is clear that the majority of the Findings & Recommendations are at a national or 'system level' and would fall largely within the remit of the State.

#	Findings	Recommendations
1.	Strong, sustained public investment in R&D (including health research) is a well-known feature of advanced economies and high performing healthcare systems. Provision of human infrastructural and knowledge capital is strongly associated with improved healthcare outcomes. It has been the objective of national policy since 2006, with the release of the Strategy for Science, Technology and Innovation 2006 – 2013 as well as subsequently R&I strategies – Innovation 2020 and Impact 2030, to increase Ireland's investment in R&D to advanced/OECD levels (often 2.5% - 3.5% of GDP) but this has not been achieved and Ireland remains consistently in the lower tiers of OECD/EU rankings for investment in research and innovation.	Deliver sustained increases in investment in Research (and health research) to a level commensurate with the ambition of the National Cancer Strategy and the performance of peer countries regarding cancer trials (~3% GDP/GNI*).
2.	As outlined previously, the funding models currently used to support CCT infrastructure are not optimal for long-term core infrastructure. The reliance on temporal, competitive grant mechanisms, more typically associated with specific research programmes, may be contributing to a lack of sustainability observed in much of the infrastructure e.g. attraction/retention of staff.	Review the funding models used for supporting CCT infrastructure to make it more sustainable, reliable and strategic (considering models which are considered more mature e.g. the UK NIHR system).
3.	The CCT system in Ireland has evolved 'organically' over time. It is a complex system with many stakeholders spanning hospitals, universities, the Department of Health, the HSE, CTI, The Society, funders, Industry, the NCCP, patients and many more. It can be a challenging system to navigate and there is ambiguity (on the part of many stakeholders we heard from) regarding the precise remit, roles and responsibilities of stakeholders, leading to gaps and overlaps. It would be desirable to remove such ambiguity via clear definition of stakeholder roles & responsibilities and, perhaps, to consider conferring on one organisation the 'ownership' of the CCT system in Ireland.	Clarify the remit, roles & responsibilities of the key players in the CCT system and consider conferring responsibility for clarity and coordination onto one appropriately resourced/mandated organisation.
4.	The approach to CCTs, and cancer research more broadly, is spread across many policy documents and organisations, ranging from the National Cancer Strategy to Sláintecare to the HRB, CTI, NCCP and others. It appears that there is no national strategy for CCTs in Ireland that is coordinated, coherent and agreed by the main parties. In effect – this means the approach to CCTs (and underpinning cancer research and clinical trials) is somewhat fragmented, and, therefore, sub-optimal.	Define a strategic approach to CCTs in Ireland to appropriately align, incentivise and nurture the stakeholder components of the CCT system to enable the vision of the National Cancer Strategy and to match best practice observed in peer countries.

EXECUTIVE SUMMARY (CONTD.)

What did we find and what do we recommend?

#	Findings	Recommendations
5.	There is widespread variation across healthcare sites in Ireland regarding the interpretation and application of data privacy/protection regulations and principles. As covered previously, this variation in practice is characterised by unpredictability and delays in trial initiation/conduct, and is making Ireland an increasingly challenging location for the performance of CCTs. A sustained initiative(s) is required to educate and inform the relevant stakeholders across the CCT landscape (healthcare sites, universities, state bodies etc.) and harmonise the approach taken to the interpretation & application of data privacy/protection regulations.	Harmonise the approaches taken across the CCT system regarding the interpretation and application of data privacy/protection legislation and principles.
6.	In terms of the Republic of Ireland (RoI) and Northern Ireland (NI), cross border collaboration, in many areas, including healthcare, has been intensifying in recent years and is likely to develop further. While there is some cooperation in terms of CCTs at present, it is largely ad hoc. A well-resourced strategic approach to CCTs would enable enhanced cross border trials, increased patient accrual and contribute to improved cancer outcomes.	Develop a strategic approach to all island/cross border CCTs.
7.	There is variation – and sometimes confusion – amongst stakeholders in the CCT system regarding the definition of key terms and metrics relating to trials e.g. patient accruals. This needs to be resolved in order to enable consistent planning and tracking of CCT performance, in line with international practice.	Secure agreement by core CCT stakeholders to apply commonly used (internationally accepted) definitions of key CCT metrics.
8.	Whilst the availability of “CCTs suitable to the patients” was identified as the primary barrier to CCT participation, logistical challenges with the locations of CCTs featured prominently in patient considerations. As trial infrastructure/activity develops and broadens out over time and acknowledging the need for critical mass in certain areas, due consideration should be given to the geographical location of CCT developments to support, to the greatest extent possible, country-wide access to CCTs.	Enable the geographical development of CCT infrastructure to support, to the greatest extent possible, country-wide access to CCTs.
9.	As shown in the documentation review, the scan of international practice and the engagement with patients, there are a number of factors that impact patient engagement in CCTs. Leaving aside the most important issue of trial availability (trials of the right type), key factors include: awareness of CCTs as a ‘regular’ treatment option (as opposed to ‘last resort’), understanding of clinical equipoise (including randomisation, blinding etc.) and the provision/availability of appropriate information in inclusive/accessible forms. Patients are a ‘broad church’ and therefore the approach to addressing their challenges is, by definition, multifactorial. For example, whilst much of the focus is on the ‘receiver’ of knowledge (the patient), much still remains to be done in terms of equipping clinicians/care giver teams with the training, resources and culture to share information in an appropriate 2-way manner that best equips patients in terms of CCTs.	Review the policy and practice regarding CCT information provision & follow up in cancer treatment in Ireland and then co-design (with patients, care givers, clinicians etc) a common process/standard to be implemented subsequently.

01

Project Description

PROJECT DESCRIPTION

Context and Background

It is well established that research-active healthcare settings provide better outcomes for patients [1]. Around 3% of cancer patients receiving treatment in Ireland in 2014 were participating in clinical trials, well below the National Cancer Strategy target of 6%. Clinical trial infrastructure in Ireland is underdeveloped and performs poorly in attracting clinical trials, attracting fewer than peer countries in Europe. Disproportionately significant impacts on clinical trials were observed with the onset of the COVID-19 pandemic: cancer clinical trial accrual fell by 54% due to lockdowns, staff reassignments, and delays in trial initiations [2]. This has caused significant ongoing impacts on CCT activity in Ireland, and the ongoing inter alia repercussions are likely to result in continued delays in clinical trial initiation and accrual in Ireland. It is in this context that The Society commissioned this scoping review of the CCT landscape in Ireland.

Objective

To develop, within the limitations of a brief scoping exercise, a knowledge and evidence base that will help inform The Society, clinical researchers, the pharmaceutical industry, healthcare practitioners and other stakeholders regarding the cancer clinical trials landscape in Ireland.

PROJECT DESCRIPTION

Scope and Approach

In brief, Forvis Mazars was commissioned to:

- Conduct a high-level analysis of the ‘as is’ CCT environment in Ireland.
- Scan international practice to identify selected elements of good practice abroad.
- Consider the Irish CCT landscape in the context of observed practice abroad (based on the above and based on its expertise).
- Write a report of the above for The Society including observations regarding the current CCT landscape in Ireland and recommendations for its enhancement

For further details on the methodology and consultations carried out see A1 and A2.

Timeframe

The review was carried out over the January – July 2024 period.

02

Cancer Clinical Trials in Ireland – A Snapshot

INTRODUCTION – CLINICAL TRIALS

- Clinical trials/studies can be broadly split into those that are interventional and those that are not.
- Interventional studies typically ‘test’ one intervention against another via a measured outcome(s), often involving randomisation. Such studies are often referred to as clinical trials. They may be regulated (CTD/R) or unregulated.
- Trials are research studies conducted in humans to evaluate the safety and effectiveness of interventions. They are crucial for advancing medical knowledge, developing new therapies, and improving patient care.
- Clinical trials follow strict protocols designed to protect participants' rights and ensure scientific validity, so that the outcomes of a trial can be applied to the overall population.
- Non-interventional clinical studies, e.g., those of an epidemiological, biobanking or translational nature, are not clinical trials per se. It is helpful to keep this distinction in mind when reading this report.
- Regulated interventional studies/trials include investigational medicinal products, medical devices, surgical and radiotherapy-based studies, in addition to cell and/or tissue products, for example
  - It is important to note that regulated studies/trials can be a combination of the above
- Non-Regulated interventional studies/trials span physiotherapy, nutrition, exercise, behavioural changes etc, for example
- Before a regulated trial begins in Ireland, it must receive approval from the Health Products Regulatory Authority (HPRA) and the relevant Research Ethics Committees (REC), which evaluate the study's design, risks, and potential benefits to participants.

- Clinical trials serve to:
  - **Evaluate Safety and Effectiveness:** Clinical trials provide a structured framework for evaluating the safety and effectiveness of new medical interventions. Without these trials, it would be challenging to determine whether a new intervention is safe and beneficial for patients.
  - **Advance Medical Knowledge:** Clinical trials contribute significantly to advancing medical knowledge and understanding of diseases, their mechanisms, and potential treatments. Through rigorous scientific study, researchers uncover new insights that lead to better healthcare practices and outcomes.
  - **Improve Patient Care:** Clinical trials help healthcare systems make informed decisions about treatment options for their patients. By participating in trials, patients gain access to new therapies that are not yet available to the public, potentially leading to better outcomes and quality of life.
  - **Support Innovation:** Clinical trials provide for the evaluation of innovative treatments. Regulatory agencies such as the FDA and the EMA require clinical trial data to assess the safety and efficacy of new interventions before approving them for widespread use. A thriving clinical trials environment supports innovation.
- In summary, clinical trials are essential for advancing medical science, developing new therapies, improving patient care, and ensuring the safety and efficacy of healthcare interventions. They are a cornerstone of evidence-based medicine and contribute significantly to the progress of healthcare worldwide.

An environment that is supportive of clinical trials enhances patient outcomes, creates value, and supports innovation

INTRODUCTION – ACCRUALS

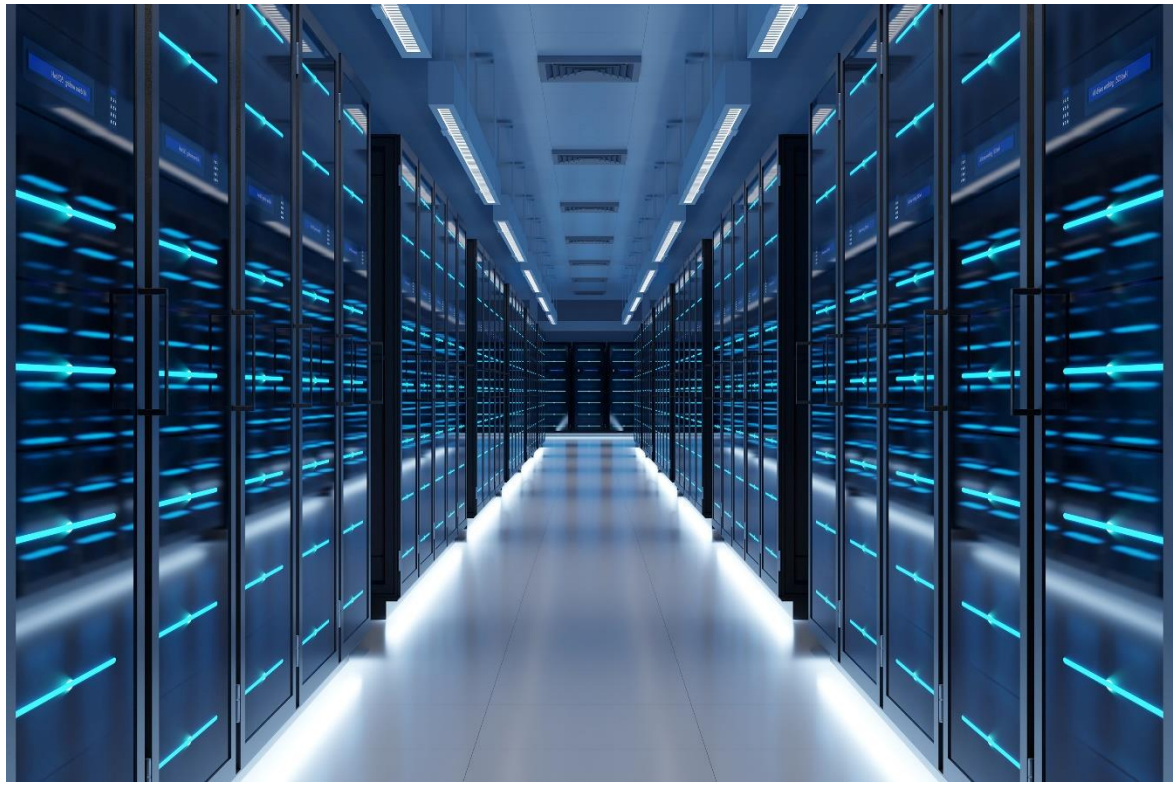
- Accrual refers to the number of patients newly recruited onto a trial for a given period (e.g. in a calendar year or in a three-month period). This does not mean that an accrued patient is actively taking part in a trial; but that they have been recruited, have consented, and are prepared to engage in the trial when appropriate.

- The % accrual is the number of patients accrued onto cancer trials in Ireland as a percentage of new cancer diagnoses in a specific period.

- The simplest method for tracking cancer trial accrual regularly is to view the cancer incidence statistics, published by the National Cancer Registry Ireland (NCRI) and the cancer trial accrual numbers which are regularly published by Cancer Trials Ireland (CTI), choose a specific period and divide this data accordingly. This will give the % accrual for patients onto cancer trials in a specific period.

- Ireland's National Cancer Strategy 2017 – 2026 set a cancer trials accrual target of 6% by 2020.

- In terms of good practice at international level, it is instructive to note that the requirement for a cancer centre to receive comprehensive cancer centre accreditation by the Organisation of European Cancer Infrastructures (OECI) is: 10% of newly diagnosed patients recruited onto a trial [3].



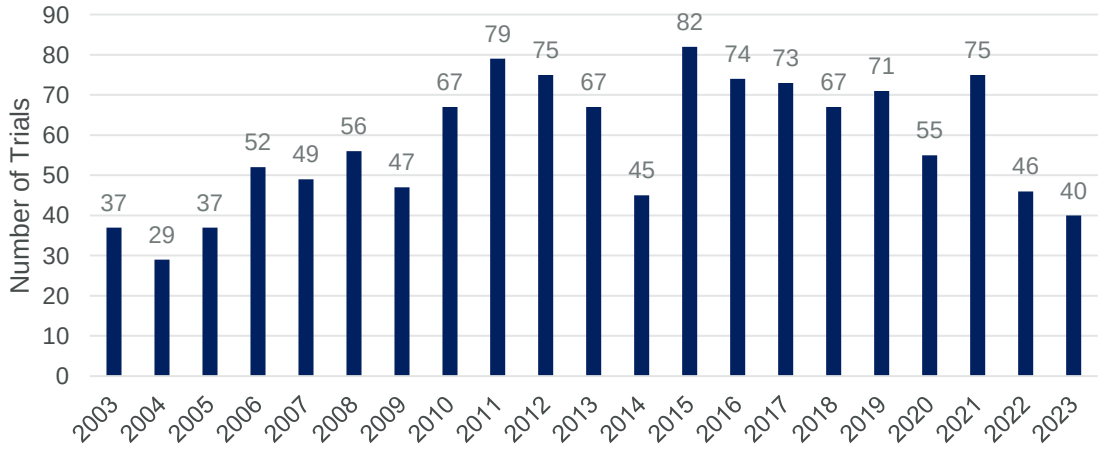
INTRODUCTION – ACCRUALS

- In Ireland, cancer stands as the most common cause of death for the population, with 30% of deaths annually being attributable to it [4].
- Approximately 42,000 people are diagnosed with cancer in Ireland each year with a mortality rate of 260.1 (per 100,000 population) in 2022* [5].

What is the level of clinical trials (all areas, incl. cancer) activity in Ireland**#?

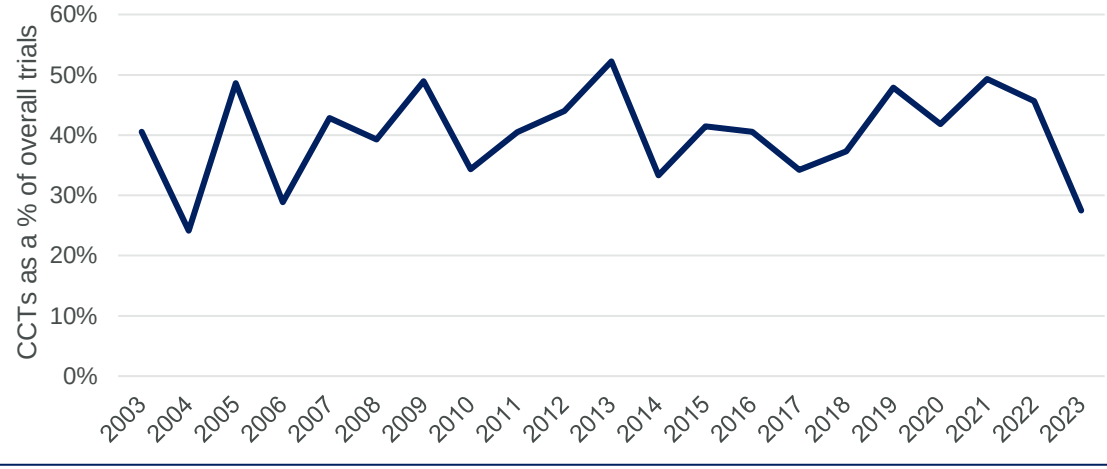
- As shown in Figure 1, the number of trials initiated each year varies from as low as 29 in 2004 to as high as 82 in 2015 [6].
- In 2023 the number initiated was 40. Of the 40 clinical trials initiated in 2023 – spanning all disease areas (see Figure 1) - 11 clinical trials focused on cancer [6].

Figure 1: Number of Interventional Clinical Trials Initiated in Ireland in 2003-2023



- Figure 2 shows Cancer Clinical Trials as a proportion of overall clinical trials over the 2003 – 2023 period

Figure 2: Interventional Cancer Clinical Trials as a Proportion of Overall Clinical Trials 2003-2023



*Cancer incidence statistics for 2023 had not yet been released at the time of the writing of this report.

** Data retrieved from clinicaltrials.gov at 23-07-24 with following criteria:

- Condition/disease: Cancer (Figure 2)
- Location: Ireland
- Study Phase: Phase 1, 2, 3, 4
- Study Type: Interventional
- Date Range, study start: 01/01/2003 – 01/01/2024

Data from public sources may have been updated by trial sponsors since the date of retrieval.

INTRODUCTION – A SNAPSHOT OF THE IRISH CCT LANDSCAPE

- During this review, we encountered variation in the understanding/definition used to express cancer trial accrual rates. Some stakeholders believe all cancer types should be considered whereas others believe only invasive cancers should be included. Furthermore, it appears that in some cases, data for patients on non-interventional studies are included in the accrual calculation whereas others believe only patient data for interventional studies should be used.
- For these reasons we present 2022 accrual rates in a number of ways, using an overall incidence figure of 42,000 (NCRI, 2022) [7], an estimate of invasive cancer incidence of 25,000 (NCRI, 2021) [7], an interventional study total of 522 (CTI, 2022) [8] and interventional + non-interventional total of 1,470 (CTI 2022) [8]:
- Arguments can be made for most of the above, however, we are of the view that B & C are probably most relevant, particularly B - given its alignment with international norms, and, for the purposes of this scoping review, positioning Ireland's accrual rate in the 2-3% range is helpful.
- The National Cancer Strategy does not define the exact basis of its 6% accrual target but consultations with some of its authors suggest the basis was likely to be consistent with the above rationale of method B (Interventional total as percentage of invasive incidence estimate).

2022 Accrual Rate Calculation		
	Method	**Result**
A	Interventional total (522) as percentage of total incidence (42,000)	1.2%
B	Interventional total (522) as percentage of invasive incidence estimate (25,000)	2.1%
C	Interventional + non-interventional (1,470) as percentage of total incidence (42,000)	3.5%
D	Interventional + non-interventional (1,470) as percentage of invasive incidence estimate (25,000)	5.9%

03

International Scan

- Denmark
- Finland
- New Zealand
- Case Study | Spain

INTERNATIONAL SCAN – WHAT DO OTHER COUNTRIES DO?

- Before examining Ireland's CCT landscape in more detail, we conducted a high-level scan of the CCT landscapes in three comparator countries: Denmark, Finland and New Zealand (NZ).

- The selection of these countries was based on a combination of factors including, inter alia, relevant size, ready access to information, and reputation/position as CCT performers.

- Spain was additionally examined as a case study. It was selected based on feedback from stakeholder consultations that it has taken significant steps in recent years regarding CCT performance.

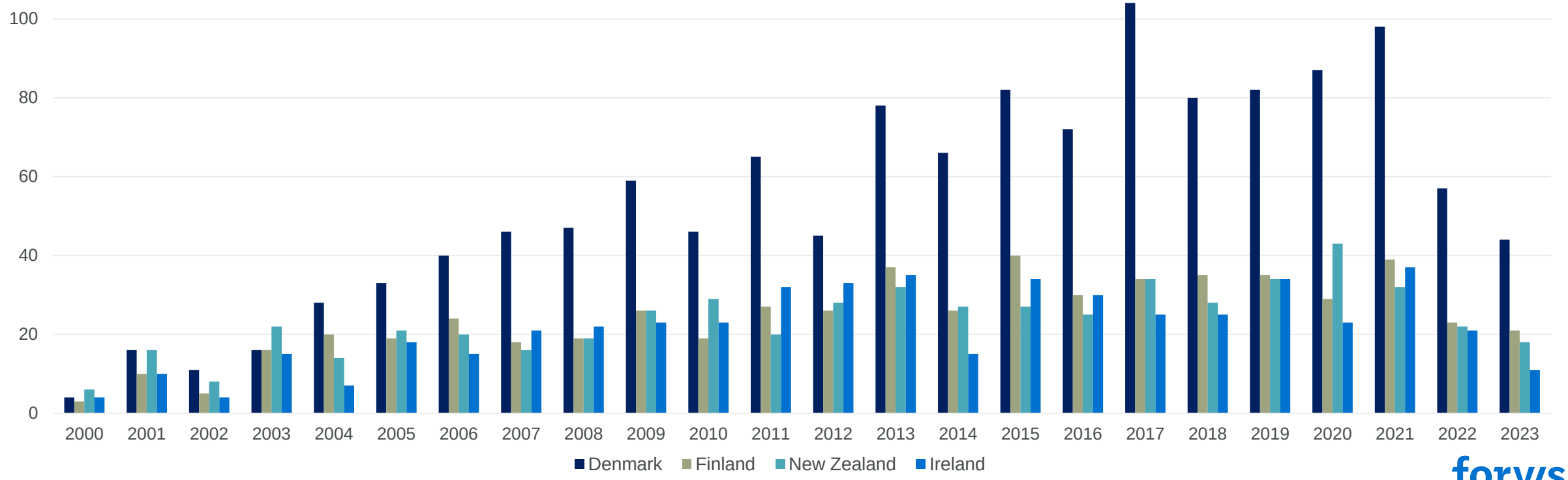
- Mindful of the high level/scoping nature of this review for each country, we provide:
  - An overview of the CCT landscape i.e. a high-level description including information on levels cancer incidences and oncologists, healthcare expenditure and Research and Development (R&D) expenditure, number of CCT's conducted etc.
  - Comments and observations on the CCT landscape.

- This information is provided to set a context in which to view the current state of the Irish CCT landscape and discuss areas in which Ireland could learn from comparator countries.

INTERNATIONAL SCAN

Before looking individually at the CCT landscapes in Denmark, Finland and NZ, it is helpful to look at the graph below (Figure 3) to visualise the number of cancer clinical trials started in Ireland and the three comparator countries from 2000 to 2023. This data was retrieved from ClinicalTrials.gov and covers phase 1- 4 interventional trials, excluding early phase 1. As the figure illustrates, the number of cancer clinical trials started in Denmark is considerably higher than the other countries in the sample. In 2017, for instance, the number of cancer clinical trials commenced in Denmark was three times higher than that in Finland and New Zealand, and four times higher than that in Ireland. What is especially noteworthy is that all four countries started from relatively similar positions in 2000.

Figure 3: Number of Cancer Clinical Trials Initiated by Country 2000-2023 [9]



INTERNATIONAL SCAN

Figure 4 Cancer Incidence per 100,000 population [10]

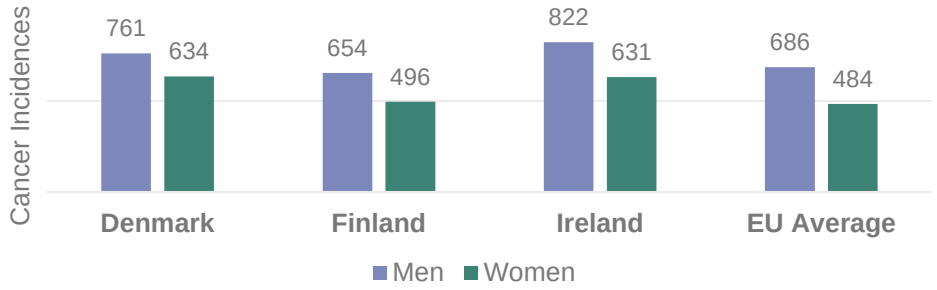
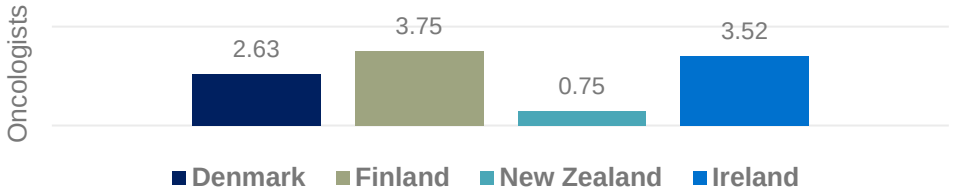


Figure 4 illustrates the incidence of cancer in Denmark, Finland, and Ireland, based on EU country cancer profiles. Ireland's cancer incidence rates for both men and women exceed those of Denmark and Finland and are also higher than the average across the EU. The OECD attributes this elevated incidence in Ireland primarily to increased life expectancy. While Figure 4 illustrates the high cancer incidence rates in Ireland, for nine of the ten most common causes of cancer death, mortality rates have been decreasing over time [10].

Figure 5 Number of Oncologists per 100,000 population [11]



As shown in Figure 5, Ireland has a higher number of oncologists per 100,000 population than both Denmark and New Zealand. Despite Ireland having a higher number of oncologists it is estimated that Ireland needs at least 60 more medical oncologists by 2028 to appropriately meet the patient demand [11]. Additionally, Ireland also has fewer radiation oncologists, surgical oncologists, and haematologists than needed [11].

Figure 6 Cancer Care Expenditure (as a percentage of total health & social care expenditure) [12]

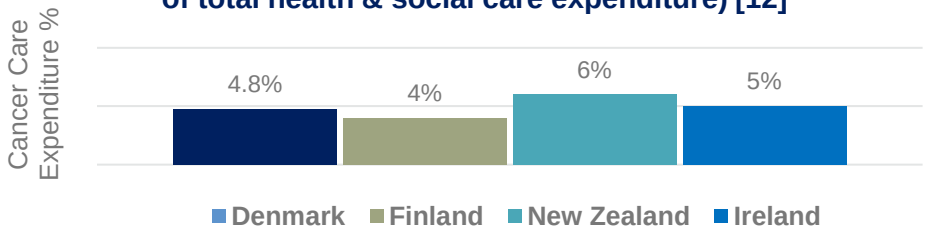


Figure 6 illustrates the proportion of total health expenditure allocated to cancer care across four countries, using data from 2014 for New Zealand and 2018 for Denmark, Finland, and Ireland. The expenditure on cancer care as a proportion of total health costs is consistent, ranging from 4% in Finland and 4.8% in Denmark to 6% in New Zealand. Thus, Ireland is broadly in line with the comparator countries from a health spending perspective at 5%.

INTERNATIONAL SCAN

Figure 7: Healthcare Expenditure and all R&D Expenditure* (per capita) [13]

	Healthcare Expenditure	R&D Expenditure
Denmark	€5,747	€1,363
Finland	€5,124	€1,254
New Zealand	€5,547	€528
Ireland	€5,534	€977

As can be seen in Figure 7, per capita healthcare expenditure is similar across Ireland and the three comparator countries. However, R&D expenditures* vary significantly, with both Denmark and Norway at the upper end, New Zealand at the lower end and Ireland falling in the middle**.

* Covers all R&D expenditure (including health R&D)
** For further information on key international comparative metrics for Life Health Sciences (LHS) Clusters see appendix 4

Figure 8: Average Number of Interventional Cancer Clinical Trials Initiated each year in a selected time period [14]

	Average CCTs Initiated annually from 2000-2023	Average CCTs Initiated annually from 2018-2023
Denmark	54	75
Finland	24	30
New Zealand	24	30
Ireland	22	25

Figure 8 shows the average number of cancer clinical trials annually across the period for all four countries. Denmark's average is approximately twice that of the other three countries. Additionally, on average, two fewer cancer clinical trials started in Ireland every year than in Finland or New Zealand. This difference is even greater when we consider only the period 2018-2023, where the number of trials started in Denmark was three times the number of trials started in Ireland. While Denmark's performance is an outlier, an average of five fewer trials took place in Ireland per year compared to Finland and New Zealand.

INTERNATIONAL SCAN – DENMARK

Snapshot

- When comparing the average number of CCT's started from 2018 – 2023, Denmark's average is approximately twice that of each of the comparator countries, Finland, NZ and Ireland.
- Denmark has the highest healthcare spending and R&D expenditure per capita compared to Finland, NZ and Ireland.
- In 2018 Denmark introduced an R&D tax deduction, escalating from a 100% deduction to a 130% super deduction for 2020-2022, and a 108% deduction for 2023-2025. Companies can opt to deduct the full amount or spread it equally. This initiative aims to bolster R&D growth, stimulate investment in R&D, and enhance economic development [15].
- The high-quality healthcare infrastructure in Denmark, with advanced medical facilities, access to data and experienced healthcare professionals, makes Denmark an attractive country for companies to conduct clinical trials.
- Denmark is characterised by a uniform and cohesive healthcare system coordinated and regulated by the central government. Treatment in Denmark is set to meet the same standards regardless of where in the country it takes place, making it easier to perform clinical trials from sites in all parts of the country. 94% of the hospital beds are publicly owned [16].
- To make Denmark an attractive place to conduct clinical research, the fees for phase 1 commercial clinical trials were dropped in 2018. Thus, the Danish Medicines Agency has exempted commercial sponsors from all fees for phase 1 trials.
    - These fees were subsequently reintroduced in early 2024, following the significant increase in the number of trial initiations – as seen in Figure 4
- Denmark has a highly digitalised healthcare system. In 2021, the European Commission concluded that Denmark has the EU's most advanced digitalised infrastructure.
- The Danish healthcare system allows for efficient patient recruitment due to its well-organised patient registries and the willingness of the Danish population to participate in the trials.
- In 2018, Trial Nation, the national association for the provision of clinical research in Denmark, was established to ensure stronger national coordination of clinical research.
    - It offers a single national entry point for life science companies, patient organisations, and clinical researchers who wish to sponsor, participate in, and conduct clinical trials in Denmark [17].
- The aim of Trial Nation is to enable a national approach to increasing performance in clinical trials. Trial Nation offers the following:
    - Identification of relevant clinical researchers and specialists
    - Fast response time on feasibility requests (5 days)
    - National recruitment strategy
    - Access to registries
    - Support of ongoing trials with focus on performance
    - Established collaboration between sites. In some therapeutic areas clinical networks are coordinated and facilitated by an administrator and led by a health care professional (a medical lead) to ensure efficient clinical trials.
- Additionally, Trial Nation strengthens frameworks and conditions to attract significantly more clinical trials at the highest international level.

INTERNATIONAL SCAN – FINLAND

Snapshot

- When comparing the average number of CCT's started from 2018 – 2023, Finland consistently performs a higher number than Ireland. Despite outperforming Ireland, Finland lags its Nordic peers. From 2010 to 2020, Finland conducted approximately 300 trials, while Denmark led with 700, Sweden followed with 580, and Norway with 400 [18].
- Like Ireland, Finland faces issues where doctors often struggle to find time for clinical research alongside their primary clinical duties.
- As can be seen in Figure 5, Finland has a higher number of clinical oncologists per 100,000 of the population when compared to the comparators – with this measure standing at approximately 3.75 oncologists per 100,000 population.
- Finland has the lowest levels of expenditure on cancer care as a proportion of total health costs, as seen in Figure 6. However, it ranks second in R&D expenditure within the sample examined, with Denmark having the highest levels in our sample.
- Finland plans to boost R&D by adding an additional €280 million of public funds into the sector annually between 2024 and 2030. The goal is to increase both public and private investment to 4% of the country's GDP by the end of the decade.
- Unlike in Denmark national co-operation structures have not yet been established in Finland leading to a more siloed system [19].
- From a pharmaceutical industry perspective, Finland faces challenges with low patient volume and a shortage of academically distinguished researchers. However, according to a representative from a clinical research institute, approximately 90-95% of research studies are driven by pharmaceutical companies [20].
- Finland is often cited in global healthcare rankings for its highly efficient healthcare system. However, while hospitals are willing and well-equipped to conduct trials, current budget constraints and resource allocations are limitations that hinder the growth of trials in Finland [21].
- The Finnish Society for Oncology (fin. Suome Onkologiayhdistys) provides a professional network, where clinicians can share opinions about the practices regarding guidelines and use of new medicines. This aims to increase the collaborative approach to undertaking CCT's.

INTERNATIONAL SCAN – NEW ZEALAND

Snapshot

- When comparing the average number of CCT's started from 2018 – 2023, New Zealand performs a higher number than Ireland.
- New Zealand follows relatively similar trends to Finland regarding the number CCTs initiated, with fluctuations year on year – but consistently initiating 20 – 40 new CCTs per year.
- As can be seen in Figure 5, New Zealand has quite a low number of clinical oncologists per 100,000 of the population – with this measure standing at approximately 0.8. This number is far lower than Ireland, with approximately 3.52 clinical oncologists per 100,000 population and Finland, with 3.75.
- Notably, New Zealand has the highest levels of expenditure on cancer care as a proportion of total health costs (as seen in Figure 6).
- Cancer Trials New Zealand (CTNZ), acts as a central coordinating body to support cancer trials in New Zealand [22].
    - It is based in the University of Auckland.
    - CTNZ works with investigators across all aspects of trials, from feasibility to study close out and from Phase 1 – Phase 4.
    - The main elements of the CTNZ service offering span:
        - Facilitation of collaborative linkages
        - Research Project Development
        - Research Project Set Up
        - Research Project Conduct and Management
        - Research Project Analysis, Reporting and Close-down
- CCTs in New Zealand are regulated by the New Zealand Medicines and Medical Devices Safety Authority (Medsafe) and the Health and Disability Ethics Committees (HDEC).
    - These bodies ensure that clinical trials adhere to ethical standards and regulations to protect the rights and well-being of participants.
- Collaboration between academic institutions, hospitals and pharmaceutical companies to conduct trials is common in NZ, with it even being common for different sponsors to refer patients to different locations for trials that may be suitable [23].
- Partnerships with industry, such as pharmaceutical companies, MedTech companied and biotechnology companies are common in NZ, with incentive given to enhance collaboration and innovation.
- In a report conducted on the NZ Clinical trials landscape in July 2022, one major element of note was that research culture in healthcare was not very prominent in NZ beyond a few specific hardworking individuals [23].
- New Zealand is now introducing new incentives to encourage the completion of more CCTs, largely in collaboration with CTNZ, to improve outcomes for patients with some key targets in mind [24]:
    - Diversifying trial participants
    - Conducting more early phase trials
    - Strengthening collaboration between stakeholders
    - Increasing funding

INTERNATIONAL SCAN – CASE STUDY | SPAIN

Spain was identified as a case study based on stakeholder-reported improvements in the effectiveness and efficiency of cancer clinical trials there. This case study aims to analyse some of the approaches taken by Spain, providing insights for researchers, funders, policymakers, and patients into methodologies, collaborative efforts, and policies that contributed to increasing the number of trials initiated from 2004 to 2023 (a significant increase from 42 to 255 new trials initiated in that time period).

The Spanish healthcare system is generally viewed well for its universal coverage and comprehensive care but historically it has faced challenges in clinical trials – specifically cancer trials, caused by procedural inefficiencies, a lack of commitment and limited participation amongst patients. However, in recent years Spain has made significant changes, which have proved to have a positive impact in terms of cancer trials.

Spain in Numbers (figures below are from 2023)

Population
48 million

No. of new cancer diagnoses
c. 280,000

Cancer Incidence Rate
583 per 100,000

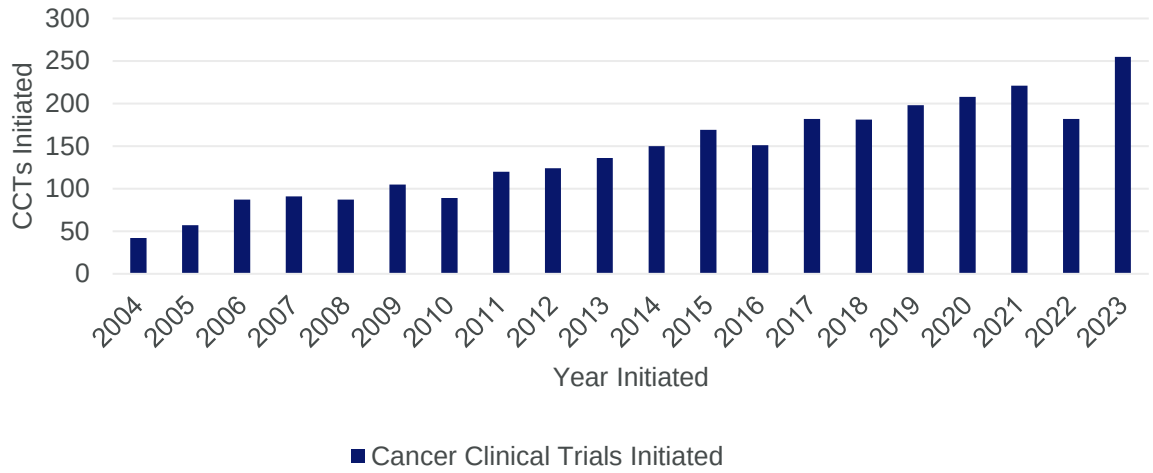
No. of patients enrolled on a CCT
75,256

Spain's investment in Clinical Trials
€789 million

Cancer Clinical Trials Initiated in Spain

Over the last 20 years, (Jan 1st 2004 – Jan 1st 2024), Spain has enrolled 1,459.880 people onto cancer clinical trials. As shown in Figure 9, over the last decade, Spain has seen a 130% increase in the number of cancer clinical trials initiated, from 2010 – 2020.

Figure 9: Cancer Clinical Trials Initiated in Spain from 2004 – 2023 (All Phases) [25]

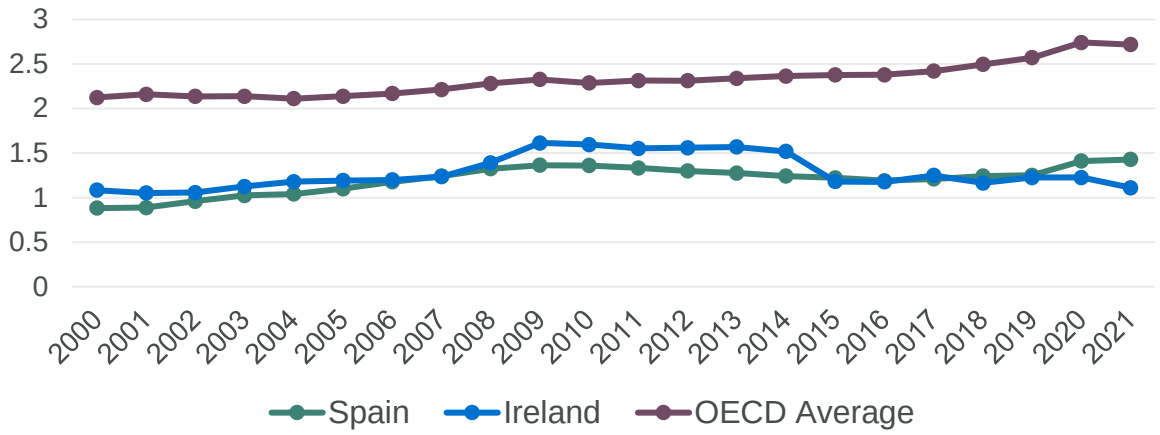


INTERNATIONAL SCAN – CASE STUDY | SPAIN

Research and Development Spend

As shown in Figure 10, Spain spent 1.4% of Gross Domestic Product (GDP) on Research and Development (R&D) in 2022. While this places Spain in the middle of the pack of OECD countries in the same category, it does show a marked improvement. Spain's total R&D spend as a percentage of GDP in 2000 was 0.883%. This is a strong indicator of the country's shift towards focusing on R&D as a whole.

Figure 10: Spain, Ireland & OECD Average R&D spend as a % of GDP from 2000 – 2021[26]



Key Reasons for Spain's Increase in Trial Performance

- Trial Designs and Methodologies – It is important to recognise the methodological advances when it comes to trial design around the world. Adaptive trial designs and precision medicine approaches have significantly elevated the quality of research conducted in Spain.
- Regulatory Changes – The introduction of the European Union Clinical Trial Regulation in early 2022 in all EU countries has streamlined the regulatory approval process significantly. This now sits at approximately 60 days average setup time for new trials. This same process took approximately 180 days under the EU Clinical Trials Directive, prior to 2022.
- Policy Changes – The introduction of the Spanish Royal Decree for Clinical Trials 1090/2015 is clear evidence of a significant change in focus and policy from the Spanish government (also simplified the ethical approval process significantly).
- Technological Advancements – Spain has successfully implemented an electronic medical records (EMR) system across each of its 17 regional governments, also known as Autonomous Communities [27].

Trialing App

Trialing is a mobile app, developed in Spain to allow Spanish Oncologists quick and easy access to a database detailing clinical trials which are recruiting for patients. This allows oncologists to easily search and filter by cancer type, Phase and location to view the most applicable clinical trials for their patients.

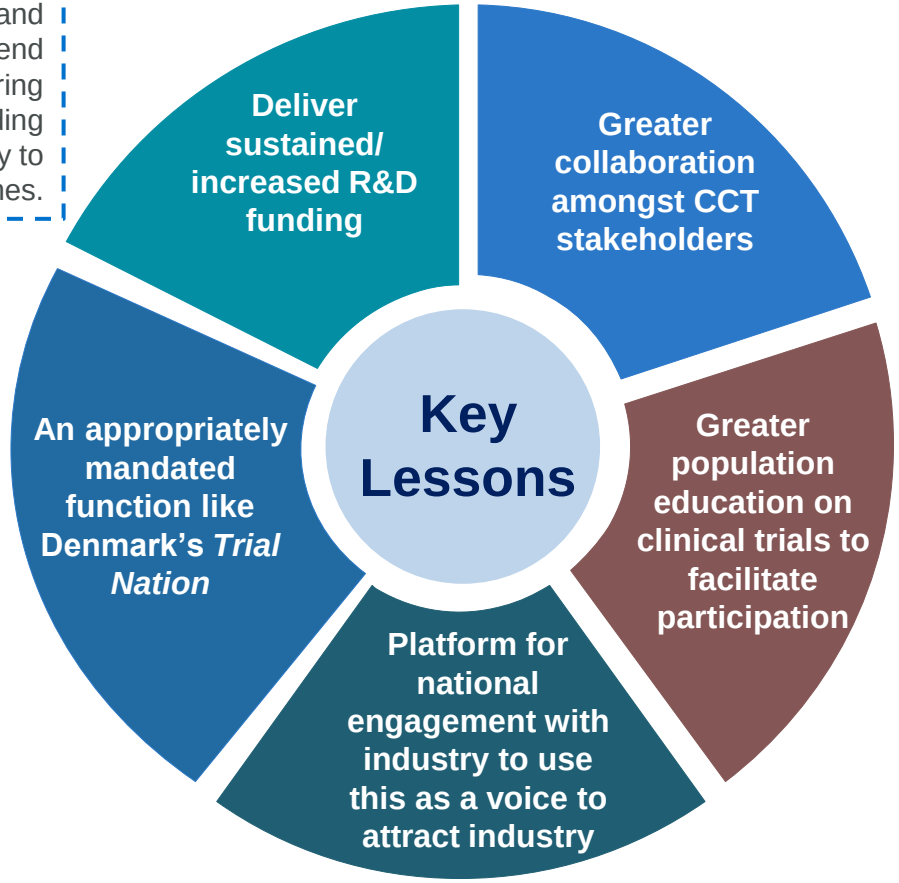
Trialing sources its information from public databases such as ClinicalTrials.gov as well as collaborations with Clinical Trial units which upload local data, this data is updated daily. Trialing can help to reduce geographical or socio-economic disparities and the effects that these factors have on patient outcomes as well as allowing patients access to trials.

THE INTERNATIONAL SCAN – LESSONS FOR IRELAND

Figure 11: Key Lessons for Ireland

High performers Denmark and Finland have significantly higher R&D spend than Ireland. Ireland delivering sustained, increased R&D funding would contribute significantly to enhanced CCT programmes.

CRF/Cs are in competition for funding and resources instead of a joint national approach – propagated by health research policy at a national level. A more strategic, national approach is needed around clinical research infrastructures in Ireland like in Finland and Denmark.



A centralised approach could streamline the process of sponsoring, participating in, and conducting clinical trials, thereby improving efficiency, enhancing coordination, and attracting more clinical trials. Implementing such a model, similar to Denmark's Trial Nation, could significantly enhance the clinical trial landscape.

Both Denmark and Finland have a relatively well-informed public regarding clinical research due to strong health education and public health initiatives. Ireland, on the other hand, has been working on improving public awareness of clinical trials but faces challenges such as limited public understanding and engagement. Ireland should continue to enhance its ongoing efforts to promote clinical trials.

Ireland is attracting fewer clinical trials relative to similarly-sized European peer countries. Establishing a properly resourced national platform to foster industry engagement in clinical trials may assist in facilitating communication, promoting capabilities, demonstrating success, coordinating efforts, and engaging stakeholders.

FIGURE 12 – ENABLING FACTORS

The following table outlines the enabling factors for clinical trial implementation/success based on international evidence/best practice.

Enabling Factors	Description
Government support	Increasing Government support for CCTs - financial backing, regulatory frameworks, and policies that prioritise and incentivise clinical research, ensuring a conducive environment for trial conduct and innovation.
Digitalised Healthcare System	The implementation of a robust digital health infrastructure in Ireland would enable electronic health records and data integration, enhancing efficiency, accuracy, and accessibility throughout the trial process.
Infrastructure and Resources	In Ireland, CCT infrastructure is underdeveloped in general, is not at a scale commensurate with the ambitions of the Cancer Strategy and is lacking outside of the major urban centres, particularly Dublin. Addressing these gaps is crucial for comprehensive trial implementation.
Industry Collaborations	Partnerships with pharmaceutical companies and biotech firms provide essential funding, resources, and expertise, facilitating access to novel therapies and enhancing trial quality. By having a coordinated approach to industry collaborations Ireland could attract more clinical trials and thus enable better access to innovative therapies for patients.
Increased awareness of clinical trials	Educating patients, healthcare providers, and the public about the importance and availability of clinical trials. This includes simplifying the enrolment process and providing comprehensive, yet tailored trial information.
Entity which has ownership for clinical cancer trials in Ireland	While CTI is funded by the HRB as the National Cancer Clinical Trial Network, there is no appropriately resourced/mandated single owner of cancer clinical trials in Ireland, leading to a lack of a joined up, strategic approach; enabling/resourcing such a body may streamline processes, improve strategic planning, increase patient participation, better foster collaboration, and boost international competitiveness.
Cohesive healthcare system	An integrated healthcare system that incorporates clinical trial activities into routine patient care can enhance trial implementation. This includes ensuring that clinical trial participation is seen as part of standard care and increasing clinician support for trial participation.

04

The Irish CCT Landscape

- Infrastructure
- Funding
- Cross Border Collaboration
- Patient Barriers
- Patient Workshop Findings
- Other
- Observations & Comments

THE IRISH CCT LANDSCAPE

Given the scoping nature of this review (and its relatively short timeframe) we focussed our assessment of the CCT landscape on a limited set of themes, as follows:

- Infrastructure
- Funding
- Cross Border Collaboration
- Patient Barriers
- Patient Workshop Findings
- Other

Our documentation review, stakeholder consultations and analysis, conducted through the lens of these themes, is presented accordingly in the following sections.

THE IRISH CCT LANDSCAPE – INFRASTRUCTURE

- Ireland has a growing network of CCT infrastructures. Key features include:
  - **Regulatory Framework:** Ireland has a well-established regulatory framework for clinical trials that adheres to European Union (EU) regulations and guidelines. The HPRA oversees the approval and regulation of interventional clinical trials, ensuring that they comply with ethical standards, patient safety requirements, and data integrity guidelines. The recently established National Research Ethics Committees also provide ethics approvals for clinical trials in Ireland.
  - **Clinical Trial Partnerships:** Ireland is part of various international clinical trial networks and collaborations, such as the European Clinical Research Infrastructure Network (ECRIN) and the European Organisation for Research and Treatment of Cancer (EORTC). These networks/collaborations work to enhance access to diverse patient populations, expertise, and resources for conducting clinical research
  - **Clinical Research Organisations (CROs):** Ireland is home to several CROs that provide a range of services to support clinical trials, including protocol development, site management, data management, regulatory compliance, and patient recruitment.
  - **Academic and Research Institutions:** Ireland's universities, medical schools, and research institutions play a central role in clinical research. They conduct a wide range of studies across various therapeutic areas, collaborate with industry partners on clinical trials, and train healthcare professionals and researchers in clinical research methodologies and ethics.
  - **Clinical Trial Sites:** Ireland has a network of clinical trial sites, including hospitals, research centres, and private clinics, where trials are conducted. These sites have experienced investigators, research staff, and infrastructure to facilitate the implementation of clinical trials and ensure patient safety and well-being during the study.
  - **Cancer Trials Ireland (CTI)** is a cancer clinical trial network dedicated to advancing cancer care through clinical trials. CTI's functions include planning, opening, co-ordinating, supporting, monitoring and auditing cancer trials. CTI was established in 1996 and is funded partly by the HRB, and The Society
- The Clinical Research Facilities/Centres (CRF/Cs) offer a broad spectrum of supports that are needed to conduct trials – from feasibility and study set up to closeout on a regular basis. These CRF/Cs are funded by the HRB as well as industry and hospital partners. These CRF/Cs are [28]:
  - Wellcome Trust – HRB-CRF at St. James's Hospital, partnered with Trinity College Dublin (TCD)
  - HRB-CRF Cork at the Mercy University Hospital, partnered with University College Cork (UCC)
  - HRB-CRF Galway at University Hospital Galway, partnered with University of Galway (UoG)
  - UCD CRC at Mater Misericordiae University Hospital (MMUH) and St. Vincent's University Hospital (SVUH), partnered with University College Dublin (UCD)
  - RCSI CRC at Beaumont Hospital, partnered with Royal College of Surgeons in Ireland (RCSI)
  - Children's Health Ireland CRC, partnered with UCD
- In addition to these CRF/Cs, there are six cancer clusters hosted at these CRF/Cs [29]:
  - Children Health Ireland Cancer Trials Group, hosted at UCD
  - Beaumont Hospital – RCSI University of Medicine and Health Sciences Cancer Trials Group, hosted at RCSI
  - Irish Research Radiation Oncology Group (IRROG), hosted at TCD
  - UCC Cancer Trials Group, hosted at UCC
  - UCD Cancer Trials Cluster, hosted at UCD
  - Trinity Academic Cancer Trials Cluster (TACC), hosted at TCD
- For additional information on the Irish Clinical Trials Infrastructure landscape, see Appendix 4

THE IRISH CCT LANDSCAPE – INFRASTRUCTURE

- CCTs in Ireland are funded by a variety of sources including Government investment, grants from health research organisations (public & private), industry sponsors and private donors.
- The HRB is the largest public funder of CCTs in Ireland, with over €80 million invested in strengthening Ireland's ability to perform cancer trials as of 2023.
- One of the largest investments in CCTs in Ireland was made by the Health Research Board (HRB) in 2022. This initial investment was a commitment of €22 million from January 2022 – 2027 in six cancer trials groups, the six clusters outlined previously.
- In addition to the dedicated cancer cluster funding, the HRB allocated grants to both the Saolta University Healthcare Group and University Hospital Limerick to enable and enhance their clinical trials capacity and capability in the 15 months after January 2022 [30].
- CTI also plays a large role in both funding and supporting cancer clinical trials across the country. CTI is funded through various sources, predominantly through the HRB and the Irish Cancer Society. It also receives philanthropic donations and donations from members of the public. In addition, it generates over 40% of its income from the academic cancer trials activity funded through international research groups and pharmaceutical grants. The Society is the largest charity funder of CTI currently investing over €1 million per year [31].
- Industry is the predominant funder of clinical research* in HRB-funded and associated clinical research infrastructures, with 58% of all active trials being supported by industry and 27% supported by national funding agencies [32].

- The majority of health research funding, including CCTs, is of a competitively allocated and nonrecurring nature, often referred to as 'soft money'
- Such funding may not be the best approach for infrastructure given its temporal nature (longer term, an enabler rather than a producer of outcomes etc.)
- Several stakeholders we consulted reported major challenges with 'soft money' funding of clinical trials infrastructure. A specific example often quoted was that of Research Nurses: critical to effective/efficient CCT conduct, trained over several years and funded from grants, exiting the CCT system to find permanent jobs elsewhere in the health service
- In some countries that perform well when it comes to cancer trials, one point of note is the approach to funding the 'architecture of a trial'.
  - As covered in Section 3, many comparators place significant emphasis on funding the architecture of a trial i.e. support infrastructure. Specific examples include personnel, equipment and services to support:
    - Research Nursing
    - Pharmacovigilance
    - Data Protection
    - Biostatistics

*Clinical research refers to clinical research of all disease types e.g. biobanking, biomarkers, physio et al.

THE IRISH CCT LANDSCAPE – CROSS BORDER COLLABORATION WITH NORTHERN IRELAND

- The Northern Ireland Cancer Trials Network (NICTN) is responsible for the co-ordination of cancer clinical trial and translational research activity throughout Northern Ireland.
- Responsibility, coordination and ownership of CCT activity in the Republic of Ireland is somewhat fragmented, as previously described.
- A lack of strategic approach and alignment between institutions is hindering collaboration, often depending on individual efforts rather than institutional support.
- Challenges of enrolling patients on CCTs across the border include complex data management issues, governance issues and disparities in regulatory interpretation between Ireland and Northern Ireland.
- Currently there is no strategic all-island approach to enrolling patients from the Republic of Ireland on CCTs in Northern Ireland and vice versa. Access to such trials for patients relies primarily on their medical team's knowledge and relationships.
- The All-Island Cancer Research Institute (AICRI) is a cross boarder virtual institute. A primary focus for AICRI is to deepen North-South collaboration in research and innovation and strengthen societal and economic links for mutual benefit. AICRI is centred on creating an overarching framework for cancer research on the island of Ireland, spanning scientific discovery to the clinic.
- A feature of AICRI is facilitation of cross-border research in priority areas, such as precision cancer medicine and data analytics. AICRI has brought together ten academic institutions throughout the island of Ireland, as well as key stakeholders from the healthcare and charity sectors, along with industry leaders and patient advocates [33].
- There is limited dedicated funding available for cross-border trials. Notable initiatives like the Peace Plus programme aim to address this gap by facilitating research with EU funding [34].
- The piecemeal nature of funding, with contributions from various sources like The Society and the HRB, creates fragmentation in the funding landscape, impacting the efficiency and effectiveness of efforts.
- AICRI has published an all-island oncology industry report capturing the current oncology and allied digital health industry landscape, highlighting the impact a well-functioning oncology and digital health ecosystem could have on the island of Ireland. Key Recommendations in the report include.
  - Establishment of an All-Island Oncology Innovation Cluster
  - Increase R&D funding to 3.5% in line with other Western countries and in line with leading Life & Health Science (LHS) clusters globally
  - Address critical gaps in clinical infrastructure such as expansion of experimental Phase I trials.

THE IRISH CCT LANDSCAPE – PATIENT BARRIERS

- Identifying and mitigating barriers to trial participation is important in maximising access to efficiently conducted trials, thus contributing to the improvement of cancer treatment outcomes. Not all patients can participate in clinical trials, regardless of their willingness. Many patients with a cancer and stage that potentially matches a trial ultimately are not eligible to participate due to specific criteria for inclusion and exclusion. These strict rules regarding patient selection help to ensure the safety of the trial and enhance the reliability of the results.
- According to CTI, 60% of those surveyed (in 2022) would be willing to participate in a clinical trial (+12% from 2020). However, despite a growing appetite for trials among members of the public, accrual rates remain low. Thus, a large gap exists between trial participation rates and the willingness to participate [35].

Key patient barriers include:

- **Awareness:** The Public expects healthcare providers to be knowledgeable about CCT opportunities, viewing them as trusted experts and primary sources of information regarding research and specific trials for which patients might be eligible. A survey of 1,089 cancer patients in Ireland showed that 66% of respondents reported never being offered the option to participate in a CCT, with only 5% of those not offered inquiring about participation [36]. Another study by the University of Limerick Cancer network highlighted poor awareness and knowledge of how to access trials among cancer patients and that it was commonly noted that patients and their families often found themselves researching clinical trials independently.
- **Understanding:** The Public can sometimes struggle to understand the methodology of CCTs and the concept of clinical equipoise. Some patients are known to struggle with the concepts of chance and randomisation and have uncertainty about the appropriateness of CCTs for serious illnesses.

When asked whether the assignment of treatments in a randomised trial is based on chance, 39% of patients believed it wasn't, while an additional 24% were unsure. Additionally, less than half (48%) were aware that CCTs were not solely an option after standard treatments had failed. This awareness was lower among older adults, single or widowed patients, and the self-employed [36].

- **Non-Sustained Patient Interest:** Despite 60% of the public expressing a theoretical willingness to participate in clinical trials, actual enrolment rates are hindered by a series of interrelated concerns and logistical challenges [36].

Key reasons why patients decline to enrol in CCTs include:

Fear of side effects: Patients express concerns such as a feeling that research is too risky or fear of adverse outcomes, toxicity, or side effects, often fearing that participation in a clinical trial could exacerbate their existing symptoms or compromise their quality of life.

Loss of control: Patients are often deterred by the fear of side effects and the discomfort with the uncertainties associated with new treatments, including the use of placebos and the process of randomisation. Patients often feel uneasy about relinquishing control over their treatment decisions to the randomisation process, which assigns treatments based on chance.

Logistical Challenges: Patients may encounter various logistical challenges including childcare duties, work commitments, financial limitations and travel time. The uneven geographical distribution of trial sites, especially in rural areas, adds another layer of difficulty.

THE IRISH CCT LANDSCAPE – PATIENT BARRIERS (CONTD.)

Costs: Patients enrolled in CCTs often face an increased burden of hospital appointments, and while some trials may offer limited cost reimbursement, the travel expenses can be significant, potentially influencing patients' decisions to participate. Reduced socioeconomic status has been linked to decreased engagement with cancer services, lower rates of CCT participation [37].

In Ireland, a study identified the absence of a suitable CCT option as the main reason for failure to recruit patients [38].

Inequitable access to oncology services for adolescents and young adults – a short study

- A paper published in the journal of ESMO (European Society of Medical Oncology) highlights a lack of available clinical trials with novel therapeutics for adolescents and young adults (AYA) with cancer aged 15-19. The issue of limited access to clinical trials for AYA is evident in historical data which shows lower improvements in survival and a correlation with lower numbers enrolled into cancer clinical trials compared with younger children or older adults [39].

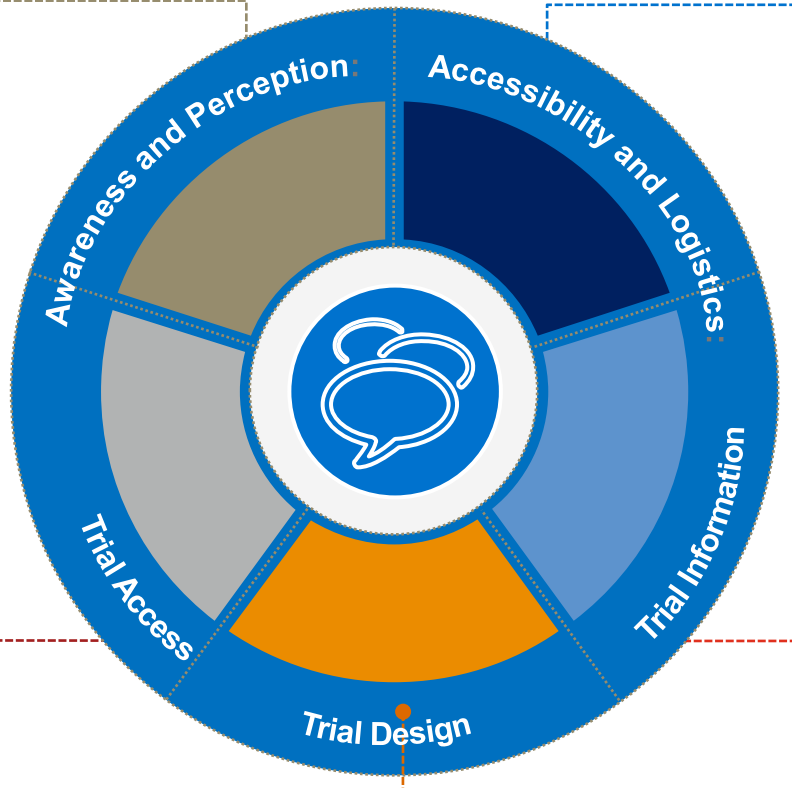
- Reasons why AYA are less likely to enrol into clinical trials include, but are not limited to:
- The paucity of trials for common AYA cancer types.
- The place of care (children versus adult hospitals).
- The restrictive age eligibility criteria, with the lower age limit of 18 years making 'young' AYA ineligible for many industry led clinical trials.
- Lack of awareness of available trials by treating physicians.
- Trial designs that do not accommodate AYA specific lifestyle, education and employment factors.

A key initiative to improving outcomes is to increase the number of AYAs on to clinical trials, as has been done successfully within paediatric services. The paper recommends diversifying interprofessional cooperation in AYA care and specific measures to improve trial accrual, including centralising care where that is the best means to achieve trial accrual.

PATIENT WORKSHOP FINDINGS

Figure 13: The following findings are based on a patient workshop convened to gain insights into patients' barriers to CCTs. See Appendix 2 for more detail.

- The common perception that CCTs are considered a last resort when other treatment options have failed rather than a potential first-line treatment option needs to be addressed.
- There is a need for improved dissemination of information about trials through various channels such as leaflets, public campaigns, posters, and informational desks in hospitals.



- Discussion focused on the need to bring trials to regional centres to improve accessibility for patients living in remote areas.
- Concerns were raised about the financial burden placed on patients participating in trials, with an emphasis on ensuring that no patient was out of pocket for enrolling in a trial and that expenses should have been reimbursed upfront.

- There was a consensus that the primary barrier to CCTs was the availability of trials.
- There was an emphasis on the notion that the onus of finding a CCT should not have been on the patient.
- Patients valued transparency from their oncologists regarding clinical trial options, prioritising being informed over being left unaware, even if the trials were not suitable for them.
- Patients highlighted the important role of their oncologists in their CCT decision-making process, noting that accessing clinical trials would have been difficult without their oncologist's support and guidance.

- There were concerns about trial designs, particularly regarding the potential assignment to the control group.

- Difficulties in finding comprehensive information about CCTs, including information about participants' potential suitability and how they could access an appropriate trial, were a recurring theme.
- There was a consensus that a patient navigator would have been useful in informing and guiding patients to trials that may have been suitable for them.
- There was an emphasis on the importance of patients being given adequate information on CCTs, with this information being provided in an accessible, inclusive manner.

PATIENT WORKSHOP QUOTES

The biggest issue is that there aren't enough trials

Even as a scientist, whose bread and butter is research and reading, it was way too much to try and find info

There should be something about trials in every single patient cancer information leaflet

Whatever your background is, you shouldn't have to school yourself on trials

It should be a given that if a patient gets onto a trial that they are reimbursed for out-of-pocket expenses

The onus should never be on the patient

It was word of mouth and pure chance that I got onto a CCT

If I got put on a trial in Dublin it would be an 8 hour round trip, trials need to be more regionalised

THE IRISH CCT LANDSCAPE – OTHER ELEMENTS

DATA PROTECTION

- Stakeholders across the Irish CCT system, ranging from patients to oncologists, report that the data protection environment in Ireland is not supportive of CCTs. Inconsistent interpretation/application of Data Protection legislation drives major variation in practice across the country with significant consequences for the predictability, reliability and attractiveness of Ireland as a trials location. Using Data Protection Impact Assessments (DPIAs) as an example:
  - We have heard that some international collaborators will no longer perform multi-country trials with Irish sites as the DPIAs are considered cumbersome here.
  - In Ireland there is no procedural agreement around DPIA approval, meaning that some stakeholders are not sure what needs to be done and when.
  - Additionally, we have heard that there is a lack of clarity surrounding when a DPIA should be completed and in extreme cases, some sites can perform over 100 DPIAs in one calendar year.

CONTRACTING OF TRIALS

- From our consultations with key stakeholders across the system, the contracting of trials is a significant element to trial start up and initiation and can have significant effects on timelines.
  - For many stakeholders, they are used to seeing a lack of predictability in the contracting of trials and often have to attempt to find workarounds to the system.
- The host site must sign the contract to initiate a trial. However, many hospitals are not resourced to do this and outsource same to legal firms to review contracts, often causing knock-on delays.
- In May 2024, at the time of writing of this report, the HSE and the IPHA launched the Tripartite Model Clinical Trial Agreement (CTA) [40]. This agreement is mandatory for any trials which involve a Commercial Sponsor, a CRO and a Hospital(s) - to streamline the contracting of certain types of trials.

TRANSITION TO CLINICAL TRIALS REGULATION

- Since the introduction of the EU Clinical Trials Regulation (CTR) in January 2022 [41] moving on from the Clinical Trials Directive which came into force in May 2004 [42]. the systems for registering trials and uploading information has changed.
  - This has allowed Ireland to have more of a ‘seat at the table’ when it comes to large, multi-site trials.
  - There have been some challenges, but the harmonised approach is proving beneficial overall.
- Under this regulation, all trials must be transitioned to the new Clinical Trials Information System (CTIS) by January 2025 [43].
  - This is very much the hard stop, and if a trial has not been transitioned to this new system by this date – there would be no legal basis for a sponsor to carry out a trial (as this would fall under the repealed Clinical Trials Directive).
  - Sponsors should have already consolidated any protocols of ongoing trials – for transition to CTIS already or be in the process of doing this.
- The European Medicines Agency (EMA) has been hosting numerous training and information sessions surrounding this procedure.
  - From our conversations with stakeholders, this engagement is seen as a real strength and has eased the burden for sponsors to complete this transition to the new platform.

THE IRISH CCT LANDSCAPE – OTHER ELEMENTS

CONNECTIVITY

- Stakeholders highlighted a lack of connectivity in the system between primary and secondary care, as well as clinical trial infrastructure.

DIGITAL INFRASTRUCTURE

- A barrier to trials expansion in Ireland is the lack of digitisation and coordination in health records. Patient records are still substantially paper based, fragmented and siloed. This makes the process of identifying suitable trial candidates difficult, time consuming and expensive.
- The use of a unique [patient] identifier and an electronic medical record in Ireland would improve the referral processes to CCTs and improve efficiencies.
- An increase in digitalisation would also assist in attracting more industry clinical trials.

DIGITAL HEALTH/CLINICAL TRIALS APP

- ONCOassist is an app for oncology professionals across the world. ONCOassist provides access to oncology tools that help clinical decision-making. These tools include a drug interaction checker, drug information and prognostic scores [44].
- In 2019 ONCOassist launched a clinical trial search engine in partnership with Cancer Trials Ireland (CTI). This tool aims to make it easier for oncology healthcare practitioners to find trials and participants.
- The search engine aims to make it easier to search for trials reducing the amount of study costs spent on recruiting patients to take part in trials, make it easier to refer patients for trials by including specific site information and raise awareness about undersubscribed trials.

THE IRISH CCT LANDSCAPE – OBSERVATIONS & COMMENTS

INFRASTRUCTURE

- CCT infrastructure is underdeveloped in general and is not at a scale commensurate with the ambitions of the Cancer Strategy.
- Countries with high performing/innovative healthcare systems tend to have CCT infrastructure sustainably integrated/supported within the health service - as part of the clinical service/education/research continuum. This is not the case in Ireland.
- CCT infrastructure is relatively difficult to access outside of major urban centres, particularly Dublin.
    - Given that clinical trial infrastructure is primarily concentrated in Dublin, patients enrolled in trials may face the challenge of traveling considerable distances. This geographical distribution can impose burdensome logistical and financial challenges on patients residing outside these areas.
- Collaboration between CRF/Cs is sub-optimal, for example, in terms of referring patients to other sites for trials.
    - From what we heard from patients and stakeholders across the system this places the onus on the patient in many cases to do their own background research and attempt to find a trial themselves.
- ‘Ownership’ of health/cancer research (particularly infrastructure), as an integrated part of healthcare, appears to be lacking in Ireland. The system appears fragmented.

FUNDING

- The competitive nature of the (infrastructure) funding landscape for CCTs in Ireland, does not always appropriately incentivise cross CRF/C referrals.
    - e.g. referring patients to another CRF/C that may be more suitable.
- With much funding being ‘soft money’ / non-recurring, this leads to significant uncertainty for stakeholders and does not enable research.
    - CRF/Cs are often unsure of the supports that can be offered to investigators in the form of research nurses, biostatisticians, or regulatory affairs staff.
    - An often heard impact of such soft money funding is research nurses leaving their positions in search of jobs and career certainty.
- Investment in CCTs (and (health) research more generally) is not at a level consistent with stated policy aims.
    - A recent Oireachtas Health Committee meeting [45] heard that the National Cancer Strategy has not been funded in five out of the last seven funding cycles.
- A coherent joined-up approach to CCTs is not apparent.
    - Substantial ambiguity exists regarding roles/remit among the entities which make up the CCT (and health research) landscape.

DIGITAL HEALTH/CLINICAL TRIALS APP

- The ONCOassist app is designed for oncology professionals, not for patients.
- In our patient workshops, a significant challenge identified was the difficulty patients face in accessing clinical trials without the support and guidance of their oncologists.

THE IRISH CCT LANDSCAPE – OBSERVATIONS & COMMENTS

CROSS BORDER COLLABORATION

- There is limited dedicated funding available for cross-border trials.
  - The piecemeal nature of funding creates fragmentation in the funding landscape, impacting the efficiency and effectiveness of efforts.
- There is no strategic all island approach to enrolling patients' cross border to clinical trials.
  - Given the lack of strategic approach to enrolling patients, it is done in an ad hoc way and often dependent on the patient's medical team or individual efforts.
- There are significant opportunities to deliver all-island CCTs .
  - These opportunities include working in collaboration with the US National Cancer Institute (NCI) in the context of the Ireland - Northern Ireland - US National Cancer Institute Consortium.
  - Ireland is now an NCI designated site and there is an opportunity to expand this ongoing partnership to leverage better opportunities for Irish patients.

PATIENT BARRIERS

- Accessibility of trials is a primary barrier.
  - Based on our interaction with patients, the primary reason cited for not participating in a CCT was a lack of availability of suitable trials. Patients advocated for the need for more available trials.
  - Additionally, patients advocated for a more proactive approach in identifying suitable trials, led by oncologists and healthcare providers. This approach involves integrating discussions about trial options into the standard treatment decision-making process and implementing a centralised system for trial information dissemination.
- There are considerable concerns surrounding trial designs, randomisation and the potential assignment to the control group.
  - Concerns surrounding trial designs, randomisation and the potential assignment to the control group, highlight the importance of patient education and support throughout the patient's decision-making process.
- Despite barriers, patients expressed a strong interest in participating in CCTs.
  - Despite significant barriers, motivations for enrolling in clinical trials remain strong, with many individuals driven by the hope for personal health improvement and a deep-seated altruism, including the desire to contribute to advancing medical research and aiding in the fight against cancer.

DATA PROTECTION

- There is significant variance in the interpretation of Data Protection legislation from site to site in Ireland.
  - We have heard from stakeholders that in a large multisite trial with 4x sites, there could be 4 different interpretations and approaches depending on the Data Protection Officer (DPO).

DIGITAL HEALTHCARE SYSTEM

- Ireland has no comprehensive electronic health records (EHR) system.
- The majority of hospitals and clinical trial sites are using paper records, contracts and agreements.
- The Digital for Care Framework released in May 2024 [46] outlines an ambition to move to fully integrated, comprehensive digital health systems to empower patients with digital access to their own health information.

05

Findings & Recommendations

EXECUTIVE SUMMARY (CONTD.)

What did we find and what do we recommend?

Due to the scoping nature of this review, its relatively limited timeline and dataset, the Findings & Recommendations following are pitched at a high level. Further work would be required to define them more granularly and to allocate responsibility for implementation accurately. Notwithstanding the above, it is clear that the majority of the Findings & Recommendations are at a national or 'system level' and would fall largely within the remit of the State.

#	Findings	Recommendations
1.	Strong, sustained public investment in R&D (including health research) is a well-known feature of advanced economies and high performing healthcare systems. Provision of human infrastructural and knowledge capital is strongly associated with improved healthcare outcomes. It has been the objective of national policy since 2006, with the release of the Strategy for Science, Technology and Innovation 2006 – 2013 as well as subsequently R&I strategies – Innovation 2020 and Impact 2030, to increase Ireland's investment in R&D to advanced/OECD levels (often 2.5% - 3.5% of GDP) but this has not been achieved and Ireland remains consistently in the lower tiers of OECD/EU rankings for investment in research and innovation.	Deliver sustained increases in investment in Research (and health research) to a level commensurate with the ambition of the National Cancer Strategy and the performance of peer countries regarding cancer trials (~3% GDP/GNI*).
2.	As outlined previously, the funding models currently used to support CCT infrastructure are not optimal for long-term core infrastructure. The reliance on temporal, competitive grant mechanisms, more typically associated with specific research programmes, may be contributing to a lack of sustainability observed in much of the infrastructure e.g. attraction/retention of staff.	Review the funding models used for supporting CCT infrastructure to make it more sustainable, reliable and strategic (considering models which are considered more mature e.g. the UK NIHR system).
3.	The CCT system in Ireland has evolved 'organically' over time. It is a complex system with many stakeholders spanning hospitals, universities, the Department of Health, the HSE, CTI, The Society, funders, Industry, the NCCP, patients and many more. It can be a challenging system to navigate and there is ambiguity (on the part of many stakeholders we heard from) regarding the precise remit, roles and responsibilities of stakeholders, leading to gaps and overlaps. It would be desirable to remove such ambiguity via clear definition of stakeholder roles & responsibilities and, perhaps, to consider conferring on one organisation the 'ownership' of the CCT system in Ireland.	Clarify the remit, roles & responsibilities of the key players in the CCT system and consider conferring responsibility for clarity and coordination onto one appropriately resourced/mandated organisation.
4.	The approach to CCTs, and cancer research more broadly, is spread across many policy documents and organisations, ranging from the National Cancer Strategy to Sláintecare to the HRB, CTI, NCCP and others. It appears that there is no national strategy for CCTs in Ireland that is coordinated, coherent and agreed by the main parties. In effect – this means the approach to CCTs (and underpinning cancer research and clinical trials) is somewhat fragmented, and, therefore, sub-optimal.	Define a strategic approach to CCTs in Ireland to appropriately align, incentivise and nurture the stakeholder components of the CCT system to enable the vision of the National Cancer Strategy and to match best practice observed in peer countries.

EXECUTIVE SUMMARY (CONTD.)

What did we find and what do we recommend?

#	Findings	Recommendations
5.	There is widespread variation across healthcare sites in Ireland regarding the interpretation and application of data privacy/protection regulations and principles. As covered previously, this variation in practice is characterised by unpredictability and delays in trial initiation/conduct, and is making Ireland an increasingly challenging location for the performance of CCTs. A sustained initiative(s) is required to educate and inform the relevant stakeholders across the CCT landscape (healthcare sites, universities, state bodies etc.) and harmonise the approach taken to the interpretation & application of data privacy/protection regulations.	Harmonise the approaches taken across the CCT system regarding the interpretation and application of data privacy/protection legislation and principles.
6.	In terms of the Republic of Ireland (RoI) and Northern Ireland (NI), cross border collaboration, in many areas, including healthcare, has been intensifying in recent years and is likely to develop further. While there is some cooperation in terms of CCTs at present, it is largely ad hoc. A well-resourced strategic approach to CCTs would enable enhanced cross border trials, increased patient accrual and contribute to improved cancer outcomes.	Develop a strategic approach to all island/cross border CCTs.
7.	There is variation – and sometimes confusion – amongst stakeholders in the CCT system regarding the definition of key terms and metrics relating to trials e.g. patient accruals. This needs to be resolved in order to enable consistent planning and tracking of CCT performance, in line with international practice.	Secure agreement by core CCT stakeholders to apply commonly used (internationally accepted) definitions of key CCT metrics.
8.	Whilst the availability of “CCTs suitable to the patients” was identified as the primary barrier to CCT participation, logistical challenges with the locations of CCTs featured prominently in patient considerations. As trial infrastructure/activity develops and broadens out over time and acknowledging the need for critical mass in certain areas, due consideration should be given to the geographical location of CCT developments to support, to the greatest extent possible, country-wide access to CCTs.	Enable the geographical development of CCT infrastructure to support, to the greatest extent possible, country-wide access to CCTs.
9.	As shown in the documentation review, the scan of international practice and the engagement with patients, there are a number of factors that impact patient engagement in CCTs. Leaving aside the most important issue of trial availability (trials of the right type), key factors include: awareness of CCTs as a ‘regular’ treatment option (as opposed to ‘last resort’), understanding of clinical equipoise (including randomisation, blinding etc.) and the provision/availability of appropriate information in inclusive/accessible forms. Patients are a ‘broad church’ and therefore the approach to addressing their challenges is, by definition, multifactorial. For example, whilst much of the focus is on the ‘receiver’ of knowledge (the patient), much still remains to be done in terms of equipping clinicians/care giver teams with the training, resources and culture to share information in an appropriate 2-way manner that best equips patients in terms of CCTs.	Review the policy and practice regarding CCT information provision & follow up in cancer treatment in Ireland and then co-design (with patients, care givers, clinicians etc) a common process/standard to be implemented subsequently.

AA

Appendices

A1

Methodology

FIGURE 14: REVIEW METHODOLOGY

Forvis Mazars used the following methodology to conduct the Review

Phase	1 Project Set Up	2 Desk Review	3 Consultations	4 Analysis	5 Reporting

Activities	• Conduct project initiation meeting(s)
	• Confirm requirements
	• Confirm information required for desk review
	• Confirm approach to project management
	• Confirm format of final outputs
	• Agree project governance (reporting lines, status reporting etc.)
		• Review key documents and data on Irish cancer trials (including documentation given to the project team as well as any relevant documentation externally)
		• Review key documents and data on international cancer trials (including documentation given to the project team by as well as any relevant documentation externally)
			• Design consultation approach, including to:
			  ○ Identify and prioritise consultees
			  ○ Prepare consultation packs and schedule consultations
			• Execute consultations
			• Liaise with The Society PSG upon completion of all initial consultations to establish if any additional consultations are required
				• Analyse data gathered by:
				  ○ Desk review
				  ○ Consultations
				• Assess in terms of current performance in Ireland and compare with international performance
				• Draft potential recommendations for ICS at direct and whole system level
					• Prepare draft report, highlighting all knowledge & insights garnered from previous phases
					• Incorporate feedback from the draft report review and submit final report

Deliverables	• Agreed project scope • Agreed project governance	• Data gathered from documents • Understanding of Irish cancer trial activity and performance • Understanding of international cancer trial activity and performance	• Data gathered from key stakeholders • Testing of data/understanding from phase 2 with stakeholders	• Quantitative and qualitative assessment of cancer trials • Draft list of recommendations for ICS	• Draft final report • Final report with ICS comments integrated

Ongoing Project Management

FIGURE 14: REVIEW METHODOLOGY (CONTD.)

To conduct a review of clinical trial landscape and to produce a set of recommendations to optimise accrual rates, Forvis Mazars adopted the following methodology:

Methodology	Project Timeline
As-Is Analysis: Analysis of current clinical trial landscape in Ireland. Assessment of documentation, consultation with key stakeholders and a patient workshop.	January 2024
Benchmark Analysis: Analysis and comparison of the clinical trial landscape in the following countries: Denmark, Finland and New Zealand Case study: Analysis of the developments in the clinical trial landscape in Spain which have resulted in increased clinical cancer trial activity	January 2024 – April 2024
Analysis of data, Findings & Recommendations: production of high level findings and recommendations for further development of the CCT system	May 2024

Stakeholder Consultations

Stakeholder Selection: A total of nine qualitative interviews were conducted between December 2023 and April 2024 using a semi-structured interview technique. The diverse interviewee sample included multiple stakeholders working within different areas of the CCT landscape (refer to Appendix 2 for the Consultation list). All interviews were conducted via video call to accommodate the wide geographical spread of participants and their high workload. Additionally, a Patient Workshop was held with 17 patients via video call. The purpose of this was to gain insight into the experience of patients within the CCT landscape.

Interview Development: The following interview themes were selected: Funding, Barriers to Trials, Accruals, Infrastructure and Cross Border Collaboration. The interview questions within these themes were then specifically tailored to each stakeholder. This ensured the conversation delved into areas most relevant to their experience.

Interview Format and Data Collection: The interview was conducted in a semi-structured format, allowing for flexibility while ensuring key topics were covered. The interview was held virtually using a video conferencing platform. Detailed notes were taken throughout the interview to capture the conversation and any nonverbal cues.

Data Analysis and Report Integration: Following the interview, the notes were analysed. Thematic analysis was then employed to identify recurring themes and key insights within the data.

A2

Consultation List

CONSULTATION LIST

Many organisations with an interest in CCTs were contacted as part of this project for consultation. The list of organisations is presented below.

Figure 15: Consultation List

Organisations Consulted
Cancer Trials Ireland
All Island Cancer Research Institute
HRB National Clinical Trials Office
Irish Pharmaceutical Healthcare Association
National Research Ethics Committee
Health Products Regulatory Authority
National Cancer Control Programme
Irish Cancer Society Patient Advisory Group
Health Research Board
UCD Clinical Research Centre
Trinity St James's Cancer Institute

A3

Documentation Reviewed

FIGURE 16: DOCUMENTATION REVIEWED

Forvis Mazars received over 20 documents. This figure lists the documents reviewed, received from The Society.

No.	Document Name
1	Cancer trial units' activity and staffing at hospital level (Survey Results)
2	IQVIA Global Trends in R&D Report
3	HSE Health Research 10 Year Action Plan
4	WHO guidance for best practice for clinical trials (Draft for Public Consultation)
5	HRB Cancer Trials in Ireland 2021 Funding Call Guidance Notes
6	ECRIN Annual Report 2022
7	European Commission EU Beating Cancer Plan
8	European Commission European Missions – Cancer Implementation Plan
9	Murphy et al. (2022) – How much is the lack of retention evidence costing trial teams in Ireland and the UK?
10	HPRA Guide to Clinical Trials Conducted under the Clinical Trials Regulation (CTR) in Ireland
11	IPPOSI Response to 2023-09 Public consultation for the WHO guidance for best practices in clinical trials
12	Irish Cancer Society Strategic Plan 2020 – 2025
13	Irish Health Research Forum Research Ethics Report 2023
14	McCarthy et al. (2023) Qualitative data sharing practices in clinical trials in the UK and Ireland: towards the production of good practice guidance
15	FutureTrials – University of Galway Institute for Clinical Trials Strategy
16	HRB NCTO International Clinical Trials Day 2023 Conference Document
17	Horizon Europe Work Programme 2023 – 2025 Missions
18	IPHA Industry Sponsored Clinical Trials Start-up & recruitment performance Infographic 2021
19	IPHA Industry Sponsored Clinical Trials Start-up & recruitment performance Report 2021
20	IPHA Industry Sponsored Clinical Trials Start-up & recruitment performance Infographic 2023
21	IPHA Industry Sponsored Clinical Trials Start-up & recruitment performance Report 2023

FIGURE 17: DOCUMENTATION REVIEWED

The figure below lists the external documents which the Forvis Mazars project team sourced (see Figure 17).

No.	Document Name
1	National Cancer Strategy 2017 – 2016
2	European Commission – Ireland Cancer Country Profile 2023
3	HRB Review of Clinical Research Infrastructure in Ireland 2019
4	Cancer Trials Ireland Just Ask 2022 – Survey Highlights
5	National Cancer Strategy 2017 – 2026 Implementation Report 2022
6	Understanding and Attitudes towards Cancer Clinical Trials among Patients with a Cancer Diagnosis: National Study through Cancer Trials Ireland
7	Leddy et al. An investigation into the factors affecting investigator-initiated trial start up in Ireland

A4

Additional Information

INFRASTRUCTURE

Cancer Trials Ireland is an organisation which is dedicated to being a hub for cancer trials, and is globally recognised for excellence in governance, collaboration, and innovation in clinical research. CTI has been funding oncology trials since 1996. CTI also plays a large role in both funding and supporting cancer clinical trials across the country. CTI is funded through various sources, predominantly through the HRB and the Irish Cancer Society. It also receives philanthropic donations and donations from members of the public. In addition, it generates over 40% of its income from the academic cancer trials activity funded through international research groups and pharmaceutical grants. The Society is the largest charity funder of CTI currently investing over €1 million per year [47].

The Health Products Regulatory Authority (HPRA) is responsible for the assessment of clinical trials with medicinal products conducted in Ireland. This category of trials is generally the most common in Ireland and Internationally. The HPRA has a significant role in the approval and ongoing regulation of Investigational Medicinal Product (IMP) trials in Ireland and is one half of the regulatory approval process for clinical trials in Ireland. Additionally, applicants must apply separately to the Local Research Ethics Committee (REC) to seek clinical trial approval [48].

The National Office for Research Ethics Committees (NREC) was established in early 2020 as an important component of the recent reform of the research ethics committee framework in Ireland – led by the DoH. National Research Ethics Committees (NRECs) are responsible for reviewing research proposals in prescribed areas of health research, with the aim of providing single national ethics opinions that are respected nationally. The National Office works with NRECs around the country to review the ethics of regulated research in a timely manner [49].

The Irish Pharmaceutical Healthcare Association (IPHA) is a body that represents the pharmaceutically companies that are its members. IPHA contributes to and works with publicly funded infrastructures in Ireland to enable industry initiated and funded research. IPHA has 46 member companies across two divisions – prescription medicines and self-care. The IPHA also have a well-established Clinical Research Exchange Group (CREG) which is specifically centred around enabling clinical research in conjunction with Industry [50].

The National Cancer Control Programme (NCCP) is a Directorate within the HSE that works with health service providers to prevent cancer, treat cancer, and increase survival and quality of life for those who develop cancer, by converting the knowledge gained through research, surveillance and outcome evaluation into strategies and actions. The NCCP works closely with the Cancer Policy Unit in the DoH as well as with other voluntary and charitable organisations [51].

The HRB Trials Methodology Research Network (TMRN) is a non-profit organisation which is funded by the HRB and is a collaborative initiative between a number of Irish and international higher education institutes and methodology centres. Its mission is to strengthen the methodology and reporting of trials in health and social care in Ireland so that they become more relevant, accessible and influential for patients and other service users, practitioners, policy makers and the public [52].

INFRASTRUCTURE (CONTD.)

In addition, to the infrastructural elements outlined in the Infrastructure section, there are some other key pieces of infrastructure that affect the wider system substantially. These elements are not necessarily directly linked to performing CCTs, however they do provide necessary supports, information and innovation to ensure that the cancer trial environment in Ireland continues to grow and improve.

The European Union (EU) Clinical Trial Information System (CTIS) is an EU-wide submission portal and management database that was introduced in January 2022 as part of a broader initiative to transform the clinical trials environment in the EU to support large scale, multi-site trials across EU countries to benefit patients [53]. This broader initiative was introduced following the introduction of the EU Clinical Trials Regulation in January 2022, which was introduced to strengthen the level of attraction for Europe as a destination for clinical trials, building on the work that had been previously completed under the EU Clinical Trials Directive. By the 31st of January 2025, all ongoing trials that had previously been approved under the Clinical Trials Directive will be governed by the new Regulation and as such, will have to be transitioned to CTIS. This will be a legal requirement and any trials not transferred to the new system will not have a legal basis.

The European Clinical Research Infrastructure Network (ECRIN) is a distributed Research Infrastructure . That means that it has a central coordinating office (located in Paris), and it brings together national scientific partners (networks of clinical trial units) across Europe. “ECRIN’s organisational model is based on country membership. Countries can either be full Members or Observers. Current Member countries include Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Norway, Portugal, Poland, Spain, and Switzerland, and Slovakia is an Observer country [54].

The Organisation of European Cancer Institutes (OECI) Comprehensive Cancer Centre Accreditation is a significantly prestigious award that is given to cancer centres located within a country that is a member of the network, that meet high standards in cancer treatment, education, and research. The OECI has 39 member countries (as of March 2024). The Trinity St. James’s Cancer Institute and the Beaumont RCSI Cancer Centre are the only Irish centres that are recognised as an OECI cancer centre. Ireland has no fully accredited comprehensive cancer centres, however – there are four additional cancer centres in Ireland which are pursuing this accreditation process [55].

The University of Galway (UoG) Institute for Clinical Trials was established in May 2023 as part of an “ambitious cross college vision to achieve a step change in research activity at the University of Galway”. The College of Medicine, Nursing and Health Sciences (CMNHS) and the College of Science and Engineering in UoG partnered closely to establish two cross-college research institutes which would support each other and work closely on joint research projects. UoG also established the first full chair, Professor of Clinical Trials post in the country, one of two to date [56].

RESEARCH & DEVELOPMENT

Figure 18: Illustrating key international comparative metrics for Life Health Sciences (LHS) clusters [57]

	Population (M)	Sector Value (€B)	Sector employees	Number of companies	Number of universities	Population (M) R&D* spend as % of GDP
Northern Ireland	1.91	1.30	19,500	250	2	2.3
Ireland	5.02	>45.00	102,000	375	9	2.0*
Golden Triangle	10.06	90.93	2,100,000	3,700	6	2.4
Biopharma Hub	7.00	78.13	106,704	>1,000	35	3.5
Biotech Bay	0.81	54.06	158,449	>200	20	3.5
Medicon Valley	4.0	5.19	2,800	180	9	2.8/3.4**

Note – this percentage represents total R&D spend not just LHS.
*This figure is a percentage of modified GNI. **Denmark = 2.8% and Sweden = 3.4%

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Glossary and Bibliography

GLOSSARY

CCT	Cancer Clinical Trial
R&D	Research & Development
ICS	Irish Cancer Society
CTR	Cancer Trials Regulation
HRB	Health Research Board
DoH	Department of Health
HSE	Health Service Executive
AICRI	AII-Island Cancer Research Institute
NCTO	National Clinical Trials Office
IPHA	Irish Pharmaceutical Healthcare Association
NREC	National Office for Research Ethics Committees
HPRA	Health Products Regulatory Authority
NCCP	National Cancer Control Programme
WHO	World Health Organisation
ICS	Irish Cancer Society
CTI	Cancer Trials Ireland
EU	European Union
NZ	New Zealand
UK	United Kingdom
GDP	Gross Domestic Expenditure
GNI	Gross National Income
R&D	Research & Development
SFI	Science Foundation Ireland
TMRN	Trials Methodology Research Network
UoG	University of Galway
UCC	University College Cork
TCD	Trinity College Dublin
RECs	Research Ethics Committees
OECI	Organisation of European Cancer Institutes
CTIS	Clinical Trial Information System
ECRIN	The European Clinical Research Infrastructure Network
DPIA	Data Protection Impact Assessment
HDEC	Health and Disability Ethics Committees
RCSI	Royal College of Surgeons Ireland
EMA	European Medicines Agency
CTNZ	Cancer Trials New Zealand
FDA	Food and Drug Administration
MMUH	Mater Misericordiae University Hospital
NCI	National Cancer Institute

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