The Value of Cancer Trials



cancer trials ireland

Together, we're finding answers to cancer.

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Introduction: CEO & Clinical Lead





This report sets out the case for a significant increase in government investment in cancer clinical trials and for increased funding for Cancer Trials Ireland, by communicating the value that cancer clinical trials bring to the people of Ireland. Government investment should not be borne solely by the Department of Health, but should involve those departments responsible for enterprise, finance, and higher education. Such vision would align with Ireland's new National Life Sciences Strategy. This is essential if we are to compete with EU counterparts to attract investment and maximise access to patients in Ireland to cancer clinical trials and improved outcomes. Collective investment across Government departments is an approach that has proved successful in other jurisdictions.

Cancer clinical trials lead to improved patient outcomes. Patients participating in the investigational arm of clinical trials have access to new drugs and treatments, whilst all patients on trials benefit from closer monitoring and understand that their altruism and participation is essential for developing new and improved treatments for future patients.

Ireland severely lags European peers with similar populations, education levels, and GDP per capita (such as Switzerland and Denmark), and even lag less wealthy peers, like Finland in terms of open cancer clinical trials.

Ireland needs increased Government investment in clinical trials. This report estimates the inward (non-governmental) investments from a sample of six trials, as well as direct drug cost savings (cost savings to the State, through the HSE) from a sample of 18 trials opened in Ireland over the past four years. Our estimates suggest that the sample of 18 trials involving 249 patients directly resulted in €14.8m in drug cost savings to the State. Meanwhile, six trials generated €36.7m of inward investment in the form of new investigational medicinal products (IMPs).

In addition, one trial unit costed the total value of medicines given to patients on cancer clinical trials at €9.7m, between years 2021-2025. This figure is a blend of both direct drug savings to the state, and inward, non-governmental investment (i.e. new IMPs/treatments) provided by the trial sponsor, typically a pharmaceutical company. Another trial unit costed the total medicines given to patients on cancer clinical trials in 2022 alone at €2.05m.

These estimates, both the direct savings to the State, and inward investments demonstrate the enormous monetary value that cancer clinical trials represent.

Cancer Trials Ireland recognises that the State has many sectors to support, many worthy causes, and vital services in and out of health. However, there are very few areas within healthcare which have the capacity to both improve patient outcomes and simultaneously generate savings, and fewer still that attract significant investment that directly benefits the people of Ireland.

The figures and estimates in this report provide a limited snapshot of the real level of savings, and inward investment in patients, that cancer trials generate. The true figure is likely to be vastly higher on savings, and larger again in terms of inward investment.

As the savings estimates stand, they exceed total government funding for Cancer Trials Ireland over the past two decades, while the true figure could significantly exceed the €22m in state funding for the Health Research Board clusters through the current Health Research Board (HRB) Grant Cycle (2022-2026). The additional contribution to cancer-related research (e.g., pre-clinical research) made by the HRB is separate to the €22m. For example, €42m was provided by the HRB in research grants between 2019-2022. This is greatly appreciated by all involved in cancer research and care.

More broadly, figures shared by the Irish Pharmaceutical Healthcare Association (IPHA), show that between 2021 and 2024, companies collectively disclosed a Health Research & Development "Transfer of Value" to Irish researchers and institutions of more than €61m. To be clear, this investment funded research outside of clinical trials, and outside of cancer – and it is also likely incomplete. The true figure may be higher again.

Investing more in Cancer Trials Ireland will directly generate more costs savings and further inward investment, through increased numbers of cancer clinical trials – and ultimately lead to improved patient outcomes and development of new treatments in oncology. This is a virtuous cycle. Our leaders must have the vision to leverage it.

Finally, the global healthcare sector is experiencing an unprecedented period of uncertainty. The current US administration is aggressively driving pharma companies to relocate their majority of manufacturing to the United States, which is a significant source of concern to the Government given the importance of the pharma sector to the Irish economy. What better way to demonstrate our intent and commitment to this sector than increasing the state's long-term investment in cancer clinical trials, and clinical trials more widely?

What the clinical oncology research community can do

It is incumbent upon all of us within the clinical oncology research ecosystem — including industry partners, Cancer Trials Ireland, the State, researchers, and clinical trial units — to collaborate even more closely, and effectively. This involves sharing data, identifying cost efficiencies and investment needs, and working together to provide data driven reports that demonstrate the year-on-year value that cancer clinical trials deliver to patients and to Ireland as a whole.

Once more: the figures cited in this document are based on estimates only. That reality reflects the difficulty of gathering accurate and comprehensive data, bearing in mind the complexity of modern trial designs and the many commercial sensitivities involved. Nevertheless, as an oncology community, we must find a way to agree on what data we can share. Without this collaboration on costs and investments, we hinder or even hamstring our ability to effectively communicate the value that cancer clinical trials generate.

What must we do? We must communicate our true value. We must work collectively to make the strongest case to support increased government investment and funding that we can, and sustain this approach, year on year, into the future.

Communicating our true value is a framework that Cancer Trials Ireland will seek to establish in 2026. Our aim is to move from an estimates position and once-off report, towards a consistent, evidence-based reporting mechanism that clearly demonstrates the significant and enduring value of cancer clinical trials to Ireland.

Prof Seamus O'Reilly, Clinical Lead, Cancer Trials Ireland
Angela Clayton Lea, CEO, Cancer Trials Ireland

At a Glance

€18.39m in Government funding through HRB over 20 years for Cancer Trials Ireland

€14.8m in treatment costs savings from 249 patients on 18 trials in past 4 years

€36.1m in inward investment over the past four years

€61m invested in R&D by industry in health research (2021-2024) (not exclusive to trials or oncology)

117 Open & Recruiting trials in Ireland as of 6th November 2025 - this represents only 1.1% of all trials opened in the EU



43 new trials opened in Ireland in 2024

2,814 patients recruited to trials in 2024

3,303 patients recruited to trials in the first 9 months of 2025

Strategic Timing and Policy Alignment

This report is published at a timely moment, for several reasons. The most immediate of these is the imminently expected Report & Recommendations of the National Clinical Trials Oversight Group (NCTOG). Cancer Trials Ireland anticipates that this Value of Cancer Clinical Trials Report will support and augment the NCTOG findings. Indeed, Cancer Trials Ireland contributed some of the figures published in this report to the NCTOG Report via the Department of Health's Cancer Policy Unit, in early October 2025.

At the 2025 Cancer Retreat in May, the chair of NCTOG, Prof Donal Brennan presented an interim report from NCTOG, noting that a central theme of NCTOG's work was the importance of seeing clinical trials not as ancillary, but as core to health service delivery. Prof Brennan also stressed that while Ireland cannot compete with larger EU nations, it can become a leader within its tier – but that doing so will require investment not only from the Department of Health, but also from departments responsible for enterprise, finance, and higher education. Cancer Trials Ireland concurs. Strengthening the trials environment in Ireland will drive economic growth – and increase the savings and investments identified in this document. Strengthening the sector will also speak to the Programme for Government 2025, and the objectives of the upcoming National Life Sciences Strategy, and the existing IDA Strategy on Sustainable Growth and Innovation (2025-2029).

Furthermore, Prof Brennan described last May how research activity should be treated as a key performance indicator for hospitals. Cancer Trials Ireland believes that such metrics could not only improve Ireland's reputation as a host for health research, but within Ireland they could help drive awareness and recognition of the importance of research at a corporate level in the health service. It is our ambition to continue to support the work of the NCTOG and its upcoming recommendations through direct engagement and in other ways, by continually highlighting the value, benefit and importance of trials.

The second key factor driving the publication of this report is that in 2026 we are entering the final year of the current HRB Cancer Trials 5-year Grant Cycle. The HRB grant cycle has provided welcome, and vital, long-term support and funding security that has been transformational for Cancer Trials Ireland, allowing for longer-term planning, and internal restructuring and reorganisation. In order to better inform the next grant phase, Cancer Trials Ireland devoted considerable time, not least at the last two Cancer Retreats (2024, 2025), to surveying HRB grant recipients with a view to providing HRB and the government with structured feedback on both the positives and challenges associated with the grant.

In line with these efforts, and the stated intent of this Report, we bolster our arguments for increased funding by describing why current funding levels cannot stay the same (see: p15).

The third and final factor making this report timely, is that development of the next 10-year National Cancer Strategy is commencing within the Department of Health. In recognition of this, Cancer Trials Ireland held a stakeholder event last March to discuss how trials and research must feature more prominently in the next strategy.

This then is the wider context in which Cancer Trials Ireland argues that increased investment is an imperative and aligns with national strategy.

The Patient Voice: Seamus Cotter



As someone who was diagnosed with Stage IV lung cancer in 2016, I am very lucky to be alive today. I was lucky to encounter a doctor who was engaged in cancer clinical trials. I was lucky that there was a trial that was suitable to my case. I was lucky that I was a suitable candidate for that trial. And I was lucky when I joined that trial that I got access to the experimental treatment.

All of those combinations of factors led to me being in remission today, some nine years later. I count myself as a very, very lucky man. That has driven me to stay involved and actively advocate for cancer clinical trials for the past six years, so that others might have the opportunity to be as lucky as I was.

Too few are. Far too few.

Yet the evidence shows that patients enrolled in cancer trials achieve better outcomes than those who are not part of such studies. Why?

Trials give patients access to new and innovative treatments that are unavailable through standard care. Participants also experience an elevated level of patient care, which has been shown to contribute to better outcomes—even for those who do not receive the experimental treatment itself.

Trials are provided at no cost to the patient or their health insurer, and in many cases, they are also free to the HSE, hospitals, or the State.

There is a clear appetite for trials in Ireland. Public understanding and support for clinical trials in Ireland has grown steadily since 2020. As of July 2024, 62% of people in Ireland say they would be willing to take part in a clinical trial—an increase of 14 percentage points from 48% in 2020. During the same period, the proportion of those unwilling to participate has fallen to just 11%, down from 24% in 2020.

Awareness of the benefits of clinical trials has strengthened as well. Nearly eight in ten people (79%) now agree that trials provide patients with access to treatments not otherwise available, up 7% since 2020. More people are also motivated by the potential for early access to new therapies, with 32% saying they would take part in a trial to receive a treatment before it becomes widely available—more than double the 15% recorded in 2020.

Overall, support for research and innovation in health remains strong. Four in five people (80%) agree that clinical trials are a good idea, and almost three-quarters (73%) believe Ireland should be doing more health research. These findings reflect growing public trust and engagement with clinical research as an essential part of improving patient care and advancing medical progress.

It is in the government's power to change things for the better. It is frustrating that the facts of cases like mine, and the proven benefits of trials are not enough to make the case for government action alone. My hope is that, bolstered by the economic argument, the government will finally seize the opportunity that now sits before it, and improve the lives of cancer patients, so many of whom could benefit were a trial available to them.

Savings & Investments

How do cancer clinical trials generate savings for the State?

Whenever a patient enrols on a cancer clinical trial, the patient's treatment costs (principally the costs of their medicines, scans and tests) are commonly paid for by the trial sponsor. Where this arises, the government/HSE does not incur these costs for that patient for the entire period that the patient remains on the trial, representing a 'treatment cost saving/avoidance' for the HSE.

Hospitals running cancer clinical trials, often also benefit from site fees, or fee per patient. This is a valuable source of revenue for both HSE and Voluntary hospitals and helps to self-fund many research posts around the country.

By estimating the per-patient value of treatment the HSE normally provides for a public patient not on a trial, we arrive at an average figure that can be multiplied by the number of patients enrolled on each trial. By repeating this process across a sample of several trials (but by no means all trials), we can produce a figure for the past four years that is indicative (if in reality very far short), of savings the state enjoys by sites enrolling patients onto cancer clinical trials.

There are significant limitations with this approach. For example, not all – or even most – patients remain on their trials in neat 12-month blocks. Meanwhile, the actual price paid by the HSE for Standard of Care treatments is, quite correctly, a confidential, commercially sensitive matter, negotiated with companies. On that basis, this Report has taken care to make conservative estimates. It also primarily focuses on estimated savings generated by academic cancer clinical trials, as these are the trials that Cancer Trials Ireland sponsor. Direct income to sites generated from industry sponsored cancer clinical trials far exceeds that of academic trials, however actual savings associated with all industry sponsored trials are outside the scope of this report. Greater data sharing, while maintaining commercially sensitive specifics, would enable fuller reporting of actual cost savings going forward.

Nevertheless, and in spite of these challenging limitations, we assert that the exercise is valuable, because it starts the process of publicly putting a value on cancer trials in Ireland, with a view to better informing our elected officials and decision-makers about the opportunity that Ireland must grasp. Estimates or not, the figures that follow almost certainly fall far short of the true savings. Our estimates overleaf are based on 249 patients recruited to 18 academic trials over a four-year period. These trials were selected as Cancer Trials Ireland had an active role in each, thereby giving greater scope to estimate cost savings etc. In 2023/2024 alone, 582 patients were recruited onto Investigational Medicinal Product (IMP) trials across academic and industry drug trials, comparable to the sample we took for this report. Estimates from our sample could therefore be extrapolated to provide a fuller estimate of direct drug savings and inward investment.

In the context of cancer clinical trials, what does ‘inward investment in patients in Ireland’ mean?

‘Inward investment’ is quite separate to treatment costs savings. This investment comes in the form of experimental treatments (new medicinal products) provided to the patients enrolled on trials, usually in addition to standard of care drugs. These new medicines being evaluated through cancer clinical trials have a monetary value, which commonly (often vastly) exceeds the price of publicly reimbursed standard of care treatments. This cost is borne by the trial sponsor and represents a significant, non-governmental inward investment in patients in Ireland that is only available through trials.

LIMITATIONS: *Figures are estimates. We foresee fewer ‘limitations’ in future as we work with the wider community to better identify confirmable data that demonstrates the value of cancer trials, both savings, and investment, in Ireland*



Cost savings (from Standard of Care drugs provided for the trial) plus Inward Investment (provision of new drug) from a sample of 18 trials opened in Ireland between 2021-2025

Trial name	Patients recruited	Total Savings (Standard of Care drug)	Note No.	Total Inward Investment (new drug)
L&H: CPD-DARA	16	779,000	1	2,831,000
L&H: CLL17	86	5,733,000	2	5,965,000
L&H: Isa-RVD	52	4,951,000	3	25,000,000
Other L&H trials (2)	12	344,000	4	
Breast trials (2)	16	1,100,000	4	
Lung trials (3)	13	1,300,000	4	
GU trial	4	400,000	4	
Gynae trials (7)	21	200,000	4	
Lung trial	7			164,000
CAR-T trial	5			2,000,000
GI (pancreatic)	17			802,000
Estimated Cost Savings - Standard of Care drugs:		**€14,807,000**		
Estimated Inward Investment Value (new drug):				**€36,762,000**

Note: Treatment cost savings calculations

1. *CPD-DARA costs savings figure calculated by the per-dose cost of daratumumab multiplied by the number of treatment cycles across all patients*
2. *CLL17 saving costs calculated through value of Ibrutinib for # of patients on that arm of trial over three years + # of patients on the Ventoclax + Obinutuzumab from Dec '22 - Aug '23 approx.*
3. *Isa-RVD savings costs calculated by approximate value of standard of treatment care provided by funder to 52 patients on trial for treatment period*
4. *These trials are Phase III/IIIb studies where CTI judges it is highly probable that the study sponsor covers the Standard of Care treatment cost. In many cases, the Standard of Care treatment includes pembro - which for the purposes of this table, and report, has been priced at €100k per patient.*

Savings arising at Trial Unit Sites

As previously stated in the introduction. There is clear, if fragmented, evidence of additional treatment cost savings at some of the individual trial sites.

- Between 2021-2024 one trial unit identified €9.7m in combined value from treatment cost savings and inward investment (site fees / per-patient fees) provided by industry trial sponsors.
- In 2022 alone, another trial unit identified €2.6 million in combined value from treatment savings and inward investment, again by industry trial sponsors.

It is important to note that the treatment costs savings that arose at HSE site level are not ring-fenced for direct use by the hospitals and sites that generate them. They remain direct savings and income to the HSE / exchequer.

Without direct access to these savings that are generated by HSE sites running cancer clinical trials, or in many cases, any funding support from the HSE or their parent hospitals for research, the trial sites rely on the following: -

1. Limited grant funding through the HRB, which must be secured through a competitive process
2. Fees provided by trial sponsors (typically pharma companies) for the delivery of trial-associated services. These might include patient screening; provision and oversight of treatment; co-ordination with pharmacy, data management, readiness for audit and inspection, and so on. By way of example, the three trials listed on page 10 (CPD-DARA, CLL17 and Isa-RVD) generated €588,000 worth of site fees for participating trial units.

To state things more plainly, many trial units are partially or even entirely self-funding. While this entrepreneurship is highly commendable, it also creates a significant structural challenge. A trial unit's dependence on incoming trials means that the unit is subject to financial volatility. This can result in increased staff turnover as research nurses, data managers and other members of the research team are often on temporary or specified purpose contracts.

In the absence of long-term security and permanent contracts, research unit staff often leave to seek more secure roles outside of trials, siphoning research units of a wealth of experience. They may also have limited career progression, as research roles have not been recognised as standalone grades within the current HSE Public Sector Agreement. This issue also relates to Health and Social Care Professionals (HSCPs), including Radiation Therapists, working in trials, and is an issue that comes up for discussion at forums and events year after year after year.

Further (non-drug) savings & investments associated with cancer clinical trials

In addition to the treatment cost savings described on page 08, trial sponsors bear the costs of all the associated treatments and procedures that may accompany trials, including all imaging (CT, MRI scans) blood and other tests, and any biopsies or procedures. These interactions represent further example of savings (where such instances would be provided as standard of care outside of a trial) and investments (in the form of extra tests that trial patients benefit from) that could easily amount to six or seven figure sums every year, considering the number of patients recruited to trials in the past three years (see: page 16).

Savings associated with Radiotherapy (RT) trials and research



Radiotherapy clinical trials are a major source of cost savings and improved efficiency in cancer care. Radiotherapy contributes to 40% of cancer cures, but represents only 5% of cancer budgets internationally. Research in radiotherapy, including the use of stereotactic ablative radiotherapy known as SABR, offers immediate and scalable economic, societal, and environmental benefits. SABR in the oligometastatic setting can delay the need for costly systemic drugs, reducing expenditure and improving patient quality of life.

A key innovation from clinical trials is hypofractionation, where treatment is delivered in fewer, higher intensity sessions. This approach maintains cancer control while reducing hospital visits, freeing up treatment capacity, and cutting travel related carbon emissions. Hypofractionation has now been adopted widely thanks to landmark studies.

FAST Forward Breast Cancer Trial: Demonstrated that five radiotherapy sessions provide the same benefit as fifteen to twenty five, transforming global practice. For Irish patients, this means fewer visits, lower costs, and less disruption to life. A retrospective review of 68 patients treated under the FAST-Forward protocol at the St. Luke's Radiation Oncology Network (SLRON) showed a total cost reduction of €47,489 and a saving of 13,820 minutes of staff time. Annually in Ireland approximately 800 patients are now treated using the FAST-Forward regime, saving an estimated €569,000 per year. The FAST Forward Boost Trial starting in 2026 will test if the radiotherapy treatment including the tumour boost can also be delivered in five sessions instead of fifteen. This trial has the potential to eliminate 9,360 fractions per year nationally saving around 2,340 hours of linear accelerator time, the equivalent to running a treatment machine 12 hours a day for 6 months, and delivering a further cost saving of approximately €482,449 per year.

Prostate Cancer Trials including CHHiP, PACE, and INSPIRE: The CHHiP and PACE studies proved that prostate radiotherapy can be safely shortened from seven or eight weeks to four weeks, and even further to just five sessions, with similar cancer outcomes. The INSPIRE trial, opening in 2026 in 12 sites across the island of Ireland, will investigate next generation five treatment schedules, with significant potential savings due to the high incidence of prostate cancer.

SABR COMET and SIMPLIFY Trials: SABR COMET showed that SABR can double progression free survival from 6 to 12 months, delaying the need for expensive drug therapies. The SIMPLIFY trial activated across all research active radiotherapy departments nationally will treat a projected 70 patients in a single session instead of three to five, saving around four treatments per patient at a cost of approximately €1000 per fraction of SABR. This will enable savings of approximately €280,000 each year this trial runs in Ireland.

> *We've tripled the number of patients on trials, but the funding hasn't changed.*
>
> ***Prof Sinead Brennan, IRROG***

Broader investments in health science research in Ireland

Industry investment in R&D – "Transfer of Value"

Since July 2016, details of companies' engagements with, and support of, healthcare professionals through direct or indirect financial support or 'Transfers of Value' have been publicly disclosed in accordance with IPHA's Code of Practice for the Pharmaceutical Industry.

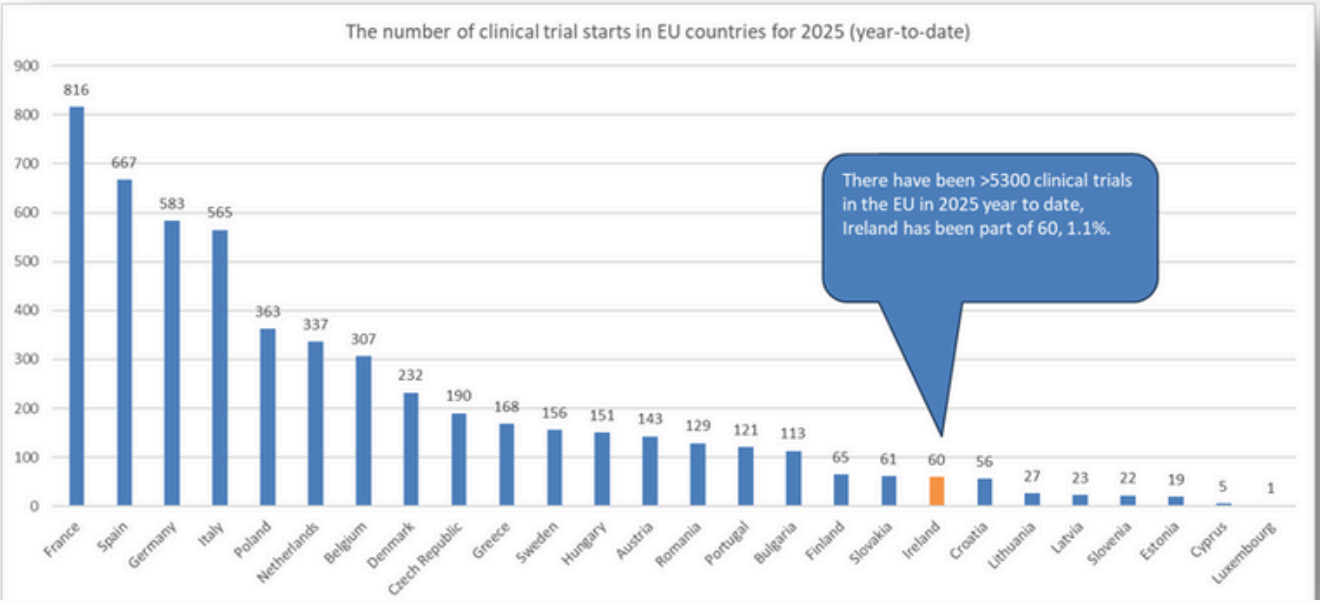
The figures below relate to 'Transfers of Value' (i.e. funding) for Research & Development. This includes clinical trials, but is not limited to drug trials only, and may include support for observational (i.e. non-interventional) studies and other types of health research outside of trials. The figures below represent aggregate disclosed amounts only.

2021	€16,312,769
2022	€12,183,444
2023	€14,274,603
2024	€18,288,926
Total:	**€ 61,059,742**

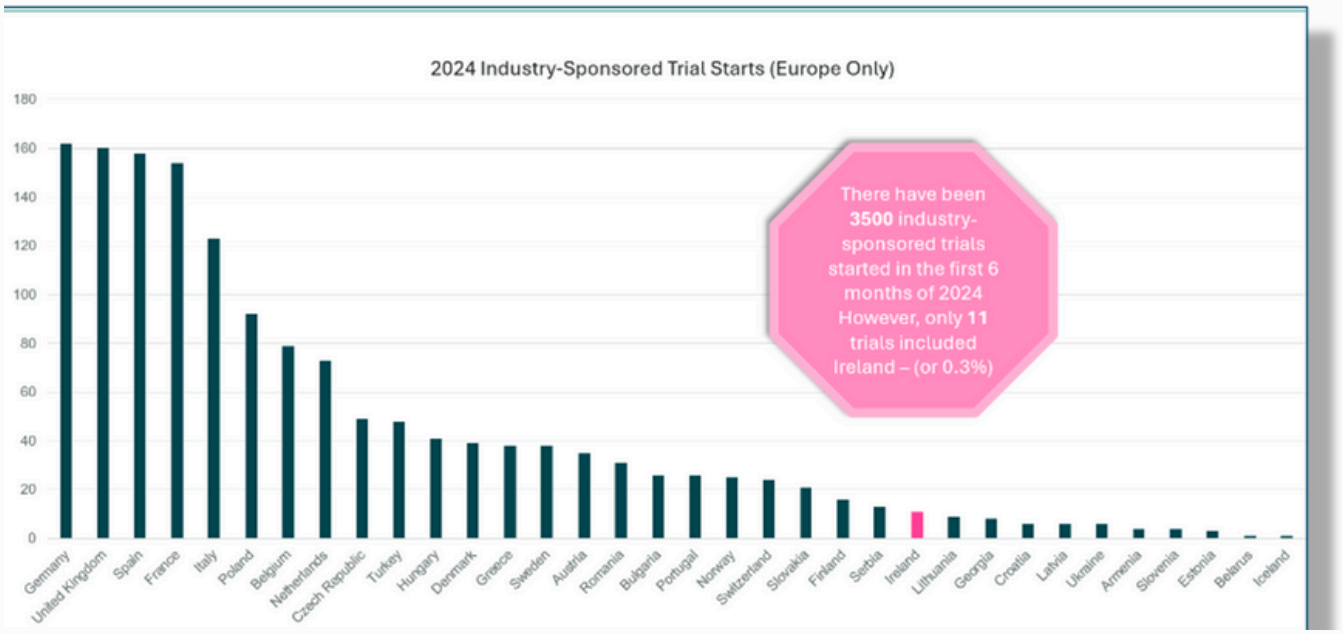
Irish Pharmaceutical Healthcare Association

Ireland's performance – clinical trials & cancer clinical trials

According to data shared by ICON Plc (below), Ireland has participated in only 1.1% of *all* trials (i.e. not only oncology trials) opened across the EU, as shown below (data accurate as of Sept 25th, 2025): -



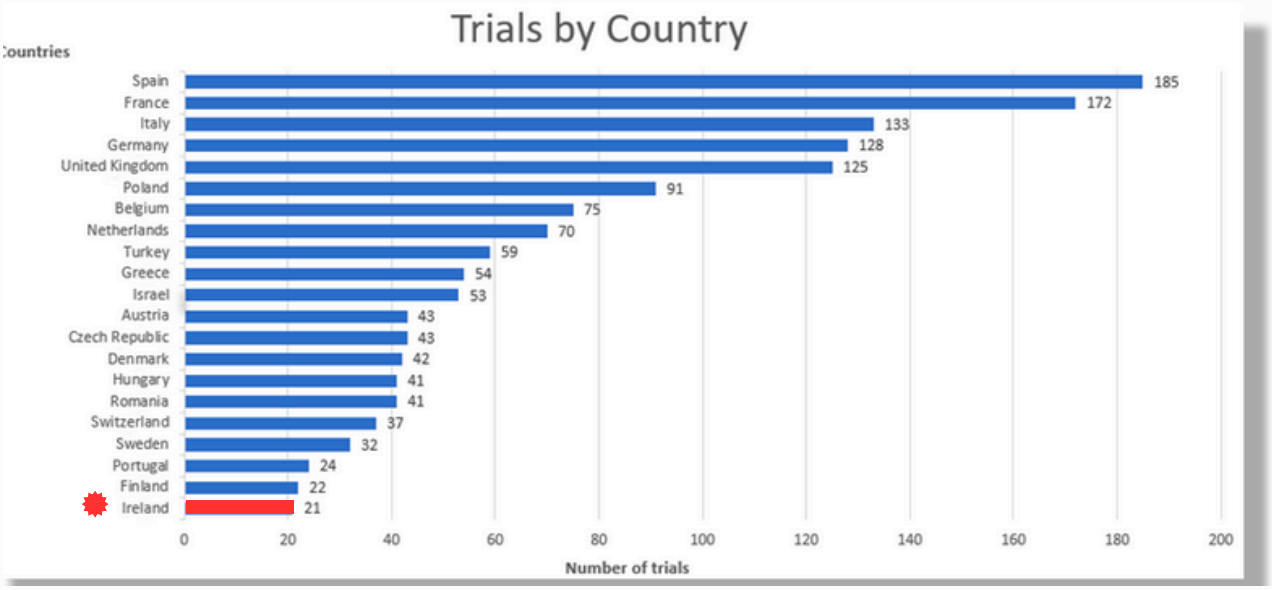
When compared to data for the first seven months of 2024 (to July 31st), there is a clear improvement in the number of trials opened (from 0.3% to 1.1%) although this increase has not been sufficient to change our overall position on the European 'leaderboard': -



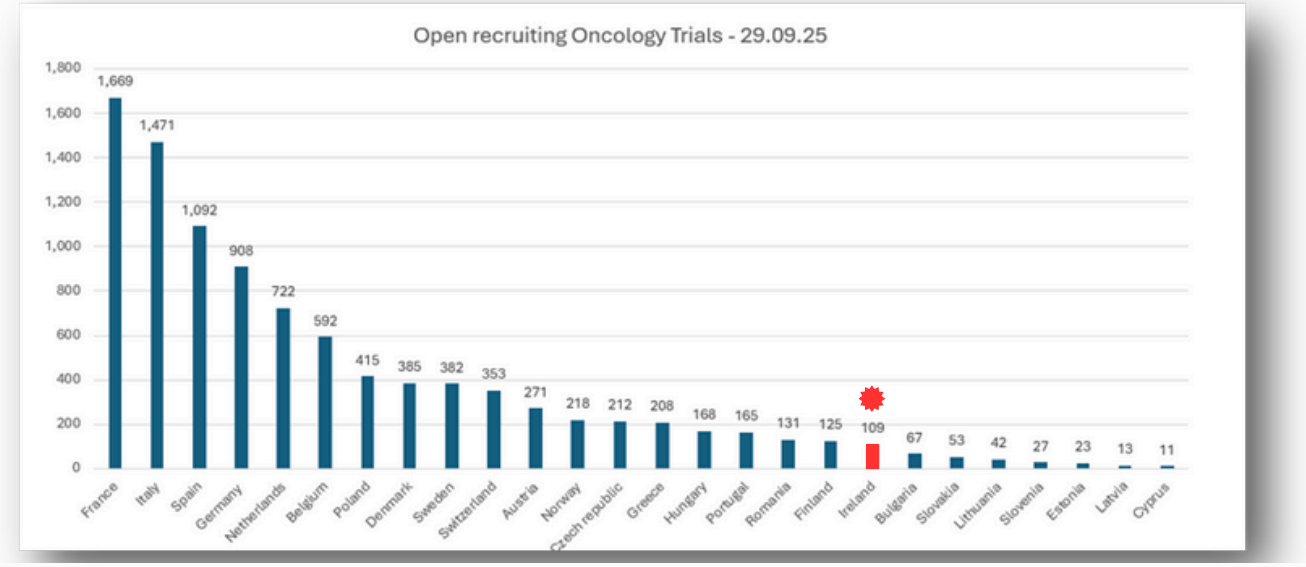
Ireland's performance – clinical trials & cancer clinical trials

Ireland's performance across both years significantly lags countries with similar sized population and education levels, and GDP per capita (Denmark, Switzerland) and falls just behind Finland, which has a lower GDP per capita than Ireland.

Considering oncology trials only, up until Sept 30th 2025, data from ICON plc showcases a similar trend for the first three quarters of this year, with Ireland opening the lowest number of trials of any EU country: -



Taking a longer-term view, according to clinicaltrials.gov, open and recruiting oncology trials as of end September 2025 is shown below. These figures, however, include trials that were open in previous years, not just those that were newly opened in 2025: -



What Cancer Trials Ireland has achieved to date – without increased funding

Patient recruitment to cancer trials in Ireland: 2024 v 2023 v 2022 (including Q1-Q3 2025)

As the figures displayed below demonstrate. Ireland has built momentum in the aftermath of the pandemic, and in spite of a crippling cyberattack on the HSE. Figures show steady rises across nearly all categories.

	2025 Q1-Q3	2024	2023	2022
Study Type		**All Trials**	**All Trials**	**All Trials**
IMP	226	281	259	250
IMP/RT	0	6	36	70
Radiotherapy	229	218	49	37
Nutrition	8	3	0	0
Med Dev/RT	0	0	0	14
Imaging /diagnostic*	1306	37	47	0
Other (acupuncture)	0	12	0	0
Other (telemedicine)	0	11	0	0
Survivorship	78	231	156	151
Surgical	15	9	0	0
AI	83	0	0	0
Survey/Questionnaire	73	87	0**	0
Observational	425	817	278	31
Translational	680	497	288	291
Biobank	80	560	374	456
Registry	100	45	127	170
Total	**3303**	**2814**	**1614**	**1470**

** 2025: 1306 patients are from the Lung Health Check Pilot*

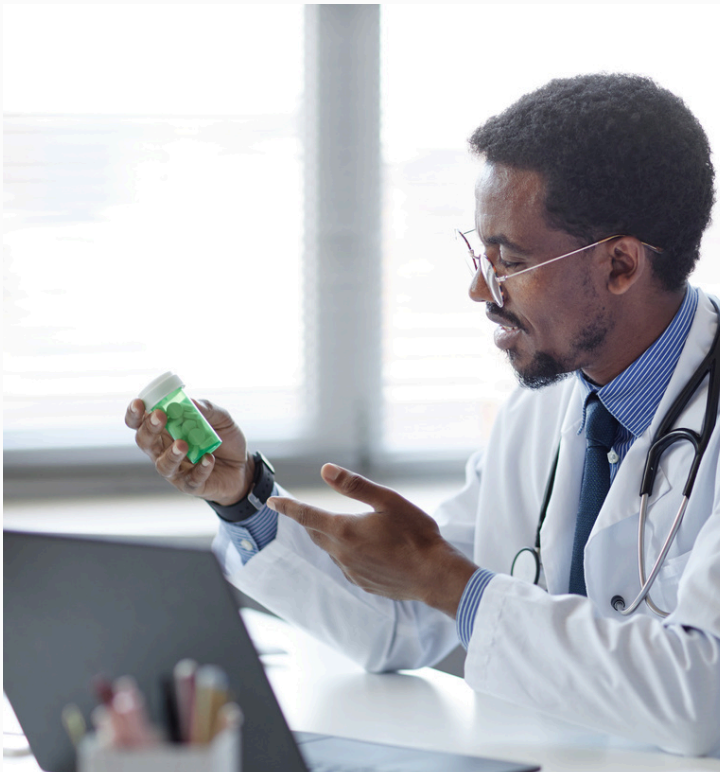
***2023: CTRIAL-IE 23-05 MBC survey accrual (246) did not involve any clinical trials units and not included in above numbers*

The same figures, expressed by cancer type:

	2025 Q1-Q3	2024	2023	2022
DSSG	**All Trials**	**All Trials**	**All Trials**	**All Trials**
Basket	503	924	363	226
Breast	688	642	533**	520
CNS	43	25	0	0
GI	23	36	114	106
GU	71	194	152	87
Gynaecology	19	11	14	9
Head & Neck	82	163	47	24
Lung*	1349	208	64	45
Lymph & Haem	288	446	263	410
Melanoma	55	116	27	22
Paeds	106	46	34	20
Sarcoma	76	3	3	1
Total	**3303**	**2814**	**1614**	**1470**

* *2025: 1306 patients are from the Lung Health Check Pilot*

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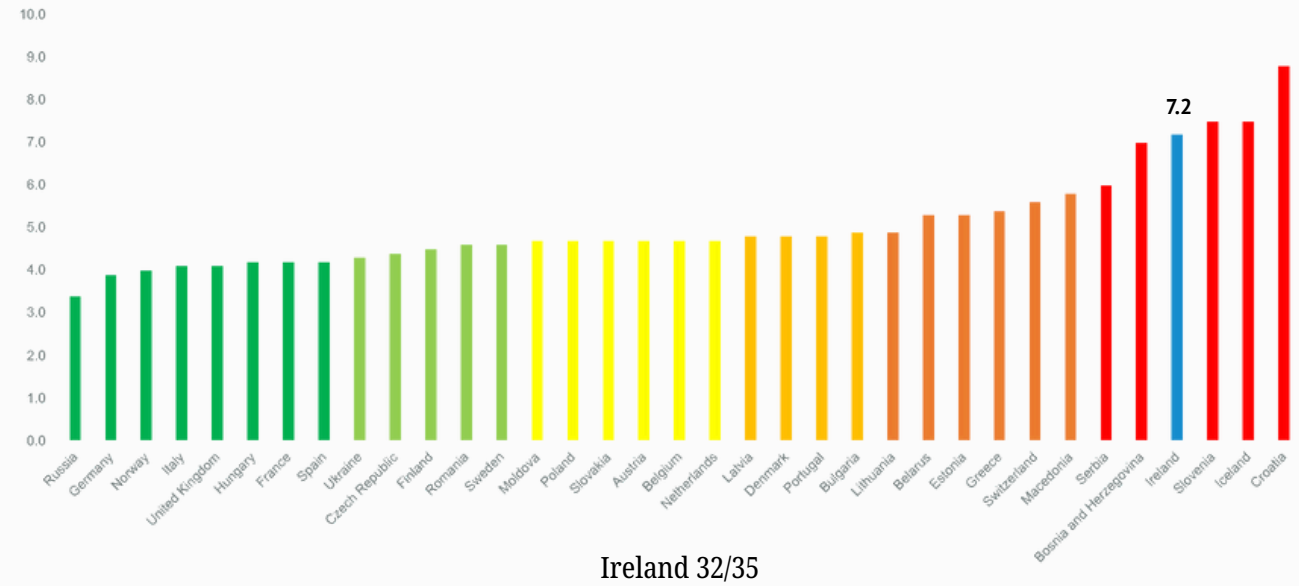


Time to First Patient

Within existing funding, Cancer Trials Ireland has continued to address challenges in clinical research, particularly those arising from GDPR's impact on conducting health research in Ireland. In October 2024, Cancer Trials Ireland published a position paper on GDPR which provided a call to action to make Ireland a more attractive site for opening trials Position papers & commentary - Cancer Trials Ireland.

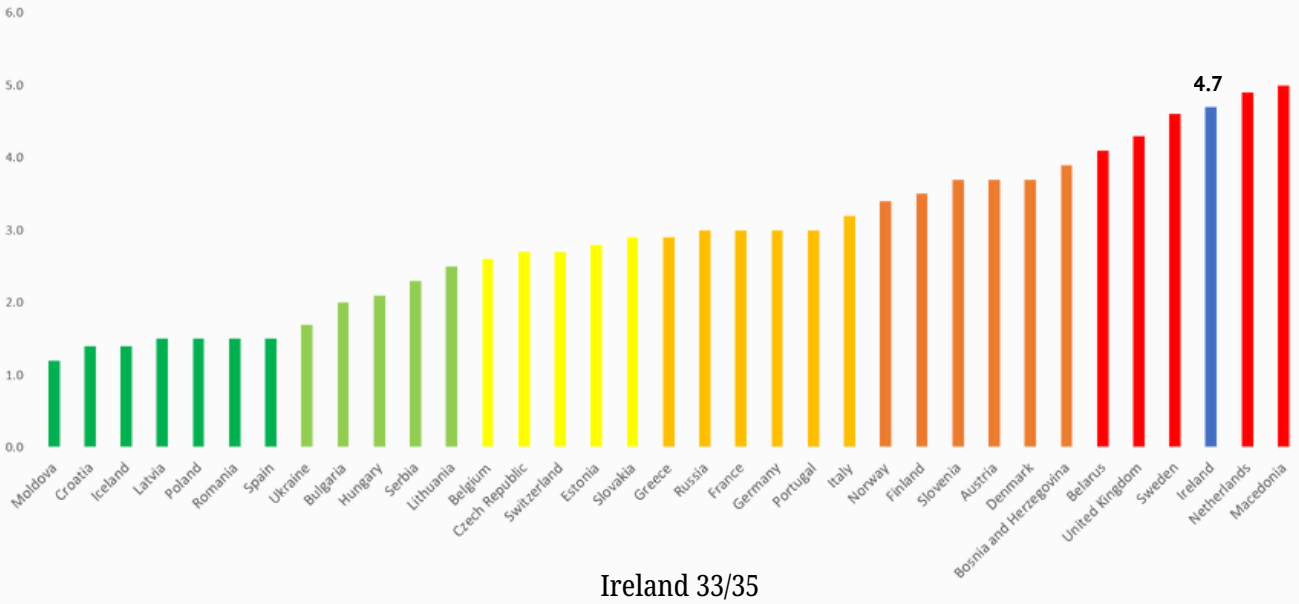
Challenges presented by the interpretation of GDPR legislation, represented some of the factors impacting on Ireland's ability to open new trials in a timely manner. Other factors have included the lack of national templates for trial contracts and site agreements, and individual site legal review. Until recently, trial start-up timelines in Ireland have been among the slowest in Europe, as shown by data provided by ICON on 2024 EU timelines: -

From Final Approved Protocol to Clinical Trial Application Submitted (months)



Ireland 32/35

From Clinical Trial Application Approval to First Site Initiated (months)



Ireland 33/35

Since 2024, National Model Clinical Trial Agreement (CTA) templates have been developed in partnership between the HSE, IPHA and commercial Contract Research Organisations (CROs). These have been widely accepted by trial Sponsors, and adopted for use by Voluntary hospitals. In addition, the HSE has recently moved to a single legal review for all HSE sites involved in clinical trials sponsored by Cancer Trials Ireland. While there is still room for further improvement, e.g., a move to a single sign-off of contracts for all HSE sites, these positive developments will have a significant impact on Ireland's ability to open trials faster.

Alongside ongoing advocacy and participation in national working groups, Cancer Trials Ireland took active steps to streamline internal processes, to reduce the time between final protocol approval and the enrolment of the first patient, known as the Time to First Patient (TTFP). It is recognised that providing consistent start-up timelines (rather than necessarily being the fastest) is essential to industry.

A dedicated Start-Up Team, established in December 2024, now leads this work. The team coordinates all start-up activities including contracts, budgets, ethics and regulatory submissions, and milestone tracking to improve efficiency and communication.

In 2024, before the team was established, start-up timelines were lengthy and variable. The table below summarises three studies that achieved site activation in Quarter 4 of 2024, representing the pre–Start-Up Team baseline.

KPI	Description	Median	Range
KPI 1	Scientific Management group (SMG) approval to site activation	511 days	447–593 days
KPI 2	Clinical Trial Agreement (CTA) received to executed	254 days	132–355 days
KPI 3	Research Ethics Committee (REC) approval to site activation	317 days	193–346 days
KPI 4	Clinical Trial Agreement (CTA) received to site activation	468 days	423–508 days

In early 2025, the Start-Up Team began managing all new study activations. The table below shows studies with Clinical Trial Agreements (CTAs) executed in Quarter 3 of 2025. Some studies were still pending activation at the time of reporting, but early results already show meaningful progress.

KPI	Description	Median	Range
KPI 1	Scientific Management group (SMG) approval to site activation	514 days*	457–572 days*
KPI 2	Clinical Trial Agreement (CTA) received to executed	137 days	7–349 days
KPI 3	Research Ethics Committee (REC) approval to site activation	244 days	192–296 days
KPI 4	Clinical Trial Agreement (CTA) received to site activation	344 days	315–373 days

**KPI 1 in 2025 includes studies that began before the Start-Up Team was in place and therefore does not yet reflect the full impact of the new process.*

Contract turnaround times (KPI 2) improved from 254 days to 137 days, a 46% reduction. The overall time from contract receipt to site activation (KPI 4) decreased from 468 days to 344 days, a 26% reduction. Variability between studies also reduced, showing stronger process control and consistency.

KPI	2024 Median	2025 Median	% Change
KPI 1	511 days	514 days*	–
KPI 2	254 days	137 days	**↓ 46%**
KPI 3	317 days	244 days	**↓ 23%**
KPI 4	468 days	344 days	**↓ 26%**

**Includes studies initiated before the Start-Up Team was established.*

The creation of the Start-Up Team has already delivered faster contracting, improved coordination and greater predictability across studies. As more new studies progress fully through this model, further improvements are expected in 2026. This initiative represents a key step in improving operational efficiency and supporting faster access to clinical trials for patients across Ireland, and has been implemented in tandem with the positive steps taken in relation to national templates / sign-off, as outlined previously.

Cancer Trials Ireland's core, ongoing offering

Cancer Trials Ireland continues to function as a highly effective national research network operating on multiple levels, from developing trial protocols with investigators, negotiating budgets and contracts, to full sponsor responsibilities for academic cancer clinical trials. Cancer Trials Ireland can act as either local (i.e., Ireland only), or EU sponsor for trials.

Geographically, it serves as a coordinating body - through the Clinical Executive - for cancer trial clusters and hospital sites funded by the HRB. Cancer Trials Ireland also functions as a professional network for oncologists specialising in individual tumour types, by facilitating three annual DSSGs that enable specialists to review disease cohort portfolios, compare trial performance and troubleshoot issues, discuss outcomes, and undertake horizon scanning.

Meanwhile, the in-house Cancer Trials Ireland team maintains its role in trial sponsorship, biometrics, pharmacovigilance, clinical project management, auditing and training. This activity is conducted while also publishing quarterly accrual data and conducting feasibility assessments for international academic and (since June 2025), for industry partners.

Cancer Trials Ireland also provides a platform for the oncology research community in policy discussions - whether concerning GDPR and health research, the nationalisation of research ethics processes, or sustainable career pathways for research nurses, data managers and HSCPs without whom oncology research could not be conducted. In parallel, we continue to explore and integrate digital platforms such as OncoAssist, Trialing and other electronic systems to enhance trial visibility, access, and patient awareness nationwide.





What Cancer Trials Ireland has achieved with increased (philanthropic) funding

In 2019, the Irish horse racing community rallied behind champion jockey Pat Smullen, who was diagnosed with pancreatic cancer in 2018 and died in 2020, raising €2.6 million to support pancreatic cancer research in Ireland. At the time, no clinical trials in pancreatic cancer were open in Ireland. Since then, philanthropic support for pancreatic research has risen to above €4m, enabling Cancer Trials Ireland and the oncology community to deliver profound results:

The first trial in Ireland specific to pancreatic cancer, Paricalcitol, opened in October 2020, recruiting 15 patients before closing in September 2022 following an interim analysis.

The second study, PATCH, launched in May 2023, with a recruitment goal of 22; 17 patients have already enrolled.

The Dose-Painting IMRT radiotherapy trial opened in January 2024 with a recruitment goal of 67 patients. 3 of 3 patients were recruited to the first dose level and following a planned six-month pause (to assess dose level safety) the trial is now open to cohort 2, with 4 additional patients recruited, giving a total of 7 patients recruited to date.

The FEED trial opened in May 2024 with a recruitment goal of 70 patients. 8 patients have been recruited so far.

Collectively, these four trials offer up to 174 patients new treatment opportunities - options that previously did not exist for pancreatic cancer patients in Ireland.





Building a Global Centre of Excellence

Alongside these trials, Cancer Trials Ireland, University College Dublin (UCD) and the National Cancer Control Programme (NCCP) developed a vision for a new Pat Smullen Chair in Pancreatic Cancer — a globally prestigious position aimed at attracting world-class clinician-scientists to Ireland. Launched in July 2023, this vision became reality with the appointment of Professor Gráinne O'Kane in 2024. Since her appointment, and with support from the Pat Smullen Research Fund, Professor O'Kane has:

- Sought funding for a screening programme for people at risk of pancreatic cancer.
- Sought to introduce a nationwide tumour testing initiative for all newly diagnosed patients to identify hereditary gene mutations.
- Begun preparations for two new clinical trials in pancreatic cancer set to launch in the coming year, representing further new treatment options for patients.

Impact

This philanthropic investment has been a catalyst in Ireland's pancreatic cancer research landscape. It has changed access to Ireland-led, world-class research for patients with pancreatic cancer, from virtually no trial options in 2019, to a pipeline of innovative treatments, national screening and genomic testing programmes, and a globally recognised research chair. It is a model of how strategic funding, clinical leadership, Cancer Trials Ireland governance and public support can accelerate progress against one of the most lethal cancers. The research that has been made possible through this philanthropic investment provides much-needed hope for pancreatic patients and their families.





Immediate actions Cancer Trials Ireland will take with increased funding

1. **Sponsor additional Investigator Initiated Trials e.g., surgical trials such as a colo-rectal (T3 Rectal) for 96 patients**
2. **Sponsor additional radiotherapy studies**
3. **Sponsor additional collaborative studies in medical oncology and haematology**
4. **Support more non-interventional studies (e.g., diet / exercise / registry) and patient-led studies**
5. **Develop decentralised trials via a 'hub and spoke' model to improve equity of access to trials for patients nationally**
6. **Invest in vital systems and AI related technologies**

Cancer Trials Ireland has a proven record of leveraging public investment effectively. For example, €4 million invested in pancreatic cancer research in recent years enabled four new trials, providing access for up to 174 patients to treatment options that otherwise would not exist, as well as the creation of a clinician–researcher post at UCD, in partnership with UCD and the HSE National Cancer Control Programme (NCCP). This work positions Ireland to become a global leader in pancreatic cancer research.



CPA Pre-Campaign

Why government funding cannot stay the same

If Ireland is to meet its target of 6% of cancer patients enrolled on interventional clinical trials (as per the current National Cancer Strategy) and open trials on a par with similarly sized European countries, then cancer clinical trials in Ireland need more government funding and investment.

This report has made the case for increased funding by highlighting how trials generate savings to the government that can outstrip government funding, emphasising how further funding is highly likely to generate even more savings and attract even greater inward investment by trial sponsors, at no cost to the government.

Moreover, at a time of global economic instability, and with the pharmaceutical sector – which is so important to the Irish economy – under significant pressure to relocate to the United States, increasing government funding for cancer clinical trials would be a clear demonstration of Ireland's commitment to this key industry.

Funding levels for the next HRB grant cycle cannot remain at current levels. Aside from the impact of inflation alone, were funding left unchanged, Cancer Trials Ireland and the six HRB clusters anticipate that two further 'group' grant recipients, University Hospital Limerick (UHL) & University Hospital Galway (UHG) will be included in the grant cycle. Inclusion of UHL and UHG is essential in order to continue to provide equity of access to trials for patients in the west of Ireland. This is widely appreciated by the oncology community, as is the dedication and positive steps taken by UHL and UHG to increase trial activity and collaborate with the other HRB clusters.

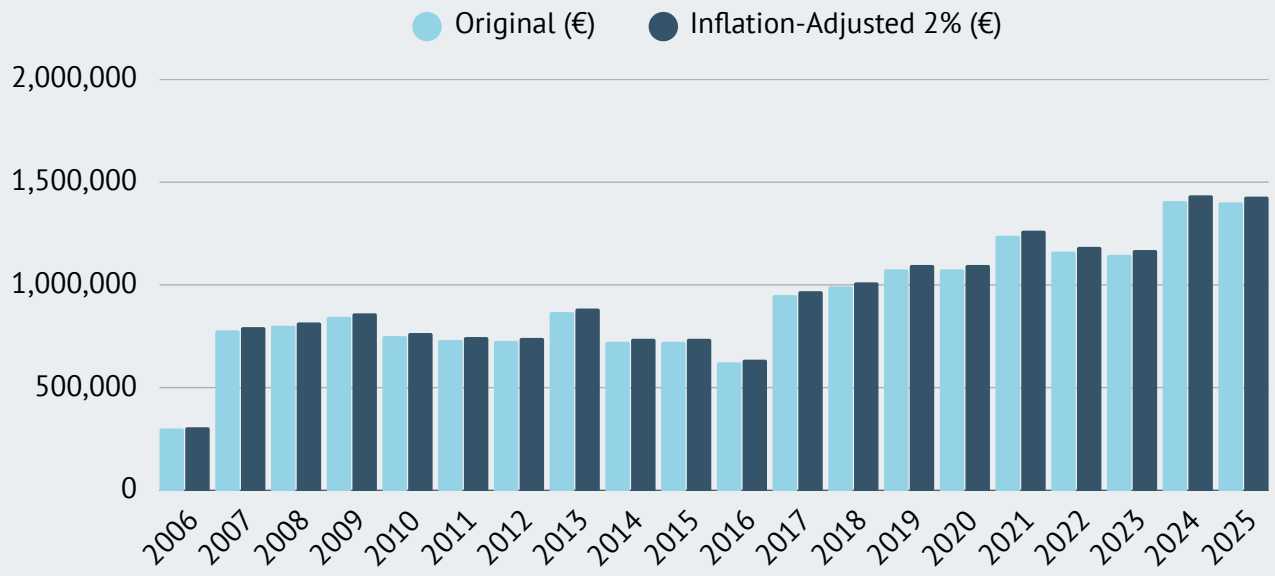
However, keeping the current funding levels as is, and dividing that between more recipients would, in effect, amount to a significant cut in government funding for each cluster. This would, in turn, lead to a decrease in the level of trial activity that could be undertaken across Ireland, instead of driving further activity, providing greater access to trials for patients, and increasing direct savings and inward investment.

Historical government funding for Cancer Trials Ireland

The chart below shows government funding (via the HRB) of Cancer Trials Ireland's Group Central Office (GCO) over the past two decades. The total figure is €18.39m. This 20-year total is almost matched by the estimated standard of care drug costs savings included in this report (€14.8m), which as has been already stated, were generated by a sample of just 18 trials that enrolled a total of 249 patients.

Based on the fact that 582 patients were recruited to IMP (i.e. drug) trials in 2023 and 2024 alone, it is reasonable to project that the true figure for savings over the past four years exceeds Cancer Trials Ireland's funding since 2006 – and may even match or exceed the government's funding, through HRB, of all cancer clinical trials for a full five-year grant cycle (2022-2026).

HRB funding: Actual vs Inflation-Adjusted Totals (2006–2025)



Government funding for all cancer clinical trials, 2022-2026

As stated previously, in 2022, the government funded all cancer clinical trial activity through a five-year HRB grant cycle that divided €22m between six 'clusters' (cancer trial units in hospitals, and their associated 'Host Academic Institutions' i.e., universities) plus a complementary 'overarching National Cancer Clinical Trials Network' which is delivered by Cancer Trials Ireland. The six clusters are: -

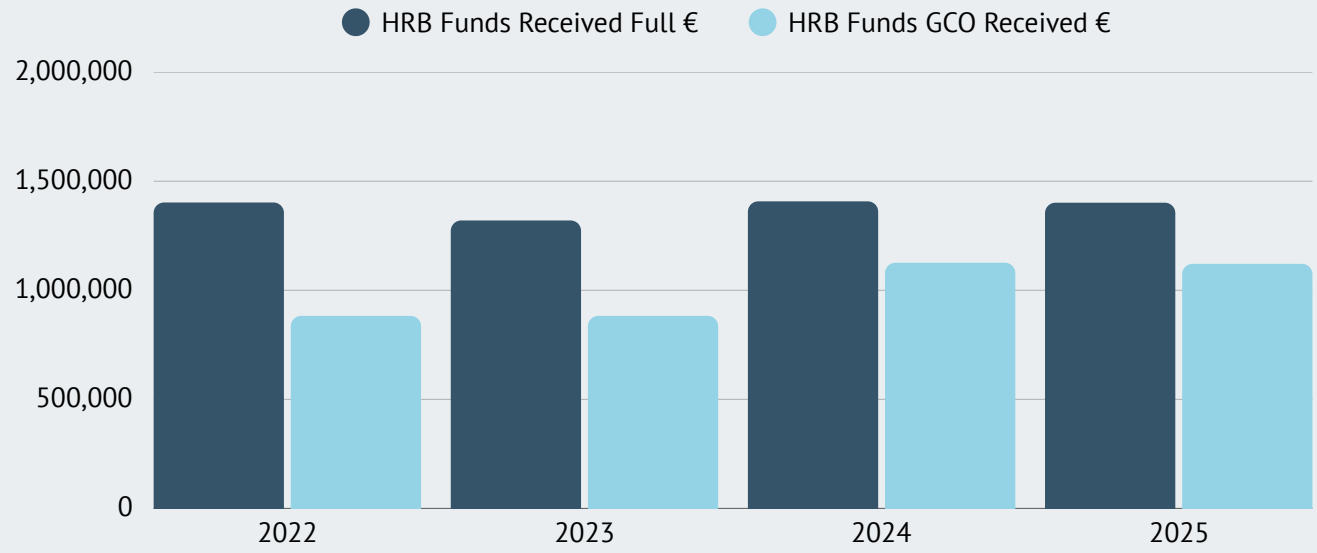
- Beaumont-RCSI
- UCD-CRC
- Wellcome-HRB CRF SJH
- IRROG
- HRB CRF-UCC
- CHI-CRC

Subsequently, in 2023, UHL (UL-UHL) and UHG (HRB-CRFG) received HRB funding under the 'Cancer Trials Enhancement Award' scheme. They each received a three-year grant of €709k.

Structurally speaking, the grant cycle was a welcome development that provided longer-term funding and thus improved stability for recipients. For Cancer Trials Ireland, our five-year HRB funding amounts to €6.9m including host institution overhead of 20%, leaving €5.5m for direct use by Cancer Trials Ireland.

See: Bar chart on the following page.

HRB funding: Totals (2006–2025)



The above chart shows that when the Host Institution overhead of 20% is subtracted (along with some historical site payments required in 2022), Cancer Trials Ireland's actual funding for the cycle averaged to €1m (1.003m) a year for five years.

Section summary:

- **Additional grant recipients.** As stated above, the current €22m grant is currently shared across seven recipients (six cluster and the Cancer Trials Ireland Network). The anticipated and much needed inclusion of UHL and UHG into the next HRB grant cycle must be properly resourced.

- **Host Institution overheads.** The terms of the HRB Grants require service providers i.e., Cancer Trials Ireland and each of the clusters, to partner with universities. This entitles the partner university to deduct a percentage of the grant total to cover their overheads. While these partnerships are welcome, and provide opportunities for research and other collaborations, in financial terms they represent a direct loss of HRB grant funding.

- **Performance & Momentum.** The accruals figures on page 16 show a steady recovery in the aftermath of the pandemic and HSE cyberattack. The steady improvement in accrual figures will not be sustainable without additional investment.

- **Inflation.** Allowing for a rate of inflation of 2% 2006-2025, government funding lags inflation by €366,473. Almost of a third of that 'loss' was incurred since 2022, over the period of the grant, where annual income is fixed.

- **Low levels of government funding historically vs. comparable EU countries.** While identifying country-specific state funding for cancer trials is difficult, comparable European countries and economies (e.g. Denmark and Switzerland) are estimated to fund cancer trials and research to a far greater extent than Ireland, reflecting the far greater number of clinical (and cancer) trials open in those countries (see: pages 14-15). Indeed, similar sized countries, like Finland, with smaller GDP per capita still manage to outperform Ireland.

Summary & Conclusion

Value of Cancer Clinical Trials

Cancer clinical trials improve patient outcomes and provide early access to new treatments. Participants benefit from enhanced monitoring and contribute to advancing cancer care for future patients.

Ireland's Current Position

Ireland lags behind European peers (e.g., Switzerland, Denmark, Finland) in number of cancer clinical trials open.

Economic Impact and Investment

- Direct cost savings:
  - 18 trials (249 patients) saved the State €14.8 million in drug costs.
- Inward investment:
  - Six trials generated €36.7 million in new investigational medicinal products (IMPs).
  - One trial unit valued trial-provided medicines at €9.7 million (2021–2025). Another at €2.05m (for 2022 alone).

Combined, these figures demonstrate high monetary and societal value. True overall savings and investment levels are likely much higher.

- True trial-related savings may exceed total government funding for Cancer Trials Ireland over 20 years.
- Savings could also surpass €22 million HRB cluster funding (2022–2026).
- HRB also provided €42 million in broader cancer research grants (2019–2022).

Radiotherapy Trials and Innovation

Radiotherapy = 40% of cancer cures but only 5% of cancer budgets. Clinical research drives major cost and efficiency gains:

- FAST-Forward Breast Cancer Trial:
  - Reduced sessions from 15–25 to 5.
  - Annual savings of ~€569,000 and significant time efficiency.
  - Upcoming "Boost" trial (2026) could save €482,000/year and major machine time.
- Prostate Trials (CHHiP, PACE, INSPIRE):
  - Shortened radiotherapy from 7–8 weeks to 4–5 sessions.
  - INSPIRE (2026) will test next-gen five-treatment schedules.
- SABR COMET & SIMPLIFY Trials:
  - Extended progression-free survival and reduced need for costly drugs.
  - SIMPLIFY: annual savings of ~€280,000 by cutting sessions.

Private Sector Contributions

IPHA data (2021–2024): €61 million in R&D "Transfers of Value" from industry to Irish researchers/institutions (includes non-trial research and non-oncology research). The true figure for total inward investment is likely higher.

Call for Increased State Investment

Greater government funding in Cancer Trials Ireland would:

- Expand the number of trials.
- Generate more cost savings and inward investment.
- Improve patient outcomes.
- Leverage a "virtuous cycle" of benefit to patients, the health system, and the economy.

Key Systemic and Funding Issues

- HRB grant (€22m) shared across seven clusters and Cancer Trials Ireland; expansion to UHL and UHG requires proper resourcing.
- University overheads reduce effective HRB funding.
- Post-pandemic trial accruals recovering but fragile without sustained funding.
- Inflation (2006–2025) eroded funding value by €366,473 — one-third since 2022.
- Government funding still low relative to peer EU countries.

Examples of Effective Public Investment

- €4 million invested in pancreatic cancer research enabled:
  - Four new trials for up to 174 patients.
  - Creation of a clinician–researcher post at UCD (with HSE NCCP).
  - Strengthened Ireland's leadership in pancreatic cancer research.

Strategic Context

- Global pharma shifts (e.g., US manufacturing repatriation) challenge Ireland's competitiveness.
- Increased state support for trials would signal commitment to the pharma sector.
- Collaboration among industry, Cancer Trials Ireland, the State, researchers, and trial units is essential to maximise efficiency and impact.



Appendix

Research and Development Transfers of Value (Irish Pharmaceutical Healthcare Association)

1. Transfers of value to healthcare professionals or healthcare organisations related to the planning or conduct of (i) non-clinical studies (as defined in OECD Principles on Good Laboratory Practice[2]); (ii) clinical trials (as defined in Directive 2001/20/EC[3]); or (iii) noninterventional studies (NIS)[4] that are prospective[5] in nature and that involve the collection of patient data from or on behalf of individual, or groups of, healthcare professionals specifically for the study.
2. The OECD Principles on Good Laboratory Practice (as revised in 1997) define nonclinical studies as follows (Section I – 2. Definitions of Terms; section 2.3.1): Nonclinical health and environmental safety study, henceforth referred to simply as "study", means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities. For complete reference, see www.oecd.org
3. EU Directive 2001/20/EC (Article 2(a)) defines clinical trials as: any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy.
4. EU Directive 2001/20/EC (Article 2(c)) defines non-interventional trials as: stud(ies) where the medicine(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data.
5. Prospective versus retrospective NIS must be considered using the following table: ToV relating to NISs that are retrospective (and thus not within the definition of R&D ToV) must be reported on an individually named basis. Activities not falling within the definition of R&D ToV, including NIS that are not conducted to maintain a Marketing Authorisation (in application of, and following, Clinical Trials Regulation 536/2014), must be disclosed under "consultancy/fee-for-services". Companies must include a comment in the Methodological Note on this, where appropriate.

Prospective NIS
Prospective cohort studies in which the prescription of the medicine is independent from the inclusion of the patient in the study. A retrospective study to which a prospective element is subsequently introduced. Long-term extension studies with patient follow up beyond trial protocol specified time for observation and active collection of additional data.

Retrospective NIS
Purely observational database review and/ or research. Retrospective review of records where all the events of interest have already happened – e.g. case-control, cross-sectional, and purely retrospective cohort studies
Studies in which the prescriber later becomes an Investigator, prescribing has already occurred – e.g. retrospective data collection from individual medical records at the site of the investigator.

Notes



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Just ask Your Team!

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Together, we're finding answers to cancer.

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