November 2026





Value of Cancer Trials 2

cancer trials ireland

Together, we're finding answers to cancer.



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Executive Summary

Cancer clinical trials improve patient outcomes, enable access to innovative treatments, strengthen healthcare services and attract international investment. Value of Cancer Trials 2 provides further evidence while highlighting opportunities yet to be realised. Its central message is clear: **clinical trials must be recognised, resourced and embedded as an integral part of healthcare delivery.**

Ireland has made progress. The National Clinical Trials Oversight Group (NCTOG) recommendations of November 2025 and the Clinical Trials Advisory Council (CTAC), established in August 2026, provide a framework for reform. Recommendation 11 calls for clinical trial activity to be recognised, measured and prioritised at corporate level throughout the health service. European initiatives reinforce this opportunity.

The report identifies considerable economic value from cancer clinical trials. Between September 2025 and August 2026, analysis of 38 investigational medicinal product (IMP) trials involving 230 patients identified estimated standard-of-care drug cost avoidance of **€6.51 million** and, from only 20 of these 38 trials, **€6.76 million in inward investment through investigational medicines.** These represent only a proportion of recruiting IMP trials. Estimated hospital site fees for 423 IMP trial participants could generate approximately **€10.5 million in revenue**, based on an assumed €25,000 per patient. Treatment-optimisation and radiotherapy trials offer further potential for recurring healthcare savings.

Despite these benefits, Ireland remains below its potential. Industry-sponsored trial activity increased by 44% in 2025, yet Ireland ranked 14th among 27 EU Member States per capita. Trial activation remains a competitive disadvantage, although Cancer Trials Ireland's start-up initiatives reduced median site agreement turnaround by 65% and ethics approval-to-activation timelines by 32% between Q4 2025 and Q2 2026.



Angela Clayton-Lea
CEO

Prof Seamus O'Reilly
Clinical Lead

Interviews with nine Principal Investigators identified workforce shortages, limited protected research time, fragmented processes and geographical inequalities. Yet public willingness is strong: **69% of the general public and 82% of respondents with cancer expressed willingness to participate in clinical trials.** The challenge is ensuring suitable trials are available, accessible and opened promptly.

The report also highlights Ireland's contribution to internationally significant research, including findings presented at ESMO 2026, and the transformative impact of philanthropy.

The priority now is to translate policy ambition into measurable improvements in clinical trial access and delivery. Implementing NCTOG recommendations through CTAC, strengthening research infrastructure and workforce capacity, and embedding clinical research within health-service accountability structures are essential.

Ultimately, the value of cancer trials extends beyond financial returns to opportunities for patients today and better cancer care for future generations. Ireland has the expertise, partnerships and public support; sustained investment and institutional commitment are needed to realise that potential.

What this report contains

Ireland has an internationally respected cancer research community, strong relationships with industry and an increasingly receptive public, yet, despite this, Ireland ranked 14th of 27 EU member states for industry-sponsored clinical trials per capita in 2025. In this regard, Ireland continues to lag behind much of Europe. European health, life sciences and industrial policy increasingly treats clinical research as central to competitiveness, and Ireland must ensure its research environment can compete for the trials and investment these policies seek to attract.

In Q3 2026, Cancer Trials Ireland commissioned Ipsos Behaviour & Attitudes (Ipsos B&A) to interview a range of principal investigators (PIs), who described a system in which research depends heavily on individual commitment rather than being embedded in the structures and priorities of the health service. In addition, engagement by Cancer Trials Ireland with industry confirms that the time taken to open a trial and recruit its first patient remains central to decisions about country selection.

The Value of Cancer Trials 2 Report reviews cancer trial activity over the past 12 months (1st September 2025 to 31st Aug 2026) and assesses Ireland's trial start-up performance against Europe and against itself, in previous years. This data is vital. International sponsors judge the performance of the system as a whole, so fast activation at one hospital does not compensate for delays elsewhere.

Thereafter, the report highlights the savings and inward investment associated with cancer trials, principally through cost savings associated with patients on trials, estimating the value of IMP delivered to patients on trials, estimating site revenue, and reviewing the value of radiotherapy trials. The report also looks at potential savings to be made through optimisation trials. The report also notes industry 'Transfer of Value' figures for the previous several years in Research & Development, as provided by IPHA.

The report then presents public attitudes to clinical trials. Cancer Trials Ireland has benchmarked public attitudes on four separate occasions over the past six years. Willingness to participate has improved substantially, a period that coincides with Cancer Trials Ireland's Just Ask campaign (now rebranded to Let's Talk Trials). For many patients the main barriers are practical rather than attitudinal. These include the impact of a trial in relation to patient travel, additional appointments and overall impact on family responsibilities, particularly for those living far from specialist centres. The report's quantitative research, considered alongside the Ipsos B&A-led PI interviews, helps distinguish issues of public perception from those relating to access and the organisation of care.

Finally, the report closes with a celebration of Cancer Trials Ireland trials presented at ESMO 2026, demonstrating that given the opportunity, Ireland can contribute significantly to global cancer research, and play its part in improving outcomes for cancer patients.

At a Glance

€6.51m

Estimated savings on standard-of-care drugs

Standard-of-care drug estimate

€6.76m

Estimated inward investment through new drugs / IMPs

Investigational medicine estimate

2,542

Patients accrued to cancer trials

+1,396 participants in the Beau–RCSI Lung Health Check *

1 September 2025 to 31 August 2026

73

Industry-sponsored trials commenced in Ireland in 2025

+44% compared with 2024

65%

Reduction in median site agreement turnaround

73 days to 25.5 days

69% / 82%

Willing to take part in a clinical trial

General public / people with cancer

* The Beau-RCSI Lung Health Check is funded by the Irish Cancer Society

Patient Voice



What Trials Mean for Patients

Martin Sweeney

Incoming Chair, Patient Consultants Committee, Cancer Trials Ireland.

Patients can benefit enormously from participating in cancer clinical trials. Trials provide treatment options that might otherwise be unavailable, giving patients access to some of the newest and most promising treatments being developed anywhere in the world.

Participation in a trial also brings an elevated level of care, including additional scans, blood tests, closer monitoring and access to a dedicated research nurse. Indeed, I think we can all agree that clinical trials should be part of cancer treatment, not an add-on or a nice-to-have. As this report demonstrates, patients also place enormous value on the contribution they make through participation in research.

As Principal Investigators reported in their qualitative interviews, patients may initially show most interest in trials because of the opportunities they may offer for their own health. However, as treatment progresses, many come to value deeply the contribution they are making towards those who will follow them.

This is reflected very clearly in the new public attitudes research. Of the 694 respondents who said they would be willing to participate in a clinical trial:

- 75% would do so to help others receive better treatment for their health conditions in the future.
- 50% would participate to improve their own health and well-being.

The same pattern holds true among respondents with cancer:

- 67% would participate to help others who come after them.
- 54% would do so to improve their own health.

These findings underline something important: patients value not only the possibility of improving their own health, but also the opportunity to give their experience of cancer a wider purpose. And there is another important message in this report: patients are not the barrier to greater clinical trial participation. Quite the opposite, in fact.

Over the past six years, willingness to participate in a clinical trial has increased from 48% to 69%. This increase coincides with sustained public awareness activity, namely Cancer Trials Ireland's Just Ask campaign, now renamed the Let's Talk Trials campaign, of which this very report is an element.

We must also acknowledge the impact of the COVID-19 pandemic, particularly in 2022, when support for clinical trials and a willingness to share health information rose sharply. That too is reflected in the data, as we shall see.

Furthermore, the barriers patients face today are increasingly practical rather than philosophical. They concern travel times, parking costs, time off work, childcare and the additional hospital visits that trial participation may require. In the past, concerns about clinical trials often centred on the perception that they were a last resort, or fears about being treated as a guinea pig. The public attitudes survey results suggest these attitudes are giving way to the practical concerns I described above, and this finding is reinforced by the Principal Investigator interviews.

As incoming Chair of the Patient Consultants Committee (PCC) at Cancer Trials Ireland, I look forward to sustaining and strengthening public and patient involvement in the organisation, and building on the considerable progress already made. My PCC colleagues and I attend Disease Specific Sub-Group meetings, review patient information leaflets and consent forms, and, where appropriate, review trial protocols. We also continually advocate for improved access to clinical trials and greater public awareness of the opportunities they offer.

On occasion, we also take a leading role in research.

I was fortunate enough to have such a role in the PRO-ACT study. PRO-ACT (Patient-led Research on sexual experience After Cancer Treatment), was funded by the Irish Cancer Society, and undertaken in partnership with Cancer Trials Ireland. The study revealed that a significant majority of prostate cancer patients feel under-prepared for the treatment's impact on their sexual function. This study (a survey of 1,150 prostate cancer patients and their partners) revealed recurring themes: the shock of diagnosis; being unprepared for treatment decisions and impacts of therapy; struggling with sexual dysfunction and urinary incontinence; relationship issues; mental health problems; and, sadly, some end-of-life discussions as well.

My hope is that its findings can inform the review of Ireland's National Clinical Guidelines on Prostate Cancer. That was also the wish of my former co-PCC member, Siobhan Gaynor, who co-led a survey of people with metastatic breast cancer. Studies like these demonstrate the impact that patients and patient advocates can have.

Finally, I want to close by acknowledging the strides being made across the cancer research community: the structures being established, the councils and committees formed and functioning, and the recommendations being developed and implemented.
But I also want to underscore the urgency with which this work must proceed.

When clinical trials are delayed, patients miss opportunities to access potentially life-changing treatments. The consequences can be devastating.

I look forward to working with the Board of Cancer Trials Ireland and the wider cancer research community in the years ahead.

Martin Sweeney

Incoming Chair of Cancer Trials Ireland's Patient Consultants Committee

When clinical trials are delayed, patients miss opportunities to access potentially life-changing treatments. The consequences can be devastating.



Irish Cancer Society

Investing in research, investing in patients:
Dr Claire Kilty, Head of Research at the Irish Cancer Society.

At the Irish Cancer Society, we believe research is one of the most powerful ways to improve outcomes for people affected by cancer. As Ireland's largest voluntary funder of cancer research, we support research across the entire cancer continuum, from prevention and early detection to treatment, clinical trials, and survivorship. Each year we invest approximately €4 million in world-class cancer research aimed at improving both survival and quality of life. In 2025, that investment funded 25 new projects and supported more than 135 cancer researchers across the country.

A cornerstone of that commitment is Cancer Trials Ireland. We have funded Cancer Trials Ireland since the late 1990s, with annual core funding dating back to 2012, and have provided more than €8 million since then. In 2021, following a hugely successful Daffodil Day, we doubled our funding for Cancer Trials Ireland. Today, €1 million each year supports Cancer Trials Ireland, and at the Cancer Trials Ireland Cancer Retreat 2026 we announced the renewal of our partnership at €1 million per year for the next three-plus years.

We make this investment because we want patients in Ireland to benefit from world-class research and expertise and to have access to the best possible treatments and care. Our ambition, which I know is shared by the wider clinical oncology research community, is that every person diagnosed with cancer who is eligible for a trial should have the opportunity to participate in one.

Not every clinical trial has, or can have, a commercial sponsor. While many drug trials are funded by the pharmaceutical industry, academic-led studies often struggle to attract industry investment. That is why the Irish Cancer Society funds a broad range of cancer research, including studies in radiotherapy, surgery, technology, psycho-oncology, exercise and nutrition. Through our recent Clinical Trials Seed Funding Award, we specifically invited applications for non-regulated interventional studies because we want people affected by cancer across the island of Ireland to have access to a diverse portfolio of world-class cancer trials and research opportunities.

The results are already reaching patients. At our 2026 Research Awards, a team from the St Luke's Radiation Oncology Network, led by Prof Sinead Brennan, won our Clinical and Translational Project of the Year for a trial supported through our €1 million investment in Cancer Trials Ireland. Using surface-guided radiotherapy, the team showed that open-faced masks deliver the same treatment precision as traditional closed masks, while significantly reducing patient distress.

Charitable funding cannot do this alone. We need a long-term national funding model that supports the full spectrum of cancer clinical research across Ireland. None of this would be possible without the generosity of the public. Every Daffodil Day donation helps bring the next trial, and the next advancement, to patients in Ireland.

EU and Irish Policy Context

Cancer clinical trials are fundamental to improving patient outcomes, advancing scientific discovery and strengthening healthcare systems. Their value extends beyond access to innovative treatments, encompassing improvements in clinical practice, research capability, healthcare efficiency and economic competitiveness. As Europe seeks to reinforce its position as a global leader in life sciences, the strategic importance of clinical trials has never been greater.

Europe faces intensifying international competition for clinical research investment. The Draghi Report highlighted the need to address regulatory complexity, fragmentation and barriers to innovation. The proposed EU Biotech Act and Accelerating Clinical Trials in the EU (ACT EU) initiative represent important steps towards simplifying clinical trial processes, strengthening cross-border collaboration and improving Europe's attractiveness as a destination for research investment.

Ireland is responding to this evolving landscape with renewed national ambition. The recommendations of the National Clinical Trials Oversight Group (NCTOG) provide a blueprint for strengthening Ireland's clinical trials ecosystem, including streamlined processes, improved trial activation timelines and greater national coordination. Of particular significance, Recommendation 11 calls for clinical trial activity to be formally recognised, tracked and prioritised at corporate level across the Health Service Executive (HSE) and regional health structures. This represents an important shift towards embedding clinical research as a core component of healthcare delivery, with greater organisational accountability, visibility and strategic prioritisation.

The establishment of the Clinical Trials Advisory Council (CTAC), chaired by Prof Donal Brennan, in 2026 represents a further step towards implementing national reform and developing a more coordinated, efficient and competitive clinical trials environment. Ireland's Presidency of the Council of the European Union in 2026 further reinforced this ambition, placing clinical trials, innovation and equitable medicines access at the centre of European policy discussions.

For cancer patients, these developments offer opportunities for earlier access to innovative therapies, optimisation of existing treatments and improved standards of care. They also strengthen Ireland's potential to attract international investment and develop sustainable research capacity.

Against this backdrop, Value of Cancer Trials 2 examines the clinical, societal, health-system and economic contribution of cancer trials in Ireland, providing an evidence base to support their formal recognition, strategic prioritisation and sustained investment as an integral component of healthcare delivery and Ireland's future competitiveness.

Principal Investigator (PI) Interviews - Structural and systemic issues

Findings from qualitative interviews

Clinical Trial Landscape & Operational Challenges

Between August and October 2026, Cancer Trials Ireland commissioned Ipsos B&A to conduct qualitative research interviews with nine Principal Investigators working in Ireland - four consultant medical oncologists; two consultant radiation oncologists, one consultant surgical oncologist and two consultant haematologists. Each 30-minute interview explored a range of issues relating to experiences of recruiting patients onto trials, and the obstacles to same, whether due to patient attitudes, trial design, PI capacity, site capacity, or wider structural / systemic issues.

This section summarises interviewees' views on structural and systemic issues, highlighting where implementation of NCTOG recommendations through CTAC could help address the challenges identified.

Responses about patient attitudes are included in a later section of the report, where they are complemented with additional quantitative research undertaken by Cancer Trials Ireland.

1. Research as an add-on

Interviewees described research as being treated as an add-on rather than a core part of the health service. Whether at hospital, HSE or regional level, trials are seen as an added extra rather than an integral part of cancer care. Research is overshadowed by service metrics such as waiting lists and throughput, and it lacks the protected time, institutional support, key performance indicators and accountability structures applied to routine clinical work. Interviewees said there is very little incentive or support to do this work. Clinical workload also competes with research: protected time is under pressure from growing service demands, so research activity continues to depend on individual commitment.

NCTOG Recommendation #11: Incorporate mandatory clinical trial performance metrics and KPIs within the reporting system to ensure that the importance of clinical trial activity is recognised at a corporate level throughout the Irish health service.

2. Workforce
Workforce was identified as a major constraint. Research nurses were described as indispensable, and data managers, pharmacists, research coordinators and administrative staff are also in short supply. Retention is particularly difficult in Dublin, where housing, commuting and parking costs, and competition for staff, are factors, and the work cannot be done remotely. Temporary contracts, uncertain funding and the approaching retirement of long-serving trial staff threaten continuity. Interviewees linked staffing shortages directly to the number of patients who can access trials. Staffing also determines how far trials are built into routine care. The gold-standard model has research nurses attending both MDTs and clinics; systematic screening works best in well-resourced units and becomes more variable when staff are stretched, and routine trial consideration was most evident within research-active teams rather than across the wider hospital.

NCTOG Recommendations #16–19: workforce data, career pathways, training, and attracting and retaining staff.

3. Reliance on individuals
Research activity relies heavily on individual investigators, research nurses and local champions. When asked how trial opportunities come about, interviewees frequently identified themselves as the driving force, with studies typically progressing because an investigator puts their hand up. Personal relationships and investigator reputation help attract studies. Interviewees expressed concern about succession planning and where future investigators will come from. Reliance on committed individuals was described as both a strength and a vulnerability. One interviewee described PIs as a "dying breed" because the complexity of running trials is increasing while the incentive to be a PI is decreasing. Interviewees supported mentoring structures to develop the next generation of investigators.

NCTOG Recommendation #19: Develop strategies to attract new talent and retain existing staff by promoting supportive and rewarding work environments.

"It is very much driven by individuals."

> **"Every week that a trial is not open is another patient that could have gone on that trial."**

4. Slow activation
Improvements in ethics and governance were acknowledged, but studies still take too long to open, with weeks or months lost between decisions. Governance requirements, regulatory approvals and study set-up were described as time-consuming, resource-intensive and administratively demanding. In some cases Irish centres open international studies as they are about to close globally, leaving Ireland a shorter recruitment window than other countries. Delays matter most in rare cancers, biomarker-selected populations and radiotherapy studies, where options are fewer. Interviewees saw faster activation as potentially more effective than efforts to encourage patient participation. Delays also affect individual patients: those with aggressive or rapidly progressing disease may become too unwell to remain eligible while activation, screening and enrolment run their course.

NCTOG Recommendations #3 and #5: Development of a universal trial contract template and national guidance that provides clear guidance on designated officer sign-off for clinical trials.

5. Eligibility
Eligibility was described as the rate-limiting step, limiting participation more often than patient willingness. More patients express interest than qualify. Some modern cancer studies require 20–40 separate eligibility criteria, and complex criteria, particularly in industry-sponsored studies, exclude older, frailer or more complex patients whom clinicians would be comfortable treating in routine practice. Screen failures on biomarker, performance status or other protocol criteria are common. Broader, more pragmatic criteria were seen as an opportunity. Few interviewees described systematically tracking why patients screen-fail or decline.

> **"That is the limiting step, eligibility."**

> **"We're a small country here, so working within a big network is very valuable to us."**

6. Growth, progress and potential
Despite these constraints, most interviewees described substantial growth in clinical trial activity over the course of their careers, with larger portfolios, stronger infrastructure and more national collaboration. One interviewee noted that work which began with them alone is no longer dependent on a single person. Ireland was seen as making an important contribution to international research despite its size. Access to many studies depends on cooperative groups, conferences and international partnerships, and working within larger networks was described as particularly valuable for a small country. Interviewees believed Ireland could deliver more research, conditional on addressing workforce, operational efficiency and infrastructure.

The National Office for Research Ethics Committees (NREC) was viewed as a major improvement, particularly for multi-centre, industry-sponsored studies. Approval timelines for academic, translational and investigator-led studies remain more variable, and contracting, governance, staffing and operational delays persist.

7. Variation by tumour type, centre and region
Research maturity varies by tumour type. Breast cancer was described as having a well-developed research ecosystem, while smaller tumour areas, including rarer haematological conditions, rely more heavily on international collaboration and are more affected by restrictive eligibility because patient numbers are small. Trial availability also varies between centres and regions, so the opportunities open to a patient can depend on geography and local research capacity. Many trials are concentrated in major centres, which particularly affects patients in rural areas, and a willing, eligible patient cannot take part if no suitable study is open locally.

8. Fragmented national landscape
A small number of interviewees described a fragmented landscape of hospitals, cancer centres and organisations, and wanted greater national alignment across hospitals, research networks, NCCP initiatives and industry partners. They saw Cancer Trials Ireland as a potential unifying force; one suggested the NCCP should recognise Cancer Trials Ireland as its clinical trials wing.

9. Digital infrastructure
Digital infrastructure varies between centres. Some have mature electronic health records; many rely on manual screening through MDT review and clinic lists. Integrated patient databases, automation and AI-enabled approaches were seen as future enablers that would reduce paperwork and free staff time for patients.

NCTOG Recommendation #20: Ensure that the technological solutions for Electronic Health Records will enable all aspects of clinical trials and promote the use of Innovative Technologies in the design of clinical trials research.

10. Where the constraints fall
The report summarises the trial pathway as constrained at four points: activation and approvals (administrative delays), site capacity (limited protected time), research staffing (nurses, data managers, pharmacists) and patient eligibility (restrictive criteria). By contrast, patient recruitment itself was described as generally less problematic than assumed: where patients are eligible and have had a good conversation with their clinician, most agree to take part. Interviewees warned that raising awareness does not by itself create trial opportunities: capacity, activation and access need to keep pace, or demand could outstrip the trials available and leave ineligible patients disappointed.

11. Patient documentation and language support
Patient information leaflets and consent packs were described as increasingly lengthy because of regulatory requirements. The volume can overwhelm patients already processing a diagnosis, particularly those with lower health literacy. Interviewees favoured concise summaries and layered materials, and one centre had used patient representatives to improve participant materials. For patients whose first language is not English, translating study documentation and arranging interpretation add complexity and delay to enrolment.

12. Funding transition (single interviewee)
One interviewee raised a concern about radiotherapy trial funding. Unlike many medical oncology studies, which are supported by industry, radiation oncology research relies heavily on academic funding streams. HRB funding was described as accounting for at least half of radiotherapy trial funding nationally, and the planned transition to an alternative funding model raised concern about funding gaps affecting staffing, studies, recruitment and Ireland's reputation as a research partner.

NCTOG Recommendations #1 and #2: Establishment of a Clinical Trials Advisory Council (CTAC) to manage the transition process required to oversee the establishment of a National Clinical Trials Body.

Ireland's Performance - Clinical Trials Activity

Ireland has made encouraging progress in clinical trial activity in recent years. However, despite these improvements, Ireland continues to lag behind many European counterparts in attracting clinical research.

According to the Irish Pharmaceutical Healthcare Association (IPHA) Clinical Trials Activity Comparison Report 2026, 73 pharmaceutical industry-sponsored clinical trials (across oncology / non-oncology) opened in Ireland in 2025, compared with 51 in 2024 and 41 in 2023. This represents a 44% increase between 2024 and 2025.

	2023	2024	2025
NO. OF CLINICAL TRIALS	41	51	73
AVERAGE TIME FROM EU APPROVAL (FD) TO TRIAL START DATE IN IRELAND (FSR)	262	231	168
AVERAGE TIME FROM TRIAL START DATE IN IRELAND (FSR) TO FIRST PATIENT RECRUITED	56	59	46

TABLE 1: NUMBER OF TRIALS AND START-UP TIME, FOR TRIALS COMMENCING IN 2023–2025 IN IRELAND

Source: IPHA Clinical Trials Activity Comparison Report – March 2026

Despite this growth, Ireland ranked 14th of 27 EU member states for industry-sponsored clinical trials per capita in 2025, improving from 18th in 2024. Countries such as Denmark continue to attract substantially more clinical trial activity.

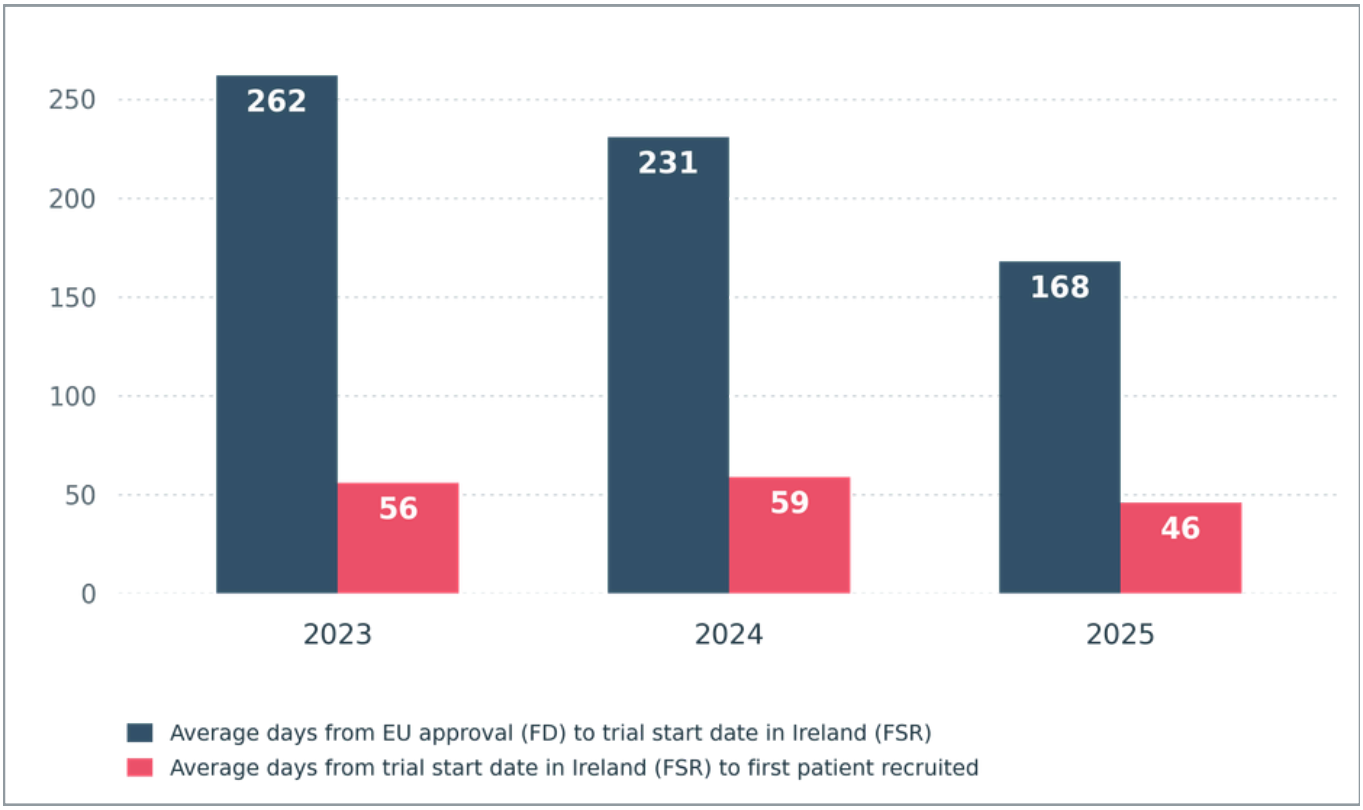
2025 trials commenced (all disease areas)	Change since 2024	EU ranking per capita
73	+44%	14 of 27 (up from 18th)

Independent analysis in the OECD Ireland Country Health Profile 2025 likewise places Ireland below the EU average for registered cancer clinical trials relative to population. Ireland's established pharmaceutical sector and clinical expertise provide a foundation on which to build, but improving efficiency and predictability remains essential to attracting additional international trial activity.

Start-Up Timelines

The IPHA 2026 report also identified a median interval of 213 days between EU regulatory approval and first site readiness for trials commenced during 2023–2025, with the annual figure falling to 168 days for the 2025 cohort. Although the measures describe different intervals, they reinforce the need to improve the whole start-up pathway, including the period before regulatory submission.

Time to 'First Patient In' and 'Final Decision to First Site Ready' in Ireland 2023-2025



Source: IPHA Clinical Trials Activity Comparison Report – March 2026



Responding to Industry — Why Start-Up Times Matter

"What are your start-up times?"

For pharmaceutical companies assessing where to open clinical trials internationally, Ireland's clinical expertise and research capability are acknowledged, but are only part of the decision. The time taken to open a study, and the predictability of that timeline, are critical considerations.

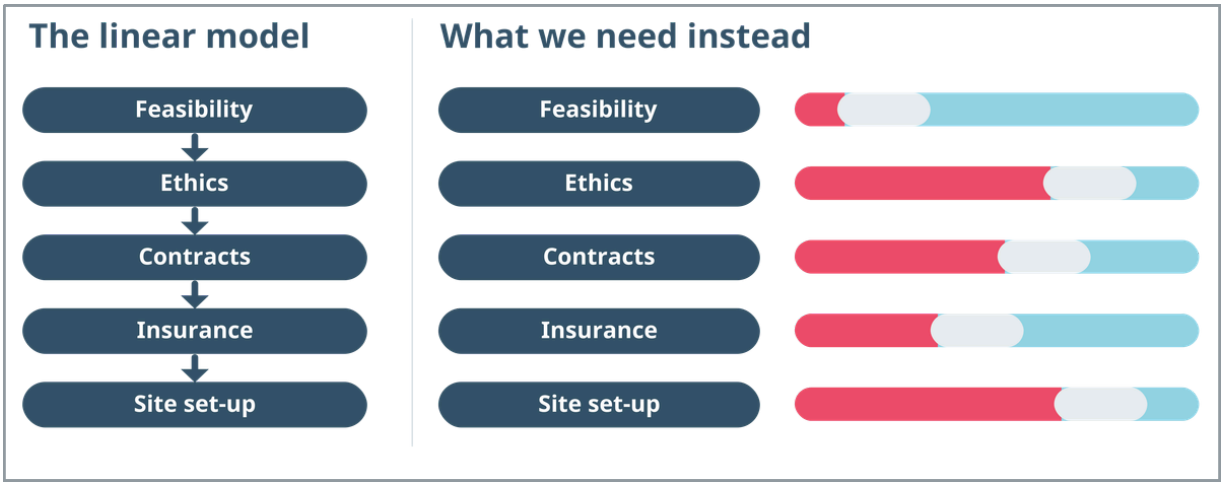
This message was reinforced through Cancer Trials Ireland's ongoing engagement with pharmaceutical industry representatives, where start-up timelines repeatedly emerge as a key global-level consideration in assessing Ireland as a destination for clinical research.

Cancer Trials Ireland's operational response

Cancer Trials Ireland established a dedicated Start-Up Team in December 2024, bringing greater coordination to the activities needed to open studies.

Throughout the last 12 months, Cancer Trials Ireland has continued to develop earlier multidisciplinary engagement, milestone tracking, streamlined contractual processes and closer operational coordination.

- Earlier identification of contracting, governance, insurance and operational dependencies.
- Greater coordination of budgets, ethics and regulatory preparation, and site readiness.
- Identifying which processes genuinely depend on preceding activities, and which can safely progress in parallel (represented on sliding bar below).
- Improved visibility of ownership, milestones and potential delays.



The aim is to reduce avoidable waiting time while maintaining appropriate regulatory, governance and patient-safety protections. Cancer Trials Ireland recognises that many remaining barriers require national collaboration beyond internal process improvements.

Delivering Measurable Start-Up Improvements

Cancer Trials Ireland's dedicated Start-Up Team has continued to improve the efficiency of clinical trial activation. The latest completed quarterly figures within the reporting period show encouraging improvements in both site agreement turnaround and ethics approval-to-activation intervals.

KPI	Q4 2025 median	Q2 2026 median	Change
Site agreement issued to executed	73 days	25.5 days	65% reduction
Ethics approval to site activation	229 days	156 days	32% reduction

Between Q4 2025 and Q2 2026, median site agreement turnaround fell from 73 to 25.5 days, a 65% reduction. Over the same period, the median interval between ethics approval and site activation fell from 229 to 156 days, a 32% reduction.

NCTOG Recommendation #6: Develop a comprehensive, user-friendly, open-access dashboard to aid accountability, which regularly publishes updates on an initial list of agreed Key Performance Indicators (KPIs) to monitor and report on clinical trials activity metrics.

These figures demonstrate encouraging progress and the value of focused start-up coordination. Further work remains, particularly in reducing the wider activation interval and addressing dependencies that sit outside Cancer Trials Ireland's direct control.



From Operational Improvement to National Leadership

National Site Start-up Timelines Working Group

Recognising that many delays to trial activation arise from processes involving multiple organisations, Cancer Trials Ireland established a **National Site Start-up Timelines Working Group** in Q3 2026, supporting the ambitions of the NCTOG recommendations.

NCTOG Recommendation #7: Develop a unified model for clinical trial delivery which harmonises infrastructures to drive efficiency, expertise and excellence and optimise impact for state investments, including activity-based funding and strategic partnerships.

The group brings together representatives from Cancer Trials Ireland, clinical investigators and site-based research professionals with practical experience of activating trials. The objective of the working group is to identify barriers and opportunities.

Initial Programme

- Commence mapping Cancer Trials Ireland and site-level start-up processes.
- Map baseline performance across participating sites and identify key bottlenecks.
- Identify opportunities to undertake independent activities in parallel.
- Agree further stakeholders for engagement, including the HSE National R&D Office and additional site personnel.

The programme is intended to inform the development and piloting of an accelerated start-up pathway with measurable deliverables and outcomes. These are future objectives, rather than completed outputs within this reporting period.

Through this work, Cancer Trials Ireland is bringing experience from the practical delivery of trials into a coordinated national improvement effort.

Addressing Practical National Bottlenecks

The National Site Start-up Timelines Working Group's practical focus is reflected in early engagement on specific barriers that can delay trial activation. Cancer Trials Ireland has sought to work with the relevant organisations and systems to develop solutions with potential application across sites.

NCCP / National Cancer Information System (NCIS) - clinical trial prescription builds

Cancer Trials Ireland identified clinical trial prescription builds as a recurring bottleneck to site activation and initiated engagement with NCCP on a more consistent national pathway. The objective is to reduce duplication, increase predictability and facilitate more efficient preparation across participating sites.

By Q3 2026, initial engagement had been undertaken and a national pathway is under development.

AON - Clinical Indemnity Scheme (CIS) cover confirmation

Cancer Trials Ireland engaged with AON to explore a streamlined confirmation process that allows earlier contact and preparation. The aim is to keep the time between approval in the Clinical Trials Information System (CTIS) and release of CIS cover confirmation as short as possible. By Q3 2026, process streamlining had been implemented.

NCTOG Recommendation #8: Review and optimise models of indemnity for clinical trial activity.

Parallel preparation during ethics review

Cancer Trials Ireland and participating sites also began examining how contracting, insurance preparation and operational readiness can progress during the ethics review period at individual sites, where appropriate, rather than waiting until approvals have issued.

NCTOG Recommendations #3 and #8: Development of a universal contract template / review and optimise models of indemnity for clinical trial activity.

Together, these examples demonstrate Cancer Trials Ireland's national leadership and its willingness and ability to address practical barriers to start-up through earlier engagement, more consistent national processes, and closer coordination across organisations.

Strengthening National Research Infrastructure

Working collaboratively with the HSE National Research and Development Office

Alongside its efforts to improve regulated clinical trial start-up, Cancer Trials Ireland continues to work closely with the HSE National R&D Office to support efficient and consistent research processes across study types.

During the reporting period, Cancer Trials Ireland collaborated with the HSE National R&D Office on developing standardised agreement templates for non-regulated studies, intended for use across HSE sites nationally. The aim is to reduce duplication in contractual review, promote consistency and simplify research contracting.

NCTOG Recommendation #3: Universal clinical trial contract template should be developed for Ireland.

A contribution across all study types

While regulated clinical trials are central to the national competitiveness challenge, many operational barriers, including contracting, governance and site-level coordination also affect non-regulated studies. Cancer Trials Ireland's approach is to apply proportionate, coordinated processes across its research portfolio.

Cancer Trials Ireland continues to explore opportunities to strengthen this national working relationship. A more formalised relationship remains an area for potential future engagement, although no such arrangement has yet been agreed.

If Cancer Trials Ireland were formally designated as a national client of the Health Service Executive's National Research Legal and Data Protection Office, it would enable a coordinated national approach to contracting and data protection reviews for the multi-site clinical trials that Cancer Trials Ireland sponsors, reducing duplication across participating hospitals and supporting more efficient study activation.

Through operational improvements, national coordination and collaboration with the HSE, Cancer Trials Ireland is contributing to a more efficient and sustainable research environment, with the ultimate objective of improving access to cancer research for patients in Ireland.

What the Cancer Trials Ireland Community Has Achieved - Recruitment

Cancer Trials Ireland continues to support cancer research across Ireland, spanning regulated interventional clinical trials and a broad range of other research studies. Accruals are reported by sites each month and recorded by Cancer Trials Ireland to provide data on overall national accruals.

Patient Recruitment by Study Type

The following data presents recruitment by study type during the reporting period, as provided by sites. Annual accrual figures are validated by sites at the beginning of each subsequent year, therefore, while Sept-Dec 2025 have been validated, it is expected that final Jan-Aug 2026 figures will vary slightly from totals included in this report. Figures shown in the tables below represent the most accurate information available to Cancer Trials Ireland at time of this report.

Interventional trials include regulated (IMP/IVDR) and non-regulated (radiotherapy, surgery, exercise, nutrition). Non-interventional includes all other studies (e.g., translational, registry, observational, survey etc).

Of the 702 patients on interventional trials, 423 patients were accrued to IMP trials, representing 2,623 patient months receiving SOC/IMP.

ACCRUALS TABLE BY STUDY TYPE: 1st SEPT 2025 TO 31st AUG 2026

STUDY TYPE	Accruals
Total participants	3,938
Patients on interventional trials	702 (423 on IMP trials)
Patients on non-interventional trials	1,840
Participants in Beau-RCSI Lung Health Check	1,396

Patient Recruitment by Cancer Type - DSSGs

A key differentiator for Cancer Trials Ireland is its coordination of national **Disease Specific Sub-Groups** (DSSGs), which bring together multidisciplinary clinical leaders, investigators, researchers, and healthcare professionals across all major tumour streams. The DSSGs represent the cancer research community, providing Cancer Trials Ireland with unparalleled access to national clinical expertise, investigator engagement, and patient pathway insight. They create an integrated national network capable of rapidly assessing feasibility, identifying appropriate sites and investigators, supporting protocol optimisation, and accelerating study activation. This infrastructure is highly attractive within the current research environment, where sponsors increasingly value bespoke access to coordinated specialist networks rather than fragmented site-by-site approaches.

The following figures represent patients accrued to each of the 10 DSSGs, based on the most accurate information available to Cancer Trials Ireland at the time of this report.

ACCRUALS TABLE BY DSSG / CANCER TYPE: 1st SEPT 2025 TO 31st AUG 2026

DSSG	Accruals
Basket	693
Breast	787
CNS	27
Gastrointestinal	44
Genitourinary	294
Gynae	36
Head & Neck	12
Lung	80 plus 1,396 Beau-RCSI Lung Health Check
Lymph & Haem	392
Melanoma	25
Paediatrics	152

Feasibilities

Clinical Trial Feasibility in Ireland

Cancer Trials Ireland's contribution is its ability to draw on a national network of cancer specialists to provide companies with informed assessments of Ireland's suitability for proposed clinical trials sponsored by industry. These feasibilities commonly require consultation with specialist investigators regarding detailed clinical assessments, estimates of eligible patient numbers and consideration of competing studies as well as information about the Irish regulatory framework.

The Steps

- A pharmaceutical company or their appointed Contract Research Organisation (CRO) approaches Cancer Trials Ireland (or sites directly) to establish whether a proposed trial could be conducted in Ireland. The company generally provides a feasibility questionnaire describing the study and the information required.

- Cancer Trials Ireland reviews the proposed study and identifies the relevant Disease Specific Sub-Group (DSSG), e.g. breast / lung / lymph & haem. Multiple DSSGs may be relevant for trials targeting tumours with particular molecular characteristics.

- Cancer Trials Ireland contacts the relevant DSSG Chair(s). The DSSG Chair may consult investigators at hospitals across Ireland for some specific information or Cancer Trials Ireland will contact the relevant investigators.

- Initially feasibilities are usually conducted at the country level, proceeding to site level if the country-level assessment indicates Ireland as a suitable location for the trial. Cancer Trials Ireland is commonly involved in coordinating country-level feasibility assessments. Site-level assessments are frequently conducted directly by companies or their appointed CROs with individual sites, with Cancer Trials Ireland supporting communications with investigators/sites.

- Depending on the information provided from the sponsor, at country level the DSSG chair assesses study design, patient population, assessment requirements, e.g. specific biomarker testing availability, investigational medicinal product (IMP) mechanism of action, availability of standard of care IMPs in comparator arm(s), competing studies, overall country expertise and capability, recommended (specialist) sites and estimated patient numbers.

- At site level, investigators and their teams assess study design, eligibility criteria, required assessments, IMP, competing studies and site capabilities including clinical expertise and resource. They also provide their site-level assessment of estimated patient numbers.

- Cancer Trials Ireland returns completed country-level assessments to the company/CRO, enabling the company/CRO to make a robust, informed decision on selection of Ireland to proceed to site-level feasibility. Cancer Trials Ireland actively supports sites in completing and returning the required feasibility assessments by communicating key timelines, sending reminders, tracking progress, and following up as necessary.

- Cancer Trials Ireland records the enquiry, key dates and responses, and monitors whether the trial subsequently progresses towards opening in Ireland.

- Industry trials that open in Ireland are thereafter adopted into the Cancer Trials Ireland portfolio which ensures that the trial progress is reviewed at regular intervals through the relevant DSSG(s) supporting accrual, referrals, trouble-shooting and any required action planning including communications to trial sponsors.

Different types of feasibility

- **Direct industry enquiries:** Pharmaceutical companies and/or Clinical Research Organisations (CROs) approach Cancer Trials Ireland, which coordinates country-level or site-level assessment through the relevant DSSG Chair(s) and/or site network.

- **Contract Research Organisations (CROs)**: CROs may initially ask Cancer Trials Ireland to identify suitable investigators and hospitals, before conducting detailed site-level feasibility assessments directly with those sites on behalf of a company.

- **For academic/ non-commercial collaborative group trials and Cancer Trials Ireland - sponsored Investigator-Initiated Trials (IITs) and external collaborative group trials**: Cancer Trials Ireland develops its own feasibility questionnaires, with the process managed by DSSG Operations Leads.



Feasibility enquiries, Sep 2025 – Aug 2026 **n = 22**

Category	Number	% of 22	Share
FEASIBILITY LEVEL			**Total 22**
Country-level	9	41%	
Site identification	8	36%	
Site identification / site-level support	4	18%	
Site-level	1	5%	
DISEASE AREA			**Total 22**
Breast	2	9%	
GI	6	27%	
GU	2	9%	
L&H	3	14%	
Lung	7	32%	
Multiple	2	9%	
SPECIFIC DISEASE AREA			**Total 22**
CLL/SLL	1	5%	
Colorectal	2	9%	
Gastric / gastro-oesophageal junction	1	5%	
Mastocytosis	1	5%	
Multiple myeloma	1	5%	
NSCLC	7	32%	
Pancreatic	2	9%	
Prostate	2	9%	
Urothelial	1	5%	
Not specified	4	18%	
CONVERTED TO STUDY			**Total 22**
Yes	7	32%	
No	4	18%	
Decision pending	6	27%	
Pre-study assessments ongoing	1	5%	
Unknown	4	18%	
ENQUIRY FROM			**Total 22**
CRO	10	45%	
Pharma company	12	55%	

Source: Feasibility summary, September 2025 – August 2026 (Summary tab). Percentages are rounded.

Savings & Investments Associated with Cancer Clinical Trials

How do cancer clinical trials generate savings for the State?

Whenever a patient enrolls 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 multiple trials, we can produce a figure that is strongly indicative of savings the state enjoys by sites enrolling patients onto cancer clinical trials. There are significant limitations with this approach. Planned study duration per patient may change. For example, patients may voluntarily withdraw from a trial or discontinue treatment. Additionally, the actual price paid by the HSE for Standard of Care treatments is, quite correctly, a confidential, commercially sensitive matter, negotiated with individual pharmaceutical companies.

On that basis, this Report has taken care to make conservative estimates. In spite of the limitations, we assert that the exercise is valuable, because it continues 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.



Source of prices
Cancer Trials Ireland generated estimates using costs derived from one of four sources:

- *HSE: Complete list of High Tech Products by Non-proprietary name as at 1st Sept 2026*
- *National Centre for Pharmacoeconomics Guidelines for Inclusion of Drug Costs in Pharmacoeconomic Evaluations*
- *Cancer Drugs Approved for Reimbursement (HSE)*
- *Where Irish prices could not be found, the NHS drug cost site: dm+d browser*

Trial schedules and SOC regimens were identified through (redacted) protocols that trial sponsors upload to the CTIS system.

A note on inward investment / IMP prices
Given that the majority of IMPs used in trials examined are not yet available in Ireland, prices were sought in Europe, the USA and globally. Acknowledging the high prices of medicines in the USA, any investment estimate based on a US price was multiplied by 0.66 to arrive at a more realistic price for Europe / Ireland. Unlike with SOC treatments (where estimated prices could be identified in the vast majority of cases) there was no price available for a significant portion of the IMPs identified in trials open in Ireland. This helps to explain the significant shortfall between Cancer Trials Ireland's estimated inward investment figure, and the Transfer of Value figure under Research & Development as identified by the Irish Pharmaceutical Healthcare Association (IPHA).

Estimated savings (standard of care) €6.51m plus estimated Inward Investment (new drug) €6.76m

Of the 423 patients in the reporting period who were accrued to 70 IMP trials, Cancer Trials Ireland was able to obtain estimated savings and inward investment for 38 of these trials (230 patients, 1,402 patient months).

The total estimated savings from 38 trials, and inward investment from only 20 of these 38 trials is shown in the table below. It could be argued that this represents approximately 50% of the actual standard-of-care savings and 30% of the actual inward investment over the reporting period (38 and 20 trials, respectively, out of a total of 70 trials), and therefore the likely actual figures are much higher.

Trial type (DSSG)	No. of trials	No. of patients	Estimated savings – standard of care drugs (EUR)	No. of trials	No. of patients	Estimated inward investment – new drug / IMP (EUR)
Lymph & Haem	8	74	€1,391,990	4	46	€3,282,654
Lung	11	45	€2,034,539	8	37	€1,296,560
GI	3	9	€147,918	2	3	€218,591
GU	7	48	€116,487	1	1	€22,050
Gynae	5	13	€743,590	3	8	€469,134
Breast	4	41	€2,071,240	2	24	€1,475,412
Total	**38**	**230**	**€6,505,765**	**20**	**119**	**€6,764,402**

Estimated per-patient site fees in Ireland: €10.5m

Cancer clinical trials generate significant direct revenue for participating hospitals, particularly through pharmaceutical industry-sponsored investigational medicinal product (IMP) trials. Sponsors typically reimburse hospitals for trial-related activities, including patient recruitment, clinical assessments, investigations, treatment administration, data management and research staff time. These payments provide an important income stream, supporting specialist research posts, clinical trials infrastructure and the sustainability of hospital-based research programmes.

International evidence demonstrates the substantial financial value of this activity. A 2024 UK analysis, undertaken for the Association of the British Pharmaceutical Industry (ABPI), estimated average commercial trial payments of £26,311 per patient in 2022/23, equivalent to £29,051 in 2026 prices. This contributed to estimated annual commercial research revenue of £1.2 billion for the NHS in 2023. Although covering all therapeutic areas rather than oncology specifically, these figures provide a useful benchmark. Converted to euro, this equates to €34,855 in 2026 prices.

Across continental Europe, published commercial estimates suggest per-patient site fees for Phase II oncology trials ranging from approximately €10,000–€22,000 in Poland to €20,000–€45,000 in Germany, with Spain, Italy and France generally falling between these ranges. Actual payments vary considerably according to trial complexity, duration and protocol requirements.

Phase I oncology studies can command substantial per-patient payments because of intensive monitoring, pharmacokinetic sampling, repeated assessments and specialised staffing. Phase III trials may involve lower site payments per patient but generate significant aggregate revenue through larger recruitment numbers.

In Ireland, no independently verified national average per-patient hospital fee for commercial cancer IMP trials has been identified. However, previous Irish economic analysis demonstrated that one cancer trials unit generated €3 in industry income for every €1 received in grant funding, illustrating the potential financial return from investment in research infrastructure.

Taking a conservative estimate of €25,000 average per-patient hospital fee, this represents estimated annual revenue of €10.5m (based on 423 patients recruited to IMP trials between Sept 2025 and August 2026).

Importantly, hospital revenue is additional to the substantial treatment costs avoided when sponsors provide investigational medicines and associated care, as outlined elsewhere in this report. Together, these benefits reinforce the economic case for expanding cancer clinical trial activity across Ireland's hospital network.

Further Inward Investment

IPHA transfer-of-value statistics

Industry investment in R&D: Transfers of Value 2025
Pharmaceutical companies disclosed **€14.5m** in Research and Development (R&D) Transfers of Value (ToV) in Ireland in 2025, a decrease of 21% on the €18.3m disclosed in 2024. R&D accounted for almost half of all Transfers of Value disclosed in 2025 (IPHA Transfer of Value Summary Report, July 2026).

R&D Transfers of Value, 2021–2025
R&D Transfers of Value include funding for clinical trials but are not limited to clinical trials. They may also include support for observational (non-interventional) studies and other forms of health research. The figures below represent aggregate disclosed amounts only.

Year	R&D ToV
2021	€16,312,769
2022	€12,183,444
2023	€14,274,604
2024	€18,310,209
2025	€14,529,723
Total	**€75,610,749**

Sources: 2021–2024, Value of Cancer Trials (p. 13); 2025, IPHA Transfer of Value Summary Report, July 2026.

IPHA recommendations

IPHA attributes the 2025 decrease in R&D expenditure to delays in clinical trial set-up, citing findings from its Clinical Trials Activity Comparison Report 2026:

- Between 2023 and 2025, 157 clinical trials commenced in Ireland, compared with 425 in Denmark (IPHA, 20 May 2026).
- Ireland recorded the longest interval of any EU member state between EU Clinical Trials Regulation (CTR) approval and the first trial site being ready, at 213 days.

IPHA considers that these delays have directly reduced R&D expenditure and that the decline may continue. It calls for:

1. The urgent implementation of the recommendations of the National Clinical Trials Oversight Group.
2. Trial site set-up to proceed in parallel with, rather than following, EU CTR approval.

NCTOG Recommendations #1 and #2: Establishment of a Clinical Trials Advisory Council (CTAC) to manage the transition process required to oversee the establishment of a National Clinical Trials Body.



Value of Radiotherapy Trials

Savings associated with Radiotherapy studies and research

Radiotherapy clinical research studies 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 radiotherapy clinical research studies is hypofractionation, where treatment is delivered in fewer, higher-intensity sessions. This approach maintains cancer control while reducing hospital visits for patients. Hypofractionation has now been adopted widely thanks to landmark studies. Furthermore, effective cancer control through radiotherapy studies leads to downstream cost savings by reducing the need for palliative radiotherapy and other supportive interventions as patient outcomes and survival improve.

Quantifying the Economic Value of Two Radiotherapy Clinical Trials in Ireland

An Irish health-economic evaluation of two radiotherapy clinical trials, **EXPERT** and **SIMPLIFY-SABR-COMET**, has quantified the costs avoided and linear accelerator capacity released through participation in treatment optimisation studies. Using activity-based microcosting, the analysis incorporated staff time, infrastructure requirements and associated costs to estimate the economic and operational benefits of these approaches within the Irish public healthcare system.

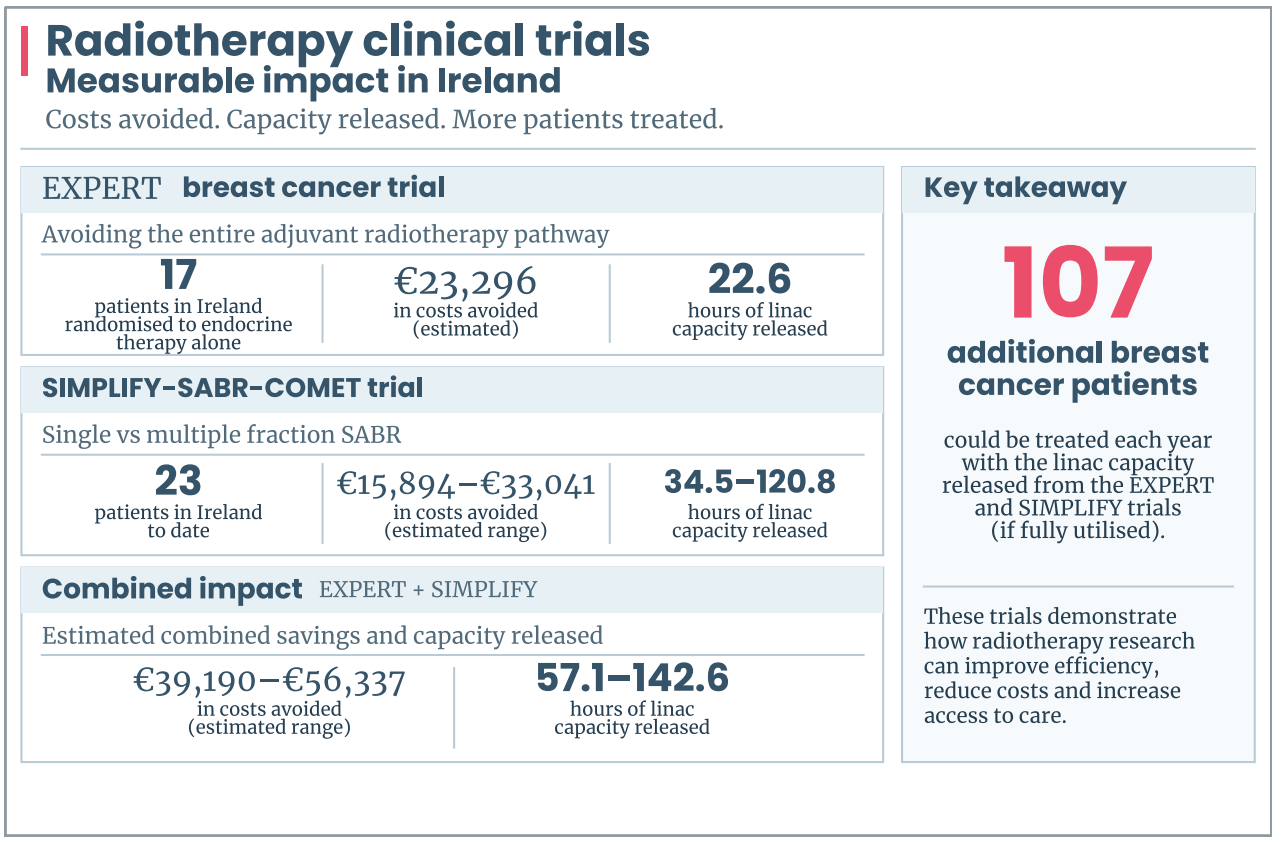
The **EXPERT Breast Cancer Study** investigated whether adjuvant radiotherapy could be safely omitted in selected women following breast-conserving surgery, comparing radiotherapy plus endocrine therapy with endocrine therapy alone. Avoiding radiotherapy eliminated the need for the entire adjuvant radiotherapy pathway, including planning and treatment delivery.

Among 17 patients in Ireland randomised to endocrine therapy alone, the analysis estimated €23,296 in costs avoided and 22.6 hours of linac capacity released. This demonstrates the potential value of research investigating whether radiotherapy can be safely omitted in appropriately selected patients, reducing treatment burden while releasing resources for other patients.

SIMPLIFY-SABR-COMET compares single-fraction with multifraction stereotactic ablative radiotherapy (SABR) for patients with oligometastatic or oligoprogressive disease. The study, open across seven Irish radiotherapy research departments, investigates whether SABR can be delivered in a single treatment session rather than across multiple visits.

SIMPLIFY-SABR-COMET retains the consultation, simulation, contouring, planning and quality assurance requirements associated with treatment. The economic analysis therefore focused on the savings attributable to omitted treatment fractions and the associated infrastructure requirements. Depending on the number of fractions avoided, estimated costs avoided ranged from €15,894 to €33,041, with an estimated 34.5–120.75 hours of linac capacity released among Irish trial participants.

Combined, the EXPERT and SIMPLIFY-SABR-COMET analyses demonstrate estimated costs avoided of €39,190-€56,337 and substantial capacity gains across Irish radiotherapy services. At the upper end of the estimated savings, the released capacity is equivalent to approximately 18 eight-hour treatment days on a single linac. Illustratively, this represents capacity for approximately 107 additional breast cancer patients receiving a five-fraction, 25Gy radiotherapy regimen, assuming the released capacity can be fully utilised.

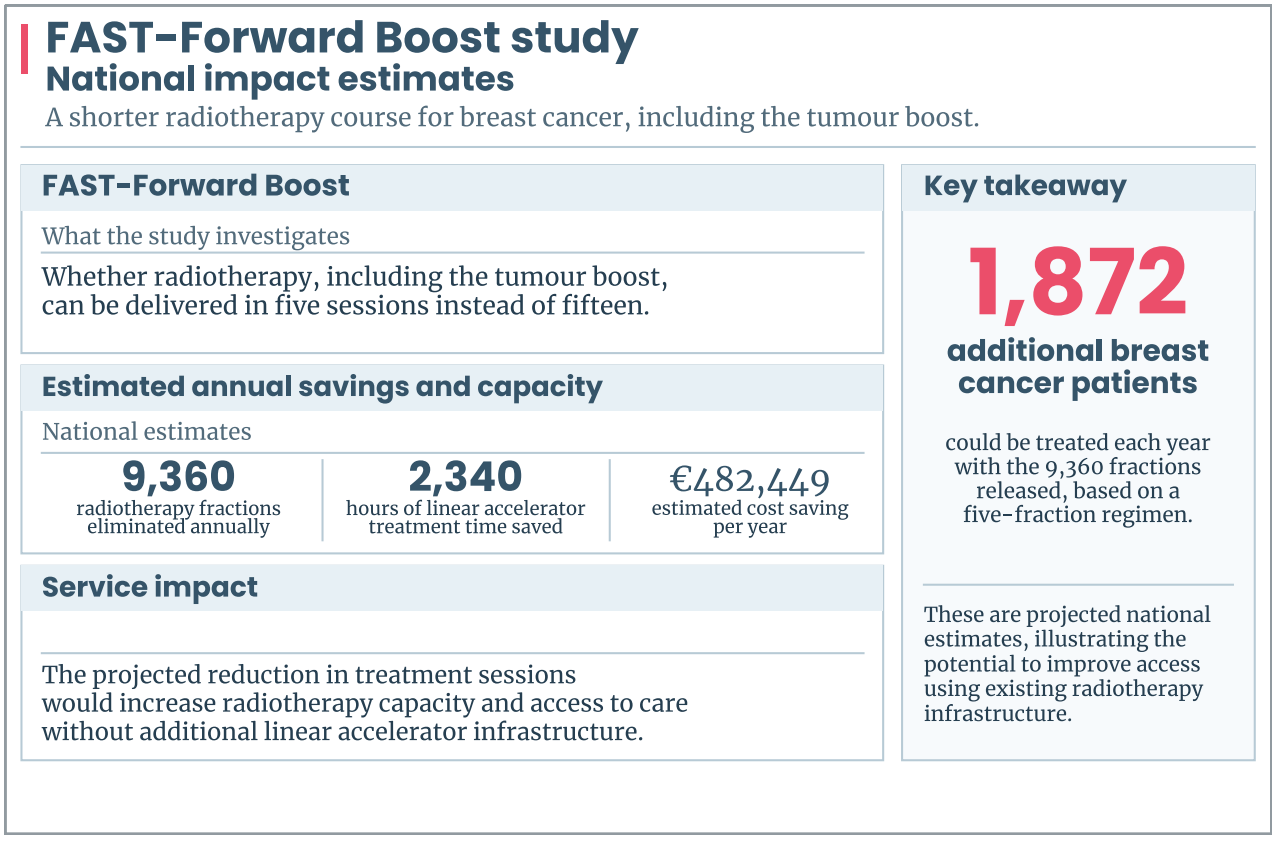


Projected National Savings and Capacity Gains from Other Radiotherapy Trials

Breast Cancer

The **FAST Forward Breast Cancer Study** demonstrated that five radiotherapy sessions provide the same benefit as fifteen to twenty-five, transforming global practice. For patients, this means fewer visits, lower costs, and less disruption to daily 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 regimen, saving an estimated €569,000 per year. The **FAST Forward Boost** Study is planned to open in Ireland in 2027. This study will test whether the radiotherapy treatment, including the tumour boost, can also be delivered in five sessions instead of fifteen.

Nationally, this approach could eliminate 9,360 radiotherapy fractions annually, saving 2,340 hours of linear accelerator treatment time and an estimated €482,449 per year. The 9,360 fractions released could provide sufficient linear accelerator capacity to treat an additional 1,872 breast cancer patients annually, based on a five-fraction treatment regimen. This illustrates how radiotherapy clinical research can increase treatment capacity and improve access to care without requiring additional linear accelerator infrastructure.



Furthermore, **PRESERVE Breast,** which opened at three Irish sites SLRON, University Hospital Galway and Cork University Hospital in September 2026, is looking at whether this shorter, one-week course of radiotherapy can be safely used for women with recurrent or a new primary breast cancer who have undergone breast-conserving surgery and radiotherapy to the breast in the past. Generally, women with this presentation are offered a 3-week course of radiotherapy. The results of this study could reduce costs for both the health service and the patient.

ROSALIE is a breast cancer study investigating the safety of omitting radiotherapy in patients who are thought to be at a low risk of tumour recurrence due to a positive response to chemotherapy and surgery. This would mean cost savings in terms of the planning and delivery of radiotherapy; travel costs for patients; and healthcare costs for the treatment of both the short-term and long-term side effects associated with radiotherapy, for example, lymphoedema.

PRADA-II is a study looking at the timing of radiotherapy for patients with breast cancer who undergo a mastectomy and are suitable for breast-conserving surgery. Generally, these patients undergo mastectomy and breast-conserving surgery followed by radiotherapy. For many patients, radiotherapy damages breast reconstructions, meaning that these women may require secondary corrective surgery with significant costs to the healthcare system. Furthermore, complications following breast reconstructive surgery can delay radiotherapy, increasing the risk of cancer recurrence. Establishing the clinical and cost-effectiveness of pre-operative radiation to improve reconstructive outcomes is a goal of this study.

Prostate Cancer

Prostate Cancer Trials including **CHHiP, PACE** and **INSPIRE**: The CHHiP and PACE studies (PACE B, PACE C and PACE NODES) 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 study investigates a ‘next-generation’ five-treatment radiotherapy schedule, with significant potential savings due to the high incidence of prostate cancer. Since opening in April 2026, 25 patients have been enrolled on the study, receiving this more innovative course of radiotherapy.

Oligometastatic Cancer

If SIMPLIFY-SABR-COMET were adopted into standard practice, treating 200 patients annually with single-fraction SABR could theoretically release approximately 400-1,400 radiotherapy fractions per year in Ireland. This additional capacity could, in theory, be used to deliver single-fraction SABR to an equivalent number of additional treatment fractions, potentially enabling a further 400-1,400 patients with oligometastatic disease to receive treatment.

In summary, radiotherapy clinical trials can deliver value beyond the generation of clinical evidence. The Irish economic evaluation of EXPERT and SIMPLIFY-SABR-COMET demonstrates how treatment omission and reduced fractionation can translate into quantifiable costs avoided and capacity released. Other ongoing and planned studies, including FAST-Forward Boost, have the potential to deliver further national savings and increase access to radiotherapy. Incorporating economic and operational evaluation into clinical research will help demonstrate the contribution of trials to sustainable cancer services, informed investment and improved patient access.

> "Combined, the **EXPERT** and **SIMPLIFY-SABR-COMET** analyses demonstrate estimated costs avoided of €39,190-€56,337 and substantial capacity gains across Irish radiotherapy services."



Potential savings from optimisation trials

What are optimisation trials?

Most clinical trials test something new: a new drug, or a new combination added to existing treatment. Optimisation trials ask a different question. They take treatments that are already approved and in use, and examine whether the dose or schedule is optimal i.e., are patients receiving treatment at the optimal dose, for the right length of time and according to the optimal schedule.

The answer may be "less would do just as well". When a cancer drug is approved, its dose and schedule are set from early studies, before anyone knows how it works across the full range of patients in the real world. The Anticancer Fund, a Belgian charity, points out that as doctors gain experience with a drug, it often becomes clear that alternative doses or schedules could deliver the same outcomes, or perhaps better, as toxicity and overall patient burden may be reduced with an optimised treatment regimen.

That is why many optimisation trials test "de-escalation": giving less treatment where it is safe to do so. At Cancer Trials Ireland's 2026 Retreat, Prof Benjamin Besse of Gustave Roussy, Paris, set out three kinds:

- **Dose**: is a lower dose just as effective?
- **Schedule:** can treatment be given less often, for example every six weeks rather than every three?
- **Duration:** can treatment safely stop sooner?

Ireland already has examples of running optimisation trials. Using the TAILORx trial results, Irish clinicians identified early breast cancer patients who could safely skip chemotherapy, and prescriptions in that group fell by 53%. The UK FAST-Forward trial showed that one week of breast radiotherapy works as well as three.
For patients, the benefits are fewer side effects, fewer hospital trips and less disruption to work and family life.

For the health system, the savings can be large. Cancer Trials Ireland's proposed collaboration on the PLANET trial estimates about €70,000 in drug savings per patient in the reduced-treatment arm.

Where changes to dose and / or schedule prove effective, the benefit of optimisation trials extends well beyond the initial trial. Savings demonstrated translate into very significant long-term savings through changes to routine clinical practice, creating recurring savings for the health service.

Pharmaceutical companies rarely fund these trials, because a study showing that less of their drug works offers them no commercial benefit. It could be argued, however, that supporting optimisation trials could open new markets for their product, as proving that less drug / a reduced schedule is equally effective brings the drug costs more within reach of countries that struggle significantly to provide cancer patients with 'best in western' medicines due to existing prohibitive costs.

The European Organisation for Research and Treatment of Cancer (EORTC) notes that work on optimisation trials has been led mainly by academic and not-for-profit groups. Other countries are now paying for optimisation trials from public funds. In the Netherlands, ten health insurers jointly fund optimisation trials of expensive drugs. The EU's Horizon Europe Cancer Mission runs funding calls for "pragmatic" trials that optimise cancer treatments.

The following are just three examples of international optimisation trials, that are open to Ireland's participation: -

1 - Breast Cancer: PLANET

What is the trial?
PLANET is an Investigator-Initiated Trial (IIT) that was developed by the Netherlands Cancer Institute (NKI). Ireland has been invited to participate in PLANET, via Cancer Trials Ireland's collaboration with the NKI. PLANET is a large trial for women and men with an aggressive type of breast cancer called triple-negative breast cancer. Before surgery, these patients receive chemotherapy along with an immunotherapy drug called pembrolizumab.
If some cancer remains at the time of surgery, patients in Ireland continue pembrolizumab treatment. They may also receive capecitabine or, if they have a BRCA gene mutation, olaparib.

Doctors do not yet know if using pembrolizumab together with capecitabine or olaparib after surgery helps patients live longer without their cancer coming back compared to using capecitabine or olaparib alone. The PLANET trial was designed to answer this question.

Why it matters

- **If pembrolizumab after surgery doesn't impact on overall survival**, patients can avoid six months of extra treatment and associated side effects, and the health service saves money

Cost savings
If 45 Irish patients join over three years (approx. 15 patients a year), this would save the state **€1.41 million** over three years, or about €472,000 a year, because 22-23 patients on the trial would not receive pembrolizumab.

2 - Melanoma: MSLT-3: The Multicentre Selective Lymphadenectomy Trial – 3

What is the trial?

MSLT-3 is a non-inferiority trial sponsored by the Melanoma Institute Australia, for people with stage III melanoma, which means the melanoma has spread to the lymph nodes. Before surgery, all patients get about 6 weeks of standard immunotherapy.

Why it matters

- MSLT-3 may establish when extensive surgery and further treatment can be avoided.
- The main question is whether patients who achieve a major pathological response following neoadjuvant immunotherapy can safely avoid extensive lymph node surgery, and also avoid additional adjuvant immunotherapy. Ireland is aiming to recruit 20 patients.

Cost savings

Of these 20 patients, it is anticipated that approximately six would not receive ongoing pembrolizumab, leading to cost savings of approx. €119,000 per patient – a saving of €714,000 for the lifetime of the trial in Ireland alone. Furthermore, when the smaller surgical operation's cost savings are taken into account (estimated at €8k per patient for 10 patients), a further saving of €80k arises, giving a total saving of €794,000.

For the health system, the savings can be large. Cancer Trials Ireland's proposed collaboration on the PLANET trial estimates about €70,000 in drug savings per patient in the reduced-treatment arm.



3 - Large B-cell lymphoma (LBCL): re-VIPRR

What is the trial?
Re-VIPRR is a HOVON-sponsored trial for patients with LBCL. About 40% of patients with this form of lymphoma relapse after first-line treatment. CAR T-cell therapy has improved outcomes, but about half of treated patients still relapse. Not all patients are eligible, and high cost limits access. A targeted five-drug combination, ViPOR, has shown strong results in one subtype of the disease. 57% of patients had a complete response, and 78% of those responses lasted at least two years (NEJM, 2024). ViPOR is expensive and is not registered or reimbursed for this use.

Why it matters

- re-VIPRR adds ritonavir, a low-cost drug that slows the body's breakdown of other medicines. This allows two of the most expensive drugs to be given at a fraction of the standard dose while reaching similar levels in the blood.
- If re-VIPRR demonstrates that for selected patients a less intensive treatment approach is equally effective, patients could avoid unnecessary treatment, toxicity and hospital visits.

Cost savings
Estimated drug cost per patient (six cycles)

- ViPOR: approx. €79,000 vs. re-VIPRR: approx. €19,000
- **Savings: minimum €60,000 per patient (roughly 75% reduction)**

The trial will recruit 48-54 patients. If the trial succeeds, it would give relapsed patients an effective targeted option at about a quarter of the drug cost, including patients who relapse after CAR T-cell therapy or are not eligible for it.



Public Attitudes to Cancer Clinical Trials & PI experiences of patients & recruitment

In 2026 Cancer Trials Ireland commissioned research into public attitudes to clinical trials and health information for the fourth time in six years. The collective findings reveal a sharp rise in public willingness to participate in cancer clinical trials over the six years since 2020, alongside an encouraging fall in unwillingness to participate, from approximately 24% to 8%.

These findings reinforce a key message emerging from the qualitative interviews conducted by Ipsos B&A with Principal Investigators: patient willingness is not the principal barrier to greater clinical trial activity in Ireland. Indeed, the quantitative findings complement many of the points investigators raised about awareness, and barriers and concerns, where the data also shows a steady albeit less dramatic rise in support.

This section of the report pairs qualitative interview findings with quantitative data generated from a recent omnibus survey of 1,000 nationally representative people (July 2026) which included a booster of 36 people with personal experience of cancer, added to the 55 encountered through the omnibus survey to provide a statistically useful sample of 91 people with cancer. The qualitative data arises from nine interviews conducted by Ipsos B&A with Principal Investigators: 4 medical oncologists, 2 radiation oncologists, 2 haematologists and 1 surgical oncologist. All qualitative answers were delivered to Cancer Trials Ireland anonymously through Ipsos B&A.

It is our hope that the data that follows proves useful to the clinical oncology research community in the coming months and years as we work together to improve the environment for opening more clinical trials.



Recruitment and Acceptance

PI interviews (qualitative): The PIs interviewed want research opportunities considered routinely for every patient and embedded in organisational culture — an aim shared across the cancer research community. One PI interviewed set out the minimum standard: "In an ideal scenario, the minute a patient walks into the hospital, they should be offered some form of research opportunity.... It should just be embedded in the structure."

Embedding is not only an aspiration; it has a direct, practical effect on how patients respond to a trial. When trials are part of the treatment conversation from the start, patients understand them as treatment: "The trial should just be another treatment option that is discussed with the patient." A trial raised early does not come as a surprise later, and it is not read as a signal that options have run out. Raised for the first time only after standard options are exhausted, the same trial is far more likely to be heard as a last chance. As one PI interviewed put it: "Clinical trials shouldn't be viewed as what you do when everything else has failed." Introducing trials early is therefore one of the most direct ways of preventing the last-resort perception.

The PIs interviewed identified trust in the treating team as the strongest influence on a patient's decision: "The trust with the doctor seems to be the top piece." Typically the consultant introduces the trial and the research nurse then explains it in detail. Patients rely on their clinician's judgement and view trials through the existing clinical relationship. Trust often outweighs concerns about side effects or uncertainty, and matters more than detailed scientific understanding. The reputation of the centre reinforces it. However, PIs interviewed noted that patients must not feel pressured: "What you do not want is duress."

Multidisciplinary team (MDT) meetings are the primary route by which patients are identified for trials. Open trials are displayed and reviewed at weekly MDTs, and research nurses frequently attend and flag opportunities. The PIs interviewed described research nurses attending both MDTs and clinics as the gold-standard model. Within research-active teams, trial consideration is part of standard care, but this is not yet the case across the wider hospital: "It should be everybody's responsibility to recruit people for trials."

Significant work takes place before a patient is approached. Research nurses pre-screen patients, coordinate eligibility reviews, explain studies and support consent, which helps ensure patients are not approached about trials that would not be relevant to them. Systematic screening works best in well-resourced units.

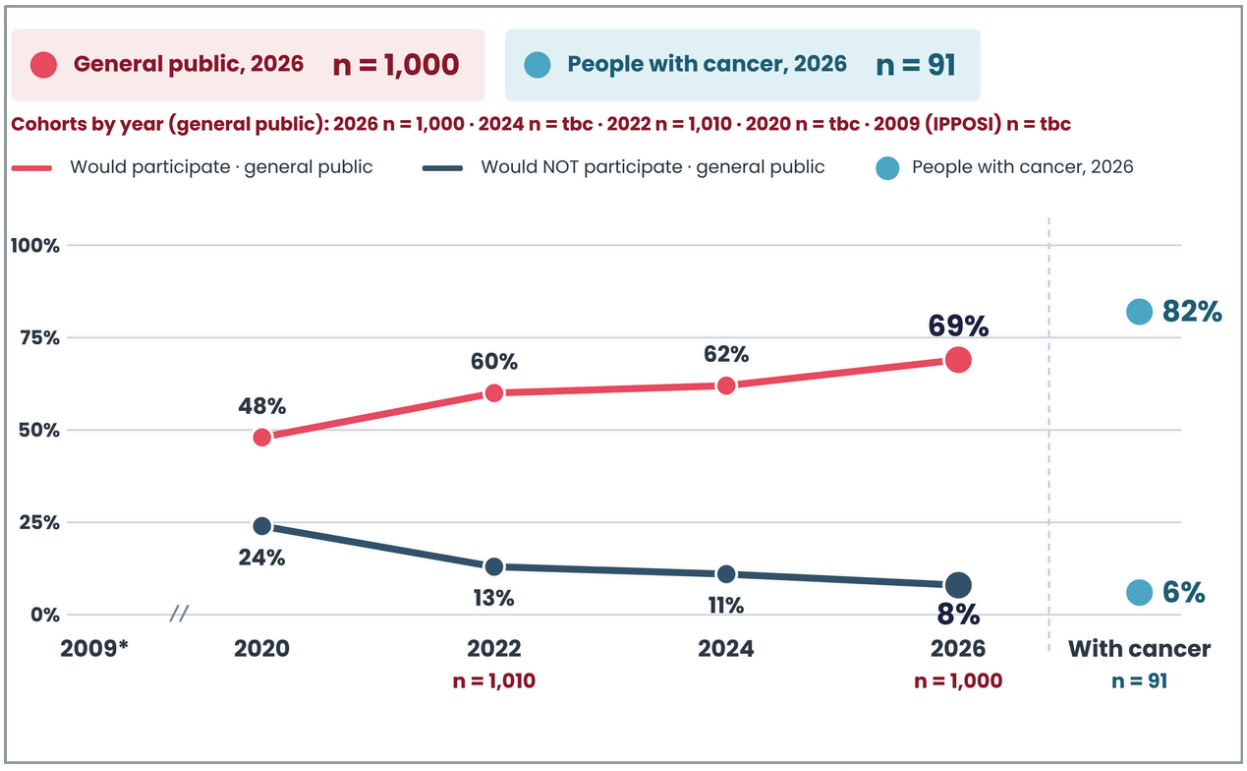
Because MDT-based screening happens before clinic appointments, trial discussions can form part of broader treatment planning, but this level of integration is difficult to achieve without sufficient research staffing, and limited protected research time alongside growing clinical workloads means research activity often still relies on individual commitment. One PI interviewed described the trial nurse as "probably one of the most important people in the whole process."

Where a suitable study exists and the patient is eligible, the PIs interviewed generally reported acceptance at approximately 50–80%: "Honestly, I think we've at least an 80% sign on." Many patients decide on the day or after a short period of reflection. Trial availability and eligibility exclude more patients than refusal does.

Patient willingness is not the limiting factor: "Most patients would be interested if there was something suitable for them."

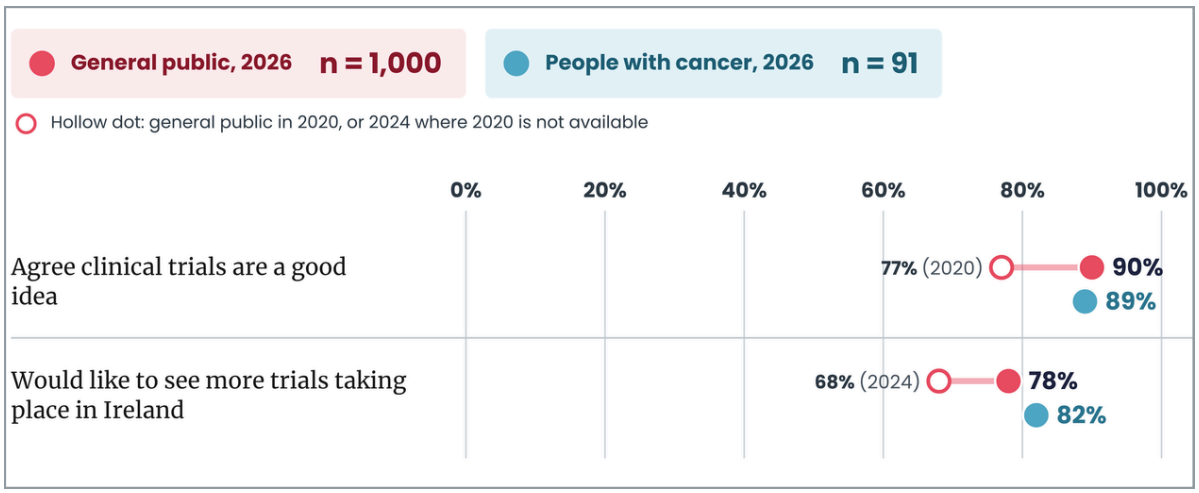
Survey data (quantitative): Survey respondents' stated willingness supports this. In 2026, 69% of the general public (n=1,000) and 82% of people with cancer (n=91) said they would be willing to take part in a clinical trial (Figure 1). 90% and 89% respectively agree that clinical trials are a good idea, and 78% and 82% would like to see more trials taking place in Ireland (Figure 2).

Figure 1. Willingness to take part in a clinical trial, 2020–2026



Source: Trial understanding & participation 2026 (updated 23.10.26).

Figure 2. Attitudes to clinical trials, 2026 (selected rows)



Source: Trial understanding & participation 2026 (updated 23.10.26).

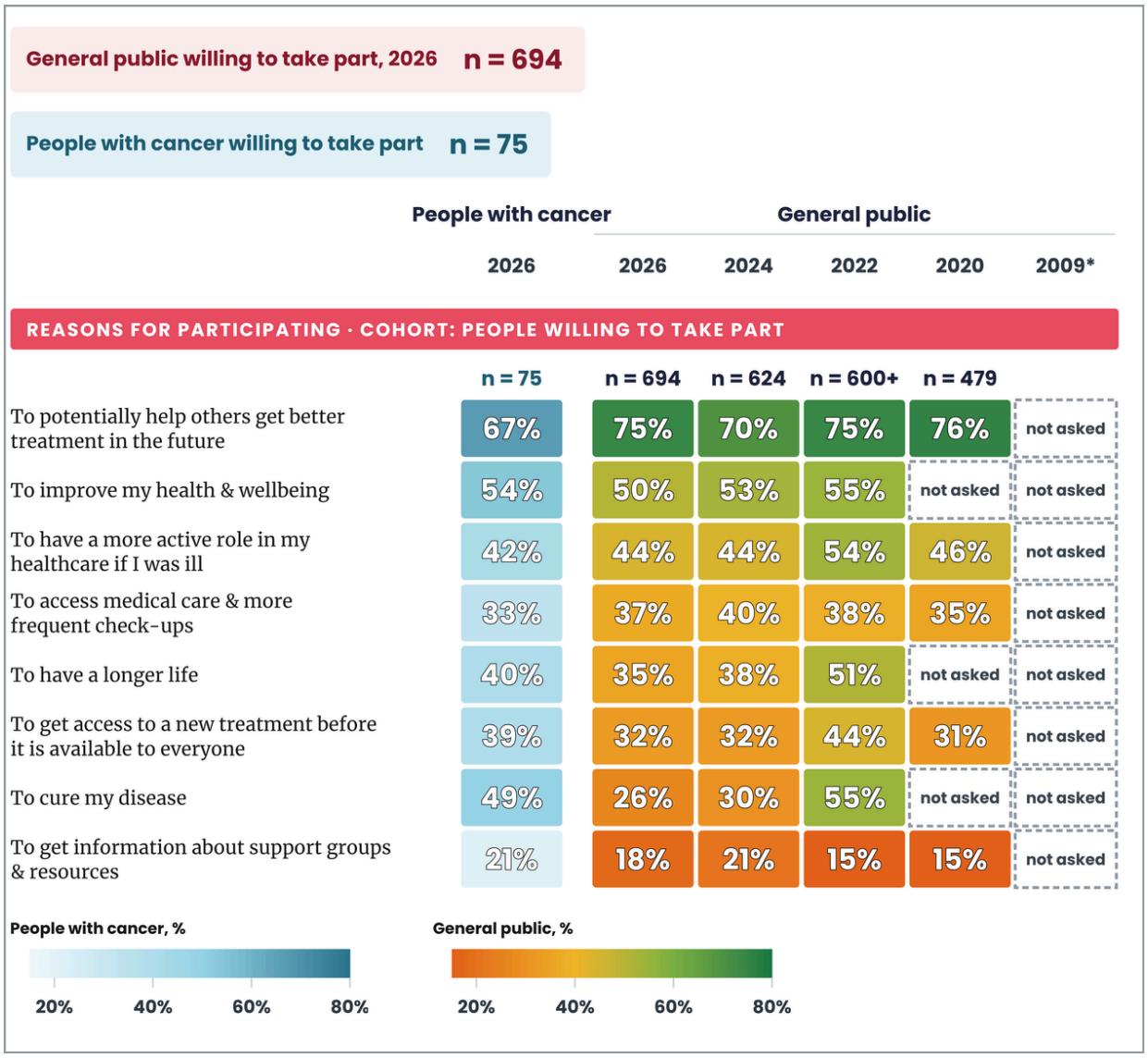
What are patients' motivations for participating in trials?

PI interviews (qualitative): Access to new treatments is the primary motivation described by the PIs interviewed, particularly where options are limited or outcomes have been poor, together with the hope of a better outcome: "This might be an opportunity to get a drug that we don't have access to otherwise." Trials are increasingly seen as a genuine treatment option rather than a last resort. Altruism is an important secondary driver and can give patients a sense of purpose: "This is me making my situation into some kind of contribution for maybe people who come after me."

Trial participants are also seen more often, monitored more closely and have more access to the team: "They are seen more often, they're monitored more often and they have more access to the team." This enhanced monitoring, together with research nurse support, makes participation more attractive and helps retention.

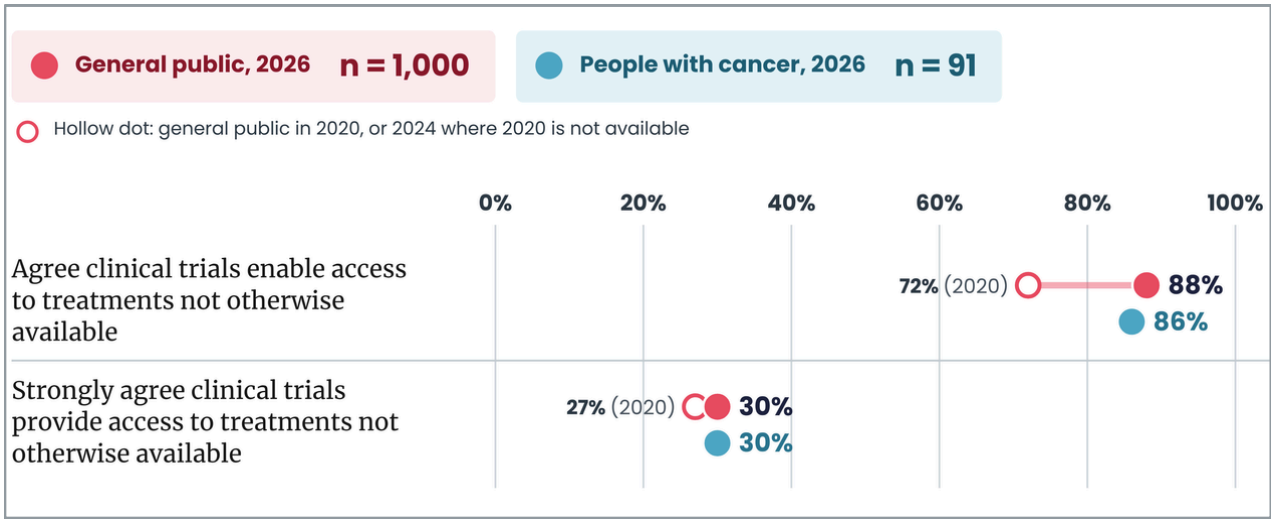
Survey data (quantitative): Survey respondents' own reasons for taking part differ from the account of the PIs interviewed (Figure 3). Among survey respondents willing to take part (general public n=694), helping others get better treatment in the future was the most frequently selected reason (75% of the general public; 67% of people with cancer), ahead of improving their own health and wellbeing (50%; 54%). Most survey respondents agree that trials give access to treatments not otherwise available (88% of the general public; 86% of people with cancer), with 30% in each group strongly agree (Figure 4).

Figure 3. Reasons for taking part (among those willing to participate), 2020–2026



Source: Trial understanding & participation 2026 (updated 23.10.26).

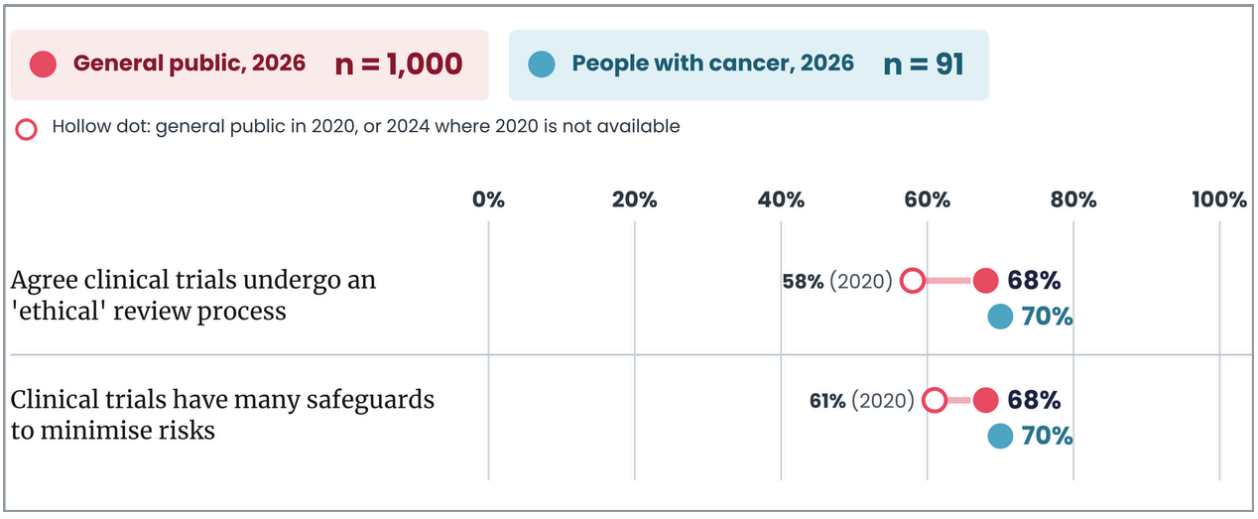
Figure 4. Agreement that trials give access to treatments not otherwise available, 2026



Source: Trial understanding & participation 2026 (updated 23.10.26).

Survey data (quantitative): Speaking to the relative confidence survey respondents have in trials and their safeguards, most survey respondents agree that trials undergo an ethical review process: 68% of the general public and 70% of people with cancer. The same proportions agree that trials have safeguards to minimise risk (Figure 5).

Figure 5. Agreement that trials undergo ethical review and have safeguards, 2026

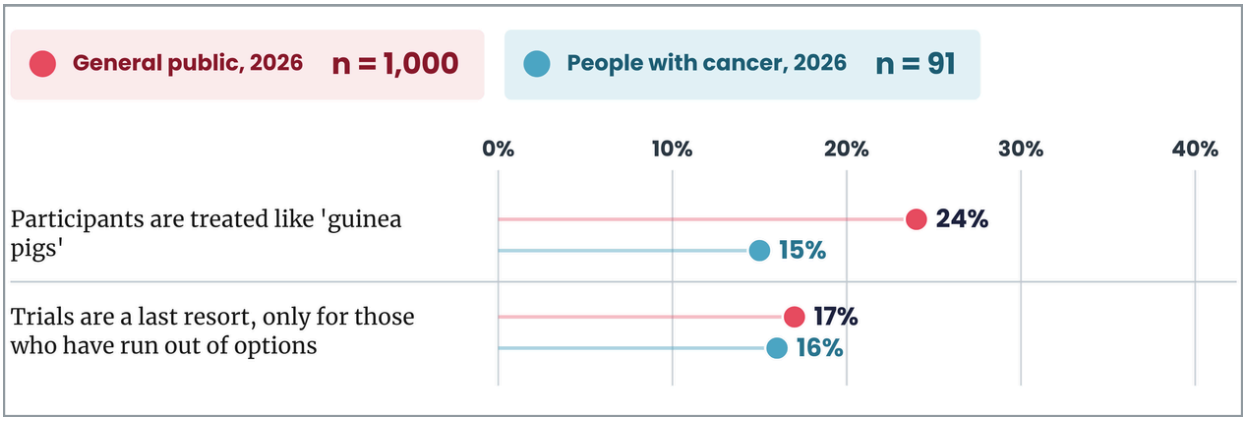


Source: Trial understanding & participation 2026 (updated 23.10.26).

PI interviews (qualitative): The PIs interviewed described the perception of trial participants as "guinea pigs" as having largely faded, although one PI interviewed identified it as a barrier: "There is still a cohort of patients who would see a clinical trial as 'I am a guinea pig'." Others no longer encounter it: "That mentality of 'I'm a guinea pig'... I don't really hear that." Concerns about side effects, effectiveness and unfamiliar treatments remain, and randomisation, particularly to a no-treatment arm, can be difficult for patients. Trust and clear explanation help to address these concerns.

Survey data (quantitative): The public survey demonstrates that although low, the perception still exists. From a prompted list, 24% of the general public and 15% of people with cancer selected the concern that participants are treated like 'guinea pigs', and 17% and 16% respectively that trials are a last resort (Figure 6). However, among the 32% of survey respondents (and 30% of cancer patients) who said they 'had concerns' about trials, unprompted responses did not include 'guinea pig' or 'last resort' and rather focused on concerns about 'safety and risk of harm'. Of the 32% and 30% saying yes to concerns, 32% and 35% cited this as their main concern, with 26% and 25% citing 'side effects'. Thereafter, 'privacy, data handling and misuse of information' was the next highest unprompted concern, with 17% and 15% expressing this concern.

Figure 6. "Guinea pig" and "last resort" perceptions as prompted concerns, 2026



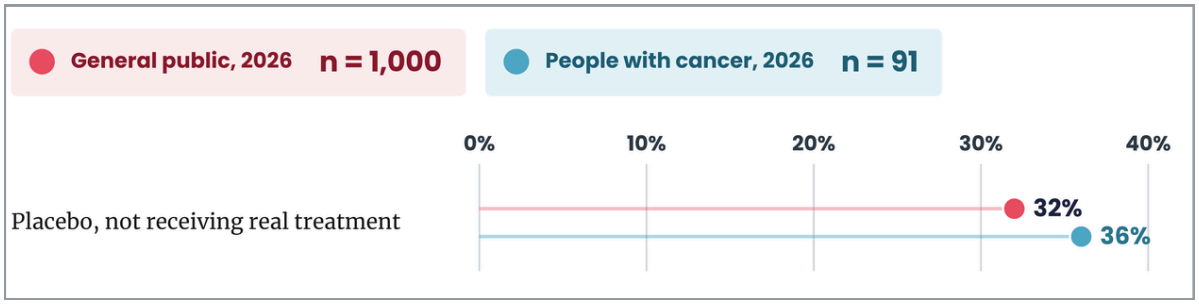
Source: Trial understanding & participation 2026 (updated 23.10.26).

Eligibility

PI interviews (qualitative): The PIs interviewed emphasised discussing uncertainty, eligibility and possible outcomes early. Being found ineligible can be distressing for patients who have become invested in a trial: "It is nearly like a second victim assault on them. One, they have cancer, and two, they are not eligible for this trial." Randomisation needs clear, early explanation, emphasising that all participants receive appropriate care, and clinicians must take care not to sway patients. Good practice involves phased discussions, research nurse support, written information and time for reflection.

Survey data (quantitative): Among survey respondents, receiving a placebo rather than real treatment was the most frequently selected concern from a prompted list (32% of the general public, n=1,000; 36% of people with cancer, n=91) (Figure 7). Of the groups expressing concerns about trials (32% overall; 30% of people with cancer) just 2% and 6% respectively raised concerns about placebo unprompted.

Figure 7. Placebo as a prompted concern, 2026 (top prompted concern in both groups)



Source: Trial understanding & participation 2026 (updated 23.10.26).

PI interviews (qualitative): More patients are excluded by eligibility than decline: "That is the rate limiting step, eligibility." Comorbidities, performance status, prior treatments and disease characteristics exclude interested patients, and studies may not be available locally. Patients with aggressive or rapidly progressing disease may not be well enough to wait for activation, screening or enrolment, and may become ineligible while waiting: "They're not well enough to wait.... A couple of weeks, maybe they're getting more unwell, and then they won't be eligible."

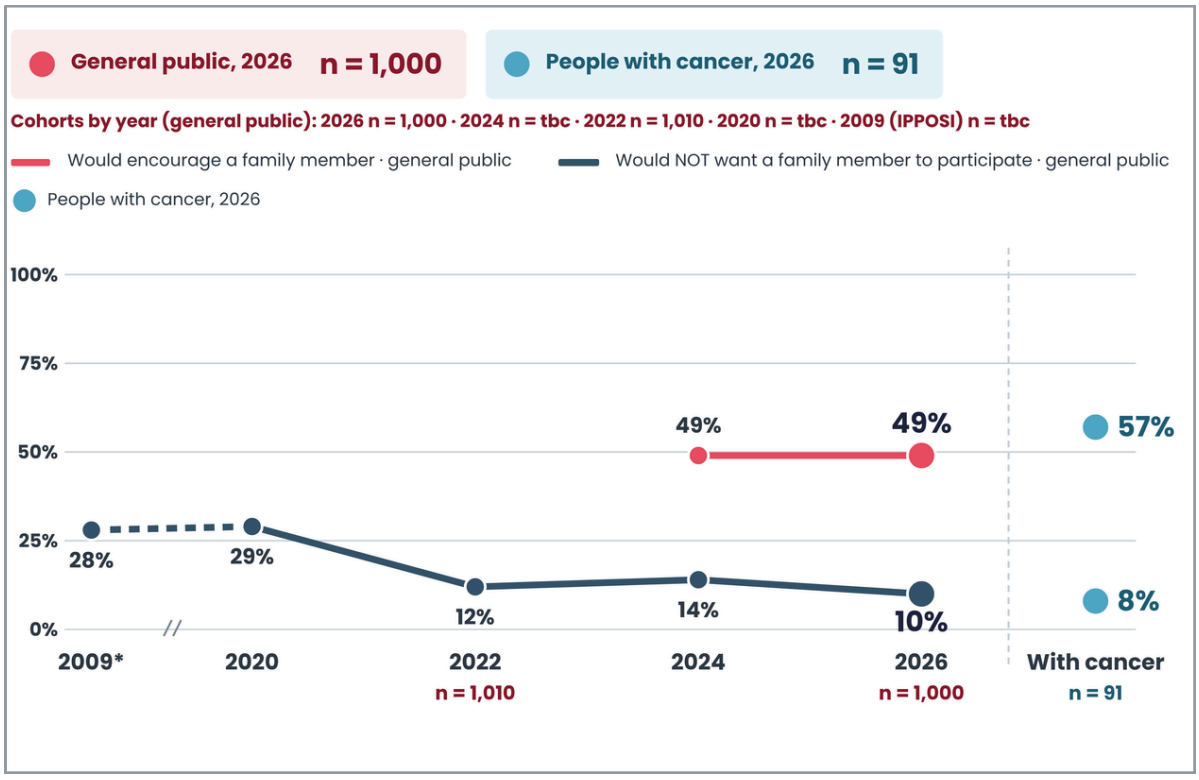
Other factors, and family / carers

PI interviews (qualitative): Willing patients may still not enrol. Screen failure, disease progression and activation delays can leave patients too unwell; additional biopsies, visits, travel and monitoring can lead to refusal; and carers can strongly influence decisions: "Carers coming in later saying no when somebody else, a patient has said yes, we have had that so many times."

PI interviews (qualitative): Decisions often involve family members, who attend consultations and assess travel and logistics collectively. Families can encourage or discourage participation, and the PIs interviewed described patients being led by the majority view in the room: "You can see that the patient themselves are being led by whatever the majority in the room is saying." Broader family engagement becomes more prominent where a trial involves significant commitments or uncertainty: "[Sometimes] The patient is happy to be enrolled but the carer is not."

Survey data (quantitative): Among survey respondents, 49% of the general public (n=1,000) and 57% of people with cancer (n=91) would encourage a family member to take part in a trial, and 10% and 8% respectively would not want a family member to take part (Figure 8). This is a general attitude; the PIs interviewed describe relatives' responses to a specific trial offer.

Figure 8. Attitudes to a family member taking part, 2009–2026 "I would encourage a family member to take part in a clinical trial."



Source: Trial understanding & participation 2026 (updated 23.10.26).

Barriers

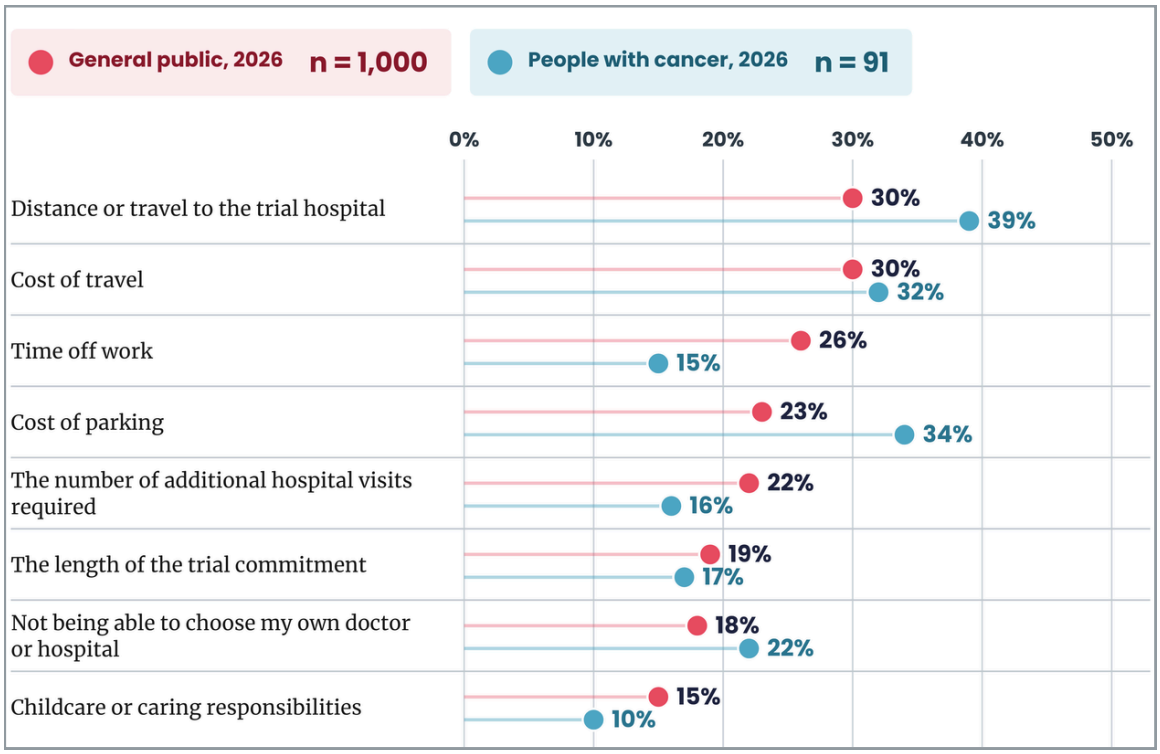
PI interviews (qualitative): Barriers to participation are usually practical rather than ideological, and the PIs interviewed rarely described active opposition to research. Barriers vary by age, disease stage, family circumstances, employment and location, and no single barrier is universal: "Some people can't travel, some people can't take the time off work, some people have caring responsibilities."

The PIs interviewed identified travel as one of the most significant barriers. Trials are concentrated in major centres, some serving patients 100–150 km away, and repeated visits become burdensome. Rural patients are disproportionately affected, as are relatives providing transport.

Trials can involve more scans, blood tests, questionnaires and visits than standard care, all of which must fit around work, family and caring responsibilities, and the cumulative burden may matter more than any single visit.

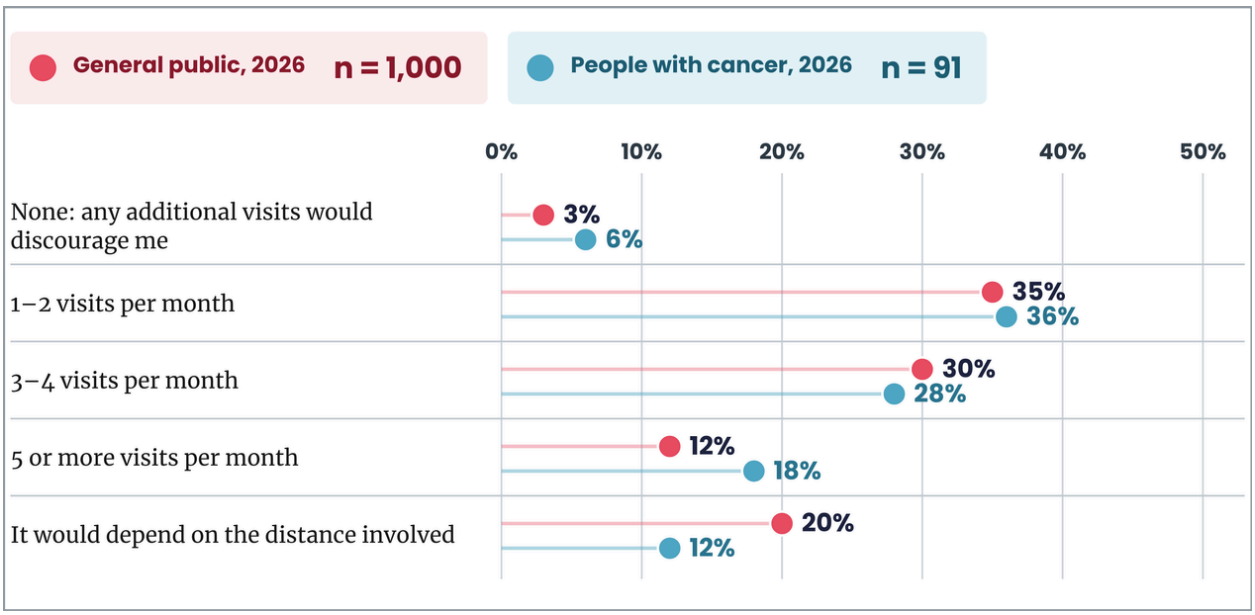
Survey data (quantitative): Survey respondents report similar barriers (Figure 9). Among people with cancer (n=91), distance or travel to the trial hospital was the most frequently selected barrier (39%), followed by the cost of parking (34%) and the cost of travel (32%). Among the general public (n=1,000), distance or travel and the cost of travel were each selected by 30%. Most survey respondents would find one to four additional hospital visits per month manageable (Figure 10).

Figure 9. Barriers to taking part in a clinical trial, 2026 (new chart) - To what extent, if at all, would each of the following be a barrier to you participating in a clinical trial, if there was a trial available for a condition you were diagnosed with?



Source: Trial understanding & participation 2026 (updated 23.10.26).

Figure 10. Manageable additional hospital visits per month, 2026: If you were diagnosed with a condition, and there was a clinical trial available, how many additional hospital visits per month would be manageable for you if participating in a clinical trial?

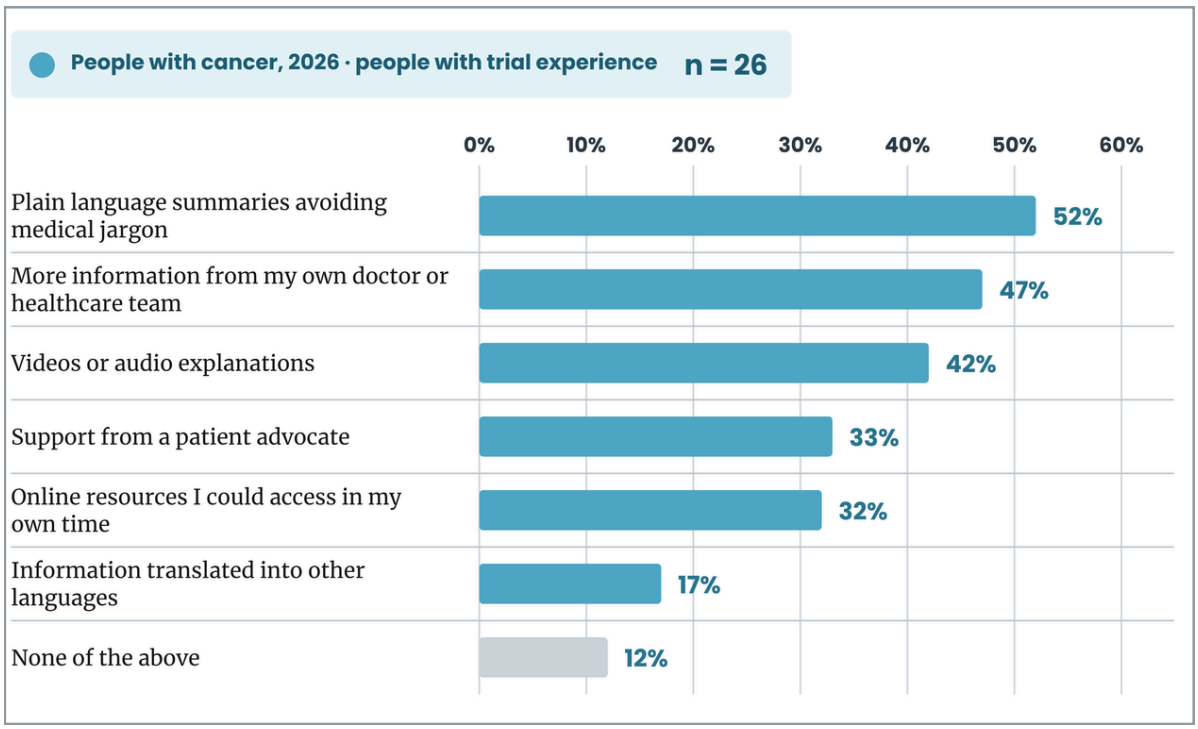


Source: Trial understanding & participation 2026 (updated 23.10.26).

PI interviews (qualitative): Patient information leaflets (PILs) and consent packs have become lengthy as a result of regulatory requirements: "We're being asked by regulators to put more and more information in these consent forms and then they're very lengthy, very complicated and they might be overwhelming to patients." The PIs interviewed described patients not reading them: "Patients will say to me, I never read that. That went behind the fridge." Layered communication, with concise summaries and verbal discussion, was favoured. One PI interviewed highlighted one-page summaries, and one centre had used patient representatives to improve materials.

Survey data (quantitative): Among survey respondents with cancer, plain language summaries (52%) and more information from their own doctor or healthcare team (47%) were the most frequently selected ways of making trial information easier to understand, followed by videos or audio explanations (42%) (Figure 11).

Figure 11. What would make trial information easier to understand, 2026 (people with cancer only)



Source: Trial understanding & participation 2026 (updated 23.10.26).

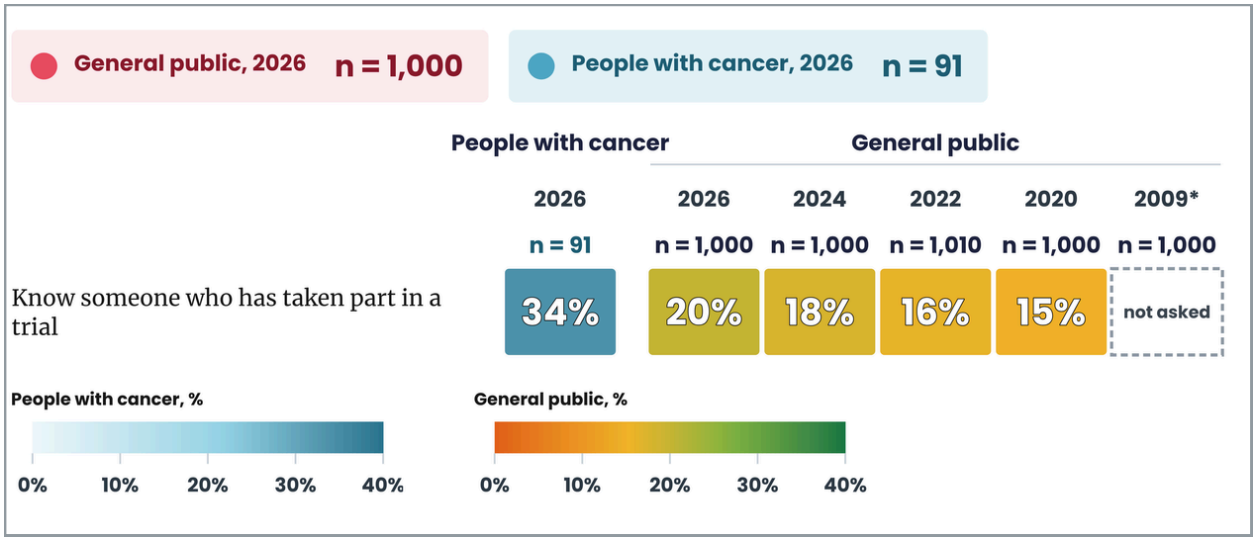
Awareness of Trials

PI interviews (qualitative): The PIs interviewed reported that awareness of clinical trials has improved considerably, and that perceptions of trials as a last resort are becoming less common: "People don't go, 'Oh, what's a clinical trial?'"

Survey data (quantitative): Among survey respondents, 20% of the general public (n=1,000) and 34% of people with cancer (n=91) know someone who has taken part in a trial (Figure 12).



Figure 12. Know someone who has taken part in a trial, 2020–2026



Source: Trial understanding & participation 2026 (updated 23.10.26).

PI interviews (qualitative): Awareness campaigns were widely supported by the PIs interviewed as a way of normalising trials and strengthening support among healthcare leaders, policymakers and the public: "If you have awareness among the patients, then you have awareness among the non-cancer treating world." Some PIs interviewed felt campaigns should build understanding and trust, not only demand, and that sustained, evaluated effort is preferable to intermittent bursts.

NCTOG Recommendation #10: public education and awareness campaigns integrated into health apps.

Several PIs interviewed warned that awareness alone will not improve participation. It does not create trial opportunities, may disappoint ineligible patients, and could generate demand that outstrips available trials unless access and capacity improve: "What's the point in getting more people to look for a clinical trial if you can't deliver it?"

Most patients learn about trials through their healthcare team, and the PIs interviewed felt responsibility should sit with clinicians and the system rather than with patients. One PI interviewed observed: "I suppose if someone's asking about it, that means I haven't mentioned it yet."

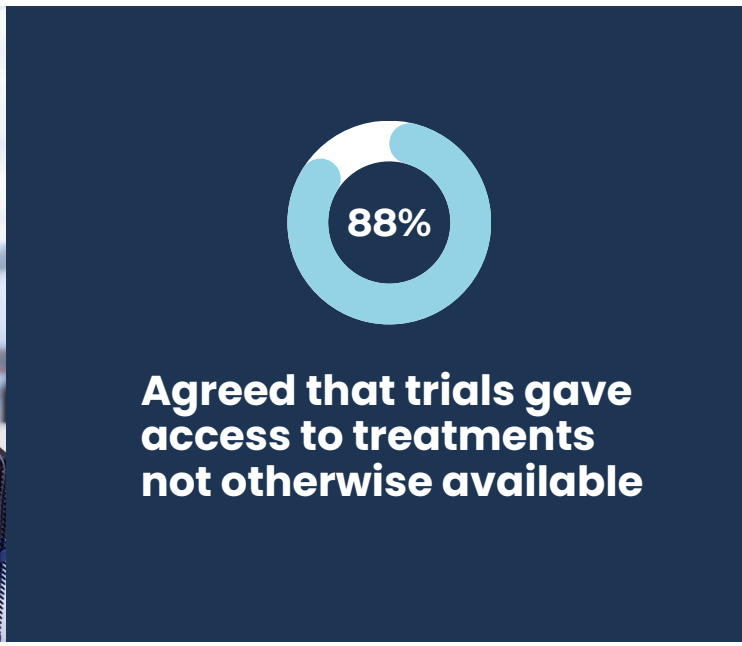
Recognising the term "clinical trial" does not mean understanding eligibility, requirements or study design, and health literacy is a factor in how well patients understand what a trial involves. One PI interviewed was more critical: "I think it is poor. It is probably not well enough articulated in our society."

Patient-initiated requests are uncommon; several PIs interviewed estimated around one in ten patients or fewer: "Now I'm the PI of 12 open trials, and I probably get one random solicitation every two to three months." Requests typically come from informed, engaged patients. Online resources, social media, patient communities and advocacy groups play a role, and patients take trust from their peers: "They're taking their trust from their peers." One PI interviewed suggested hearing from people who have been on a trial can resonate more than information alone. Patients with fewer remaining options are more likely to ask. Breast and ovarian cancer patients were described as particularly engaged and informed, with awareness lower in other settings; the PIs interviewed linked these differences to health literacy and socioeconomic background.

NCTOG Recommendation #9: a unified online platform for the public to connect with relevant clinical trials.

Understanding varies widely: "Patients often do not even understand their cancer diagnosis and the treatment you are about to give them." Information and consent documents can be overwhelming soon after diagnosis. Language barriers add complexity and delay, requiring translation and interpretation. Clear explanations can overcome many concerns.





Trial Achievements and Ireland's Research Reputation

Irish clinical trial achievements presented at ESMO 2026

Members of Cancer Trials Ireland's Leadership Team travelled to the ESMO Congress in Madrid in October 2026. A structured schedule was developed ahead of the congress, with over 30 meetings set with industry and collaborative groups. The aim was to engage at global level, renew ongoing relationships and form new connections, discuss ongoing and new opportunities, and advance Cancer Trials Ireland's objective to attract more research to Ireland.

Another key objective was to highlight and support the work of Cancer Trials Ireland's community - investigators, clinicians, researchers and collaborators based in Ireland. Cancer Trials Ireland's Head of Marketing, Claire Hopkins, travelled as part of the Cancer Trials Ireland team to provide social media coverage both during and immediately after the congress, highlighting involvement from Ireland. This included oral presentations, session roles, research contributions and posters. A website page was developed in advance on the Cancer Trials Ireland website to recognise the work of Cancer Trials Ireland's members and collaborators at ESMO 2026.

The following is a sample of four trials presented at ESMO 2026, which involved Cancer Trials Ireland / sites in Ireland: -

DASL-HiCaP: International prostate cancer trial

DASL-HiCaP, an international trial for which Cancer Trials Ireland acted as EU and UK sponsor, reported findings at ESMO 2026 that could change how men with very high-risk prostate cancer are treated. It also shows Ireland's capacity to recruit patients to, sponsor and deliver complex international studies.

Addressing a significant clinical challenge
Prostate cancer is the most commonly diagnosed invasive cancer among men in Ireland, with approximately 4,500 new diagnoses each year.[1] For men with very high-risk localised or locally advanced disease, treatment generally involves radiation therapy with androgen deprivation therapy (ADT), which reduces testosterone levels. This does not eliminate the risk of the cancer returning or spreading.

The international, investigator-initiated Phase III trial tested whether adding darolutamide, an oral medicine that blocks the effects of male hormones on cancer cells, improves outcomes. Patients were randomly assigned to standard treatment plus darolutamide or plus placebo, with neither patients nor clinicians knowing which they received. The principal measure was metastasis-free survival: how long patients remained alive without evidence of their cancer spreading.

Findings with potentially significant implications

The first planned analysis, presented at the European Society for Medical Oncology (ESMO) Congress in Madrid on 24 October 2026, showed that adding darolutamide reduced the relative risk of cancer spreading or death by 58%. At four years, 95% of patients receiving darolutamide were alive without metastases, compared with 88% receiving placebo.[2] Fewer patients also had a rise in prostate-specific antigen (PSA), which can indicate recurrence.

Preventing or delaying spread can spare patients the consequences of advanced disease and further treatment. Follow-up is continuing to determine the impact on overall survival.

Cancer Trials Ireland's role

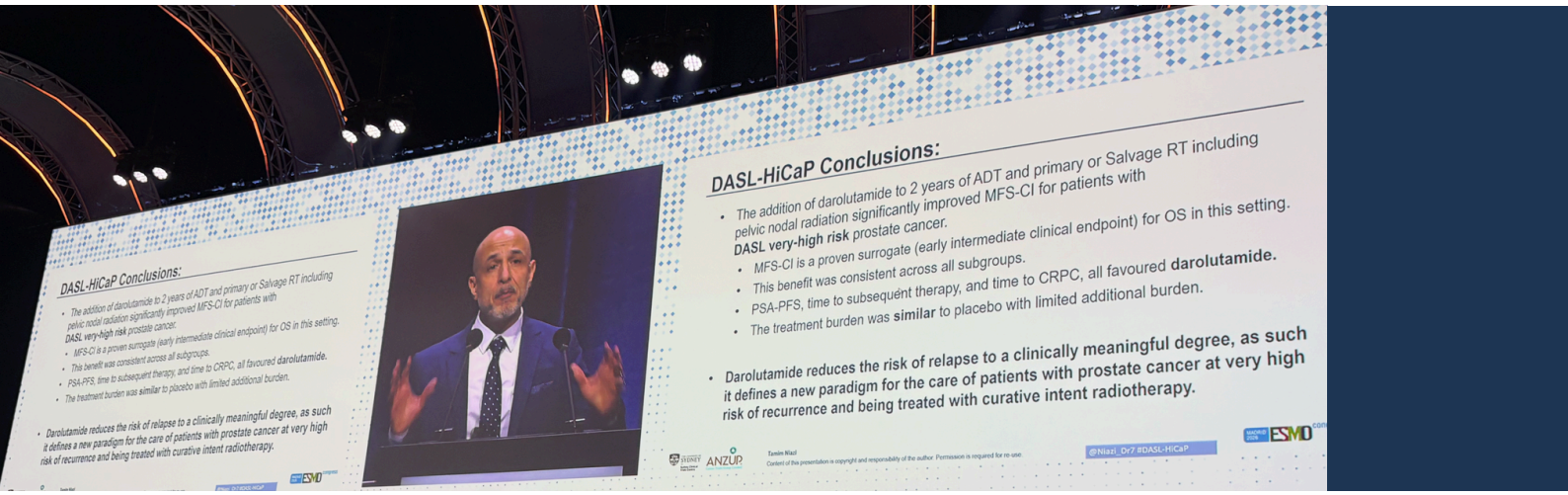
DASL-HiCaP was jointly led by the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) and the Sydney Clinical Trials Centre at the University of Sydney. Cancer Trials Ireland acted as EU and UK sponsor, supporting delivery across both jurisdictions.

The trial recruited 1,106 patients internationally, including 95 across Ireland and the UK: 36 in Ireland, at nine hospitals, and 59 in the UK, between July 2021 and August 2023.[1] Prof. Ray McDermott and Prof. Paul Kelly led the study in Ireland; Dr Simon Hughes led the UK contribution.[3]

Ireland's contribution is therefore not confined to recruiting patients into studies managed elsewhere: Irish organisations can also take on sponsorship and deliver research across borders.

The wider significance for Ireland

For patients, international trials provide access to research into treatments that may improve on existing standards of care. For Ireland's research system, they build expertise, strengthen international partnerships and demonstrate the capability of its infrastructure. DASL-HiCaP shows what Ireland can achieve with the organisational capacity, clinical expertise and international relationships to take part meaningfully in major global studies. The challenge is to sustain and build on that capacity.



NATALEE: International breast cancer trial demonstrates lasting benefits of treatment to prevent recurrence

New findings from a major international breast cancer trial involving patients and researchers in Ireland show that adding a targeted medicine to standard hormone therapy can improve survival and reduce the risk of cancer returning. The results were presented at the European Society for Medical Oncology (ESMO) Congress in Madrid in October 2026.

Reducing the risk of breast cancer returning

Hormone receptor-positive, HER2-negative (HR+/HER2-) breast cancer is a common form of the disease in which cancer cells respond to hormones such as oestrogen. After surgery and other initial treatment, patients commonly receive endocrine therapy to reduce the effects of these hormones. However, some remain at considerable risk of their cancer returning, sometimes many years after diagnosis.

The international Phase III NATALEE trial investigated whether adding ribociclib, a targeted medicine that blocks proteins involved in cancer cell growth, could improve outcomes. It recruited 5,101 patients with stage II or III HR+/HER2- early breast cancer across 20 countries, including Ireland. Participants were randomly assigned to endocrine therapy alone or endocrine therapy with ribociclib for three years.[4] The principal measure was invasive disease-free survival: how long patients remained free from invasive cancer recurrence or certain other serious disease events.

Significant findings after six years

Professor Dennis Slamon presented the latest results at ESMO on 23 October 2026, after a median overall-survival follow-up of approximately five and a half years. Earlier analyses had established that ribociclib reduced the risk of recurrence; the latest findings also show a positive effect on overall survival.

At six years, approximately 91.9% of patients who received ribociclib were alive, compared with 89.7% of those receiving endocrine therapy alone: a relative reduction of approximately 19% in the risk of death.[5] Invasive disease-free survival was 83.2% with ribociclib and 77.9% without, an absolute improvement of 5.3 percentage points.[5] The benefits continued to be seen several years after patients had completed ribociclib.
The six-year analysis was prespecified and descriptive, and longer-term follow-up remains important.

Ireland's contribution to international research
NATALEE was a large, industry-sponsored study conducted across hundreds of clinical sites, including hospitals in Ireland. At the Mater Private Network, the study was led locally by Professor Catherine Kelly and Professor John McCaffrey.[6] Professor John Crown, Consultant Medical Oncologist at St Vincent's University Hospital, Dublin, is a co-author of the latest NATALEE publication in Annals of Oncology.[5]

The wider significance
NATALEE addresses how to reduce the likelihood of a potentially curable cancer returning after initial treatment. Establishing that a treatment prevents recurrence is one step; showing that this translates into longer lives can take considerably longer. NATALEE demonstrates the value of both, and of partnerships between hospitals, academic investigators and industry in studies that need large patient numbers and extended follow-up.

NSABP B-42: Fifteen-year findings demonstrate lasting benefits of extended breast cancer treatment

An international breast cancer trial, supported in Ireland by Cancer Trials Ireland under its former name, ICORG, has reported significant long-term findings that could help inform treatment decisions for women at risk of their cancer returning. The final analysis, presented at the European Society for Medical Oncology (ESMO) Congress in Madrid in October 2026, provides evidence of the benefits of extending hormone therapy.

Addressing the long-term risk of recurrence
For women diagnosed with hormone receptor-positive breast cancer, the risk of recurrence can persist long after initial treatment. After surgery, patients commonly receive endocrine therapy, which reduces the effects of hormones such as oestrogen. Aromatase inhibitors, including letrozole, are widely used for this in postmenopausal women. An important question has been whether extending treatment beyond the conventional five years provides enough additional benefit to justify the longer period of medication.

The international Phase III NSABP B-42 trial recruited 3,966 postmenopausal women with hormone receptor-positive early-stage breast cancer who had completed approximately five years of endocrine therapy and remained free of disease. They were randomly assigned to a further five years of letrozole or a placebo.[7]

Findings after fifteen years

Professor Eleftherios Mamounas presented the final analysis at ESMO on 23 October 2026, after a median follow-up of 15.9 years. At fifteen years, disease-free survival was 61.6% with additional letrozole and 56.5% with placebo: an absolute improvement of 5.1 percentage points and a 15% relative reduction in the risk of a disease-free survival event.[7]

Extended treatment also reduced the relative risk of distant recurrence, where breast cancer spreads to other parts of the body, by 28%. The cumulative incidence of distant recurrence was 6.9% with letrozole and 9.7% with placebo.[7]

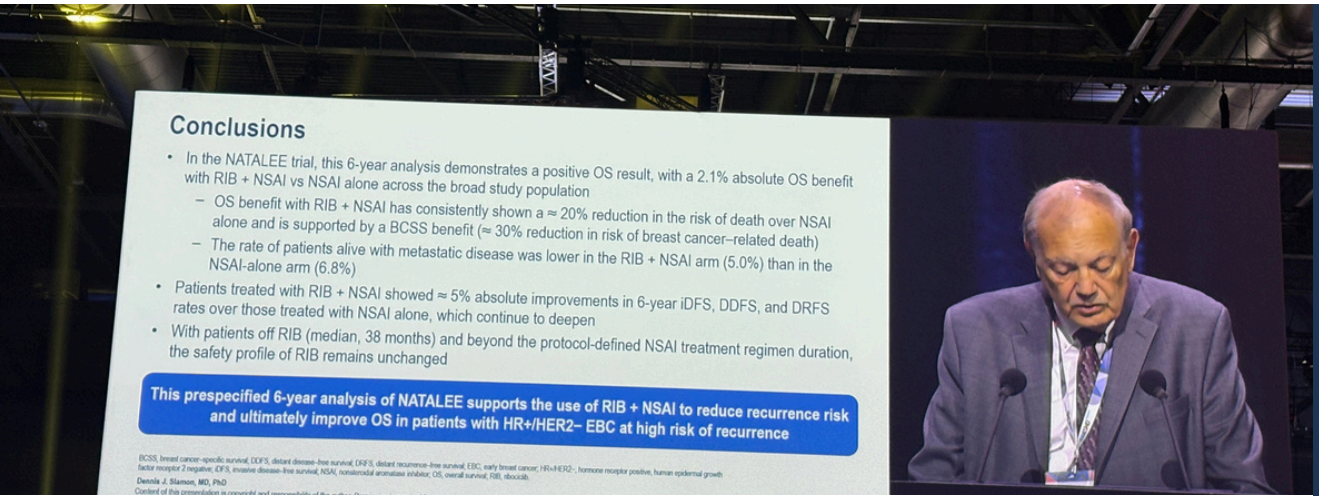
The trial did not demonstrate a statistically significant improvement in overall survival, so the reduction in recurrence has not been shown to translate into longer life. Researchers reported no statistically significant increase in osteoporotic fractures or arterial thrombotic events, two recognised safety concerns with extended aromatase inhibitor treatment.[7]

Cancer Trials Ireland's contribution

NSABP B-42 was conducted through the National Surgical Adjuvant Breast and Bowel Project (NSABP), subsequently part of NRG Oncology. In Ireland it was supported by ICORG, now Cancer Trials Ireland, which the European Clinical Trials Register identifies as the non-commercial sponsor under protocol ICORG 06-32/NSABP B-42.[8] Cancer Trials Ireland still lists the study in its portfolio of collaborative trials in follow-up.[9]

The wider significance

The treatment period lasted five years, but establishing how durable its benefits were required more than fifteen years of observation. Clinical trials do not end when the last patient completes treatment, particularly in cancers where recurrence may occur many years after diagnosis. For Ireland, NSABP B-42 shows the importance of maintaining the clinical and organisational infrastructure needed to take part in international research over extended periods.



PEACE-1: Long-term results demonstrate significant survival gains for men with advanced prostate cancer

New findings from a major international prostate cancer trial involving Irish patients and researchers show substantial improvements in long-term survival for men whose cancer has already spread at diagnosis. The findings from PEACE-1 were presented at the European Society for Medical Oncology (ESMO) Congress in October 2026.

Addressing advanced prostate cancer
PEACE-1 included men with de novo metastatic castration-sensitive prostate cancer: cancer that has spread at the time of diagnosis but still responds to treatments that reduce testosterone, the hormone that helps prostate cancer grow. Standard treatment has traditionally centred on androgen deprivation therapy (ADT). Adding chemotherapy and newer hormonal medicines has improved outcomes, but important questions remained about how best to combine these treatments.

The international Phase III trial examined whether adding abiraterone, a medicine that further suppresses androgen production, and/or radiotherapy to the prostate could improve outcomes. It enrolled 1,173 men across several European countries, including Ireland, who were randomly assigned to different treatment combinations.[10]

Results that demonstrate the value of long-term research
Professor Karim Fizazi presented the latest findings at ESMO in Madrid on 24 October 2026, after a median follow-up of 7.7 years. Across the overall study population, adding abiraterone increased median survival from 4.6 years to 6.1 years, a 25% relative reduction in the risk of death.[11]

The findings were particularly significant among patients also receiving docetaxel chemotherapy. Adding abiraterone to ADT and docetaxel, an approach known as triplet therapy, increased median overall survival from 4.4 years with doublet therapy to 6.2 years with triplet therapy. At eight years, 40.3% of patients receiving triplet therapy were alive, compared with 27.1% receiving ADT and docetaxel alone.[12]

The benefits of triplet therapy extend across patients with differing levels of metastatic disease, although the strength of the evidence varies between subgroups. The extended follow-up identified no new long-term safety concerns.[12]

Ireland's contribution to PEACE-1

PEACE-1 is an academically led European study, with Cancer Trials Ireland participating as an international collaborative trials partner. It is recorded in Cancer Trials Ireland's portfolio as CTRIAL-IE13-09 and remains in long-term follow-up.[13]

Professor Ray McDermott, Consultant Medical Oncologist at St Vincent's University Hospital, Dublin, was among the authors of the original PEACE-1 publication in The Lancet in 2022, and both Professor McDermott and Dr Paul Kelly contributed to subsequent research examining the role of radiotherapy.[14]

The wider significance

The initial results helped establish the benefits of combining treatments for advanced prostate cancer. The latest analysis, after almost eight years of observation, provides stronger evidence of the extent and durability of those benefits. The value of a clinical trial does not end when recruitment closes. For Ireland, maintaining the capacity to take part in such research matters both for the patients who may benefit directly and for the contribution Irish clinicians and research organisations make to cancer care worldwide.



The Power of Community Support: Transforming Pancreatic Cancer Research in Ireland

Since 2019, the extraordinary generosity of supporters of the Pat Smullen Fund and the Pat Smullen Race Day at the Curragh has raised over €4 million for pancreatic cancer research, transforming Ireland's capacity to deliver clinical trials in this challenging disease area.

This community-driven investment has enabled Cancer Trials Ireland to open four pancreatic cancer trials since 2020, recruiting 75 patients across multiple hospitals. It has also supported the establishment of the Pat Smullen Chair in Pancreatic Cancer at UCD, held by Professor Gráinne O'Kane, investment in advanced genomic sequencing technology, and the development of a high-risk pancreatic cancer surveillance service. This growing research infrastructure has helped attract further investment, including a €1 million grant to establish an all-island pancreatic cancer research network.

Importantly, this investment has positioned Ireland to participate in the next generation of potentially practice-changing pancreatic cancer research. Recent advances, including daraxonrasib, a targeted therapy that has demonstrated promising survival benefits in advanced pancreatic cancer, offer new hope for patients.

Ireland's strengthened research expertise, infrastructure and proven ability to deliver trials mean that international pharmaceutical partners are increasingly recognising Irish hospitals as potential sites for innovative studies. The anticipated opening of trials involving daraxonrasib and other KRAS inhibitors could provide Irish patients with earlier access to emerging treatments.

This is a powerful example of how community fundraising can create lasting national research capability, attract international investment and translate public generosity into meaningful opportunities for patients, extending benefits well beyond the original investment.



Conclusion



Value of Cancer Trials 2 reinforces the substantial clinical, economic and societal contribution of cancer clinical trials to Ireland. Beyond providing patients with access to innovative treatments, trials generate significant savings for the health service, attract international investment, support research employment and contribute to advances in cancer care that benefit current and future generations.

The findings also highlight a clear disconnect between Ireland's research potential and its current performance. Despite internationally recognised clinical expertise, established research networks and strong public willingness to participate, structural barriers continue to constrain trial activity. Delays in trial activation, workforce pressures, fragmented processes and geographical inequalities limit patient access and Ireland's ability to compete internationally for clinical research investment.

Encouragingly, recent operational improvements demonstrate that progress is achievable. The establishment of the Clinical Trials Advisory Council (CTAC), alongside the recommendations of the National Clinical Trials Oversight Group (NCTOG), presents a timely opportunity to deliver meaningful national reform. Central to this is Recommendation 11, which calls for clinical trials to be formally recognised, tracked and prioritised across the health service. Translating this ambition into measurable accountability, sustained investment and coordinated delivery will be critical. Importantly, the report demonstrates that Ireland has the clinical expertise, research capability, international partnerships and public support necessary to achieve considerably more.

The challenge now is not only to continue to demonstrate that cancer clinical trials deliver value, but to ensure that Ireland fully realises that value. Embedding clinical research as a core component of healthcare delivery is essential to improving equitable patient access, strengthening national competitiveness and ensuring that more patients in Ireland benefit from advances in cancer treatment.

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Appendix: NCTOG Final Recommendations

The NCTOG has set out a clear plan, comprising 20 recommendations across the six priority areas listed below, to strengthen Ireland's clinical trials ecosystem:

Implementation and Development of a National Clinical Trials Body

1.Establish a Clinical Trials Advisory Council (CTAC) by Q1 2026 to implement the NCTOG recommendations.

2.CTAC should manage the transition process required to oversee the establishment of a National Clinical Trials Body by Q3 2027.

Creating Agile and Responsive Systems

3. Universal clinical trial contract template should be developed for Ireland.

4. Develop national guidance outlining requirements around data protection responsibilities.

5. Develop national guidance that provides clear direction on designated officer sign-off for clinical trials.

6. Develop a comprehensive, user-friendly, open-access dashboard to aid accountability, which regularly publishes updates on an initial list of agreed Key Performance Indicators (KPIs) to monitor and report on clinical trials activity metrics.

7. Develop a unified model for clinical trial delivery which harmonises infrastructures to drive efficiency, expertise and excellence and optimise impact for state investments, including activity-based funding and strategic partnerships.

8. Review and optimise models of indemnity for clinical trial activity.

9. Develop a unified online platform for the public to connect with relevant clinical trials.

Enhance Patient and Public Engagement

10. Create public Educational and Awareness Campaigns which should be integrated into Health Apps to increase awareness of clinical trials.

11. Incorporate mandatory clinical trial performance metrics and KPIs within the reporting system to ensure that the importance of clinical trial activity is recognised at a corporate level throughout the Irish health service.

Promoting Value and Incentivising Activity

12. Develop and pilot a standardised clinical trial costing template and process for commercial and non-commercial clinical trials, ensuring the methodology is robust and broadly applicable across stakeholders.

13. Establish and implement a centrally approved itemised pricing schedule for a range of fixed clinical research specific activities/ procedures.

14. Establish a standardised national approach to indirect costs (e.g. overheads/ activity/ capacity-building) across all clinical trial activity. On a pilot basis, a maximum indirect cost rate of 40% should be applied to commercially sponsored clinical trials, to be managed as per established indirect cost practices of participating sites.

15. For complex trials a proportion of costs should be paid at the contract signature stage to ensure start-up costs incurred are recovered regardless of trial progression.

Strategic Workforce Development

16. Systematically collect and analyse workforce data to understand current capacity, predict future needs, and inform strategic planning.

17. Develop standardised career pathways by establishing stable job roles and clear, consistent routes for professional advancement to enhance retention and motivation.

18. Develop education and training resources to support Ireland's clinical trials workforce, helping to ensure that staffing needs can be fulfilled as the sector expands in future.

19. Develop strategies to attract new talent and retain existing staff by promoting supportive and rewarding work environments.

Promote Use of Innovative Technologies

20. Ensure that the technological solutions for Electronic Health Records will enable all aspects of clinical trials and promote the use of Innovative Technologies in the design of clinical trials research.

Source: Department of Health, National Clinical Trials Oversight Group Final Report and Recommendations, Executive Summary (pp. 6–9).

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Together, we're finding answers to cancer.



THANK YOU

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