

ANNUAL REVIEW 2024



*Together, we're finding
answers to cancer.*



WHO WE ARE

Cancer Trials Ireland is the national network dedicated to advancing cancer care through clinical trials, where new treatments and approaches are thoroughly tested. As a cornerstone of Ireland's cancer research infrastructure, we unite clinical specialists, researchers, and key stakeholders to drive evidence-based improvements in cancer outcomes.

Our organisation comprises nearly all cancer-treating specialists in Ireland, collaborating through eight HRB-funded cancer trial clusters and 19 hospital-based Cancer Clinical Trials Units (CCTUs) across the country. Supported by a central team of clinical researchers, project managers, and data experts, our trials are crucial for developing new treatments that enhance patient care. In addition to sponsoring our own academic trials, we work with international research groups and pharmaceutical companies, which brings substantial investment and innovative therapies to Irish patients.

Cancer remains a significant global health challenge, accounting for nearly 10 million deaths worldwide in 2020, according to the World Health Organisation. In Ireland, one in two people will face a cancer diagnosis in their lifetime.

However, thanks to decades of research and clinical trials, many of these diagnoses now have effective treatments, with over 60% of patients surviving at least five years, and many being cured. Today, more than 200,000 people in Ireland have survived a cancer diagnosis.

Despite this progress, the National Cancer Registry of Ireland (NCRI) reports that nearly 25,000 people are diagnosed with invasive cancer annually, a number expected to double as our population ages.

The 2017 National Cancer Strategy emphasises the critical role of research and trials, aiming to have 6% of cancer patients in interventional trials. While only approx. 1.5% of Irish patients were on interventional clinical trials at the end of 2023, Cancer Trials Ireland has made significant strides, with a 51% increase in patient participation in all trials in 2024 compared to the previous year.

Our ongoing commitment to cancer research ensures that Ireland continues to build on past successes, offering patients access to cutting-edge treatments and contributing to the global fight against cancer.





VISION AND MISSION

Vision:

Maximise cancer trial access and outcomes to prolong patient lives and expand cancer research in Ireland.

Mission:

To be an indispensable all-Island hub for cancer trials, globally recognised for excellence in governance, collaboration and innovation in clinical research.

OUR TEAM



Angela Clayton-Lea,
CEO



**Deirdre Somers, Chair of
the Board of Directors**



Prof Seamus O'Reilly,
Clinical Lead



**Prof Gerry Hanna, Vice
Clinical Lead**



**Patrick Kivlehan,
Chair of the Patient
Consultants Committee**



WELCOME FROM THE CHAIR

DEIRDRE SOMERS

I am pleased to report that 2024 marked another year of growth and resilience for our organisation. Accruals continued their upward trend, rising once again from 2023 and 2022. This was driven by strong engagement across many DSSGs, with particularly heartening progress in lung, reflecting the dedication of our teams and collaborators.

Our funding base remained robust, though reliant on key supports. The Irish Cancer Society grant and philanthropic income together accounted for 36% of overall income, with the HRB grant contributing a further 20%. Encouragingly, industry and collaborative fees increased to 41%, underscoring our relevance as a trusted partner in clinical research.

In January, we convened a Strategy Day with stakeholders, the PCC, and our project managers to identify and address roadblocks to clinical trials in Ireland. This highly productive session, enriched by contributions from the Irish Cancer Society and the HSE National Cancer Control Programme, highlighted the continuing challenge of GDPR interpretation in Ireland. Unlike our European peers, patients here face restricted opportunities due to uncertainties in opening trials, creating a serious barrier for both companies and collaborative groups.

In response, and aligned with our third strategic objective, we produced a position paper on GDPR, setting out a clear advocacy pathway.

With respect to staff, I am pleased to confirm that levels remained strong throughout 2024, ensuring we have the capacity and expertise to meet our commitments and continue supporting patients. Together, these achievements provide a solid foundation for the year ahead.

Finally, I want to thank my Board colleagues and the organisation's executive team and staff for their support. In particular, I wish to thank outgoing Board members, Prof Ray McDermott, Dr Ruth Barrington, Ms Anne Byrne and Ms Sharon McCabe. I especially wish to recognise Prof McDermott, and his commitment to Cancer Trials Ireland which has stretched over 16 years, and to wish Prof Seamus O'Reilly and Prof. Gerry Hanna well as they take up their respective roles of Clinical Lead and Vice Clinical Lead from January 2025.

Cancer Trials Ireland has 5 Key Strategic Objectives (KSOs) for 2022-2026.

Maximise contribution to National Cancer Strategy.

Optimal, stable, and scalable talent to serve growth.

Position clinical research as an integral part of cancer care through thought leadership, advocacy, and influence.

Deliver a compelling "All-Island" cancer trial proposition.

Financially sustainable and funded for growth.



WELCOME FROM THE CEO

ANGELA CLAYTON-LEA

In January 2024, CTI held its Annual Strategy Day with CTI Board members, CTI senior leadership and key stakeholders. The event included an online session with CTI's External Advisory Board. The purpose of the Strategy Day was to discuss current challenge sand opportunities, and to agree key actions and outcomes.

Four priority areas were identified and agreed, with the collective aim of reducing 'Time to 1st Patient'. These were: -

- LEAN – optimising operational efficiency.
- Clinician Engagement – securing and enhancing collaboration and support.
- GDPR – identifying and eliminating issues.
- Funding – maximising funding opportunities

A CTI sub-committee was established for each of the four priority areas, led by CTI's then CEO, COO or a Board member, with additional Board sponsors agreed and appointed in accordance with their area of experience / value-add. As then COO, I chaired the subcommittees on LEAN and Clinician Engagement, working with colleagues to deliver meaningful change.

Our shared ambition was to reduce trial start-up times, strengthen Ireland's capacity to attract industry and collaborative group studies, and ensure recognition as a leading European destination for clinical research.

As part of the LEAN activity, restructuring the Group Central Office throughout 2024 enabled the formation of a dedicated Start-up Team in December, led by Olivia McLoughlin, to take ownership of studies from final protocol through to site initiation. This will rebalance project manager workloads and improve accountability.

The Start-up Team was introduced to members and stakeholders through a communications campaign. Success will be judged by shorter start-up timelines, stronger EU performance, more efficient resource use, and ultimately more trials opening in Ireland.

Staff also embraced Lean Six Sigma training, with fourteen colleagues completing White Belt certification and six progressing to Green Belt. These projects were applied directly to improvement processes, embedding a culture of efficiency and accountability across CTI.

Cancer Trials Ireland also invested in electronic systems for trial management, quality and training documentation, and trial master files. These platforms went live in late 2024 and helped improve audit readiness and streamline operations.

Clinician engagement in 2024 was equally important. Expanding the network and increasing trial numbers depends on close collaboration with investigators. Engagement covers involvement in study design, selection and conduct, as well as overall support for CTI's mission. Several initiatives in 2024 gave clinicians greater scope to shape our work.

For example, we strengthened Disease-Specific Sub-Groups (DSSGs) by appointing surgical and radiation oncology co-chairs in GI and CNS, with further appointments to follow in 2025. I continued a programme of on-site visits with PIs and CTRU staff, giving me direct insight into day-to-day challenges and opportunities. Combined with support for younger investigators in developing IITs, these initiatives will ensure clinician engagement grows in both depth and breadth.

CEO MESSAGE CONT.

January’s National Training Day produced actions published in a formal report. Mentorship, chosen as the theme of our Spring DSSG Stakeholder Session, also resulted in published outcomes. We restructured Clinical Executive Committee and DSSG meetings to allow more discussion, ensuring clinician voices guide decision-making.

Another priority was GDPR. The publication of Cancer Trial Ireland’s Position Paper in October followed months of engagement and consultation. Its launch featured powerful testimony from our Patient Consultants Committee and contributions from across health, industry and research, with advocacy support provided by the Irish Cancer Society. The paper is already having an impact: it was acknowledged by Minister for Health Stephen Donnelly and brought before the National Clinical Trials Oversight Committee. Cancer Trials Ireland will continue to advocate for reform, as timely trial openings are not just policy matters but, for many patients, questions of life and death.

Funding underpins all of the work described above. Planning for the next HRB grant cycle has begun, and we have sought to influence its design through workshops, surveys and discussions at our May Cancer Retreat, the outcomes of which were published in a formal report. Our aim is to help shape the next grant cycle, while pressing for increased support. The Irish Cancer Society remains a steadfast partner, and philanthropy provides essential funding, however the State must do more to fund cancer research in Ireland if we are to fully develop Ireland as a prime destination for cancer clinical trials, and reach our collective target of enrolling a minimum of six per cent of cancer patients on interventional trials.



WELCOME FROM OUR CLINICAL LEAD



PROFESSOR SEAMUS O'REILLY

Streamlining processes and regulations around clinical trials is essential if Ireland is to remain competitive internationally. As Clinical Lead for Cancer Trials Ireland, I am deeply committed to ensuring that trials open quickly and patients can access innovative therapies.

While passion among investigators and site staff has always been the driving force, relying on this alone is no longer sustainable. Working with the executive team and Board, a key goal is reducing the time from trial setup to first patient enrolment.

Oncology in Ireland is at an exciting point, with many new agents in development worldwide. A prime example is the class of antibody–drug conjugates, with over 160 drugs in the global pipeline. Ensuring that Irish hospitals provide access to such innovations is crucial. Cancer Trials Ireland has therefore identified four central themes for the next four years: streamlining, expanding studies, succession, and sustainability.

The first theme, streamlining, means removing barriers to trial activation. This is covered in the CEO's message in detail. The second theme was expanding access to new studies.

This involved building relationships with pharmaceutical companies and international cooperative groups, and consistently highlighting Ireland's infrastructure, expertise, and engaged patient population.

Succession formed the third theme. For long-term growth, Cancer Trials Ireland must nurture the next generation of clinical trial professionals. This includes not only doctors but also nurses, data managers, and coordinators. Building and retaining skilled teams is the foundation of sustainable trial delivery.

Finally, sustainability has become an urgent issue. Healthcare contributes significantly to carbon emissions, and fossil fuel pollution is linked to cancer incidence. In 2022, Cancer Trials Ireland established a national green cancer clinical trials initiative and created a Green Charter. The group has also contributed to pioneering literature, coining the term "climate toxicity" in a published paper.

As 2024 closes, there are tangible signs of progress. Accruals across clinical, radiotherapy, and translational studies have risen steadily compared with 2022 and 2023. Although translational research remains outside the scope of current HRB funding, there is hope that its importance will be recognised in future grant cycles.

Cancer Trials Ireland currently has many trials in development for 2025 across breast, gynaecological, lung and haematology, and genitourinary cancers. This strong pipeline reflects the determination of investigators to deliver trials despite systemic challenges.

Efforts in 2024 also targeted increasing trial activations. Cancer Trials Ireland published a report on the challenges of GDPR and the associated patient costs. Engagement with industry and cooperative partners at international meetings such as ESMO and ASCO has further advanced collaboration. Young investigators are being encouraged to attend these meetings, and their participation is expected to grow in 2025.

Finally, Cancer Trials Ireland has strengthened its international presence on the climate agenda. In 2024, it co-hosted a global webinar on climate change and cancer care with partners in Latin America and Europe. Investigators also contributed to publications on the carbon footprint of trials and on climate policy in oncology journals.

2024 AT A GLANCE

In 2024, 8% of the enrolling trials were Investigator-Initiated Trials (IITs) (2023: 8%, 2022: 5%) with Cancer Trials Ireland providing direct support via funding from grants received from the Health Research Board and the Irish Cancer Society. 14% (2023: 15%, 2022: 17%) of open trials involved collaboration with cancer research groups and/or were IITs, which are funded through pharmaceutical companies.

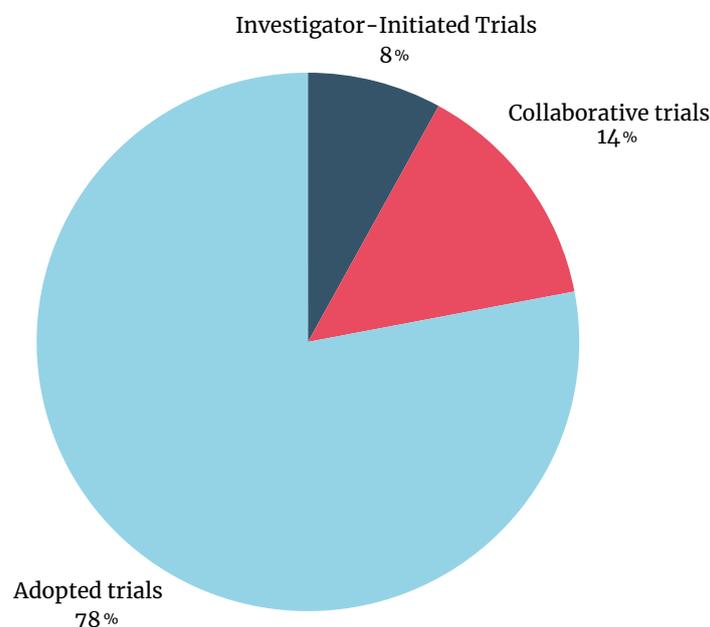
The 78% balance (2023: 77%, 2022: 78%) of open trials are adopted trials, including trials run by international pharmaceutical companies in Irish hospitals, where staff at the Group Central Office (GCO) capture accrual data only and provide updates for Disease Specific Subgroup Meetings.

Cancer Trials Ireland adopts these to capture a bigger picture of cancer clinical trial activity in Ireland. During 2024, the 19 hospital-based cancer trial research units were working on 331 (2023: 279) active cancer trials (including trials in development and follow-up).

All these trials involved a highly cooperative effort between investigators, research teams in each hospital-based research unit and the staff at our GCO.

Of the 137 (2023: 100) trials that were open and recruiting patients during 2024:

- 8% were Investigator-Initiated Trials (which Cancer Trials Ireland initiates, manages, sponsors, and monitors) and are generally funded by grants received from the Health Research Board (HRB), the Irish Cancer Society, or pharmaceutical companies.
- 14% were Collaborative trials, which involve working closely with other cancer research groups worldwide.
- 78% were adopted trials, including Industry trials, which were initiated and managed by the cancer trials units themselves, universities, or pharmaceutical companies.





53%

Overall increase in the number of patients participating in all trials in 2024 compared to 2023 (2,838 vs. 1860).

250+

Registered attendees from the cancer trials community in Ireland for the fourth Cancer Retreat.

218

Patients accrued to Radiotherapy trials in 2024, up from 49 patients in 2023.

1st

Irish patient-led research project presented at ASCO and ESMO in 2024, by Siobhan Gaynor (PCC)



ACHIEVEMENTS AND PERFORMANCE

Cancer Trials Ireland continued year 3 of the 5-year Health Research Board Cancer Trials Network with the RCSI as the Host Institution. The grant will award €6.9m to Cancer Trials Ireland over 5 years from January 2022.

In 2024, 137 trials in the CTRIAL portfolio were open to patient accrual. Of these 8% were Investigator-Initiated Trials (IITs) (2023: 8%), and 14% (2023: 15%) collaborative trials, which involve collaboration with other collaborative groups in EU and globally. The 78% (2023: 77%) balance of open trials are adopted trials.

- There was a 53% overall increase in the number of patients participating in all trials in 2024 compared to 2023 (2,838 vs. 1,860). Strong growth was seen in radiotherapy trial accruals, increasing to 218 patients in 2024 compared to 49 patients in 2023.
- The 2024 trial portfolio covered most disease areas including breast (33), gynaecological (24), genitourinary (19), haematological and lymphoma (10), gastrointestinal (6), lung (5), Head & Neck (4), CNS (2), melanoma (2) and 5 basket trials, which cover more than one disease area.

The portfolio included a variety of trials and studies with differing impact on the participating patients:

- Trials testing the reduction of chemotherapy/radiotherapy dosing given in one indication with reaching the same effect on the cancer but decreasing side effects and increasing quality of life: EORTC 2129 / TREAT ct DNA (23-03), SHAMROCK (22-01), EXPERT BIG (19-03), PREcoopERA (23-13). Under this category also falls a surgical trial MelMarT (20-37) evaluating the minimal incision necessary for a maximal outcome in melanoma. Scar size can substantially effect the patient including damage of certain structures and aesthetic appearance.
- Comparison of 2 standard treatments (possibly in different countries or different indications) to decide which is of greater benefit (20-36 NEEDS).
- Repurposing a drug, which has been used in non-cancer treatments, and adding it to standard of care cancer treatment testing for a possible enhanced outcome (20-27 PATCH).
- The collection of patients' samples (blood, tissue) is a vital part of cancer research. While this has no direct effect on the sample donor it allows researchers to find specific biomarkers, to understand how a drug works and helps to get a better understanding of cancer, which will benefit future patients (a variety of translational studies).

ACHIEVEMENTS AND PERFORMANCE CONT...

As part of the Just Ask campaign, a hybrid (in-person & virtual) Cancer Retreat was held for a fourth year in 2024. The event involved the Director of Trinity St James's Cancer Institute, Prof Maeve Lowery, representatives from the Irish Cancer Society, seven leading oncologists & haematologists, three cancer clinical trial unit site managers, and members of industry, with 250+ registered attendees from the cancer trials community in Ireland.

Siobhan Gaynor (PCC) presented a poster on her Metastatic Breast Cancer (MBC) Survey project at ASCO and ESMO in 2024, which was a first for patient-led research in Ireland.

In October 2024, Cancer Trials Ireland launched a GDPR Position Paper, including an interactive event with stakeholders, report contributors and guest speakers. The paper highlighted obstacles to the timely opening of trials. GDPR was also the topic for one of four podcasts recorded and published as part of the 2024 Just Ask campaign.

In November 2024, ahead of the General Election, Cancer Trials Ireland hosted a hustings on cancer clinical trials that included four candidates (or elected representatives). The hybrid event highlighted cancer trials among key political audiences, leading to clinical trials mentions in the Fianna Fáil manifesto and subsequent programme for government.

Prof. Seamus O'Reilly, of Cancer Trials Ireland's Clinical Leadership, published a peer-reviewed paper entitled "Climate toxicity: An increasingly relevant clinical issue in Cancer Care"

(<https://www.sciencedirect.com/science/article/pii/S2213538323000279>). He also presented at the ESMO Climate Change Taskforce.

Cancer Trials Ireland facilitated regular Stakeholder Engagement and Patient Consultation Committee (PCC) meetings in 2024.

Philanthropy in 2024 was strong with the Property Picnic (raised €129,000+), the Pat Smullen Race Day at the Curragh (see below), the Friends of Cancer Trials Ireland lunch (raised €130,000+), in addition to smaller sums raised by groups and individuals throughout the year.

The Pat Smullen Fund committee continued to meet with friends of Pat in 2024 to oversee the spending of funds and to take advice on future projects. In August, the Pat Smullen Race Day at the Curragh (including the Coast to Curragh cycle) raised €230,000+ for pancreatic cancer research.

Philanthropy continues to drive revenue and subsequent academic trials activity in Cancer Trials Ireland e.g. Friends of Cancer Trials Ireland, Property Picnic and the Pat Smullen Fund.

Cancer Trials Ireland organised fortnightly Clinical Trials Unit staff meetings (Team Leaders) and one workshop with the CEO, Quality and Communications to look at how best to support the units and streamline cancer trials.



MAXIMISING OPERATIONAL EFFECTIVENESS: INTRODUCING A START-UP TEAM

Cancer Trials Ireland's vision is to maximise access to cancer trials and improve outcomes for patients across the country. Achieving this requires not only scientific excellence, but also operational efficiency. At the Board Strategy Day in 2024, leaders identified the time to first patient (TTFP) as a pivotal measure of success. Delays in opening trials can escalate costs, extend timelines, and most importantly, mean missed opportunities for patients.

To address these challenges, Cancer Trials Ireland established a dedicated Start-up Team, led by a newly appointed Head of Start-up. The creation of this team marks a strategic shift in how trials are opened in Ireland, with a clear focus on reducing TTFP and ensuring that patients can access innovative treatments more quickly.

The Start-up Team concentrates exclusively on the earliest stages of the trial lifecycle, including contract negotiation, site activation, and ethics and regulatory submissions.

By focusing specialised expertise on this phase, the team is able to anticipate bottlenecks and streamline processes, applying lean methodologies to eliminate waste and shorten timelines.

This renewed focus on operational excellence is already embedding a culture of efficiency and agility across the organisation. The impact will be felt in faster trial openings, increased confidence from collaborators, and ultimately, greater access to trials for Irish patients. By reimagining the start-up process, Cancer Trials Ireland is strengthening Ireland's position in the competitive global landscape of cancer clinical research, while keeping patients at the heart of its mission.

“Dedicated Start-up Team created in 2024 to reduce the time to first patient in Irish cancer trials.”



DRIVING CHANGE ON GDPR FOR TRIALS

In 2024, Cancer Trials Ireland took a decisive step in addressing one of the most significant barriers facing cancer clinical research in Ireland: the interpretation and application of the General Data Protection Regulation (GDPR). Over the course of the year, our team worked intensively with legal experts, clinicians, patient representatives and stakeholders to produce a comprehensive position paper on GDPR and its impact on cancer trials. This paper set out, for the first time, a detailed and practical framework of solutions to streamline processes and remove unnecessary obstacles, while safeguarding patients' rights. It was an important moment for Cancer Trials Ireland, demonstrating our ability to bring together the voices of the research community and patients, and to provide leadership on a critical national issue.

The publication of the GDPR Position Paper was followed in October 2024 by a major launch event at the Royal College of Surgeons in Ireland. The event attracted a broad and diverse audience, with board members, funders, patient advocates, regulators, hospital research staff, and representatives of the pharmaceutical industry all in attendance. More than 130 participants also joined online, underscoring the level of national interest in the subject. The Irish Cancer Society was among those present, reflecting its strong support for tackling barriers to trial participation.

The discussions at the launch brought to life the findings of the paper. Stakeholders highlighted how delays in opening trials, often caused by inconsistent or overly complex GDPR procedures, are directly limiting opportunities for Irish patients to take part in research. Speakers reinforced the importance of standardisation, clarity and efficiency, and the need for a whole-system approach to reform. The event ended with a strong call to action for government and health authorities to implement solutions that would make Ireland a more attractive place to run cancer trials, ensuring that patients are not left behind in accessing cutting-edge treatments.

By pairing the publication of a substantive policy paper with a successful, inclusive launch, Cancer Trials Ireland not only highlighted the urgency of GDPR reform, but also demonstrated the organisation's capacity to lead complex debates in the national interest. The work of 2024 laid down a clear marker: that patients, clinicians and researchers are united in their commitment to overcoming regulatory barriers, and in their determination to ensure Ireland remains competitive and compassionate in cancer trial delivery.



PUBLIC AND PATIENT INVOLVEMENT (PPI) AT CANCER TRIALS IRELAND IN 2024

2024 was a year of change, achievement and visibility for Public and Patient Involvement at Cancer Trials Ireland.

We said a warm thank you and goodbye to Sarah McLoughlin, our first PPI Co-ordinator, whose dedication helped shape the Patient Consultants Committee (PCC). In September, we welcomed Emer Mulvaney as our new PPI Programme Manager, ensuring continuity and bringing fresh energy to the role.

The year brought important milestones for patient-led research. The Metastatic Breast Cancer Survey (CTRIAL-IE 23-05), led by PCC member Siobhán Gaynor, gained national and international recognition:

- Awarded the Irish Cancer Society’s PPI Project of the Year 2024
- Presented in two posters at ASCO 2024 and two posters at ESMO Breast 2024
- Published in The Breast journal in November 2024 (ahead of print in February 2025)

In November, we also celebrated the opening of PRO-ACT, a study co-designed by PCC members Martin Sweeney and Jacqueline Daly, focusing on sexual wellbeing and associated mental health after prostate cancer treatment. This project is another powerful example of patients leading research that matters deeply to them and their communities.

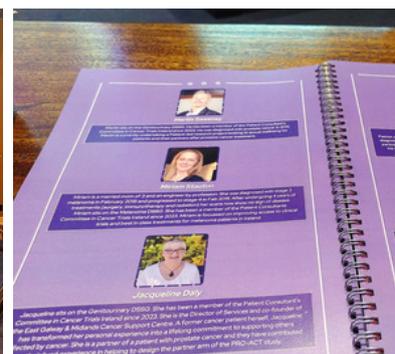
The PCC Strategy Day in November 2024 set out our priorities for 2025 and 2026, with members leading the conversation on where PPI should go next. Our community grew with new members joining, while long-standing contributors continued to share their experience and guidance.

Throughout the year, PCC members represented the patient voice at events, conferences and Disease Specific Subgroup (DSSG) meetings, ensuring that lived experience informs trial development and the review of study materials.

The Chair of the PCC continued to sit on the Board of Cancer Trials Ireland, making sure the patient perspective is present at the highest level of decision-making.

We were also delighted to host a two-day visit from the Northern Ireland Cancer Research Consumer Forum (CRCF) with the Irish Cancer Society, strengthening cross-border collaboration and shared learning.

Looking back, 2024 was a year where patient involvement was recognised, celebrated and made a real impact. Looking forward, we are excited to build on this momentum, continuing to work side by side with patients, families, clinicians and researchers, and ensuring that every trial we support is shaped by the voices of those who matter most: the people living with and beyond cancer.



INCREASING AWARENESS OF CANCER TRIALS IRELAND – COMMUNICATIONS & MARKETING

A number of activities are undertaken during the year to increase the awareness of cancer trials and showcase the work that is being done across the country. These opportunities will continue to be pursued during the coming years. They include the following:

International Clinical Trials Day: This is the organisation’s annual set piece publicity event which results in a boost to the organisation’s profile, the work of its members and contribution of patients. In 2024, we hosted Ireland’s the fourth Cancer Retreat, which was a hybrid event attended by 250+ members of the Irish clinical oncology research community virtually & in person. This was supported by significant digital and media communications leveraging patient stories, where possible on Investigator-Led Trials, to maximise the reach of our message to “Just Ask”.

Mainstream media relations: There were two significant events driving outreach to mainstream media in 2024 – the launch of Cancer Trials Ireland’s Position Paper on GDPR, and significant local (with limited national) media relations in support of a public webinar on cancer trials around international clinical trials day.

Specialist media relations: Details of trials are featured regularly in specialist medical press such as the Medical Independent, Cancer Professional and UPDATE Oncology and Haematology Journal.

Online: In 2024, the Just Ask campaign focused on digital executions and outputs – videos of our staff PCC members in a range of campaigns, which were leveraged via paid and organic social media channels. Cancer Trials Ireland also produced its third podcast series, featuring four episodes.

DSSG Digest: The DSSG Digest newsletter lists the latest news and up to date listing of open cancer trials. It is widely distributed within the community (including the media) both electronically and in hard copy in the Spring and late Autumn.

Annual Review: The publication of the organisation’s Annual Review is another opportunity used to profile the organisation’s successes and progress.

Conferences: Attendances at conferences are used regularly to raise the profile of the organisation’s work

Quarterly accruals published: We established a process for publishing the accruals figures for each quarter, broken down by study type and disease area. members on study news and updates.



FEATURED STUDY

PRESERVE: PROTECTING QUALITY OF LIFE IN HEAD AND NECK CANCER

The PRESERVE trial (CTRIAL-IE 20-04) is an international, randomised study that tested whether reducing the area of radiation delivered to the neck after surgery for oral cavity squamous cell carcinoma can maintain cancer control while lessening long-term side effects. The trial sought to determine if limiting radiation volumes leads to better swallowing outcomes and improved quality of life, without compromising effectiveness.

In Ireland, the trial was open at St Luke's Radiation Oncology Network (SLRON), Cork University Hospital and University Hospital Galway. SLRON recruited 30 patients and was the most successful site worldwide in patient enrolment. University Hospital Galway also joined in 2023, highlighting how the Irish Research Radiation Oncology Group (IRROG) is expanding trial access to patients across the country.

Clinical importance

Radiotherapy is a vital treatment for head and neck cancer, but it can cause life-altering side effects, particularly difficulties with swallowing. By comparing standard treatment fields with reduced fields, PRESERVE aimed to generate robust evidence on how to protect function and quality of life while still ensuring effective cancer treatment.

Irish leadership

Ireland's strong performance in this trial significantly helped to shape international practice. With SLRON as the highest recruiting site globally, and patients accessing the trial across multiple Irish centres, PRESERVE demonstrates the impact of collaborative networks like IRROG in driving innovation and ensuring patients benefit from cutting-edge, patient-centred research.

“Ireland was the highest-recruiting country internationally on PRESERVE.”



NLI on PRESERVE: Prof Sinead Brennan

FEATURED STUDY

PROACT: PATIENT-LED RESEARCH ON PROSTATE CANCER RECOVERY

The PROACT survey (Patient-led Research On sexual experience After prostate Cancer Treatment) is the first all-island initiative to explore the sexual and emotional impact of prostate cancer treatment on patients and their partners. Sponsored by Cancer Trials Ireland, and co-led by patient advocate Martin Sweeney and Dr Paul Kelly, PROACT has opened up vital conversations about intimacy, identity and recovery after cancer.

Launching in 2024, the anonymous survey encourages respondents to share their unique lived experiences of dealing with their prostate cancer treatment and the impact on their lives. It also includes a dedicated partner survey for partners of prostate cancer patients to share their experiences similarly, led by partner advocate Jacqueline Daly.

Objectives and significance

PROACT aims to generate robust evidence on issues that are often under-researched and under-discussed in cancer care, such as sexual recovery and emotional well-being. The findings will be used to inform more compassionate, holistic care pathways and to influence future clinical practice and policy.

Impact and innovation

The project is breaking new ground by centring patient and partner voices, using powerful advocacy videos to encourage participation and spark public discussion. It is hoped that the evidence gathered will provide a crucial platform for enhanced care for those living with and beyond cancer and will be presented at future oncology conferences to drive change both nationally and internationally.

Collaboration and support

PROACT was devised and launched with the support of the Irish Cancer Society, the Patient Consultants Committee of Cancer Trials Ireland, and Bon Secours UPMC Cancer Centre. The project demonstrates the value of partnership and patient-led innovation in shaping the future of prostate cancer care.

“The evidence gathered will provide a crucial platform for improving life after cancer and driving change both nationally and internationally.”



**Patient Advocate & Co-PI
Martin Sweeney**



**Patient Advocate
Jacqueline Daly**

FEATURED STUDY

ISA-RVD TRIAL: ADVANCING FRONTLINE TREATMENT FOR MULTIPLE MYELOMA

The Isa-RVD trial (CTRIAL-IE 22-02) is a Phase II, multi-centre study sponsored by Cancer Trials Ireland. It is evaluating a four-drug combination – isatuximab, lenalidomide, bortezomib and dexamethasone – as a new frontline option for patients with newly diagnosed multiple myeloma (NDMM).

“This study reflects the strength of Ireland’s cancer trials community and the value of international collaboration.”

Recruitment opened in March 2022 and is expected to be completed by early 2025. The trial is open at five Irish sites and one international site in Denmark. Participating hospitals include:

- Mater Misericordiae University & Mater Private Hospital
- University Hospital Limerick
- University Hospital Waterford
- Beaumont Hospital
- St James’s Hospital
- Aarhus University Hospital, Denmark

Primary objective

The study’s primary endpoint is to assess the rate of Very Good Partial Response (VGPR) or better after two cycles of induction therapy, as defined by the International Myeloma Working Group (IMWG) criteria.

Clinical significance

By incorporating isatuximab, a monoclonal antibody targeting CD38, into an established regimen, the trial aims to improve depth of response while maintaining a manageable safety profile. Results will provide vital insights into optimal frontline treatment strategies for myeloma.

Collaboration and commitment

Led by Prof. Peter O’Gorman and colleagues across the network, this study reflects the strength of Ireland’s cancer trials community and the value of international collaboration. The dedication of patients, clinicians and research staff has been central to its success to date.



NLI on Isa-RVD, Prof Peter O’Gorman

FUNDRAISING

Irish Cancer Society

The Irish Cancer Society sustained its €1m in funding for Cancer Trials Ireland, and furthermore secured future donations at this level as part of a signed Memorandum of Understanding (MOU) with Cancer Trials Ireland.

Fundraising in memory of Louise Creevy

Louise Creevy, who passed away in July 2021, has inspired an incredible amount of fundraising for Cancer Trials Ireland, through her family, friends and colleagues. In May 2023, Louise's colleagues in Bannan Property organised and hosted a live music event, the Property Picnic, which went on to raise more than €129,146. Meanwhile, the colleagues of Louise's husband in Nestle maintained their fundraising for Cancer Trials Ireland in 2024 as their staff charity. In all, Nestle donations amounted to donating €29,879 in the year.

Pancreatic

The work of Pat Smullen and his family, friends, and the horse racing community in 2019 put Cancer Trials Ireland on the fundraising map, linking the organisation with pancreatic trials research in the minds of the public.

In 2024, the Curragh to Curragh cycle once again teamed up with The Curragh and Frances Smullen to host the Pat Smullen Race Day in August. The event raised €240,000 for pancreatic cancer trials and associated initiatives. This fantastic donation was augmented with the news that The Curragh and the Committee for the Pat Smullen Race Day were committed to hosting the event for the coming few years.

There were further very significant donations towards pancreatic in 2024, including €168,000 on behalf of Prof Doug Veale, €22,712 from the Shanahan & Cantrell families in association with Woodbrook Golf Club; €15,000 on behalf of Brian Cummins; €10,000 on behalf of Tommy Creighton; €7,863 from the TCD Horse Racing Society; €4,650 from Rory Duggan; €1,115 from the Farrier Competition and €1,100 via Anne Eighan, on behalf of the Mullingar Golf Club Bridge Club.



FUNDRAISING CONT.

Rob Murray & Lena Quinn Kilimanjaro Climb

In June 2024, Rob Murray and Lena Quinn undertook a climb of Mount Kilimanjaro to raise funds for Cancer Trials Ireland. Inspired by Rob’s mother’s ongoing cancer journey, they covered their own expenses to ensure all donations went directly to support cancer trials. Their efforts were met with incredible generosity, raising €18,809 through community support.



The Property Picnic 2024

Additional Fundraisers

- Rachel McCann / 5k Charity Walk - €10,000
- 2024 Dublin City Marathon (various donors) - €9,029
- Pdraig Murphy - €2,000
- Daragh Callanan, Ballyfoyle Agriculture Show - €1,600
- Ciaran Dixon, Marathon runner - €380



The Curragh to Curragh Cyclists cross the finish line



Rob Murray & Lena Quinn, at the summit of Mount Kilimanjaro

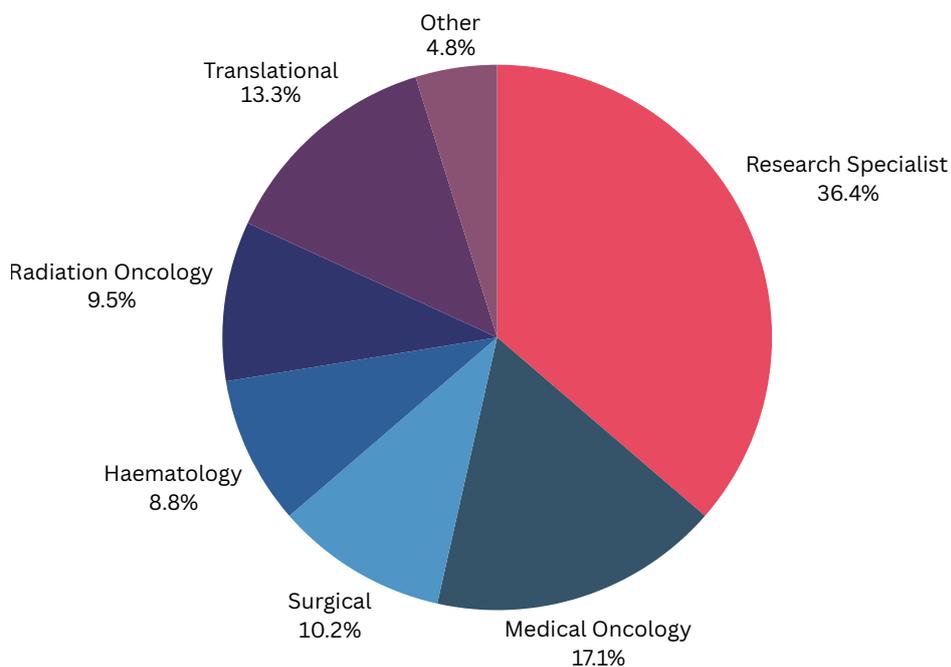


Friends of Cancer Trials Ireland, L to R: Rita Lovett, Kim Fitzgerald, Deirdre McDermott, Paula Murphy, Liz Coghlan, Fiona Collins, Grace McDermott, Katherina Sheahan, Mairead O'Brien & Julie Liston.

MEMBERSHIP IN 2024

This metric records the number of registered Members of Cancer Trials Ireland. Cancer Trials Ireland total membership on 31st December 2024 was 729 (38 new members joined during 2024).

Type	No.
Research Specialist	265
Medical Oncology	125
Surgical	74
Haematology	64
Radiation Oncology	69
Translational	97
Other	35



98%

of Irish Oncologists are our members

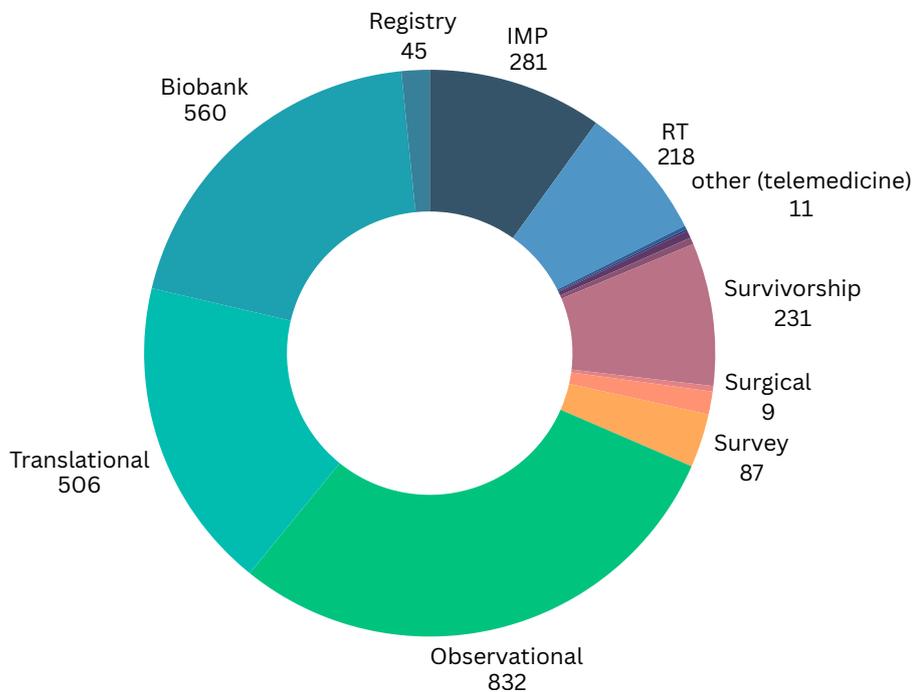
14%

increase in membership since March 2023

ACCRUALS

2024 accruals by Study Type

Study Type	All Trials
IMP	281
RT	218
IMP/RT	6
Nutrition	3
other (acupuncture)	12
other (telemedicine)	11
Survivorship	231
Surgical	9
Imaging	37
Survey	87
Observational	832
Translational	506
Biobank	560
Registry	45
Total	2838



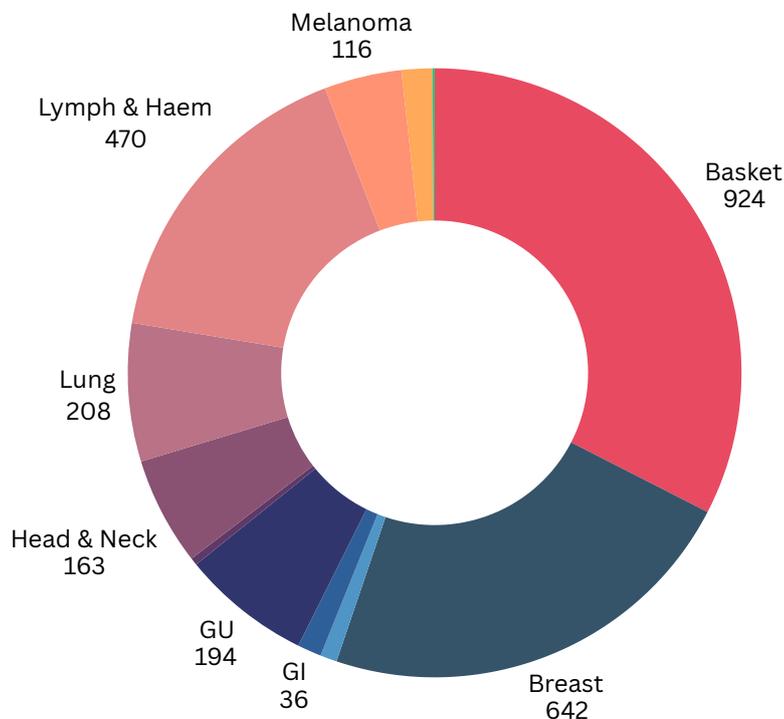
- **Total Accruals to Interventional Trials (Drug / Radiotherapy / Medical Device/Surgery) = 808**
- **Total Accruals to Non-Interventional Trials ((Biobank / Observational / Registries / Translational) = 2030**



ACCRUALS

2024 accruals by Disease area.

Disease Group	2024
Basket	924
Breast	642
CNS	25
GI	36
GU	194
Gynaecology	11
Head & Neck	163
Lung	208
Lymph & Haem	470
Melanoma	116
Paeds	46
Sarcoma	3
Total	2838



TRIALS PORTFOLIO

This metric records the number and type of trials open and developing during 2024. Investigator-initiated and Collaborative trials (involving research organisations in other countries) were essential areas of focus during 2024. Both investigator-initiated trials (funded by HRB, Irish Cancer Society and other supports and/or directly by pharmaceutical companies) and Collaborative trials are fully supported by our GCO clinical, professional, operations and administrative teams. The third type of trial included in our portfolio is an adopted trial. While these trials are carried out in the various cancer trials research units, GCO staff are minimally involved.

The table shows the total number of trials active in a particular disease group. ‘Active’ means trials in development, open, treatment, and follow-up.

Disease Group	2021	2022	2023	2024
Basket	9	10	10	26
Breast	47	44	41	61
CNS	5	4	2	4
Gastrointestinal	31	30	18	22
Genitourinary	46	44	40	58
Gynaecological	15	20	21	30
Head & Neck	10	10	7	8
Lung	32	33	29	37
Lymph & Haem	45	45	33	47
Melanoma	8	8	11	14
Paediatric	42	40	38	41
Total	290	288	250	348

TRIALS PORTFOLIO

The table shows the total number of trials open to accrual at year end. This includes collaborative and IIT and adopted. Includes Interventional and Non-Interventional.

Disease Group	2021	2022	2023	2024
Basket	4	5	5	18
Breast	13	10	6	10
CNS	5	0	1	2
Gastrointestinal	14	7	6	9
Genitourinary	17	9	10	12
Gynaecological	6	4	3	5
Head & Neck	3	3	2	3
Lung	9	9	7	8
Lymph & Haem	14	15	9	15
Melanoma	3	4	4	7
Paediatric	19	20	14	6
Total	105	86	67	95

OUR GLOBAL NETWORK



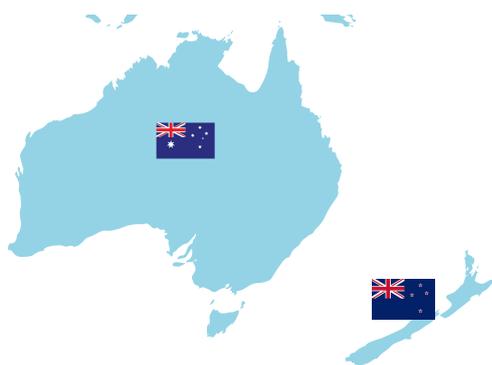
Cancer Trials Ireland works in collaboration with leading cancer research organisations worldwide.

United States and Canada

International partnership is central to our mission, ensuring that patients in Ireland have access to the latest treatments and innovative clinical trials.



Europe



Through these collaborative efforts, we contribute to global advances in cancer research while delivering tangible benefits to patients and families here at home.

Australia and New Zealand

COLLABORATIONS WITH INTERNATIONAL RESEARCH GROUPS

A large part of the 2024 portfolio of studies in development, open and in follow up studies originate from successful collaborations with international groups.

Acute Myeloid Leukemia Study Group (AMLSG)
Austrian Breast & Colorectal Cancer Study Group (ABCSCG) (Austria)
Associazione Italiana Ematologia/ Oncologia Pediatrica (AIEOP)
Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)
Breast International Group (BIG)
BC Cancer (British Columbia)
St. Anna Children's Cancer Research Institute (CCRI)
Canadian Cancer Trials Group (CCTG)
Centre hospitalier de l'Université de Montréal (CHUM)
Children's Cancer Research Institute Vienna
Christie NHS Foundation Trust
Dutch Childhood Oncology Group (DCOG)
Dr David Palma (Lawson Health Research Institute (Canada))
Deutsche Studiengruppe CLL (DSCLLG)
ECOG-ACRIN Cancer Research Group
European Network for Gynaecological Oncological Trial groups (ENGOT)
European Organisation for Research and Treatment of Cancer (EORTC)



COLLABORATIONS WITH INTERNATIONAL RESEARCH GROUPS

A large part of the 2024 portfolio of studies in development, open and in follow up studies originate from successful collaborations with international groups.

Erasmus Medical Centre
ETOP IBCSG Partners Foundation
Fondazione IRCCS 'Istituto Nazionale Tumori' (INT)
Fondazione Michelangelo
Fundacion Para la Investigacion Hospital Universitario La Fe
German Breast Group (GBG)
GEICAM (Grupo Español de Investigación en Cáncer de Mama)
Great Ormond Street Hospital (GOSH UK)
Gruppo Oncologico Nord-Ovest (GONO)
Gustave Roussy Institute
Hopp Children's cancer centre Heidelberg
Hemato-Oncologie voor Volwassenen Nederland (HOVON)
Institute of Cancer Research UK
Karolinska University Hospital
Melanoma and Skin Cancer (MASC) Trials
Melanoma Institute Australia
Multicenter Italian Trials in Ovarian cancer and gynecological malignancies (MITO) (Italy)
Monash Health (Australia)
Leiden University Medical Centre (LUMC)
Netherlands Cancer Institute (NKI)
North-Eastern German Society of Gynaecological Oncology (NOGGO) (Germany)

NRG Oncology
NSABP Foundation Inc
Prostate Cancer Clinical Trials Consortium (PCCTC)
Princess Margaret Cancer Centre (Canada)
Princess Máxima Center for Pediatric Oncology, Utrecht
Royal Marsden Hospital NHS Foundation Trust
Swedish Association of Breast Oncologists (SABO), Sahlgrenska University Hospital (Sweden)
SIOP (International Society of Paediatric Oncology)
Southwest Oncology Group (SWOG)
Trans-Tasman Radiation Oncology Group (TROG)
Unicancer
University College London
University Hospital Basel (Switzerland)
University Hospital Freiburg
University of Birmingham
University of Health Network, Toronto & Bladder Cancer Canada
University of Liverpool
University of Oxford (UK)
University of Toronto (Canada)
Walton Centre NHS Foundation Trust



TRAINING

Training courses are conducted by the GCO training team, with attendance by GCO staff and investigators/investigational staff from research units. Note: a significant number of our training courses are being recorded and are available on our online learning Management system for self-training. As a result, these numbers of self-learners are not included in the numbers below.

Type of Training	Number of Sessions	Number of attendees (Central Office Staff)	Number of attendees (Research Unit Staff)
Data Protection	3	31	0
Good Clinical Practice Training	10	31	19
Induction Trainings, all departments	14	33	0
Site visit training (e.g. monitoring, site initiation, close out), IMP/pharmacy training	13	36	0
Pharmacovigilance Training	5	7	0
RECIST 1.1	2	13	0
Clinical Trial Regulation and Serious Breach Training	3	1	45
Trial Master File + essential documents + archiving Training	12	22	0
Systems training	3	52	0
Audit/ inspection preparation	1	0	20

CANCER CLINICAL TRIAL RESEARCH UNITS MONITORING

The conduct of a clinical trial should be adequately monitored in order to ensure the reliability and robustness of the results. Monitoring of clinical trials is a requirement of ICH-GCP, EU and national regulations. Monitoring activity is carried out on a study by study basis both in the individual Cancer Clinical Trial Unit and remotely. Each study undergoes a risk analysis, prior to the study being open to patients, which determines the level of monitoring activity and rationale for the chosen monitoring strategy. The risk-based monitoring plan contains detailed information on how the study will be monitored from the time of study initiation to study closure. Adaptive strategies were developed to facilitate monitoring during the COVID pandemic. This flexibility continues in effect.

The monitoring level is now a combination of on-site or remote and centralised monitoring activities as appropriate to the risk inherent to the type of study and other identified risks. Triggers for decreased or more frequent targeted on-site or remote monitoring visits can be identified in the monitoring plan. The monitoring level can also be determined on a site-by site basis depending on the previous or unknown experience of the investigational site

Pharmacovigilance

Pharmacovigilance activity	Number
SAEs received and processed by Cancer Trials Ireland (from Medical Oversight Meeting (MOM) reviewed studies)	105
SUSARs Entered onto Eudravigilance Database by Cancer Trials Ireland	33 SUSARs submissions
PhV SOPs updated	0
Annual Development Safety Update Reports (produced in-house) distributed to relevant Ethics Committees and Competent Authorities by Cancer Trials Ireland	10
6 Monthly SUSAR line listings produced	14
Safety and clinical database reconciliations	38

Audit activities

Number of days spent in 2024 by GCO staff preparing for and conducting audits and follow-up activity as well as active participation in external sponsor and third party audits at our central office and at cancer trials research units around the country.

The total is 72 working days.

Audit Type	Preparation, Conduct, and Follow-up (days)	%
Audit Strategy and Planning	8	11%
Audit and Inspection Readiness	8	11%
Audit of Investigator site by Sponsor	10	14%
Audit of CTI by CTI	21	29%
Audit of Investigator site by CTI	25	35%
Inspection of CTI or Investigator site	N/A	N/A

Note: Preparation and follow-up processes take on average 4 times the conduct time.

PARTICIPATION IN CONFERENCES & MEETINGS

Event	Month
Cancer Trials Ireland/ISMO – National Training Day	January
American Society of Clinical Oncology Gastrointestinal (ASCO GI) Cancers - Symposium	January
American Society of Clinical Oncology Genitourinary (ASCO GU) Cancers - Symposium	January
A Joint US-FDA MHRA-UK Health Canada Good Clinical Practice & Pharmacovigilance Compliance Symposium	February
European Association for Cancer Research (EACR)-American Association for Cancer Research (AACR)-Irish Association for Cancer Research (IACR) Basic and Translational Research Conference: How to bring basic science discoveries to the clinic	February
Gynecologic Cancer Intergroup (GCI) – Spring 2024 Meeting	March
Breast International Group (BIG) – Virtual Scientific Meeting	March
European Network for Gynaecological Oncological Trial groups (ENGOT) – Spring meeting	April
All Ireland Lung Cancer Conference	April
German CLL Study Group - XIVth International Workshop	April
HOVON Leukemia working group – semi-annual meeting	April
John Fitzpatrick GU Cancer Conference	April
Irish Melanoma Forum	May
Irish Breast Cancer Update Meeting – Mater Misericordiae University Hospital	May
Environmental Protection Agency: Climate Change Conference 2024 - Ireland Living in a Changed Climate	May
ESMO Breast Cancer 2024	May
Irish Society of Gynaecological Oncology (ISGO) - Public and patient involvement(PPI)	May
Irish Research Radiation Oncology Group (IRROG) Study Day	May

PARTICIPATION IN CONFERENCES & MEETINGS

Event	Month
Irish Health Research Forum (IHRF) – semi-annual symposium: Empower, Innovate, Transform: Driving the Future of Health Research	May
International Breast Cancer Study Group – Annual Meeting	May
European Society for Medical Oncology (ESMO) – Breast Cancer 2024	May
Blood Cancer Network Ireland (BCNI) – Annual Symposium	May
Irish Melanoma Forum	May
Cancer Trials Ireland Cancer Retreat	May
European Clinical Research Infrastructure Network (ECRIN): Data Centric Clinical Research	May
All-Island Cancer Research Institute (AICRI)-Cancer Trials Ireland-Irish Society for Gynaecological Oncology (ISGO) – Ireland-US Cancer Collaboration	June
American Society of Clinical Oncology (ASCO) – Annual Meeting	June
European Haematology Association (EHA) – Congress	June
Irish Association for Cancer Research (IACR) Retreat	June
Breast International Group (BIG) – Ordinary General Assembly	June
Irish Society of Medical Oncology (ISMO) – post ASCO updates	July
European Organisation For Research And Treatment Of Cancer (EORTC) Horizon Europe Cancer Mission ‘Diagnosis and treatment’ cluster	September
Haematology Summit 2024	September
Breast International Group (BIG) – Scientific Meeting	September
European Society for Medical Oncology (ESMO) – Congress	September
International Symposium on Translational Research in Oncology (CCRT)	September
European Network for Gynaecological Oncological Trial groups (ENGOT) – Assembly	September
HOVON Leukemia working group – semi-annual meeting	October
Marie Keating Foundation Metastatic Breast Cancer Day	October
PRO-EX Prostate Cancer Symposium	October
Health Products Regulatory Authority (HPRA) - Patient Speaker Forum	October

PARTICIPATION IN CONFERENCES & MEETINGS

Event	Month
Gynecological Cancer Intergroup (GCIG) Cervical Cancer Consensus Conference	October
International Gynecological Cancer Society (IGCS) – Annual Global Meeting	October
The All Ireland Colorectal Cancer Conference 2024	October
European Thoracic Oncology Platform (ETOP) Annual Meeting	November
The Gathering around Cancer	November
Health Research Data Protection Network (HRDPN) – Creating a Brighter Future for Data Protection in Clinical Research in ROI	November
Health Research Board-Trials Methodology Research Network (HRB-TMRN) – Winter School Innovations in Cancer Trials Methodology	November
Irish Health Research Forum (IHRF) – semi-annual symposium: Public trust in health research: are we doing enough?	November
The Irish Platform for Patient Organisations, Science & Industry (IPPOSI) – conference: “PREPARING FOR THE SECONDARY USE OF HEALTH INFORMATION: IS IRELAND GAINING GROUND?”	November
Millin Meeting 2024	November
Irish Lung Cancer Community (ILCC) Patient Symposium	November
Research Quality Association (RQA) International Quality Assurance Conference	November
Pancreatic Society of Great Britain and Ireland Annual Meeting 2024	November
Health Research Board-National Clinical Trials Office (HRB NCTO): Enabling High Quality Clinical Trials	November
Gynecologic Cancer Intergroup (GCIG) - Autumn 2024 meeting	November
American Society of Haematology – Annual Meeting	December
Irish Society for Gynaecological Oncology (ISGO) – Annual Meeting	December

PUBLICATIONS

This metric records the publications in peer-reviewed journals and abstracts accepted at top level international meetings based on the findings of trials the Members of Cancer Trials are, or have been, involved in.

Publications Summary Table (2024)

Area	Peer Reviewed Journal Articles 2024	Abstracts: Poster/Oral Presentations 2024
Basket	1	1
Breast	13	4
CNS	0	0
Gastrointestinal	2	1
Genitourinary	6	2
Gynaecological	7	1
Head and Neck	0	0
Lung	0	0
Lymphoma & Haematological	0	0
Melanoma	0	0
Other	6	3
Total	35	12

A full list of all Peer-reviewed Journal Articles is available on our website: www.cancertrials.ie/resources/journal-publications

FINANCIAL STATEMENTS

Statement of income & retained earnings for the financial year ended 31 December 2024

	<i>Notes</i>	2024 €	2023 €
Income	4	4,396,436	4,540,911
Expenditure		(4,430,421)	(4,416,291)
(Deficit) / Surplus on ordinary activities before interest		(33,985)	124,620
Interest receivable and similar income	5	36,604	295
SURPLUS FOR THE FINANCIAL YEAR	6	2,619	124,915
RETAINED EARNINGS AT THE BEGINNING OF THE FINANCIAL YEAR		588,611	463,696
RETAINED EARNINGS AT THE END OF THE FINANCIAL YEAR		591,230	588,611

Balance Sheet as at 31 December 2024

	<i>Notes</i>	2024 €	2023 €
Fixed Assets			
Tangible assets	10	51,753	79,521
Current Assets			
Debtors	11	2,046,547	1,977,411
Cash and cash equivalents		4,329,514	4,165,337
		6,376,061	6,142,748
Creditors: Amounts falling due within one year	12	(5,836,584)	(5,633,658)
Net Current Assets		539,477	509,090
Net Assets		591,230	588,611
Reserves			
Retained earnings		591,230	588,611
		591,230	588,611



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by



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answers to cancer.*

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