

ANNUAL REVIEW



2023



Together, we're finding answers to cancer.

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Who We Are



Cancer Trials Ireland is a 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 Cancer Clinical Trials Groups and 18 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 about 2% of Irish patients were on interventional clinical trials in 2021, Cancer Trials Ireland has made significant strides, with a 27.5% increase in patient participation in all trials in 2023 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.

Meet Our Team



Deirdre Somers

CHAIR

Deirdre Somers is Chair of the board of Cancer Trials Ireland since 2021 having served on as a director from 2019.



Eibhlín Mulroe

CEO

Eibhlín has overseen a period of huge growth and expansion since joining in 2015. She is a driving force for bringing new trials to Ireland.



**Prof Ray
McDermott**
CLINICAL LEAD

Prof McDermott is a Medical Oncologist at SVUH, TUH, and the Beacon Clinic and provides clinical leadership to the organisation.



**Angela
Clayton-Lea**
COO

Angela provides overall direction, leadership, and expertise, ensuring Cancer Trials Ireland's strategy is achieved.

Chairperson's Message



In 2023, the Board of Cancer Trials Ireland continued to focus on the five key strategic objectives that were agreed in 2022, at the outset of a new five-year HRB grant funding model.

Speaking to the first objective (maximising our contribution to the National Cancer Strategy), I can report that trial recruitment figures continued to rise, in the aftermath of the pandemic, and cyberattack of previous years. Meanwhile, staff retention levels are also on the rise in 2023, which speaks to our second objective of optimising for stable, scalable talent.

Third, as we continue to position clinical research as a fundamental part of care through advocacy, and influence, I note that once again the Cancer Retreat, and stakeholder meetings attached to the Disease Specific Sub-Group (DSSG) meetings continue to demonstrate community leadership on the many challenges we face.

Regarding our fourth objective, to deliver a compelling all-island cancer trial proposition, I refer you to the CEO's message which details our part in a cross-border delegation visiting USA around St Patrick's Day.

On the matter of organisational funding, our fifth strategic objective, 2023 saw another very significant development with Cancer Trials Ireland signing an MOU with the Irish Cancer Society that sees annual funding increase to €1m annually with a 3-year commitment. I also want to recognise significant, ongoing philanthropic efforts by the Property Picnic, and the Pat Smullen Race Day, among many others.

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 Paula Murphy and Darren Byrne for their efforts and commitment over several years of service. Darren chaired the Audit and Risk Committee and worked closely with the team to ensure we met our governance obligations and those to funders and patients.

Ms Deirdre Somers, Chair of the Board



One major highlight of 2023 saw Cancer Trials Ireland join a delegation from the All-Island Cancer Research Institute (AICRI), which travelled to Washington, D.C., during St. Patrick's Day. The objective was to promote collaboration in cancer trials and research between Ireland, Northern Ireland, and the U.S. The delegation met with influential organizations including leadership of the National Cancer Institute (NCI), the US-Ireland Research Partnership, the US State Department, members of Congress and Irish and British political leaders, to emphasize the importance of an All-Island and transatlantic approach to cancer research.

Into the summer, I worked with key stakeholders to bring about the establishment of the Pat Smullen Chair in Pancreatic Cancer in UCD, which was made possible by support from UCD, the NCCP, but most especially the vision of Frances Crowley, the family of Pat Smullen, and the racing community. The role aims to establish Ireland as a global hub for pancreatic cancer research. It honours the Smullen's legacy and will benefit Irish patients facing this challenging cancer in the years ahead.

I brought a team of 3 to both ASCO, Chicago in June and ESMO conference in Madrid in October, where we led over 25 meetings at both events with international collaborative groups and companies, before supporting a range of Irish investigators and researchers making presentations, publishing posters and taking part in panels. These discussions caught up with partners on trials we are running together, identifying issues, and learning from successes. Other discussions helped position Cancer Trials Ireland as a key partner for international groups looking to bring innovative trials to Europe. Expanding trials at Irish sites aligns with Cancer Trials Ireland's mission of global recognition in clinical research and improving outcomes for Irish patients.

In October, we made a significant new appointment within Cancer Trials Ireland, enhancing the clinical team operational capability and bringing on board a new Chief Operating Officer, Angela Clayton-Lea. An exciting appointment which will be a game changer for our sites with an eye firmly on improving efficiency and clinical trial timelines. Meanwhile our Public & Patient Involvement commitment went from strength to strength as we dramatically increased Patient Consultants Committee membership to 17 members. 2023 also saw the development of our first patient-led research project, around metastatic breast cancer led by Siobhan Gaynor, patient advocate and scientist. Siobhan has led from the front and given all of us a masterclass in how to lead a multidisciplinary approach to cancer research. I am in awe of her commitment and strength, no matter what the hurdle along the way, heroic.

In closing, I want to thank our Chair and Board for their support and guidance in 2023, and I look forward to continuing our close and fruitful relationship in the coming year. I also want to thank the teams at our office and at sites, for their passion and commitment. With new staff and supports in place, we look forward to building on our successes in 2024.

Ms Eibhlín Mulroe, CEO

From our Clinical lead



In 2023, I came to the end of my tenure as Clinical Lead for Cancer Trials Ireland taking on the Vice-Lead role for 2024. I am pleased to reflect on successes we have enjoyed in 2023. Investigator-led trials have seen a resurgence after the pandemic-related disruptions. Key trials like SHAMROCK, led by Prof. Bryan Hennessy, and ADEPPT, led by Prof. Jarushka Naidoo, have enrolled their first patients. In addition, several radiation therapy (RT) trials got underway, with two of these being investigator-led as well. These trials are essential to advancing cancer research in Ireland, addressing critical academic questions that drive progress.

Meanwhile, translational studies such as CADY (breast cancer) and nutritional studies such as FEED (pancreatic cancer), also progressed thanks to funding received from pharma and philanthropy respectively, reflecting the determination of investigators to pursue vital research.

Irish investigators continue to make an impact at key international conferences, like ASCO and ESMO, and I want to commend those colleagues who saw their work celebrated at these events and published in prestigious journals like the LANCET (Neo-AEGIS) and NEJM (CLL13). Through these publications, and the work that investigators do at major conferences, we showcase our ability to offer our support to international collaborative groups wishing to bring their trials to Europe. Cancer Trials Ireland is in a unique position to do this. Opening innovative, high-quality trials at Irish sites directly supports our mission to be globally recognised for collaboration in clinical research and will ultimately deliver improved outcomes for Irish patients.

Furthermore, I am delighted that the Board of Cancer Trials Ireland has agreed to support the annual award of one fellowship programme at Memorial Sloan Kettering, New York. This is a fantastic opportunity to forge partnerships with our respected colleagues across the Atlantic and deliver expert training opportunities to our doctors. Networking internationally has been a real strength for Irish investigators training abroad, and this initiative builds on that strong tradition.

Finally, I want to wish the incoming Clinical Lead for 2024, Prof Seamus O'Reilly, the very best of luck for the coming years. Cancer Trials Ireland is a dedicated, indefatigable organisation that will comprehensively support him in the years ahead.

Professor Ray McDermott, Clinical Lead

2023 at a Glance

In 2023, 8% of the enrolling trials were Investigator-Initiated Trials (IITs) (2022: 5%) with Cancer Trials Ireland providing direct support via funding from grants received from the Health Research Board and the Irish Cancer Society.

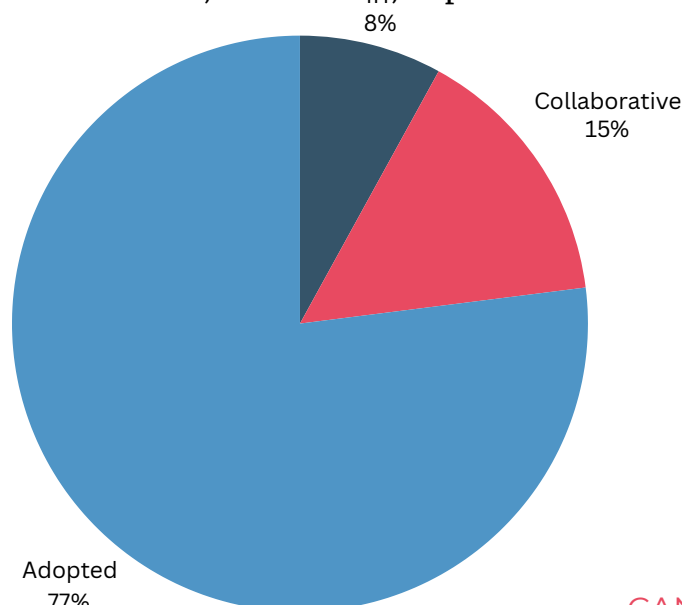
15% (2022: 17%) of open trials involved collaboration with cancer research groups and/or were IITs which are funded through pharmaceutical companies.

The 77% balance (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. These are adopted by Cancer Trials Ireland to capture a bigger picture of cancer clinical trial activity in Ireland.

During 2023, the 14 hospital-based cancer trial research units were working on 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 100 trials that were open and recruiting patients during 2023:

- 8% were Investigator-Initiated Trials (which Cancer Trials Ireland initiates, manages, sponsors and monitors) and are generally funded by the grants received from the Health Research Board (HRB), and the Irish Cancer Society or pharmaceutical companies.
- 15% were Collaborative trials which involve working closely with other cancer research groups around the world.
- 77% were adopted trials including Industry trials which were initiated and managed by the cancer trials units themselves, universities, or pharmaceutical companies.



Vision & Mission



VISION

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

MISSION

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

Strategic Objectives

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.



Key Achievements 2023

- Cancer Trials Ireland progressed into the second year of its five-year Health Research Board Cancer Trials Network grant, hosted by RCSI, securing €6.9 million over five years starting from January 2022.
- In 2023, 100 trials were open for patient accrual, including 8% Investigator-Initiated Trials (IITs) and 15% collaborative trials with international groups. The remaining 77% were adopted trials, reflecting a shift towards more collaborative research.
- Strong recruitment continued in 2023 across key trials, such as the SASCIA breast cancer trial, which exceeded its target, and the PRESERVE and CompARE head and neck cancer studies, showing significant year-on-year increases in patient enrolment.
- New trials initiated in 2023 included the SHAMROCK breast cancer IIT and the ADEPPT lung cancer IIT. Recruitment also began for the PaTcH pancreatic cancer IIT, with patients enrolled at multiple sites.
- As part of the Just Ask campaign, Cancer Trials Ireland hosted a hybrid Cancer Retreat featuring key stakeholders and over 250 registered attendees from the Irish cancer trials community.
- CEO Eibhlín Mulroe joined an Irish delegation to the US, advocating for an all-island approach to cancer trials with influential American stakeholders, including the National Cancer Institute and the US State Department.
- Prof. Seamus O'Reilly published a paper on the clinical impacts of climate change in cancer care and presented at the ESMO Climate Change Taskforce.
- Philanthropy remained strong, with significant funds raised through events such as the Property Picnic, Friends of Cancer Trials Ireland, and the Pat Smullen Race Day, which raised over €250,000 for pancreatic cancer research.
- Cancer Trials Ireland held regular stakeholder and Patient Consultation Committee meetings, organised staff workshops and continued to streamline support for Clinical Trials Units across Ireland.



Promoting an All-Island Cancer Trials Initiative

In March 2023, the All-Island Cancer Research Institute (AICRI) delegation, including leaders from Cancer Trials Ireland, Queen's University Belfast, HRB, and SFI, traveled to Washington, DC, during St. Patrick's Day week to promote a unified approach to cancer trials and research. The delegation, led by Eibhlín Mulroe (CEO, Cancer Trials Ireland), engaged with key US institutions such as the National Cancer Institute (NCI), the US-Ireland Research Partnership, and members of Congress to advocate for increased investment in cancer research on the island of Ireland.

A key highlight of the visit was an event organized by Queen's University Belfast at the NCI in Bethesda, celebrating 25 years of the Good Friday Agreement and the importance of All-Island collaboration. Delegates, including Mairead O'Driscoll and Mark Lawler, presented on the success of cross-border trials and the partnership with NCI, which has allowed Irish patients access to innovative treatments and fostered the training of cancer researchers. The group also toured the NCI's dedicated clinical trials facility, illustrating the potential to bring similar advanced trials to Ireland.

During presentations at the US-Ireland Research Partnership, the delegation emphasized the need for strategic investment in Irish cancer trials, highlighting the economic and medical benefits of expanding research efforts. Mark Lawler discussed the history of cross-border collaboration, while Eibhlín Mulroe made a compelling case for supporting cancer trials, stressing their importance in bringing new treatments to patients and boosting the research landscape.

The delegation also met with influential figures, including Senator Joe Kennedy and Taoiseach Leo Varadkar, to advocate for stronger transatlantic collaboration. High-level engagements throughout the visit underscored the commitment to advancing cancer research through strategic partnerships.

This impactful visit highlighted the shared goal of enhancing cancer research across Ireland, fostering stronger international ties, and ensuring that Ireland remains a leader in global cancer research initiatives. The relationships forged, and insights gained will be crucial in shaping future efforts to improve cancer care and clinical trials for Irish patients.



FEATURED STUDY



Prof. Bryan Hennessey

**BREAST
CANCER
IRELAND**
researching a cure

SHAMROCK Study: Advancing HER2-Positive Breast Cancer Treatment

Funded by Breast Cancer Ireland and sponsored by Cancer Trials Ireland, the SHAMROCK study (CTRIAL-IE 22-01) is an innovative Phase II open-label, single-arm, multicentre trial led by Prof. Bryan Hennessey. The study aims to evaluate the efficacy of trastuzumab deruxtecan (T-DXd) as a neoadjuvant therapy for patients with early-stage or locally advanced HER2-positive breast cancer.

Participants receive T-DXd intravenously every three weeks for up to six cycles. Following two cycles, a mandatory biopsy assesses the RNA Disruption Index (RDI) score to predict pathological complete response (pCR). Imaging assessments guide subsequent treatment, with patients showing complete response proceeding to surgery after four or six cycles, depending on RDI and imaging results.

Primary objectives include evaluating T-DXd's efficacy using pCR as the main endpoint, while secondary measures include event-free survival (EFS) and overall survival (OS). Translational sub-studies will explore tumour evolution and aim to develop predictive biomarkers for pCR.

The SHAMROCK study will recruit 80 patients with HER2-positive stage 2-3 breast cancer. Recruitment began at Beaumont Hospital in October 2023, with additional sites, including St. Vincent's University Hospital, Cork University Hospital, St. James's Hospital, and University Hospital Limerick, planned.

The study is supported by AstraZeneca and Daiichi-Sankyo, who co-developed T-DXd and are supplying the drug for this groundbreaking research.

Communications in 2023

Increasing awareness of Cancer Trials Ireland

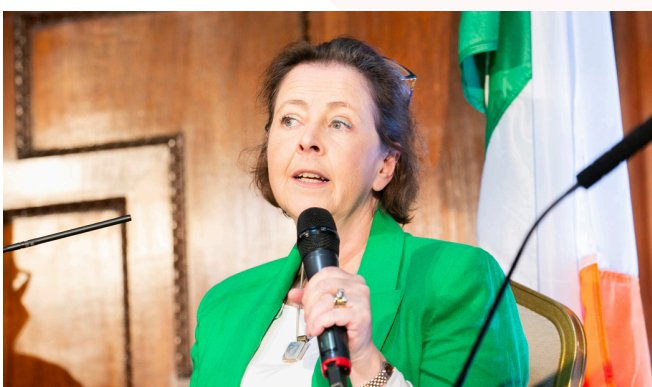
A number of activities are undertaken during the year to increase the awareness of cancer trials and showcase the work that is being done across the country. These opportunities will continue to be pursued during the coming years. They include the following:

- **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 2023, we hosted Ireland's the third 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 2023 – the launch of Cancer Trials Ireland's first patient-led research project (in metastatic breast cancer), and the announcement of the Pat Smullen Chair in Pancreatic Cancer in UCD. Both initiatives drove considerable print and broadcast media coverage in national and regional media.
- **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 2023, 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.

Communications in 2023

Implementing public and patient involvement (PPI)

- Augmented by the appointment of Sarah McLoughlin as Public & Patient Involvement (PPI) Co-ordinator in late 2022, the Patient Consultants Committee (PCC) flourished in 2023, adding a significant number of members.
- The PPI Co-ordinator, and the Head of Communications, drove a membership campaign leveraging video interviews with PCC members. The campaign drove 70 online form completions.
- In the summer of 2023, the new applicants to the PCC were invited to RCSI for a meeting to introduce and explain the fundamentals of Public & Patient Involvement.
- Siobhan Gaynor (PCC member) was a panellist at the Cancer Retreat, at which she celebrated the submission to ethics of her patient-led metastatic breast cancer research project.
- Most of the DSSGs have patient consultants in attendance at closed meetings, and where PCC members are not available, the PPI co-ordinator attends on their behalf.
- The PCC was set up as a sub-group of the Board in 2018. The Chair of the PCC now sits on the Board of Cancer Trials Ireland and a new Chair was appointed in 2020.



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

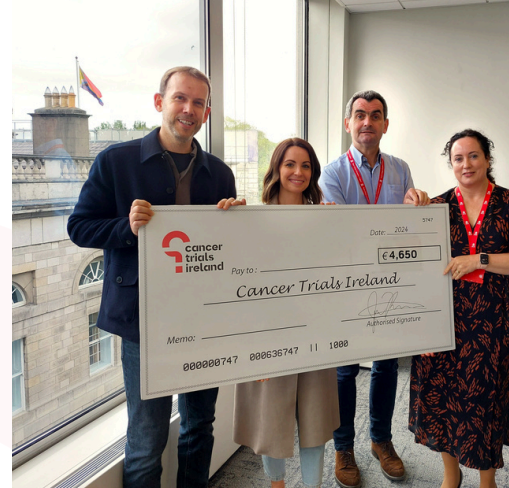
Louise Creevy, who passed away in July 2021, has inspired an incredible amount of fundraising for Cancer Trials Ireland, through her family, friends and colleagues. In May 2023, Louise's colleagues in Bannon Property organised and hosted a live music event, the Property Picnic, which went on to raise more than €130,000. Meanwhile, the colleagues of Louise's husband in Nestlé chose Cancer Trials Ireland as their staff charity, donating €7,690 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 2023, the Coast 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 €167,000 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. Meanwhile, Noel Connellan raised €5,715 in April.

Gastrointestinal

As in previous years, the Oesophageal Cancer Fund organised a charity walk to raise money to support the NeoAEGIS trial. Their target was €50,000, which they more than met. Thanks also to the Cancer Trials Ireland staff members who took part themselves.



Fundraising (continued)

Breast

A private, Irish-based donor organisation, delivered a third instalment of €30,000 for breast cancer research (having already donated €30,000 in 2021 and 2022). Once again, Cancer Trials Ireland is extremely grateful for the donations and we will keep our membership informed on decisions about how this money is allocated to breast cancer trials research.

Friends of Cancer Trials Ireland

After a few years absence due to the pandemic, the Friends of Cancer Trials Ireland once again hosted their gala lunch event in November, which raised €100,092 for ovarian cancer trials and research in 2022. Huge thanks to the organising committee for this event.

SJK Foundation

In September, a team of 6 women cycled from Paris to Nice and raised an impressive €70,000 in aid of the SJK Ralston project, a study for Irish Carcinoma of Unknown Primary (CUP) patients that will be run through the MTB.

Other

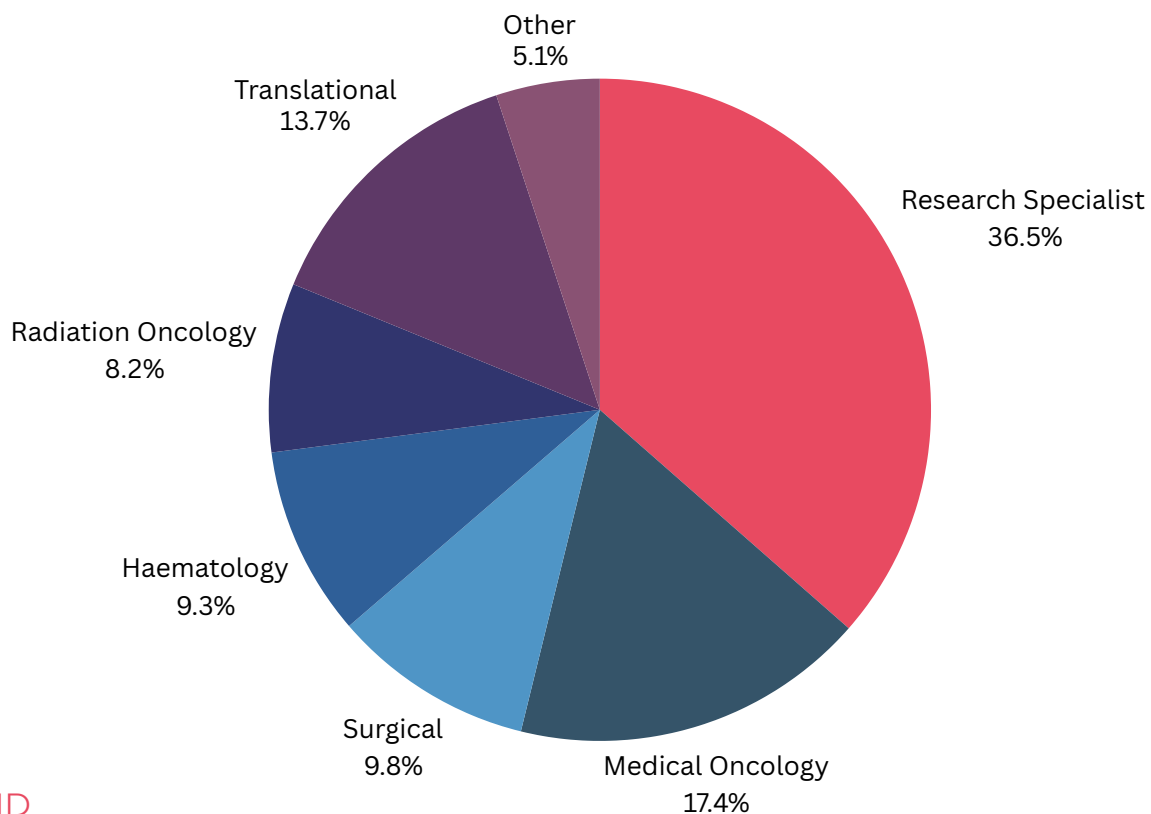
- Dunnes Stores HQ (colleagues of Kay Butler) - nearly €6,700
- Friends and family of Cathryn Gibney (Ballymacad trek, hike, and auction) - €26,650
- Horse Racing Society at Trinity College Dublin (TCD) - €7,640
- Edmondstown Golf Club (Captain's Charity event and raffle) - €7,313
- Aisling Gannon & Brian McKeon - €1,000 (plus €2,920 from a previous donation in October)
- Friends and family of the late Virginia Duffy - €700
- Barberstown Castle (Cheltenham preview night) - €575
- Guy O'Leary (swimming a mile each day in May) - €4,615
- Ballyfoyle Agricultural Show - €1,000
- "The Nancys" (Women's Mini Marathon in memory of Nancy Ward) - €7,000
- Friends of Cancer Trials Ireland (gala event) - €100,092
- Templeogue Tennis Club (Ladies Committee) - €6,818
- Irish Life Dublin Marathon 2023 campaign: €816
- A bequest of €180,000
- TMF Group - €12,086
- CDR Philanthropic Foundation - €10,000

Membership

This metric records the number of registered Members of Cancer Trials Ireland. Cancer Trials Ireland total membership on 31st December 2023 was 691 (56 new members joined during 2023).

During 2023 there were 234 Stakeholder members (this number is broken down between Patient Advocates and Industry).

Type	No.
Research Specialist	252
Medical Oncology	120
Surgical	68
Haematology	64
Radiation Oncology	57
Translational	95
Other	35



Performance Metrics

In line with best practice among similar international collaborative research groups, we measure our performance using a series of recognised metrics.

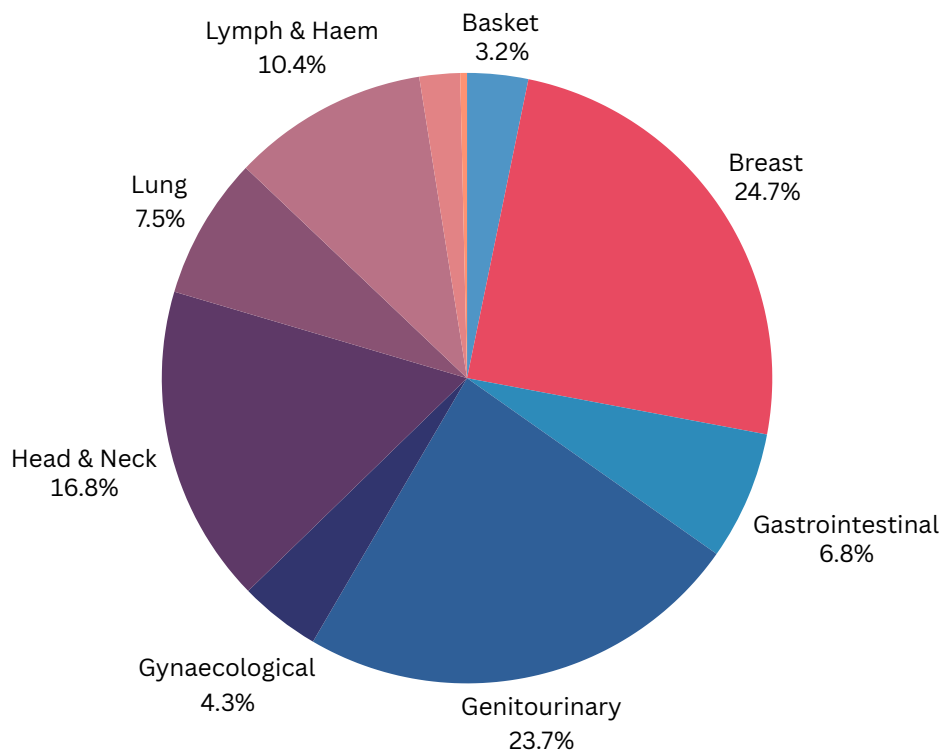
Our performance against these metrics is outlined over the following pages:

Performance Metric	Explanation
Accrual	Refers to the number of patients recruited to a trial.
Trials portfolio	The number and type of trials in our portfolio.
Collaborations	The organisations Cancer Trials Ireland works with on trials
Training	The number of training courses conducted and attended
Cancer trials research unit monitoring	Monitoring activity of cancer trials research units includes a broad range of activities conducted from trial commencement until close-out.
Pharmacovigilance	Serious Adverse Events (SAEs), Suspected unexpected Serious Adverse Events (SUSARs)
Participation	Attendances at scientific meetings, International Meetings
Publications	The number of publications in peer-reviewed journals and abstracts accepted at top level international

Accruals

Interventional Trials (Drug / Radiotherapy / Medical Device/Surgery) by Disease area.

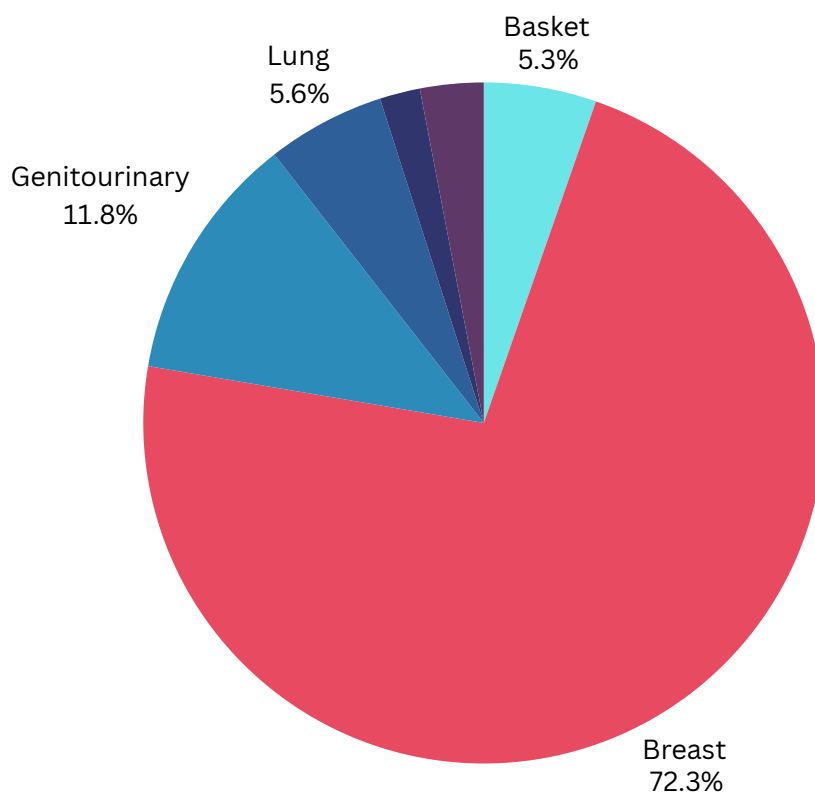
Disease Group	2023
Basket	9
Breast	69
Gastrointestinal	19
Genitourinary	66
Gynaecological	12
Head & Neck	47
Lung	21
Lymph & Haem	29
Melanoma	6
Paediatric	1
Total	279



Accruals

Non-Interventional Trials (Biobank / Observational / Registries / Translational)
By Disease area.

Disease Group	2023
Basket	39
Breast	528
Genitourinary	86
Lung	41
Lymph & Haem	14
Paediatric	22
Total	730



Trials Portfolio

This metric records the number and type of trials open and developing during 2023. Investigator-initiated and Collaborative trials (involving research organisations in other countries) were essential areas of focus during 2023. 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 adopted trial. While these trials are carried out in the various cancer trials research units, GCO staff are minimally involved.

Table 1 shows the total number of trials active in a particular disease group. 'Active' means trials in development, open, treatment, and follow-up.

DSSG	2019	2020	2021	2022	2023
Basket	5	9	9	10	10
Breast	57	45	47	44	41
CNS	5	5	5	4	2
Gastrointestinal	40	31	31	30	18
Genitourinary	46	42	46	44	40
Gynaecological	16	14	15	20	21
Head & Neck	11	11	10	10	7
Lung	34	30	32	33	29
Lymph & Haem	31	30	45	45	33
Melanoma	12	8	8	8	11
Paediatric	38	43	42	40	38
Total	295	268	290	288	250

You can find information about all currently recruiting cancer clinical trials on our website: www.cancertrials.ie

Table 2 shows the total number of trials open to accrual at year end.

DSSG	2019	2020	2021	2022	2023
Basket	4	7	4	5	5
Breast	13	13	13	10	6
CNS	2	2	5	0	1
Gastrointestinal	10	14	14	7	6
Genitourinary	12	13	17	9	10
Gynaecological	7	8	6	4	3
Head & Neck	0	2	3	3	2
Lung	10	5	9	9	7
Lymph & Haem	6	7	14	15	9
Melanoma	0	2	3	4	4
Paediatric	26	22	19	20	14
Total	90	95	105	86	67*

**An additional 33 trials closed to accrual between Jan '23 - Dec '23, meaning that a total of 100 trials were open to accrual at some point during the year.*

Collaborations with international research groups

A large part of the 2023 portfolio of studies in development, open and in follow up studies originate from successful collaborations with international groups.

Austrian Breast & Colorectal Cancer Study Group (ABCSCG)	ETOP IBCSG Partners Foundation	Princess Máxima Center for Pediatric Oncology, Utrecht
Associazione Italiana Ematologia/ Oncologia Pediatrica (AIEOP)	Fondazione IRCCS 'Istituto Nazionale Tumori' (INT)	Royal Marsden Hospital NHS Foundation Trust
Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP)	Fondazione Michelangelo	SIOP (International Society of Paediatric Oncology)
Breast International Group (BIG)	Fundacion Para la Investigacion Hospital Universitario La Fe	Southwest Oncology Group (SWOG)
BC Cancer (British Columbia)	German Breast Group (GBG)	Trans-Tasman Radiation Oncology Group (TROG)
St. Anna Children's Cancer Research Institute (CCRI)	GEICAM (Grupo Español de Investigación en Cáncer de Mama)	Unicancer
Canadian Cancer Trials Group (CCTG)	Great Ormond Street Hospital (GOSH UK)	University College London
Children's Cancer Research Institute Vienna	Gustave Roussy Institute	University Hospital Freiburg
Dutch Childhood Oncology Group (DCOG)	Hopp Children's cancer centre Heidelberg	University of Birmingham
Dutch Gynaecological Oncology Group (DGOG)	Hemato-Oncologie voor Volwassenen Nederland (HOVON)	University of Health Network, Toronto & Bladder Cancer Canada
Dr David Palma (Lawson Health Research Institute (Canada))	Institute of Cancer Research UK	University of Liverpool
Deutsche Studiengruppe CLL (DSCLLG)	Karolinska University Hospital	Vastra Gotaland Region (Sweden)
ECOG-ACRIN Cancer Research Group	Melanoma and Skin Cancer (MASC) Trials	Walton Centre NHS Foundation Trust
European Network for Gynaecological Oncological Trial groups (ENGOT)	Leiden University Medical Centre (LUMC)	
European Organisation for Research and Treatment of Cancer (EORTC)	NRG Oncology	
Erasmus Medical Centre	NSABP Foundation Inc	
	Prostate Cancer Clinical Trials Consortium (PCCTC)	

Training

Training courses conducted by the GCO training team along with attendance by GCO staff and investigators/ investigational staff at 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 (GCO Staff)	Number of attendees (CCTU Staff)
Data Protection	4	33	0
Introduction to Clinical Research/Trials	5	47	0
Good Clinical Practice Training	7	24	37
Induction Trainings, all departments	10	14	0
Site visit training (e.g. monitoring, site initiation, close out), IMP/pharmacy training	8	17	0
Pharmacovigilance Training	7	13	0
RECIST 1.1	1	1	0
Regulatory training, incl. Clinical Trial Regulation and CTIS	3	52	0
Trial Master File+ essential documents + archiving Training	13	27	0
Disease specific training	2	60	0
Insurance/indemnity training	1	0	6

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. The COVID pandemic required to develop adaptive strategies to facilitate continued trial conduct and develop resilience for clinical trial conduct in a pandemic reality. It can include the possibility of remote monitoring and close out which, with the support of the hospital, allows for the clinical trial to be monitored without the need to have staff visit the hospital.

The monitoring level can be 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 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 2022 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.

Audit Type	Preparation (days)	Audit/ Attendance (days)	Follow up (days)
Cancer Trials Ireland Internal Audits	1	4	8
Cancer Trials Ireland Audit of Research Units	18	12	18
Cancer Trials Ireland Audit of Third parties/vendors	5	1	3.5
Regulatory inspection of research units	10	4	11
Audit strategy/planning and audit/inspection readiness	5	-	-

Participation in conferences & meetings

Event	Month
Breast International Group (BIG) - General Assembly	January
Irish Research Radiation Oncology Group (IRROG) – inaugural conference	January
American Society of Clinical Oncology Genitourinary (ASCO GU) Cancers - Symposium	February
All-Island Cancer Research Institute (AICRI) - Queen's University Belfast (QUB) – National Cancer Institute (NCI) 'Cancer Knows No Borders' Symposium 2023	March
European Network for Gynaecological Oncological Trial groups (ENGOT) – Spring meeting	March
Breast International Group (BIG) – Virtual Scientific Meeting	March
Queen's University Belfast – Agreement 25 'Cancer Knows No Borders' Showcase event	April
John Fitzpatrick GU Cancer Conference	May
The Irish Platform for Patient Organisations, Science & Industry (IPPOSI) -conference	May
Irish Health Research Forum (IHRF) – semi-annual symposium	May
2nd Genomic Profiling Symposium	May
Irish Melanoma Forum	May
Cancer Trials Ireland Cancer Retreat	May
University of Galway Institute for Clinical Trials: Future Trials	May
Gynecologic Cancer Intergroup (GCIIG) - Spring 2023 Meeting	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

Participation in conferences & meetings

Event	Month
Irish Society of Medical Oncology (ISMO) – post ASCO updates	July
Stereotactic Radiosurgery & Stereotactic Ablative Radiotherapy Symposium	September
UCD Cancer Research Symposium	September
All-Island Cancer Research Institute (AICRI) Showcase: Vision and Progress	September
International Symposium on Translational Research in Oncology (CCRT)	September
Blood Cancer Network Ireland (BCNI) - Annual Symposium	September
Health Research Board–National Clinical Trials Office (HRB NCTO): Clinical Investigations & Performance Studies in Ireland under the MDR/IVDR	October
European Society for Medical Oncology (ESMO) – Congress	October
American Society for Radiation Oncology (ASTRO) – Annual Meeting	October
European Network for Gynaecological Oncological Trial groups (ENGOT) – Assembly	October
Clinical Research Facility–University College Cork: Data Management in Health Research	October
European Thoracic Oncology Platform (ETOP) Annual Meeting	November
The Gathering around Cancer	November
Irish Health Research Forum (IHRF) – semi-annual symposium	November
HPRA/EMA - EU-Innovation Network Conference: Strengthening life-sciences innovation across Europe	November
National Conference on Research Ethics	November
Research Quality Association (RQA) International Quality Assurance Conference	November
Health Research Board–National Clinical Trials Office (HRB NCTO): Enabling Quality Clinical Trials	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 (2023)

Area	Peer Reviewed Journal Articles 2023	Abstracts: Poster/Oral Presentations 2023
Basket	0	0
Breast	8	1
CNS	0	0
Gastrointestinal	2	1
Genitourinary	9	3
Gynaecological	4	0
Head and Neck	0	0
Lung	3	0
Lymphoma & Haematological	1	0
Melanoma	0	0
Other	6	1
Total	33	6

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 2023

	Notes	2023 €	2022 €
Income	4	4,540,911	3,958,709
Expenditure		(4,416,291)	(4,380,850)
Surplus / (Deficit) on ordinary activities before interest		124,620	(422,141)
Interest receivable and similar income	5	295	1,005
SURPLUS / (DEFICIT) FOR THE FINANCIAL YEAR	6	124,915	(421,136)
RETAINED EARNINGS AT THE BEGINNING OF THE FINANCIAL YEAR		463,696	884,832
RETAINED EARNINGS AT THE END OF THE FINANCIAL YEAR		588,611	463,696

Balance Sheet as at 31 December 2023

	Notes	2023 €	2022 €
Fixed Assets			
Tangible assets	10	79,521	120,003
Current Assets			
Debtors	11	1,977,411	1,893,543
Cash and cash equivalents		4,165,337	4,298,305
		6,142,748	6,191,848
Creditors: Amounts falling due within one year	12	(5,633,658)	(5,848,155)
Net Current Assets		509,090	343,693
Net Assets		588,611	463,696
Reserves			
Retained earnings		588,611	463,696
		588,611	463,696



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Together, we're finding answers to cancer.