DSSG DIGEST

Spring 2026

cancer trials ireland

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Irish Cancer Society

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Clinical Lead Message

Clinical Lead: Prof Seamus O'Reilly

I would like to begin by briefly looking back at some of our strategic objectives for 2025, particularly our goal of streamlining and improving how we work. In just the past month, we have seen real progress in this area, which reflects the work of the Start-Up Team. The Start-up Team has been nominated for an award (see: page 5) so congratulations to Olivia, Emer, Fiona, Aoife, Sheila, and Abhi – and also to Anna Shevlin and the supporting project management team.

Efforts to reduce the time to first patient in cancer clinical trials sponsored or managed by Cancer Trials Ireland are continuing to show positive trends. In Q4 of last year, trial agreements with sites were executed within 73 days, down from 143 days in the previous quarter. Sites were then activated 12 days after initiation, representing a 45% improvement.

KPI	KPI Text	Q3 24	Q3 25	Q4 25	% Change this quarter
1	Overall median days from SMG approval to first site activation	n/a	457	388	↓ 15%
2	Draft Head Contract (Sponsor or funder) ready to review (Day 0), to execution	254	137	90	↓ 34%
3	Site agreement issued → site agreement executed	n/a	143	73	↓ 49%
4	Clinical Trial Agreement received to site activation	468	344	219	↓ 36%
5	EC approval to 1st site activation	317	244	229	↓ 6%
6	SIV to activation (each site)	n/a	22	12	↓ 45%

The dedicated Start-Up Team encompasses contract management, data protection, regulatory and ethics processes — and these aspects have been central to improvements. The team has worked closely with operational clinical sponsors, programme managers, sponsors, the HSE Research Office, and hospital site teams. The adoption of the HSE-approved national clinical trial templates has also played an important role in helping to reduce start-up timelines within Cancer Trials Ireland.

Another improvement I would like to note is that, while time to first patient and trial start-up timelines remain a critical metric for everyone working in this space, I note that the conversation has largely moved on from the challenges related to GDPR.

This reflects strong collaboration across the research community to resolve and align thinking on an issue that had been causing significant delays and ultimately impacting patients. That progress represents another positive step for Cancer Trials Ireland and for the wider research community, and it was another objective we had set ourselves for 2025.

A third theme in 2025 was succession and planning for the future. In recent days, we published the report from the National Training Day 2026, and I think it speaks volumes about the effort, interest and enthusiasm of the next generation of investigators — the principal investigators of tomorrow. I would encourage you to take a look at that report, which is available here.

Clinical Lead Message cont.

Looking now to the months ahead, I very much welcome and look forward to the launch of the INSPIRE trial in April at the Royal College of Surgeons in Ireland. INSPIRE is an important cross-border trial that will open across 11 sites on the island of Ireland, two in Northern Ireland and nine in the Republic, with 136 patients the target for accrual. I want to applaud the efforts of everyone involved for achieving funding for this radiotherapy trial. As our colleagues in radiation oncology know only too well, funding Investigator-Initiated Trials absent of IMP is a major challenge.

And it is on the point of IITs that I want to close today's message.

This spring marks the closure of the Breast International Group (BIG), which has had a transformative impact on breast cancer care in Ireland. I stepped down from the BIG Executive Board in February to help facilitate the wind-up. Our involvement with BIG spans the length of the organisation itself and includes pivotal trials in breast cancer medicine (HERA, ALTO, Taormina), and collaborations in neuro-oncology, molecular diagnostics, climate impact research, and patient and public involvement. The bi-directional learning we gained through BIG, particularly around PPI integration into trial development, has shaped how we work today. But perhaps the biggest loss is networking, the infrastructure that allows innovative academic studies to happen across borders.

BIG's legacy endures in the work we continue to do, but it is closing primarily because of lack of funding. It's closure highlights the precarious nature of research funding at a time when academic studies are needed for optimisation of treatments, integration of new agents with existing ones, development of non-pharmacological treatments such as exercise and lifestyle medicine into cancer care, and answering important clinical questions that can't be resolved by a randomised trial. The loss of BIG also points to the need for implementation of the recommendations of the National Clinical Trials Oversight Group to reinforce our clinical research ecosystem. An ecosystem that is increasingly needed by patients with cancer and their families in Ireland to benefit from scientific advances in cancer care.

CEO Message

CEO: Angela Clayton-Lea

Welcome to the Spring 2026 DSSG Digest, and happy Irish Cancer Society Daffodil Day! Please donate if you can - as you know the Irish Cancer Society are vital supporters of cancer trials and research in Ireland. I was privileged to attend the launch of this year's Daffodil Day, and I immensely enjoyed hearing Prof Janice Walshe deliver the keynote address on the importance of trials and the impact of practice-changing studies such as TAILORx and POSITIVE.

As you may know, the Irish Cancer Society is represented on the Board of Cancer Trials Ireland by their Director of Clinical Services, Ms Amy Nolan, who also joined us for our CTI Board Strategy Day in January.

That strategy day gave rise to six themes for 2026: balancing our portfolio, strengthening partnerships and international collaboration, leveraging trial data, optimising use of emerging technologies, continuing to communicate our value, and crucially, maintaining a relentless focus on 'time to first patient' (TTFP).

Of these themes, TTFP remains our primary objective and fittingly is the focus of today's stakeholder meeting (March 20th). Today's meeting brings together representatives from the Department of Health, the HSE, trial sites, cancer trials programs, and industry partners. Our objective is to establish a shared understanding of the issues and perspectives we all experience in relation to conducting cancer clinical trials in Ireland.

CEO Message cont.

That reflects the broader intentions of our stakeholder meetings - to create a platform where issues of common concern across the clinical oncology research community can be raised, discussed, and understood from multiple perspectives. This foundation is vital to meaningful advocacy and systemic change.

Further to which, the National Clinical Trials Oversight Group released their final report last November, that prompted urgent action across our sector. One of the key recommendations from that report calls for the establishment of a Clinical Trials Advisory Committee (CTAC) by the end of the first quarter in 2026, a deadline now measured in days. We have written to the Minister of Health and to members of the Oireachtas Health Committee, seeking CTI representation on CTAC. This is part of our broader commitment to advocacy: to ensure that the voices of those working in clinical trials, the researchers, nurses, therapists, data managers, pharmacists, and many others, are heard at the highest levels of decision-making.

This advocacy work intensified earlier this week when Dr Veronica McInerney (UoG/HSE West & Northwest Region) and I appeared before the Oireachtas Joint Committee on Further and Higher Education, Research, Innovation and Science. Our appearance provided an opportunity to highlight longstanding challenges faced by cancer clinical trial teams: issues around employee contracts, career pathway development, and workforce stability, which have persisted for too long without adequate attention or resources. The joint statement drafted in advance with the help of site team leaders articulated these concerns with clarity and urgency and was informed by the lived experience of those who navigate these challenges daily.

On the strategic front, CTI continues to engage with the key players and groups developing long term cancer research plans in Ireland. As a member of the NCCP National Cancer Research Group (chaired by Prof Donal Brennan), CTI is keen to engage with the development of Ireland's National Cancer Research Plan. As part of this process, I will be representing CTI (as a key stakeholder) at an upcoming stakeholder engagement series which will be conducted by the PRiCAN Research Group at RCSI (led by Prof Patrick Redmond) to inform the development of Ireland's National Cancer Research Plan. We look forward to contributing to this essential project.

In January, Prof Donal Brennan was a guest on CTI's podcast series, with AICRI's Prof Liam Gallagher participating in February. Before Christmas, the podcast series covered our own 'Value of Cancer Trials Report', the ENGOT collaboration with the Gynae DSSG, and patient experiences of trials (thanks to members of our Patient Consultants Committee). Our PPI group, through the work of colleagues like Martin Sweeney, has been instrumental in bringing patient and public perspectives to our research.

Recent presentations on studies like PRO-ACT demonstrate our commitment to research that addresses not only survival but quality of life, with the findings from this study being presented by Martin Sweeney at the EAU Conference in London last week. We anticipate expanding further public-facing communication around this study as the year progresses. Meanwhile, on 22nd April, we will host the launch of the all-Island INSPIRE study. This will be a collaborative event, bringing together colleagues from Northern Ireland Cancer Centres, Queen's University Belfast, CTI and IRROG who have been instrumental in developing this trial. On 22nd May, at the CTI Cancer Retreat, we aim to bring in an international speaker to lead a discussion on de-escalation (optimisation) trials, arising from the attendance by Prof Seamus O'Reilly and myself at a EUnetCCT De-escalation Symposium in Amsterdam.

With all the activity outlined above in mind, I very much look forward to engaging with you in the months ahead, and I hope today's DSSG and Stakeholder meetings are useful, productive and reflective of the level of commitment to research that is evident across the CTI community.

Irish Cancer Society Research Awards

At the Irish Cancer Society Research Awards in February 2026, Aoife Shannon, Radiotherapy Programme Manager at Cancer Trials Ireland, was named Support Staff of the Year 2026.

The award recognises Aoife's sustained contribution to radiotherapy research and clinical trial delivery in Ireland over the past 17 years. Aoife joined Cancer Trials Ireland in 2009 following completion of a PhD in Oncology at RCSI and a postdoctoral fellowship at the University of Manchester. She now provides national oversight of the radiotherapy portfolio alongside surgical, translational and lifestyle-focused studies.

Aoife leads a specialist team supporting the set-up, governance, monitoring and delivery of approximately 70 studies nationwide. Her role involves close collaboration with investigators and site teams to ensure that complex radiotherapy trials open efficiently and are delivered safely in routine clinical settings. This work has strengthened national capacity in radiotherapy research and supported patient access to cancer trials at sites across Ireland.

The awards ceremony also recognised a number of Cancer Trials Ireland collaborators and colleagues. The Lung Health Check project received the Public & Patient Partnership Award. Seamus Cotter, a member of the Cancer Trials Ireland Patient Consultants Committee and Lung Disease Site Specific Group, was part of the team recognised alongside Anne-Marie Baird and colleagues. The award highlights the role of patient partnership in the development and delivery of cancer research initiatives.

Colleagues in Cork were also recognised for the LIAM Mc Trial and IMPROVE_TMZ studies. Both studies have been led from Cork and reflect ongoing activity in survivorship and investigator-led research.

The Irish Cancer Society Research Awards annually highlight achievements across the cancer research community in Ireland, spanning clinical, translational and patient partnership initiatives.

Aoife Shannon, Radiotherapy Programme Manager

2026 National Training Day

The 2026 Cancer Trials Ireland National Training Day brought together more than 265 attendees for a truly multidisciplinary programme, with strong engagement from medical oncology, haematology, radiation oncology, surgery, allied health and translational research. The event reflected the continued expansion of cancer trials in Ireland as a collaborative, cross-disciplinary endeavour.

The programme included 20 trainee oral presentations and more than 65 posters, alongside keynote addresses from Prof Brendan Kelly and Prof Suzanne Crowe. Sessions explored the growing complexity of modern cancer trials, the responsible integration of artificial intelligence, and the importance of strong research cultures.

A focus on the "hidden curriculum" emphasised mentorship, leadership and professionalism as central to trainee development, while a closing patient contribution reinforced that research progress must ultimately translate into meaningful impact for patients.

National Training Day

Read the Report

Cancer Trials Ireland Start-Up Team shortlisted for Women in Pharma Award

Cancer Trials Ireland's Start-Up Team has been shortlisted for Best Female Led Team at the 2026 Women in Pharma Awards.

The team was established in December 2024 to improve the efficiency and consistency of clinical trial start-up across sites in Ireland, through enhanced coordination and shared expertise.

Within its first year, the team delivered a 46% reduction in contract timelines and a 26% reduction in time to site activation. These improvements have strengthened predictability in trial delivery and supported more timely access to cancer trials for patients in Ireland.

Start-Up Team

The Women in Pharma Awards, launched under the auspices of the Pharma Industry Awards, recognise innovation, leadership and excellence across the pharmaceutical sector. The winners will be announced on 29 April.

Breast Updates

In development/to open soon

NOAX (CTRIAL-IE 25-72)
This international randomised trial (OPBC-10/NOAX) investigates whether tailored axillary surgery (TAS) combined with axillary radiotherapy (ART) is better than the current standard treatment, axillary lymph node dissection (ALND), for patients with clinically node-positive breast cancer undergoing upfront surgery. The study aims to determine if TAS + ART can improve arm-related quality of life and reduce lymphedema two years after treatment. The trial is sponsored by University Hospital Basel and coordinated in Ireland by Cancer Trials Ireland, with planned sites including St. Vincent's University Hospital, St. James's Hospital, University Hospital Galway, Beaumont Hospital and the SLRON Network. The study is currently undergoing ethical review and is planned to open to accrual in Q2 2026.

OPTIMA YOUNG (CTRIAL-IE 24-79)
This study evaluates whether a genomic test (Prosigna®) can guide treatment decisions for premenopausal women with hormone receptor–positive (HR+), HER2-negative early breast cancer who are at higher risk of recurrence. Currently, these patients are usually treated with chemotherapy plus hormone therapy, but chemotherapy can cause significant side effects, particularly in younger women.

The trial compares standard treatment (systematic chemotherapy plus hormone therapy) with a test-guided approach, where treatment is determined by the Prosigna® genomic score. Depending on the result, patients may receive either chemo-endocrine therapy or endocrine therapy alone with ovarian function suppression. The aim is to determine whether this strategy is as effective at preventing cancer recurrence while potentially avoiding unnecessary chemotherapy.

The study will also assess quality of life, economic impact, and patient perspectives on treatment de-escalation over five years of follow-up. The study is sponsored by Unicancer and is planned to open in Ireland at seven sites in Q3–Q4 2026.

Open to accrual

ASCENT-05 (CTRIAL-IE 24-36)
ASCENT-05 is an international, randomised, open-label Phase III trial sponsored by Gilead Sciences. It evaluates sacituzumab govitecan-hziy and pembrolizumab versus treatment of the physician's choice (TPC) in patients with triple negative breast cancer (TNBC) who have received neoadjuvant chemotherapy, with or without checkpoint inhibitor therapy, and have residual invasive disease in the breast or axillary lymph nodes after surgery.

The study will assess sacituzumab govitecan with pembrolizumab, or pembrolizumab with or without capecitabine, in patients with high-risk early TNBC without BRCA1 or BRCA2 mutations. The primary objective is to compare invasive disease-free survival between sacituzumab govitecan and pembrolizumab versus TPC.

The study plans to enrol 1,514 patients globally, including 25 across Irish sites. All five Irish sites are open to accrual: St James's Hospital (PI: Dr Niamh Coleman), Beaumont Hospital (PI: Prof Patrick Morris), University Hospital Limerick (PI: Dr Grzegorz Korpanty), Mater Misericordiae University Hospital (PI: Dr Shahid Iqbal), and Cork University Hospital (PI: Prof Seamus O'Reilly). Six patients have been randomised in Ireland to date, and active screening continues. Accrual will remain open until Sept 2027.

CAMBRIA-2 (CTRIAL-IE 23-06)
CAMBRIA-2 is an AstraZeneca sponsored Phase III open-label randomised study to assess if camizestrant improves outcomes compared to standard adjuvant endocrine therapy for patients with ER+/HER2- early breast cancer with intermediate-high or high risk for disease recurrence who completed definitive locoregional therapy (with or without chemotherapy).

The primary endpoint is invasive breast cancer-free survival (IBCFS), and main secondary endpoints include invasive disease-free survival (IDFS), distant relapse-free survival (DRFS), overall survival (OS), safety, and clinical outcome assessments (COAs).

Breast Updates

The global accrual target is 5,500 patients, with 56 to be recruited across Irish sites. CAMBRIA-2 is nearing its global accrual target and will close soon. All seven Irish sites are open to accrual: St Vincent's University Hospital (PI: Prof Michaela Higgins), Mater Misericordiae University Hospital (PI: Dr Shahid Iqbal), Mater Private Hospital (PI: Prof Catherine Kelly), Beaumont Hospital (PI: Prof Patrick Morris), Cork University Hospital (PI: Prof Seamus O'Reilly), University Hospital Waterford (PI: Dr Miriam O'Connor), and University Hospital Galway (PI: Prof Maccon Keane). To date, 40 patients have been screened and 26 randomised in Ireland. A recruitment cap for abemaciclib and N0 patients has been implemented at all sites, including those in Ireland, significantly affecting accrual.

TREAT ctDNA (CTRIAL-IE 23-03)
The CTRIAL-IE 23-03 TREAT ctDNA study is an international, collaborative, EORTC-sponsored, Phase III, open-label, randomised superiority trial. It compares elacestrant to standard adjuvant endocrine therapy in patients with ER+/HER2- breast cancer and ctDNA relapse.

The main objective of this study is to evaluate whether elacestrant can delay the occurrence of distant metastasis or death when compared to standard endocrine therapy in ER+/HER2- patients with ctDNA relapse. Elacestrant, a new oral selective estrogen receptor degrader, has shown significant clinical benefits in patients with ER+/HER- advanced or metastatic breast cancer following progression on a CDK4/6-inhibitor and could be used at the time of ctDNA relapse to delay the occurrence of distant metastasis.

The global accrual target is 220 patients, with a goal of enrolling 12 to 15 patients across Irish sites. To date, 39 patients have been registered in the screening Phaseat five Irish sites. To date, four patients have been identified as ctDNA-positive, of whom two have been randomised to the study, and the other two did not meet eligibility criteria.

All five Irish sites are open to accrual: St James's Hospital (PI: Dr Ciara O'Hanlon Brown), Beacon Hospital (PI: Dr Lisa Prior), Mater Private Hospital (PI: Prof Catherine Kelly), Mater Misericordiae University Hospital (PI: Dr Shahid Iqbal), and University Hospital Waterford (PI: Dr Miriam O'Connor). St. Vincent's University Hospital is in the process of joining the study soon.

MK-2870-012 (CTRIAL-IE 24-58)
The MK-2870-012 study is a Merck Sharp & Dohme sponsored randomised, open-label study comparing the efficacy and safety of adjuvant sacituzumab tirumotecan (MK-2870) in combination with pembrolizumab compared to treatment of the physician's choice (TPC) in participants with triple-negative breast cancer (TNBC) who received neoadjuvant therapy and did not achieve a pathological complete response (pCR) at surgery. The primary objective is to compare sacituzumab tirumotecan plus pembrolizumab to TPC (pembrolizumab or pembrolizumab plus capecitabine) with respect to invasive disease-free survival (iDFS) per investigator assessment. It is hypothesised that sacituzumab tirumotecan plus pembrolizumab is superior to TPC with respect to iDFS per investigator assessment.

This study aims to recruit 1530 patients globally. MK2870-012 is progressing well in Ireland. We have 11 women randomised and one more in screening. The three Irish sites are actively screening and randomising additional participants and have received approval to go beyond the original target: St. Vincent's University Hospital (PI Prof Janice Walshe), Bon Secours Hospital Cork (PI: Dr Conleth Murphy), and University Hospital Galway (PI: Prof Maccon Keane). The last patient is projected to be screened in October 2027.

Breast Updates

DESTINY-Breast15 (CTRIAL-IE 24-98)
DESTINY-Breast15 study is Daiichi Sankyo sponsored Phase IIIb, interventional, open-label study to evaluate the safety and efficacy of trastuzumab deruxtecan (T-DXd) in participants with human epidermal growth factor receptor 2 (HER2)-low or HER2 immunohistochemistry (IHC) 0 (who are both hormone receptor [HR]-negative and HR-positive) unresectable and/or metastatic breast cancer.

The global study accrual target is 250 patients, with the aim of recruiting 14 patients across the Irish sites. 94% overall enrollment globally is already completed and accrual is expected to be closed by Q2 2026. Only Cohort 1 (HR neg/HER2- low) is open to accrual, all other cohorts are closed.

12 patients have been screened in Ireland to date and 4 patients have been randomised: 2 patients at Beaumont Hospital (PI: Prof Patrick Morris), one patient at St Vincent's University Hospital (PI Prof Janice Walshe) and one patient at St James's Hospital (PI: Dr Ciara O'Hanlon-Brown). The remaining open sites are Cork University Hospital (PI: Prof Roisin Connolly) and University Hospital Galway (PI: Prof Maccon Keane).

MK-2870-010 (CTRIAL-IE 24-113)
MK-2870-010 is Merck Sharp & Dohme sponsored open-label, **randomised** Phase III study to compare sacituzumab tirumotecan as a single agent, and in combination with pembrolizumab, versus Treatment of Physician's Choice (TPC) in participants with hormone receptor positive/human epidermal growth factor receptor-2 negative (HR+/HER2-) unresectable locally advanced, or metastatic, breast cancer.

The global study accrual target is 1200 patients, with the aim of recruiting 18 patients across the Irish sites. Over 90% of the target has been already randomised globally and 15 patients have been randomised in Ireland across 3 sites (St Vincent's University Hospital (PI Prof Michaela Higgins), Bon Secours Hospital Cork (PI: Dr Conleth Murphy) and Mater Misericordiae University Hospital (PI: Dr Darren Cowzer). In Ireland screening closure estimated at end of March 2026.

Recently closed to accrual

EMBER-4 (CTRIAL-IE 24-07)
EMBER-4 is a randomised, open-label, Phase III study comparing adjuvant imlunestrant to standard adjuvant endocrine therapy in patients with ER+, HER2- early breast cancer at increased risk of recurrence who have previously received 2 to 5 years of adjuvant endocrine therapy.

The primary objective of this study is to evaluate the efficacy of imlunestrant compared to standard hormone therapy in participants with estrogen receptor-positive (ER+) and human epidermal growth factor receptor 2-negative (HER2-) early breast cancer.

The EMBER-4 trial completed enrollment in December 2025, randomising 8,052 patients globally. In Ireland, 143 participants were screened, of whom 114 were randomised. Currently, 99 participants remain active in the study. St Vincent's University Hospital, led by PI Prof Janice Walshe, was the highest recruiter with 43 patients randomised. Other contributing Irish sites include St James's Hospital (PI: Dr Ciara O'Hanlon Brown), University Hospital Galway (PI: Prof Maccon Keane), Cork University Hospital (PI: Prof Seamus O'Reilly), Beaumont Hospital (PI: Prof Patrick Morris), Beacon Hospital (Prof Jennifer Westrup), University Hospital Waterford (PI: Dr Miriam O'Connor), and Sligo University Hospital (PI: Dr Michael Martin).

Breast Updates

FourLight-3 (CTRIAL-IE 25-49)
FourLight-3 trial is an interventional, open-label, randomised, multicenter phase-3 study of PF-07220060 plus Letrozole compared to CDK4/6 inhibitor plus Letrozole in participants with hormone receptor (HR)-positive, HER2-negative advanced/metastatic breast cancer who have not received any prior systemic anticancer treatment for advanced/metastatic disease.

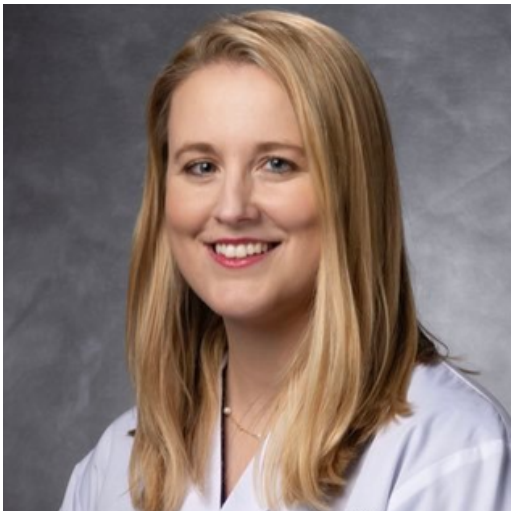
The purpose of this study is to determine the safety and efficacy of PF-07220060 with letrozole compared to approved treatments (ie, palbociclib, ribociclib or abemaciclib with letrozole) in people with breast cancer.

The global study accrual target is 1020 patients, with the aim of recruiting 10 patients across the Irish sites. Five sites are open to accrual in Ireland: Beaumont Hospital (PI: Prof Patrick Morris). St Vincent's University Hospital (PI Prof Janice Walshe), St James's Hospital (PI: Dr Niamh Coleman), Mater Misericordiae University Hospital (PI: Dr Shahid Iqbal) and Mater Private Hospital (PI: Prof Catherine Kelly). Three patients have been randomised in Ireland to date.

A recruitment pause has been in place across Europe (including Ireland) since November 2025. Study is planned to close to accrual in late March 2026.

Prof Patrick Morris

Prof Cathy Kelly



Dr Niamh Coleman

Lung Updates

Lung Portfolio: Spotlight on ETOP ARCH (CTRIAL IE: 25-24)

Led by Prof Patrick Forde, this is a randomised Phase III trial of adjuvant cemiplimab in patients with resected stage II-IIIA NSCLC who have not received prior adjuvant chemotherapy. Patients with non-small cell lung cancer (NSCLC) that has not spread outside the lung are usually treated with surgery to remove the tumour and nearby lymph nodes. After surgery, many patients receive chemotherapy to help reduce the chance of the cancer returning.

In some cases, immunotherapy is also given with or after chemotherapy to help the immune system destroy any remaining cancer cells. At the moment, immunotherapy can only be used alongside chemotherapy or after it. However, chemotherapy is not suitable for everyone. Some people may be too unwell for chemotherapy, while others may decide not to have it because of potential side effects. As a result, these patients are currently unable to receive immunotherapy after surgery.

Presently, we don't know if immunotherapy on its own can help lower the risk of lung cancer coming back after surgery in people who cannot have chemotherapy. The ARCH study is designed to answer this question. It aims to find out whether the immunotherapy drug cemiplimab can reduce the chance of lung cancer returning after surgery in patients who have not received chemotherapy.

In December 2025, this study opened in Ireland at St James's Hospital and Beaumont Hospital. St James's Hospital had their first patient randomised in Feb 2026 and we plan to recruit 50 patients to this study. Both sites welcome referrals.

Lung Portfolio: Spotlight on ORIGIN2 (CTRIAL IE: 25-11)

Overcoming Resistance to Immunotherapy combining Gemcitabine with Ivonescimab in advanced NSCLC progressing on immune checkpoint inhibitors: A multicenter, single-arm, open-label Phase II trial.

Prof Jarushka Naidoo and Cancer Trials Ireland are collaborating with the Swiss Cancer Institute (SCI) to investigate this second line treatment option for patients with advanced NSCLC who have progressed on immunotherapy.

Ivonescimab is a PD-1/VEGF bispecific antibody. The main objective of this trial is to evaluate the efficacy of gemcitabine combined with ivonescimab in patients with mNSCLC progressing during or after CIT and prior systemic therapy regimens. The primary endpoint of the trial is objective response rate (ORR) according to RECIST v1.1.

NSCLC remains the second most common malignancy diagnosed worldwide, with approximately 2600 cases per year in Ireland, and is the leading cause of cancer-related death, accounting for 20% of cancer-related deaths. A significant number of patients with NSCLC progress on immunotherapy. After relapse, treatment options are limited.

The trial, which is due to open this year, will include 47 patients from sites in Ireland and Switzerland who will receive the combination treatment for two years.

Lung Updates

Lung Portfolio: IMP Trials currently open to accrual

Stage IB-III NSCLC – Neo Adjuvant
NeoCOAST-2 (CTRIAL IE: 22-23) This Phase II open-label, randomised study of Neoadjuvant and Adjuvant treatment in patients with resectable, early-stage (II to IIIA) NSCLC is open and accruing patients at St James's Hospital, Beaumont Hospital, University Hospital Galway and the Mater Hospital.

ETOP ADOPT (CTRIAL IE: 25-60) This multicentre, open-label randomised Phase III trial to evaluate the benefit of adding adjuvant durvalumab after neoadjuvant chemotherapy plus durvalumab in patients with stage IIB-IIIB (N2) resectable NSCLC is open at St James's Hospital and Beaumont Hospital.

V940-009 (CTRIAL IE: 25-01) is a Phase III randomised Double-blind Study of Adjuvant Pembrolizumab With or Without V940 in Participants With Resectable Stage II to IIIB (N2) NSCLC not Achieving pCR After Receiving Neoadjuvant Pembrolizumab With Platinum-based Doublet Chemotherapy. It is open to accrual at Tallaght University Hospital, St. James's Hospital and Cork University Hospital.

Stage IB-III NSCLC – Adjuvant
ETOP ARCH (CTRIAL IE: 25-24) A randomised Phase III trial of adjuvant cemiplimab in patients with resected stage II-IIIA NSCLC who have not received prior adjuvant chemotherapy, this study is open at St James's Hospital and Beaumont Hospital.

V940-002 (CTRIAL IE: 24-51) This study of V940 plus pembrolizumab (MK-3475) versus placebo plus pembrolizumab in participants with non-small cell lung cancer is open at Tallaght University Hospital.

NSCLC 1st Line Metastatic
ARTEMIDE-Lung04 (CTRIAL IE: 25-21) A Phase III, randomised, double-blind, multicenter, global study of rilvegostomig or pembrolizumab monotherapy for the first-line treatment of patients with PD-L1-high metastatic non-small cell lung cancer. This study is open at Beaumont Hospital, Mater Private Hospital, St James's Hospital, Tallaght University Hospital and St Vincent's University Hospital, with Cork University Hospital and University Hospital Galway to open soon.

HARMONi-3 (CTRIAL IE: 24-24) A randomised, controlled, multiregional Phase III Study of ivonescimab combined with chemotherapy versus pembrolizumab combined with chemotherapy for the first-line treatment of metastatic non-small cell lung cancer. This study is open and recruiting at Beaumont Hospital, University Hospital Galway and St. James's Hospital.

RELATIVITY 1093 (CTRIAL IE: 24-106) A Phase III, randomised, open-label study of nivolumab + relatlimab fixed-dose combination with chemotherapy versus pembrolizumab with chemotherapy as first-line treatment for participants with non-squamous (NSQ), stage IV or recurrent non-small cell lung cancer and with tumor Cell PD-L1 expression of 1-49%. This study is open at St James's Hospital and Tallaght University Hospital, opening soon at the Beacon.

MK-2870-023 (CTRIAL IE: 24-107) This study of pembrolizumab with or without maintenance sacituzumab tirumotecan(Sac-TMT; MK-2870) in metastatic squamous non-small cell lung cancer (NSCLC) is open at St. James's Hospital.

1st Line KRAS
KRYSTAL-7 (CTRIAL IE: 22-07) A Phase2 trial of adagrasib monotherapy and in combination with pembrolizumab and a Phase III Trial of adagrasib in combination with pembrolizumab versus pembrolizumab in patients with advanced non-small cell lung cancer with KRAS G12C mutation. This study is open at Beaumont Hospital, University Hospital Waterford, St James's Hospital, Tallaght University Hospital and University Hospital Galway.

Lung Updates

KRYSTAL-4 (CTRIAL IE: 25-22) A study of adagrasib plus pembrolizumab plus chemotherapy vs. placebo plus pembrolizumab plus chemotherapy in participants with previously untreated non-squamous non-small cell lung cancer with KRAS G12C mutation. Open at Mater Private Hospital, St. James's Hospital, Beaumont Hospital, Cork University Hospital and the Beacon Hospital.

KRASCENDO-2 (CTRIAL IE: 25-23) A Phase III, randomised, open-label study evaluating the efficacy and safety of divarasib plus pembrolizumab versus pembrolizumab plus pemetrexed and carboplatin or cisplatin in patients with previously untreated, KRAS G12C-positive, advanced or metastatic non squamous non-small cell lung cancer. This study is now open at St. James's Hospital, The Mater Hospital, Beaumont Hospital and Tallaght University Hospital.

2nd Line KRAS

RASolve 301 (CTRIAL IE: 24-105) is a global, randomised, open-label, Phase III study designed to evaluate the efficacy and safety of daraxonrasib compared to docetaxel in patients with previously treated, locally advanced or metastatic, RAS-mutant NSCLC. It is open at the Mater Private Hospital, Beaumont Hospital and University Hospital Limerick, with Tallaght University Hospital, University Hospital Galway, Cork University Hospital and St. Vincent's University Hospital due to open soon.

Small Cell Lung Cancer

GSK 223674 (CTRIAL IE: 26-02) This Phase III, multicenter, randomised, open-label clinical study of GSK5764227, a B7-H3 antibody drug conjugate (ADC), compared with topotecan in participants with relapsed small cell lung cancer (SCLC) is currently open at Beaumont Hospital.

GU Updates

CTRIAL 24-67 STAMPEDE2

CTRIAL 24-67 STAMPEDE2 is a University College of London (UCL)-sponsored, randomised, controlled open-label platform trial evaluating whether the addition of experimental treatments (Arm S – SABR or Arm P – [177Lu]Lu-PSMA-617) to separate standard of care (SoC) improves outcomes for patients with newly diagnosed (de novo) or relapsed metastatic hormone sensitive prostate cancer (mHSPC).

The study aims to determine whether these investigational treatments can improve disease-specific outcomes and all-cause mortality when added to SoC. Tolerability, toxicity, quality of life, and treatment-pathway costs will also be assessed.

The global accrual target is 1,920 patients into Comparison S and 1,440 patients into Comparison P, with approximately 50 patients expected to be enrolled across the Irish sites. The overall study duration is 10 years, including a 6-year accrual period, with treatment duration varying by comparison.

The National Leads in Ireland are Dr Lynda Corrigan (Tallaght University Hospital) and Dr Martin Higgins (Cork University Hospital). Since the last update, the study was submitted and successfully obtained ethical approval. Start-up activities are now underway, and contracts will be issued to participating sites in the coming weeks. Site initiation visits are anticipated for late April/early May 2026.

The study will initially open in seven Irish sites: Tallaght University Hospital (referring site only, Principal Investigator (PI): Dr Lynda Corrigan), Cork University Hospital (PI: Dr Martin Higgins), St Luke's Radiation Oncology Network (PI: Prof Brian O'Neill), Beaumont Hospital (PI: Dr Min Yuen Teo), St Vincent's University Hospital (PI: Prof Ray McDermott), Mater Misericordiae University Hospital (PI: Prof Martin O'Connell) and UPMC Hillman Cancer Centre Waterford (PIs: Dr Ciara Lyons & Dr Muhammed Jamaluddin).

GU Updates

CTRIAL-IE 24-32 De-Escalate

The De-Escalate Trial aims to evaluate whether treating patients with metastatic hormone-sensitive prostate cancer (mHSPC) using intermittent hormone therapy, rather than continuous hormone therapy, can reduce side effects and improve quality of life without negatively affecting survival outcomes.

The current standard of care for mHSPC patients involves continuous hormone therapy, typically androgen deprivation therapy combined with an androgen receptor pathway inhibitor (ADT + ARpI), which is generally continued for the remainder of the patient's life.

Patients eligible for the De-Escalate Trial will have been receiving continuous hormone therapy for 6–12 months and must have achieved a very low prostate-specific antigen (PSA) level. Participants will then be randomised to one of two groups; continuous hormone therapy, continuing the current standard treatment approach or Intermittent hormone therapy where treatment is paused and restarted based on PSA levels.

Participants in the intermittent group will stop their continuous hormone therapy and will undergo close PSA monitoring. Treatment may be restarted if their PSA rises significantly. Once PSA levels fall again to a very low level, therapy may be paused once more. This cycle may be repeated for as long as it is considered appropriate by both the patient and their treating physician.

The goal of the intermittent approach is for patients to receive only as much hormone therapy as necessary to maintain low PSA levels, potentially reducing treatment-related side effects while preserving disease control.

This study is now open in Ireland at Tallaght University Hospital (Dec 2025), Cork University Hospital (Feb 2026), University Hospital Limerick (Mar 2026) and St James's Hospital (Mar 2026). We are actively working towards opening the remaining sites approved to open in Ireland, including, Beaumont Hospital, Mater (Public & Private Hospitals), University Hospital Galway, Beacon, and St Vincent's University Hospital.

This study is recruiting well with 149 patients registered globally, 8 of which have been registered in Ireland. This is a fantastic start to accrual in Ireland.

Dr Lynda Corrigan

Prof Brian O'Neill

Dr Min Yuen Teo

Lymph & Haem Updates

Overview

The Lymphoma & Haematology portfolio continues to grow across multiple disease areas, with a strong mix of international collaborations, industry-sponsored trials, and academic initiatives. Several studies have recently activated all Irish sites, resulting in a notable expansion of national accrual capacity. Accrual remains particularly strong in acute leukaemia, myeloma, and lymphoma programmes, with Ireland participating in many of the largest global consortia such as HOVON, EORTC, EMN, and the German CLL Study Group.

Beyond active recruitment, the development pipeline remains strong. Several trials are nearing activation following regulatory approval or final feasibility review, particularly in AML, CLL, and DLBCL. Many programmes also align with the evolving integration of targeted agents, bispecific antibodies, and maintenance-modifying strategies. Collectively, the portfolio reflects a maturing national infrastructure with increasing cross-site alignment and steady engagement from investigators across all major regions.

Open to accrual

CTRIAL-IE 24-92 – EVOLVE-2 (NPM1-mut / KMT2A-rearranged AML)

EVOLVE-2, an international HOVON-led study, is now open across Beaumont Hospital, Cork University Hospital, Galway University Hospital, Mater Misericordiae University Hospital, St James's Hospital, St Vincent's University Hospital and Waterford Regional Hospital, with Dr Janusz Krawczyk serving as National Lead. Ireland is approved to enrol twelve patients as part of a global cohort of 415, evaluating azacitidine and venetoclax with or without the novel menin inhibitor revumenib. Several Irish sites have recently activated, and first patient accrual is expected imminently.

CTRIAL-IE 24-34 – CLL18 / MORAI (Frontline CLL/SLL)

This study offers a new opportunity for patients with Chronic Lymphocytic Leukaemia (CLL) to access an innovative treatment approach. This international study is designed to evaluate the effectiveness and safety of different treatment strategies for CLL, with the goal of improving patient outcomes and quality of life.

The primary objective of the study is to compare the efficacy of MRD-guided Venetoclax/ Pirtobrutinib vs fixed-duration (15 cycles) Venetoclax/ Pirtobrutinib and MRD-guided Venetoclax/ Pirtobrutinib vs. fixed-duration (12 cycles) Venetoclax/Obinutuzumab by measuring progression-free survival (PFS) in patients with previously untreated CLL/SLL.

Led by Prof Patrick Thornton at Beaumont Hospital, the study has now opened at all seven Irish sites and is actively recruiting. To date, twelve patients have been enrolled in the study, with several patients currently in screening. It is expected that this study will recruit well here in Ireland.

Prof Patrick Thornton

Lymph & Haem Updates

In development

CTRIAL-IE-25-29 HO168
Title: Epcoritamab in Addition to R-Mini-CHOP Compared to R-Mini-CHOP in Elderly Frail or Unfit Patients with Diffuse Large B-cell Lymphoma. The purpose of this Phase IIb trial is to evaluate whether the addition of epcoritamab to R-mini-CHOP can improve outcomes compared to R mini-CHOP alone in elderly, frail or unfit patients with newly diagnosed DLBCL.
Diffuse large B-cell lymphoma (DLBCL) is the most common type of aggressive lymphoma and accounts for approximately 40% of non-Hodgkin lymphoma (NHL) cases. The median age at diagnosis is currently 68-70 years.

Led by Dr Janusz Krawczyk (University Hospital Galway), the Irish accrual target is 38, across 6 sites (Beaumont Hospital, University Hospital Galway, Mater Misericordiae University Hospital, University Hospital Limerick, Saint James's Hospital and University Hospital Waterford). This study is currently in the early start-up phase, with site activation estimated for September 2026.

CTRIAL-IE 24-91 – EVOLVE-1 (IDH1-mut AML / MDS-AML)
EVOLVE-1 has secured regulatory approval and accrual is expected to open shortly at Cork University Hospital, Galway University Hospital, the Mater, University Hospital Waterford and St James's Hospital, under the national leadership of Dr Janusz Krawczyk. This study will assess ivosidenib plus azacitidine with or without venetoclax, further expanding Ireland's access to targeted AML therapies.

CTRIAL-IE 24-81 – HO501 (Venetoclax with Intensive AML Induction)
The HO501 Phase III study is currently in late-stage feasibility, with 5 Irish sites expected to participate. Led by Dr Janusz Krawczyk, the trial aims to investigate whether venetoclax can be safely integrated into intensive induction and consolidation regimens for AML.

CTRIAL-IE 24-44 – CLLRT2 (Richter Transformation)
Expected to open in May 2026, CLLRT2 is planned to open at Beaumont Hospital and Galway University Hospital, under Prof Patrick Thornton. The study will compare pirtobrutinib and epcoritamab against R-mini-CHOP for Richter transformation.

CLL2000 Registry (Ireland-wide)
This observational registry is in development for long-term outcomes in patients previously treated on frontline CLL13/14/17 studies. Planned Irish sites include Beaumont, Cork University Hospital, the Mater Misericordiae University Hospital, St James's Hospital, St Vincent's University Hospital, University Hospital Galway, University Hospital Limerick and University Hospital Waterford, led by Prof Patrick Thornton.

Dr Janusz Krawczyk

Radiotherapy Updates

NRG BN013 (CTRIAL-IE 24-87) is a collaborative study aiming to compare Single Fraction Stereotactic Radiosurgery (SRS) with Fractionated SRS (FSRS) for Intact Brain Metastasis. The study is open in BonS UPMC. Several sites (SLRON, UHG, CUH and MPH) are working closely with CTI to open.

SIMPLIFY SABR COMET (CTRIAL-IE 24-09) aims to determine if single fraction of SABR is non-inferior to multiple fraction SABR, with respect to grade 3-5 adverse events related to treatment. The study is now open at 7 Irish sites - SLRON, Beacon, BonS UPMC, CUH, UPMC Whitfield, UHG, and MPH. The first patient was randomised in October 2025, and since then 26 patients have been enrolled in Ireland (40% of all patients recruited globally!). The Irish NLI is Prof Aisling Barry.

NRG GU012 SAMURAI (CTRIAL-IE 22-17) aims to determine whether the addition of SABR to the primary tumour in combination with standard of care immunotherapy improves outcomes compared to immunotherapy alone in Renal Cell Carcinoma (RCC) patients. Irish NLI is Prof Alina Mihai. Study is open in Beacon and SLRON, with 4 patients enrolled. Study set up ongoing at MPH and UHG.

TAORMINA (CTRIAL-IE 22-16) aims to assess the efficacy and safety of SABR and systemic therapy (investigational arm) compared with systemic therapy alone (standard treatment) in patients with oligometastatic breast cancer. In addition, the study aims to evaluate potential biomarkers of response and early progression by use of tumour tissue and blood. Co-NLIs: Prof Frances Duane, Prof Seamus O'Reilly. The study is open in SLRON, SJH and the BonS UPMC, and to date, 2 patients have been enrolled. Several sites are working closely with CTI and the sponsor SABO (Swedish Association of Breast Oncologists) to open.

Spine SABR (CTRIAL-IE 20-03) 'Dose-escalated SABR (stereotactic ablative radiotherapy) for Solid Tumour Spine Metastases'. The aim of this Investigator-initiated study (IIS) is to determine the maximum RT dose that can be delivered safely to spinal metastases, without increasing the amount of treatment-induced side effects. Prof Clare Faul is the Study CI. This study is open in SLRON, Beacon, and BonS UPMC. Based on the accumulated patient data, on 11-Feb-2026 the study opened to accrual of low-risk patients on dose level 3. One patient slot remains on dose level 2 in the high-risk arm. This study has Irish Cancer Society (ICS) funding.

Prof Aisling Barry

Prof Alina Mihai

Prof Clare Faul

Radiotherapy Updates

E2RADIatE (CTRIAL-IE 21-28) OligoCare/Re-Care Cohorts: The aim is to collect real-world data on cancer patients treated with radiotherapy, to support radiotherapy research and to provide evidence of the role of radiation oncology in a multidisciplinary approach. This study is open in SLRON, Beacon and UHG. Prof Frances Duane (SLRON) is the Irish NLI.The study is coordinated internationally by EORTC.

SOURCE Lung – 'Stereotactic Ablative Radiation Therapy Of UltRaCEntral LUNG tumours' (CTRIAL-IE 18-33) is an IIS which is open at SLRON and Beacon Hospital. This study aims to assess the safety/impact on side effects of delivering the same overall dose of radiotherapy, in fewer fractions, to patients with high-risk centrally located NSCLC tumours and single pulmonary oligometastatic lesions (whose disease is inoperable), through SABR. Prof Armstrong (SLRON) is the Study CI. Two translational sub-studies are associated with this research study, and they involve Raman spectroscopic analysis (Focas Research Institute, TU Dublin) and Proteomic analysis (Conway Institute, UCD). Belfast site ethics application preparation is ongoing.

[ON HOLD:] NRG HN009 (CTRIAL-IE 22-04) aims to determine whether RT with cisplatin weekly is superior, in terms of acute toxicity and overall survival, to RT with cisplatin every 3 weeks for patients with locoregionally advanced squamous cell carcinoma of the head and neck. Irish NLI is Prof Sinead Brennan. The study opened in January 2025 in UHG (3 patients enrolled). Accrual paused since September 2025 for ~8 months before Ph II study moves to Ph III. SLRON will join when Phase III is open to accrual.

Studies pending / in development:

TOURIST Platform Lung (CTRIAL-IE 24-75) is a collaborative group RT Phase III platform lung study designed to use advanced radiotherapy techniques to establish the utility of thoracic radiotherapy in the treatment of stage IV NSCLC. The trial comprises of the PRINCE and QUARTZ LUNG studies. Irish NLI is Prof Gerry Hanna. SLRON initiated in Feb 2026 – site activation is pending, further to site agreement completion and green light approval. The study will also open in UHG.

OPTIMISE Lung SABR (CTRIAL-IE 24-15) is an IIS which aims to evaluate the safety of standard five fraction SABR and optimised three fraction SABR in patients with inoperable peripherally located NSCLC tumours or with an inoperable peripherally located single pulmonary oligometastatic lesion. The study includes two optional translational sub-studies. Prof Pierre Thirion is the CI, and Dr Lorna Keenan is Co-CI. The study has ethics approval, site contract approval is pending, and first site initiation visit is planned over the coming weeks.

PRESERVE Breast (CTRIAL-IE 24-35) aims to evaluate the risk of adverse events for a 1-week ultra-hypofractionated repeat partial breast irradiation regimen following breast-conserving surgery for patients with localised, recurrent or new primary breast cancer. NLI is Prof Aisling Barry. The study will open in CUH, SLRON, and UHG. Ethics approval is in place, and contract reviews are ongoing.

Radiotherapy Updates

FAST FORWARD BOOST (CTRIAL-IE 24-85) is a collaborative RT study aiming to compare 1-week Simultaneous integrated boost (SIB) with 3-week SIB in breast cancer patients requiring a tumour bed boost. The study has received conditional approval from the ethics committee, and the global sponsor has advised that international sites are expected to open from June 2026.

INSPIRE (CTRIAL-IE 24-72) is an IIS for an all-island multi-centre prospective single arm Phase2 trial of 'next-generation' prostate SABR with a number of toxicity reduction strategies, which will open at 11 RT centres in ROI and Northern Ireland. The planned number of participants is 136, including eligible low-, intermediate- and high-risk prostate cancer patients. Ethics approval is pending along with contracts.First site initiation visit planned over the coming weeks.

SHORT OPC (CTRIAL-IE 25-04) is a collaborative RT study looking at stereotactic boost and short-course RT for HPV-associated oropharyngeal cancer. Study set-up is pending sponsor confirmation of how study will be managed in Ireland.

Prof Gerry Hanna

Studies in early stages of development:

USZ STRIKE (CTRIAL-IE 25-54) is a collaborative, Phase III, randomised (1:1), superiority study for patients with newly diagnosed and untreated (except for surgery) asymptomatic or oligo-symptomatic brain metastases from melanoma or non-small cell lung cancer, with indication for systemic therapy. In this study patients will be randomised to have immunotherapy or targeted therapy with (Arm A) or without (Arm B) stereotactic radiosurgery. Contract work has commenced, and the study will be submitted to ethics in due course.

PRADA II (CTRIAL-IE 25-70) is a collaborative study comparing pre-operative RT (investigational arm) to post-operative RT (standard treatment) for patients with breast cancer requiring mastectomy and radiation who are desiring and suitable for immediate autologous breast reconstruction. Study set-up is pending sponsor confirmation of how study will be managed in Ireland.

NRG GI011 LAP 100 is a collaborative RT study looking at dose escalated radiation in locally advanced pancreas cancer patients. NCI / NRG Oncology issues mean the study set-up is currently on hold in Ireland.

PREVENT Lung (CTRIAL-IE: 25-67) is a collaborative RT study looking at dose-escalation with oesophageal-sparing for patients requiring palliation of intra-thoracic tumours. Initial study site feasibility is due to be conducted shortly.

ROSALIE is a collaborative RT study looking at radiation omission in patients with clinically node negative breast cancer undergoing lumpectomy with a pathologic complete response after neoadjuvant chemotherapy. The sponsor is working on a start-up package for international sites to join the study.

GI Updates

PaTcH (CTRIAL-IE 20-27)
The PaTcH study has now closed to accrual earlier than planned. This decision was taken by the Safety Monitoring Committee, the Chief Investigator, Dr Darren Cowzer, and Cancer Trials Ireland after reviewing the data collected so far.

At the time accrual stopped, 20 of the planned 22 patients had joined the study, with 19 patients evaluable for analysis. Based on the pre-specified statistical assumptions for the trial, it is now considered statistically unlikely that the study would reach its primary endpoint even if accrual continued, and therefore the decision was made to stop enrolling new patients.

Patients already participating in the study will continue their scheduled follow-up visits, and the trial will remain open for follow-up until 12 months after the last patient was registered. One patient remains in follow-up. Once this follow-up period is complete, the data will be analysed and the study results will be prepared for publication.

We would like to extend our sincere thanks to the Pat Smullen Pancreatic Cancer Fund for supporting this work, and to the patients, clinicians, and research teams who contributed to the trial. Their participation helps us continue to learn and improve treatment approaches for pancreatic cancer.

Prof Gerard McVey

DP-IMRT Pancreas (CTRIAL-IE 17-12)
'A non-randomised PhaseI/II study of dose-escalated hypofractionated Dose-Painted Intensity Modulated Radiotherapy (DP-IMRT) in resectable/borderline resectable pancreatic adenocarcinoma'.The aim of this IIS is to improve outcomes in pancreatic ductal adenocarcinoma by delivering higher RT doses targeted directly at the centre of the tumour. The study is open in SLRON and SVUH, and the CI is Dr Gerard McVey with Co-CI Dr Maeve Keys. This study is partly funded by HRB, Pat Smullen fund and ICS. The Translational sub study aims to identify plasma biomarkers for predicting response and patient prognosis (Prof Martin Clynes, National Institute for Cellular Biotechnology, DCU). The study has just completed evaluating patients at dose level 2, and is expected to re-open for dose level 3 shortly. The study is in set-up at CUH and Beacon.

FEED (CTRIAL-IE 20-26): Open

FEED (CTRIAL-IE 20-26), 21 of the planned 70 patients have been recruited to the FEED study, a nutritional intervention which aims to strengthen patient resilience and recovery from pancreas tumour resection (surgery). This study had a successful pilot programme, and models similar approaches established in other kinds of cancer.

Participants will participate in a 12-week multi modal nutritional care package while undergoing standard chemotherapy for pancreatic cancer at SVUH. The care package consists of diet, supplements, daily step target and dietitian and physiotherapist appointments. The FEED study is open in SVUH.

Gynae Updates

GYNAE DSSG OVERVIEW

The Gynae DSSG has seen incredible developments throughout 2025 and into 2026. The portfolio currently comprises studies across all gynae areas: 14 in ovarian, 2 in endometrial, 2 in cervical, and 3 studies in vulvar. Additionally, research in translational, surveys, surgical, registry and nutrition are all available, or will be available, to gynae patients in 2026. The DSSG aims to open studies across all areas of Gynaecology Oncology and in numerous sites across the country, which is one of the goals of the PCC members of the group.

ADOPTION ONLY – OPEN STUDIES:

Study Name	Disease Area	Open Locations	Referral Contact
HELP-ER	Ovarian Cancer	Beacon	Karen.Ryan@beaconhospital.ie
AFG post RT	Vulvar cancer	MMUH	aisling.mcdonnell2@ucdconnect.ie
Vulvar Survivorship survey	Vulvar cancer	MMUH	aisling.mcdonnell2@ucdconnect.ie
TUBA WISP		CUH	Vicki.cleary@hse.ie
Micro-GI Feasibility	Endometrial cancer	SLRON	Roisin.OMaolalai@slh.ie

OPEN STUDIES

25-16 RAMP 301
Open in St. James's Hospital and led by Prof Karen Cadoo, RAMP-301 is a Phase III, randomised, open-label study of combination therapy with Avutometinib plus Defactinib versus investigator's choice of treatment in patients with recurrent Low-Grade Serous Ovarian Cancer (LGSOC). This study has recruited 3 patients since May 2025. Screening is ongoing with limited patient slots available across two new patient cohorts, the non-randomised Cardiac Cohort and Moderate Hepatic Impairment Cohort. The study is due to close to recruitment towards end of this year.

24-68 ENGOT-ov83_NOGGO_TORL
Led by Prof Austin Duffy, this study is a Phase2 evaluating the efficacy and safety of TORL-1-23 in Women with advanced platinum-resistant epithelial ovarian cancer (including primary peritoneal and fallopian tube cancers) expressing Claudin 6 (CLdn6).

This study is now open in START, Mater Misericordiae University Hospital, St. James's Hospital, University Hospital Galway and is opening soon in Cork University Hospital. There has been a tremendous start to this study in Ireland with a total of 8 patients enrolled to date.

25-17 ENGOT en29/Trofuse-033
Led by Dr Dearbhaile Collins, this study is to compare the efficacy and safety of Sacituzumab Tirumotecan in combination with Pembrolizumab versus Pembrolizumab alone as first-line maintenance treatment in participants with mismatch repair proficient endometrial cancer. This study is open at SJH, CUH, MMUH and SVUH with one patient currently enrolled.

Gynae Updates

IN DEVELOPMENT

24-41 ENGOT-ov84
Led by Prof Karen Cadoo, this is a Phase III study of MK-2870 maintenance treatment with or without bevacizumab versus standard of care, after second-line platinum-based doublet chemotherapy in patients with platinum-sensitive recurrent ovarian cancer. This study is due to open at SJH and SVUH this year with 6 patients planned to be enrolled onto this study in Ireland.

24-42 ENGOT-ov85
Led by Dr Lynda McSorley, this is a Phase III study of MK-2870 with or without bevacizumab as maintenance treatment in Newly Diagnosed Advanced HRD-Negative Ovarian Cancer following platinum-based chemotherapy. This study is opening in SJH, CUH and SVUH this year. 11 patients are expected to be enrolled onto this study in Ireland.

25-37 TroFuse-036 /ENGOT cx22
Led by Dr Dearbhaile Collins, this is a Phase III study evaluating Sacituzumab Tirumotecan with Pembrolizumab (with or without Bevacizumab) versus standard care as first-line maintenance treatment in participants with persistent, recurrent, or newly diagnosed metastatic cervical cancer (TroFuse-036 / GOG-3123 / ENGOT-cx22). The study is planned to commence globally before the end of 2025, with first sites in EEA countries opening in early 2026. The study is planned to open at SJH, CUH and MMUH with site initiation visits scheduled for Q12026.

24-70 Expression IX
Led by Dr Sharon O'Toole, Expression IX is a study looking at Longterm survival in patients with any gynecological cancer by a survey. It is assumed to collect 150-200 surveys per country with a target of 1500 surveys. There are currently 702 surveys completed, and the study is expected to remain open until the 1500 surveys are completed; expected approx. 2028. We are hoping to open this very soon in SLRON, Sligo University Hospital, Tullamore, Mater University Hospital, St. James's Hospital & St. Vincent's University Hospital. We encourage all sites to open this study, so please contact the gynae DSSG team if your site is interested.

24-71 STRIVE
STRIVE, STRatIfication of Vulvar squamous cell carcinoma by HPV and p53 status to guide Excision is a Phase II randomised control trial; 2:1 randomisation for HPV-I VSCC and prospective cohort trial for HPV-A VSCC, is a newly adopted study into the CTI portfolio, which is Cancer Trials Ireland's first Vulvar study. This study will aim to open in Q2 2026 in collaboration with CCTG. Mater University Hospital and St. James's Hospital have expressed interest.

ENGOT ov93 / TREVI
Led by Dr Lynda McSorley, this study is a Randomised, Open-Label Phase III Study of AZD5335 vs. Mirvetuximab Soravtansine in FRα-High and AZD5335 vs. Investigator's Choice Chemotherapy in FRα-Low Expressing High-Grade Platinum-Resistant Epithelial Ovarian Cancer Patients. This study is due to open shortly in SVUH, MMUH, SJH, CUH and UHW. The first CTR submission was made with approvals expected mid April 2026.

ENGOT ov95 CDK2i
Led by Prof Karen Cadoo, this is a Phase III, randomised, Open-Label Study of INCB123667 Versus Investigator's Choice of Chemotherapy in Participants With Platinum-Resistant Ovarian Cancer With Cyclin E1 Overexpression. This study has been submitted under the CTR and approvals are expected in May 2026. This study is expected to open in SJH, UHW, MMUH, SVUH and GUH.

ENGOT ov97 / FRAmework 01
Led by Prof Karen Cadoo, this is a Two-Part Phase III Study of LY4170156 versus Chemotherapy or Mirvetuximab Soravtansine in Platinum-Resistant Ovarian Cancer (PROC), and LY4170156 plus Bevacizumab versus Platinum-Based Chemotherapy plus Bevacizumab in Platinum-Sensitive Ovarian Cancer (PSOC). This study will be opening in SJH, SVUH and CUH. Study submitted under CTR and pending approvals.

Gynae Updates

IN DEVELOPMENT:

LASH
Led by Dr Catherine O'Gorman, this is a surgical study looking at Minimally Invasive Simple Hysterectomy in Low-Risk Cervical Cancer (LAcc trial & SHape trial- LASH). This study is in development with ethics submission to SJH REC nearly complete. This study will open in SJH and referrals are welcome.

STUDIES IN EARLY DEVELOPMENT:

The following studies are also in early stages of development and will aim to open throughout 2026: ENGOT ov104 RAINFOL-07, ENGOT en35, with multiple more in early stage development.

RECENTLY CLOSED STUDIES:

20-07 OVHIPEC-2 (13 patients accrued), 22-08 XPORT-EC (3 patients accrued), 24-10 ENGOT-cx20 (10 patients accrued), IMGN-151 (8 patients accrued), IMGN-853-0424 (6 patients accrued).

Dr Lynda McSorley

Cancer Retreat 2026 - Save the Date

Cancer Trials Ireland will host the 2026 Cancer Retreat on Friday, 22nd May, at College Hall, RCSI, Dublin.

This year's retreat will maintain focus on the issues affecting trial start-up and the value that cancer clinical trials bring to patients, hospitals, the Irish health system, and Ireland Inc.

Further details and registration information will be shared soon.

Academic Publications from Cancer Trials Ireland Investigators

Breast:

CTRIAL-IE 16-20: IBCSG 48-14 POSITIVE
Hormonal factors predictive of fertility in patients with breast cancer interrupting adjuvant endocrine therapy to attempt pregnancy in POSITIVE trial. Demeestere I, Niman SM, Partridge AH, Diego DS, Kammler R, Ruggeri M, Colleoni M, Shimizu C, Saura C, Gelmon KA, Saetersdal AB, Kroep JR, Mailliez A, Amant F, Ruiz-Borrego M, Lee JE, Kataoka A, Walshe JM, Takei J, Borstnar S, Borges VF, Saunders C, Susnjar S, Bjelic-Radisic V, Cardoso F, Meisel JL, Kawwass JF, Spanic T, El-Abed S, Piccart M, Korde LA, Goldhirsch A, Gelber RD, Pagani O, Azim Jr HA, Peccatori FA; International Breast Cancer Study Group and the POSITIVE Trial Collaborators. Breast. 2025 Oct; 83:104547. PMID: 40743662 DOI: 10.1016/j.breast.2025.104547

Evolving incidence patterns for locally advanced operable breast cancer by receptor status: SEER 2010 -2021. Thomas A, Rhoads A, Mayer EL, O'Reilly S, Harbeck N, Curigliano G, Zhou Y, Adam V, Chan N, Conway KM, Ignatiadis M, Kalinsky K, DeMichele A, Romitti PA. NPJ Breast Cancer. 2025 Nov 13;11(1):127. PMID: 41233330 DOI: 10.1038/s41523-025-00835-7

CTRIAL-IE 16-20: IBCSG 48 -14 POSITIVE
Corrigendum to "Hormonal factors predictive of fertility in patients with breast cancer interrupting adjuvant endocrine therapy to attempt pregnancy in POSITIVE trial" [The Breast 83 (2025) 104547]. Demeestere I, Niman SM, Partridge AH, Diego DS, Kammler R, Ruggeri M, Colleoni M, Shimizu C, Saura C, Gelmon KA, Saetersdal AB, Kroep JR, Mailliez A, Amant F, Ruiz-Borrego M, Lee JE, Kataoka A, Walshe JM, Takei J, Borstnar S, Borges VF, Saunders C, Susnjar S, Bjelic-Radisic V, Cardoso F, Meisel JL, Kawwass JF, Spanic T, El-Abed S, Piccart M, Korde LA, Goldhirsch A, Gelber RD, Pagani O, Azim Jr HA, Peccatori FA; International Breast Cancer Study Group and the POSITIVE Trial Collaborators. Breast. 2025 Dec; 84:104570. PMID: 40987054 DOI: 10.1016/j.breast.2025.104570

Author Correction: Advancing equitable access to innovation in breast cancer. O'Reilly S , Luis IV, Adam V, Razis ED, Urruticoechea A, Arahmani A, Carrasco E, Chua BH, Bliss J, Straehle C, Goulioti T, Lindholm B, Werutsky G, Brain E, Bedard PL, Curigliano G, Loi S, Saji S, Cameron D. NPJ Breast Cancer. 2025 Dec 16;11 (1):140. PMCID: PMC12708722 DOI: 10.1038/s41523-025-00871-3

CTRIAL-IE 15-17 : PALLAS
Palbociclib with adjuvant endocrine therapy in early breast cancer: five-year follow up analysis of the global multicenter, open-label, randomized phase III PALLAS trial (ABCSG-42/AFT-05/PrE0109/BIG-14-13). Mayer EL, Hlauschek D, Gnant M, O'Brien PJ, Bellet-Ezquerra M, Goetz MP, Ruiz-Borrego M, Chan A, Clifton K, Egle D, Lake D, Cabrera P, Mamounas T, Pristauz-Telsnigg G, Dayao Z, Gil Gil M, Cameron D, Traina T, Morris PG, Sabanathan D, Rinnerthaler G, Meisel J, Prat A, Wolff AC, Tseng L-M, Isaacs C, Singer CF, Rubovszky G, Foukakis T, Jassem J, Winer EP, Vetter M, Federmann J, Metzger O, Schurmans C, Gauthier E, Lu DR, Fesl C, Dueck A, DeMichele A. Ann Oncol. 2026 Feb: 37(2):271-277. PMID: 41110701 DOI: 10.1016/j.annonc.2025.10.003

CTRIAL-IE 21-05: DESTINY Breast 12
Neoadjuvant trastuzumab deruxtecan alone or followed by paclitaxel, trastuzumab, and pertuzumab for high-risk HER2-positive early breast cancer (DESTINY-Breast11): a randomised, open-label, multicentre, phase 3 trial. Harbeck N, Modi S, Pusztai L, Ohno S, Wu J, Kim S-B, Yoshida A, Fabi A, Cao X, Joseph R, Li R, Żurawski B, Escrivá-de-Romaní S, Meneguetti R, Supavavej A, Chen S-C, Liu Z, Kelly C, Curigliano G, Symmans WF, Gufran M, Ke J, Konpa A, Herbolsheimer P, Boileau J-F; DESTINY-Breast11 Trial Investigators. Ann Oncol. 2026 Feb: 37(2):166-179. PMID: 41130363 DOI: 10.1016/j.annonc.2025.10.019

The Breast International Group (BIG) Patient Partnership: Embedding meaningful patient involvement in the design and conduct of breast cancer clinical research. Caballero C, Adam V, Birta O, Meheus L, Needham J, Hodgdon C, Gilhams L, Biurrun C, MacKenzie M, Spanic T, Stobart H, Belhadi L, Maués J, Casas A, Schumacher-Wulf E, Straehle C, O'Reilly S, Cameron D, Piccart M, Bliss J, Chua B. Breast. 2026 Feb:85:104642. PMID: 41265194 DOI: 10.1016/j.breast.2025.104642

Corrigendum to "Climate change impacts and sustainability integration among breast international group members" [The Breast Volume 81 June 2025 104469]. O'Reilly S, Griffiths J, Fox L, Weadick CS, Oo NM, Murphy L, O'Leary R, Goulioti T, Adam V, Razis ED, Lindholm B, Werutsky G, Cameron D, Bliss J. Breast. 2026 Feb:85:104653. PMID: 41253617 DOI: 10.1016/j.breast.2025.104653

"Silent Spring" revisited : Implications for breast cancer care. O'Reilly S, Wildiers H, Thomas A. Breast. 2026 Feb:85:104643. PMID: 41240589 DOI: 10.1016/j.breast.2025.104643

CTRIAL-IE (ICORG) 15-34: Recurrence Score
CTRIAL-IE (ICORG) 15-34: The impact of the 21 gene breast recurrence score® assay on chemotherapy prescribing in oestrogen receptor positive, lymph node positive early-stage breast cancer in Ireland. Mullally WJ, Hassan A, Keegan N, O'Leary C, McSorley L, Mahgoub T, O'Reilly S, Walshe J, Kennedy MJ, Coate L, O'Connor M, Keane M, Kelly CM, Duffy K, Murphy CG, Milewski M, Molloy S, Egan K, Murphy V, Breathnach OS, Grogan L, Hennessy BT, Morris PG. Ir J Med Sci. 2025 Jun; 194(3):839-846 PMID: 40214845 DOI: 10.1007/s11845-025-03922-7

Gastrointestinal:

Interrogating the immune landscape of microsatellite stable RAS-mutated colon cancer. Dienstmann R, García-Galea E, O'Farrell A, Kinsella Z, Meylan M, Petitprez F, Arijs I, Venken T, Ps H, Lärkeryd A, Miller I, Selves J, Meindl-Beinker N, Ruiz-Pace F, Élez E, Comas-Navarro R, Lincoln F, Fey D, Nyamundanda G, Nolan A, Lewin J, Perez-Lopez R, Briody J, Bennett K, Kolch W, Matallanas D, Kel A, Arenas E, Arribas J, Ghesquière B, Tabernero J, Meilleroux J, McNamara D, McDermott R, Lim M, O'Reilly M, Bird B, Stack L, Moloney L, Morris P, Egan K, Milewski M, Scheuer L, Behringer J, Bolz G, Salazar R, Santos C, Ruiz A, Casey O, Murphy V, Ebert M, Trusolino L, Lambrechts D, Sadanandam A, Sautès-Fridman C, Prehn J, Nuciforo P, Fieschi J, Monville F, O'Connor D, Fridman W, Byrne A. **Mol Oncol. 2026 Feb 24**; PMID: 41733106 Doi: 10.1002/1878-0261.70225 – Online ahead of print

Bevacizumab for Metastatic Colorectal Cancer with Chromosomal Instability: Cost-Effectiveness Analysis for a Novel Precision Treatment Approach in Germany, Ireland and Spain. Briody J, Miller IS,

Academic Publications from Cancer Trials Ireland Investigators

O'Mahony JF, Tilson L, O'Farrell AC, Chen Q, Murphy V, Casey O, Schulte N, Ebert MP, Prehn JHM, Lambrechts D, Ylstra B, Dienstmann R, Byrne AT, Bennett K. **Pharmacoeconomics. 2026 Mar**;44(3):359-374 PMID: 41636995 DOI: 10.1007/s40273-025-01585-x

Genitourinary:

CTRIAL-IE 14-06: ENZAMET

Association of the circulating lipid panel, PCPro, with clinical outcomes in metastatic hormone-sensitive prostate cancer: post-hoc analysis of the ENZAMET Phase 3 randomised trial (ANZUP 1304). Lin H-M, Scheinberg T, Portman N, Kim RMN, Mellor R, Hunyh K, Faulkner AN, Mellett NA, Davis ID, Martin A, Sullivan D, Joshua A, McJannett M, Subhash V, Yip S, Azad AA, Marschner IC, North SA, McDermott RS, Chi KN, Stockler MR, Sweeney CJ, Meikle PJ, Horvath LG. Ann Oncol. 2025 Sep;36(9):1068-1077 PMID: 40403846 DOI: 10.1016/j.annonc.2025.05.529

CTRIAL-IE 14-07: ENZARAD

LBA86 Randomised phase III trial of androgen deprivation therapy (ADT) with radiation therapy with or without enzalutamide for high risk, clinically localised prostate cancer: ENZARAD (ANZUP 1303). Nguyen PL, Sweeney C, Stockler MR, Thomas H, Mak B, Zhang A, Lim TS, Jose5 CC, Martin J, Patanjali N, Pryor D, Tran P, Mangar S, Mihai AM, Beresford M, Sedlmayer F, Kelly PJ, Hughes S, Davis ID, Williams S. Volume 36, Supplement 2S1628-S1629; September 2025 DOI: 10.1016/j.annonc.2025.09.102

CTRIAL-IE 14-07: ENZARAD

Baseline disease characteristics of participants enrolled on ENZARAD (ANZUP1303) and DASL-HiCaP (ANZUP1801) trials of highly effective androgen receptor antagonists in high-risk localized or locally advanced prostate cancer (PCa). Niazi T, Nguyen PL, Williams S, Stockler MR, Martin AJ, Horvath L, Thomas H, Zebic DS, Roncolato F, Lim T, Jose C, Martin J, Chung HT, Ebacher A, Morgan SC, Hughes S, McBride SM, Kelly PJ, Davis ID, Sweeney C, The Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP). Journal of Clinical Oncology, 328 (2024) Volume 42, Number 4_suppl. DOI: 10.1200/JCO.2024.42.4_suppl.328

Early termination of NCT04617067, a phase II, open label, clinical trial of oral paricalcitol in combination with gemcitabine and NAB-paclitaxel therapy in advanced pancreatic cancer. Easty D, McDermott R, Murphy AG, Grogan L, Morris PG, Breathnach OS, Egan K, Toomey S, Horgan A, Power D, Osman N, Parker I, Donachie V, Shevlin A, Barrett A, Nolan M, Marron J, Farr CJ, Hennessy BT. BMC Cancer. 2026 Jan 15. doi: 10.1186/s12885-025-14512-2. PMID: 41535788 DOI: 10.1186/s12885-025-14512-2

CTRIAL-IE 14-06: ENZAMET

Radiographic Progression Without Prostate-specific Antigen Progression in Metastatic Hormone-sensitive Prostate Cancer: A Retrospective Analysis of the ENZAMET Trial (ANZUP 1304). Inderjeeth AJ, Martin AJ, Zielinski RR, Begbie S, Cheung L, Chowdhury S, Frydenberg M, Horvath LG, Joshua AM, Lawrence NJ, Marx G, McCaffrey J, McDermott RS, McJannett M, North SA, Parnis F, Parulekar WR, Pook DW, Reaume MN, Sandhu S, Tan A, Tan TH, Thomson AH, Vera-Badillo F, Williams SG, Thomas H, Yip S, Zhang AY, Chi KN, Stockler MR, Sweeney CJ, Davis ID; ENZAMET Trial Investigators and the Australian and New Zealand Urogenital and Prostate Cancer Trials Group. Eur Urol Oncol. 2026 Feb 2: S2588-9311(26)00029-5. PMID: 41633909 DOI: 10.1016/j.euo.2026.01.008 - Online ahead of print.

CTRIAL-IE 23-05: Metastatic Breast Cancer Survey

Regional differences in experiences of patients with metastatic breast cancer in the Republic of Ireland and Northern Ireland: a comparative analysis (CTRIAL -IE 23-05). Flynn CR, McBrien A, Gaynor S, O'Meara Y, Mulvaney E, Keogh RJ, Weadick CS, Duane F, Greally H, O'Leary MJ, Teiserskyte I, Beristain I, Marron J, Mulroe E, Donachie V, McLoughlin S, O'Reilly S. BMJ Open Qual. 2025 Jul 1;14(3):e003254. PMID: 40592729. DOI: 10.1136/bmjoq-2024-003254

Gynaecology:

CTRIAL-IE 19-20: ENGOT en-9/MK7902-001/LEAP-001

First-line lenvatinib plus pembrolizumab versus chemotherapy for advanced endometrial cancer: 1-Year follow-up after final analysis of the ENGOT-en9/LEAP-001 phase 3 trial. Marth C, Moore RG, Bidziński M, Salutari V, Altundağ O, Rubio MJ, Levy T, Stillie A, Vulsteke C, Witteler R, Ariyoshi K, Wu X, Frentzas S, Mattar A, Slomovitz BM, Lheureux S, Chen X, Hasegawa K, Magallanes M, Choi CH, Shalkova M, Kaen DL, Cadoo K, Yao L, McKenzie J, Okpara CE, Meng R, Orlowski R, Gilbert L, Makker V. Int J Gynecol Cancer. 2026 Jan;36 (1):102795. PMID: 41494216 DOI: 10.1016/j.ijgc.2025.102795

Lymph and Heam:

CTRIAL -IE 16-60: CLL13

Fixed-Duration versus Continuous Treatment for Chronic Lymphocytic Leukemia. Al-Sawaf O, Stumpf J, Zhang C, Simon F, Bosch F, Feyzi E, Ghia P, Gregor M, Kater AP, Lindström V, Mattsson M, Niemann CU, Staber PB, Tadmor T, Thornton P, Wendtner CM, Janssens A, Noesslinger T, Bohn JP, Cunha-Bang C, Poulsen CB, Ranti J, Illmer T, Schoettker B, Böttcher S, Gaska T, Vandenberghe E, Clifford R, Benjamini O, Frustaci AM, Scarfò L, Sportoletti P, Schreurs J, Levin MD, Straaten H, Klift M, Tran H, Serna J, Loscertales J, Lindblad O, Sandstedt AB, Goede J, Baumann M, Fink AM, Fischer K, Ritgen M, Kreuzer KA, Schneider C, Tausch E, Stilgenbauer S, Robrecht S, Eichhorst B, Hallek M; CLL17 Trial Investigators. N Engl J Med. 2026 Mar 12;394 (11):1084-1096. PMID: 41358601 DOI: 10.1056/NEJMoa2515458

CTRIAL-IE 19-34: ISA RVD

Isatuximab (Isa) plus lenalidomide (R), bortezomib (V), and dexamethasone (d) (Isa-RVd) as induction therapy in transplant-eligible patients with newly diagnosed multiple myeloma: primary analysis of parallel phase 2 studies. O'Gorman P, et al. Blood. 2025;146(Suppl 1):4030. Abstract presented at: 67th American Society of Hematology Annual Meeting; 2025 Nov 3; Orlando, FL. https://doi.org/10.1182/blood-2025-4030

CTRIAL-IE 19-17: CPD Dara

Phase Ib study of cyclophosphamide, pomalidomide, dexamethasone, and daratumumab (CPD-DARA) in relapsed/refractory multiple myeloma: Safety and efficacy in a heavily pretreated population. Krawczyk J, Swan D, Quinn J, Mykytiv V, et al. Blood 2025;146 (Suppl 1):4031. 2025 Nov 3. https://doi.org/10.1182/blood-2025-4031

Academic Publications from Cancer Trials Ireland Investigators

Lung:

Is it my last Christmas?' Using real-world data as a prompt to reflect on goal-concordant advanced lung cancer care-a retrospective, longitudinal study. Forrest C, Twomey J, Qayoumi M, Bryan A, Collins DC, Noonan S, Dennehy K, Gaynor S, O'Dea P, O'Sullivan H, O'Reilly S. BJC Rep. 2025 Nov 20;3(1):71. PMID: 41266597 DOI: 10.1038/s44276-025-00169-8

Other:

Cutting waste in cancer care: acceptability of novel waste-reduction strategies in oral therapies amongst Irish oncology stakeholders. Kieran R, Coakley K, Macanovic B, Weadick C, Keogh R, Cooke K, Allen M, Higgins M, O'Reilly S. 2026 Feb;195(1):35-39. PMID: 41240258 DOI: 10.1007/s11845-025-04152-7

Enhancing Clinical Cancer Research Through Sharing of Data and Biospecimens. Wildiers H, Adam V, O'Reilly S, Cauwenberge JV, Arahmani A, Arteaga CL, Bedard PL, Bliss J, Boussis P, Brain E, Buyse M, Caballero C, Cameron D, Cardoso F, Carrasco E, Casas A, Chua B, Curigliano G, DeMichele A, Esserman L, Floris G, Goetz MP, Goulioti T, Haibe-Kains B, Hodgdon C, Ignatiadis M, Kok M, Lacombe D, Linderholm B, Loi S, Lord CJ, MacKenzie M, Maues J, Meheus L, Needham J, Neven P, Parsons H, Piccart M, Pusztai L, Razis E, Saji S, Schumacher-Wulf E, Sonke GS, Spanic T, Tannock IF, Tutt A, Urruticoechea A, Veer L, Vaz-Luis I, Werutsky G, Yee D, Zaman K, Desmedt C. JAMA Oncol. 2026 Feb 1;12(2):200-207. PMID: 41410930 DOI: 10.1001/jamaoncol.2025.5376

Accruals: Tables key, Paeds & all other trials

Purple	Industry Study		**Site open to accrual (or closed to accrual since the last DSSG)**
Green	Investigator-initiated trial/ study (IIT/IIS)		**Site to be initiated (TBI) i.e. approvals in place**
Orange	Collaborative Study		**Site in Set -up (ISU) i.e. submission/ approval/contract pending**
Blue	Adopted IIT/IIS	*CTI has no role - no CTI resource involved*	**Site initiated but not active (Pending)**
Grey	**Adopted Collaborative Study**	***CTI has no role - no CTI resource involved***	*Note: Grey adopted Collab Study in 'bold' font (to differentiate from green IIT as colours look similar in the table)*

Note: Tables on pages 26-29 should be viewed in two-page spread

DSSG	General Group	Cancer Trials Ireland No:	Study Name:	Accrual (to 31-Jan-2026)	CHI
Paeds	Trans	16-34	LLR Leukaemia Cell bank (on hold)	67	67
Paeds	Registry	16-37	EWOG-MDS-2006	10	10
Paeds	Trans	16-42	Renal IMPORT	65	65
Paeds	Trans	16-43	Tumour Banking Study	182	182
Paeds	Trans	16-46	EWOG-SAA 2010	24	24
Paeds	Trans	16-49	NB SCI Study	3	3
Paeds	Clinical	16-81	SIOP Ependymoma II (closed to accrual since last DSSG)	11	11
Paeds	Clinical	18-18	LCH IV	11	11
Paeds	Clinical	19-31	DIPG Registry	1	1
Paeds	Clinical	20-09	ALLTogether	68	68
Paeds	Registry	20-29	LOGGIC CORE	6	6
Paeds	Registry	23-26	EBMT	40	40
Paeds	Clinical	23-33	Interfant 21	1	1
Paeds	Clinical	24-108	LOGGIC/FIREFLY	4	4
Paeds	IMP	19-29	FaR-RMS	4	4
Paeds	Trans	23-28	MAGIC-1	64	64
Paeds	Registry	23-32	ITCC/SACHA Registry	7	7

DSSG	General Group	Cancer Trials Ireland No:	Study Name:	Total Accrual (to 31-Jan-2026)	TUH	Beacon	Beaumont	BonS Cork	BonS UPMC Cork
Breast	Trans	09-07	Breast Cancer Proteomics and Molecular Heterogeneity	5710			3857		
Breast	Clinical	22-01	SHAMROCK (on hold)	11			7		
Breast	Radio	22-16	TAORMINA	2			ISU		Open
Breast	Radio	24-35	PRESERVE (Breast)	0					
Breast	Trans	22-21	Exosomes in TNBC	46					
Breast	Clinical	23-03	EORTC 2129 TREAT ctDNA (screening phase)	39		1			
Breast	Clinical	23-03	EORTC 2129 TREAT ctDNA (randomisation phase)	2		Open			
Breast	Clinical	23-06	CAMBRIA-2	26			7		
Breast	Clinical	24-07	EMBER-4 (closed to accrual since last DSSG)	114		0	13	5	
Breast	Trans	24-08	PRIMROSE CSF	2			2		
Breast	Clinical	24-36	ASCENT 05	6			1		
Breast	Clinical	24-58	MK-2870-012	11				5	
Breast	Feasibility	24-59	HER2-CNS SURVEILLANCE	0			Open		
Breast	Clinical	24-98	DESTINY-Breast15	4			2		
Breast	Trans	24-100	BCRF	12					
Breast	Clinical	24-113	MK-2870-010	15				7	
Breast	Trans	25-15	PRISM	27			27		
Breast	Clinical	25-49	FourLight-3 (closed to accrual since last DSSG)	3			1		
Breast	Surgery/ Radio	25-65	ATNEC	4			Open		
CNS	Radio	20-03	Spine SABR	11		4			1
CNS	Trans	24-90	IMPROVE TMZ	26					
GI	Radio	17-12	DP-IMRT Pancreas	6		ISU			
GI	Clinical	20-27	PaTcH (closed to accrual since last DSSG)	20					
GI	IIT	20-26	FEED	19					
GI	Clinical	24-16	Cardia	1					
GI	Clinical	20-36	NEEDs	0					
GI	Clinical	23-25	Mountaineer-03	3			Open	Open	
GI	Clinical	24-01	SARONG II	104					
GI	Clinical	24-114	BOLD-100-101	3					
GU	Radio	22-17	NRG GU012 SAMURAI	5		1			
GU	Clinical	21-20	MK3475- 365	5	5				
GU	Clinical	20-32	PEACE 6: VULNERABLE	3	3				
GU	Trans	17-30	IRONMAN	133	62	9			
GU	Clinical	22-11	SABRE (closed to accrual since last DSSG)	61					25
GU	Registry	23-09	SLECT	104	94				
GU	Inventional Programme	23-18	LIAM Mc (closed to accrual since last DSSG)	56					
GU	Clinical	24-02	MK5684-003	13	8				
GU	Clinical	24-03	MK5684-004	7	5				
GU	Clinical	24-65	MK5684-01A	8	5				
GU	Cinical	24-48	SGNDV-001 (closed to accrual since last DSSG)	2	2				
GU	CInical	24-32	EORTC De Escalate	4	4	TBI	Open		
GU	Clincial		MK2400-001	4	2				
GU	Clincial		MK2400-01A	0	TBI		Open		
GU	Clincial		CA071-1000 rechARge	7	3		2		
Gynae	Clinical	20-07	OVIHIPEC 2 (closed to accrual since last DSSG)	13					
Gynae	Trans	22-05	ENGOT ov47 HELPER	3		3			
Gynae	Clinical	22-08	ENGOT en-20 SIENDO Part 2 XPORT	3					
Gynae	Clinical	21-29	NRG GY019 (closed to accrual since last DSSG)	3					
Gynae	Clinical	24-10	ENGOT cx20 (closed to accrual since last DSSG)	10					
Gynae	Clinical	22-18	GLORIOSA (closed to accrual since last DSSG)	2			0	1	
Gynae	Clinical	25-16	RAMP 301	3					
Gynae	Clinical	24-68	ENGOT ov83 TORL	8					
Gynae	Clinical	25-17	Trofuse-033	1					
Gynae	Surgical	24-117	AFG Post RT (closed to accrual since last DSSG)	3					

CUH	UHG	LUH	Mater	MWROC at UHL	MRH	MUH	OLLHD	CHI	Hospic-es*	UHL	SLRON	SJH	SUH	SVUH	UHW	UPMC Whit-field	Interna-tional Site
1113										381					359		
3										1		Open		Open			
ISU	ISU										2	Open		ISU			
ISU	ISU										ISU						
			11											35			
			9									24		ISU	5		
			Open									2		ISU	Open		
1	5		6											6	1		
12	16											15	2	43	8		
2			1							Open		2					
	1													5			
Open	Open											1		1			
12																	
			3											5			
ISU	ISU																
			Open									2		Open			
	3										Open			1			
											6						
26																	
ISU											3			3			
			11											9			
														19			
									0			1					
												Open					
Open			2											1	Open		
	ISU					20						84					
Open			1											2			
	TBI		TBI								4						
			Open							ISU				Open			
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																	36 (BCH)
										ISU		10					
56																	
2														3			
														2			
2														1			
0																	
Open	TBI		TBI							Open		Open		TBI			
2														Open			
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2																	
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1	0											1		1	0		
1												2					
2			6									2					
1	0											0	0		0		
												3					
0			8									Open					
0			1									Open		Open			
			3														

DSSG	General Group	Cancer Trials Ireland No:	Study Name:	Total Accrual 31-1-2026	TUH	Beacon	Beaumont	BonS Cork
Gynae	Survey	25-40	Vulvar Survivorship Survey	63				
Gynae	Observational	25-63	Micro GI Feasibility	15				
Gynae	Surgical	25-55	TUBA-WISP	20				
Gynae	Clinical	24-06	IMGN-151 (ERGOMED Phase 1) (closed to accrual	8				
Gynae	Clinical	24-116	IMGN-853-0424 (closed to accrual since last DSSG)	6			0	
H&N	IMP	22-04	NRG HN009	3				
H&N	IMP	23-35	VERSATILE 003	0				
H&N	Radio	25-04	SHORT OPC	0				
H&N	IMP	25-07	Bicara BCA101X301	0			ISU	
H&N	Surveillence	25-68	DETECT	0				
Lymph & Haem	Clinical	19-34	Isa-RVD (closed to accrual)	54			4	
Lymph & Haem	Clinical	21-22	MK1026-003	0			Open	
Lymph & Haem	Clinical	23-21	MajesTEC-4	1			1	
Lymph & Haem	Clinical	23-20	CA057-001 SUCCESSOR-1 (closed to accrual since last	6				
Lymph & Haem	Clinical	24-30	Beigene 311-308 / Mahogany	7				
Lymph & Haem	Clinical	24-92	HOVON 177/Evolve 2	0			ISU	
Lymph & Haem	Clinical	24-34	CLL18	6			Open	
Lymph & Haem	Clinical	25-26	MK 2140-011	0				
Lung	Radio	18-33	SOURCE Lung	55		6		
Lung	Clinical	22-07	KRYSTAL-7	2	Open		1	
Lung	Trans	23-11	BRAND (closed to accrual)	108			51	
Lung	Radio	24-15	OPTIMISE Lung SABR	0		ISU		
Lung	Clinical	24-51	V940-002	5	5			
Lung	Clinical	24-24	HARMONi-3	19			6	
Lung	Radio	24-75	TOURIST Platform (PRINCE and QUARTZ LUNG)	0				
Lung	Clinical	25-24	ETOP ARCH	0			Open	
Lung	Clinical	25-43	Abbil1TY	2			2	
Lung	Clinical	24-106	RELATIVITY 1093	0	Open	ISU		
Lung	Clinical	25-22	KRYSTAL-4	2		Open	Open	
Lung	Screening	24-94	Lung Health Check Pilot	1757			1757	
Clinical	Clinical	24-107	MK-2870-023	0				
Lung	Clinical	22-23	NeoCOAST-2	7			1	
Lung	Clinical	25-20	TACTI-04	3	1		1	
Melanoma	Clinical	18-50	R2910-ONC-1788 (closed to accrual since last DSSG)	8				
Melanoma	Clinical	20-37	MelMarT-II (closed to accrual since last DSSG)	24	2			
Melanoma	Clinical	22-25	R3767 ONC 2055 (closed to accrual since last DSSG)	26			13	
Melanoma	Clinical	22-26	R3767 ONC 2011 (closed to accrual since last DSSG)	12				
Basket	Radio	19-21	SABR COMET-3 (closed to accrual since last DSSG)	15		0		
Basket	Radio	21-28	E2RADIatE	89		12		
Basket	Radio	24-87	NRG BN013	0				
Basket	Registry	21-30	WAYFIND R	123	13	36		
Basket	Clinical	22-22	Immuno Fertility	8			8	
Basket	Observational	24-18	POST	709				
Basket	Trans	24-19	TANGNEY	37				37
Basket	Clinical	24-11	ANTHOS ANT 007 - Aster	19			1	5
Basket	Clinical	24-23	Gut Microbiome	36			36	
Basket	Clinical	24-17	MK 3475-587/ Keynote-587	9	3			
Basket	Clinical	24-12	ANTHOS ANT 008 - MAGNOLIA	6			2	Open
Basket	Clinical	23-07	CAReS	5	Open			
Basket	Observational	24-54	TPAC	106				
Basket	Observational	24-61	GAMBIT	87			87	
Basket	Clinical	24-57	DS7300-203	25	Open			
Basket	Observational	24-101	HRQOL	46				
Basket	Survey	24-103	EUonQOL	99				
Basket	Radio	24-09	SIMPLIFY SABR COMET	26		8		
Basket	Clinical	25-41	J5J-OX-JZZA/MOONRAY-01	0				
Basket	Clinical	25-42	MDNA11-01/ABILITY-1	3				
Basket	Clinical	25-44	STX-478-101	10				
Basket	Observational	25-64	SPAREKID-Chemo	33				

BonS UPMC Cork	CUH	UHG	LUH	Mater	MWROC at UHL	MRH	MUH	OLLHD	CHI	Hospic-es*	UHL	SLRON	SJH	SUH	SVUH	UHW	UPMC Whit-field	Int'l Site
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PCC Progress Update: March 2026

Since our last update in November, the Patient Consultants Committee (PCC) has continued to strengthen its role within Cancer Trials Ireland, contributing to research activity, strategic discussions, and the development of future patient partnership initiatives across the network.

Research Activity and Impact
Patient contributors continue to play an active role in supporting research outputs and shaping discussions within the clinical trials portfolio. A notable milestone during this period has been the continued progress of the PRO-ACT patient-led research project exploring sexual wellbeing and mental health following prostate cancer treatment. From the outset, patients have been central to the development and delivery of this work - helping to shape the research question, design the survey, interpret the findings and guide dissemination. The project was recently presented at the European Association of Urology (EAU) Congress 2026, with PCC member Martin Sweeney presenting the findings, ensuring that the patient perspective remained front and centre in an international clinical forum. This represents an important achievement for patient-led research within Cancer Trials Ireland. We would like to acknowledge and commend Martin Sweeney, Jacqueline Daly, Paul Kelly, John Sullivan, Calvin Flynn and Seamus O'Reilly for their commitment and work in bringing this important project forward and helping ensure that the patient voice is represented in research discussions at an international level.

Patient contributors have also continued to support grant development and research proposals, including input to emerging studies within the network. Discussions are also progressing around new patient-led initiatives, including the development of the "Brothers in Arms" peer-support concept, which aims to explore new ways of supporting men following cancer treatment.

Patient Insight Informing Research Discussions
During this period, PCC members have continued to contribute ideas that help inform research conversations within Disease Specific Subgroups. One example involved a PCC member highlighting the ACT-BT initiative developed by Leeds Cancer Research Centre and The Brain Tumour Charity, which brings together an expert panel to review individual brain tumour cases and identify potential eligibility for clinical trials. Recognising the relevance of this model to challenges in CNS research, including limited trial availability and low participation rates, we have begun engaging with colleagues at Leeds Cancer Research Centre to better understand the initiative and explore whether elements of this approach could inform future efforts to improve awareness of and access to clinical trials for patients in Ireland. This interaction highlights the value of embedding patient partners within the research network, enabling ideas from lived experience to inform discussions with clinical leaders and support new collaborations aimed at improving trial access for patients.

Engagement Across the CTI Network
PCC activity has also continued across Cancer Trials Ireland's wider governance and engagement structures. In January, the PCC Chair attended the Cancer Trials Ireland Board Strategy Day, helping to ensure that patient perspectives were represented during strategic discussions about the organisation's future direction. PCC members also participated in Cancer Trials Ireland's National Training Day, engaging with clinicians, researchers and staff across the network. These opportunities help strengthen relationships between patient contributors and research teams and support a shared understanding of how patient involvement can enhance the development and delivery of clinical trials. More broadly, PCC members continue to represent Cancer Trials Ireland in national discussions about patient involvement in research and are working with us to strengthen our collaboration with the Irish Cancer Society, supporting new opportunities for partnership, engagement and shared initiatives.

PCC Progress Update: March 2026

Supporting Patient Contributors

Alongside visible research activity, an important part of the PCC programme continues to focus on supporting contributors themselves. Ongoing engagement with PCC members helps ensure that both new and experienced contributors feel confident participating in research discussions. This includes providing reassurance around role expectations and reinforcing the message that meaningful patient contribution does not require technical expertise or public speaking, but rather the insight that comes from lived experience. Creating an environment where contributors feel supported and valued remains essential to sustaining meaningful and inclusive patient involvement.

Developing the PCC Training Programme

During a recent PCC meeting, contributors suggested that it would be helpful to better understand the training and development needs of the group. In response, a short survey was circulated to gather feedback on training priorities and preferred learning formats. Feedback highlighted strong interest in developing a deeper understanding of clinical research processes, including how clinical trials are designed, how Disease Specific Subgroups identify and prioritise studies, and how patient perspectives can influence research questions and trial development. There was also interest in practical skills development, including communication skills, engaging with media opportunities, and supporting the review of patient-facing materials such as Patient Information Leaflets. These insights are now informing the development of a structured PCC training and engagement programme, which will include welcome and orientation sessions for contributors, workshops on how clinical trials are developed, guidance on reviewing patient materials, and communications and media training. Opportunities to support patient-led research initiatives will also be explored.

Looking Ahead

As we move further into 2026, PCC activity will continue to focus on strengthening meaningful patient partnership across Cancer Trials Ireland.

Key priorities for the year ahead include:

- Supporting dissemination of patient-led research outputs
- Continuing to embed patient perspectives in research development and trial design
- Expanding training and mentorship opportunities for PCC members
- Supporting patient-led initiatives emerging from lived experience
- Strengthening collaboration with partners including the Irish Cancer Society

The continued growth of the PCC reflects the commitment of patient contributors, clinicians, researchers and partners across Cancer Trials Ireland to ensuring that cancer research is informed by the experiences and priorities of those it ultimately seeks to serve.

Martin Sweeney at the EAU Conference

Miriam Staunton at the National Training Day

Fundraising News

Friends of Cancer Trials Ireland

Last November, the seventh Friends of Cancer Trials Ireland gala lunch took place in the InterContinental Hotel and raised an incredible €109,000 for cancer clinical trials. Once again, it was a top-class event, featuring contributions from Prof Janice Walshe, Prof Peter O'Dwyer, Prof Seamus O'Reilly, and a patient who shared her experience of a cutting-edge lung cancer trial in Tallaght Hospital. The Board and team in Cancer Trials Ireland are once again enormously grateful to this group of intensely committed supporters.

Indeed, another of 2025's major fundraisers came through a connection with the Friends of Cancer Trials Ireland, via one of its committee members. In that regard we once more thank the Portmarnock Golf Club Captain for 2025, Mr Tom Coghlan, and his fellow members who raised €33,325 for Cancer Trials Ireland.

Tom Coghlan & Angela Clayton-Lea, Cancer Trials Ireland CEO

Friends of Cancer Trials Ireland Gala Lunch

Pancreatic

In the pancreatic cancer space, the Raheens Kildare GAA team ran a blitz for the second year over the Christmas period raising a further €6,350 for the Pat Smullen Fund. Thanks to all involved, particularly Mikey McGovern, the organiser. Meanwhile, at the Rome Marathon which takes place this Sunday coming, we send our support and best wishes to Sonia Mullen, who will race on behalf of the Pat Smullen Fund. At the time of writing, Sonia had raised over €4,000 for the fund. Thanks also to the Racecourse Integrity Services and Annette Walsh for a €500 donation. Finally, we want to acknowledge the repeated efforts of James Capstick, whose contribution is listed below. This is the third year in a row that James has supported the Pat Smullen Fund.

Other fundraising

Elsewhere, we want to thank the family, friends and colleagues of Tony Boyle, who raised €4,700 through a cake sale and associated fundraising events. These funds will be allocated towards supporting Glioblastoma multiforme research.

Last December, our CEO, Angela Clayton-Lea attended the annual Christmas dinner of CIBSE, the maintenance engineers representative body, in the Round Room at the Mansion House. CIBSE chose Cancer Trials Ireland as their charity for 2025 and 2026, attendees raised €5,177 at their Christmas event. Elsewhere, thanks also to Eamon O'Ruis and the Lough Sheelin Anglers (USE PIC), who have made an annual contribution to Cancer Trials Ireland for several years. This year, their contribution was €3,455.

Other fundraising cont.

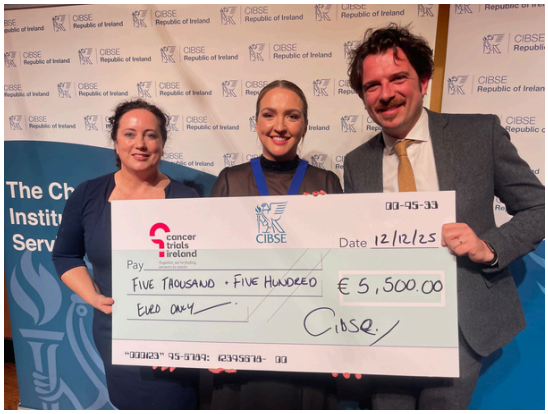
We also want to recognise the recent contribution of Craig Doyle, who ran the Barcelona marathon in memory of his grandfather George. George had attended one of the Friends of Cancer Trials Ireland dinners several years ago to share his trial experience publicly. This week, Craig, his grandson raised €3,361.

Finally, we would like to recognise another repeat contributor: Daragh Callanan of the Ballyfoyle Agricultural Show, who along with his colleagues and fellow committee members, who raised €2,000 last November. They have been donating to Cancer Trials Ireland for several years, and we remain deeply appreciative of their continued support.

Our thanks also go to:

John & Noreen Rafferty – €1,000
Annette Walsh – €500
Kinnegar brewing - €435
Bowie Festival - €105 (PICS)
James Capstick (pancreatic): - €111

Lough Sheelin Trout Protection Association (LSTPA)



CIBSE Christmas Fundraiser

Fundrasier in memory of Tony Boyle

Dublin Bowie Festival

cancer trials ireland

Together, we're finding answers to cancer.

Cancer Trials Ireland is supported by:

Irish Cancer Society & HRB Health Research Board