cancer trials ireland

Together, we're finding answers to cancer.

DSSG Digest

Winter 2026










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funded by HRB Health Research Board & Irish Cancer Society

Clinical Lead Message

I want to begin by welcoming two new DSSG co-chairs: Dr Lynda McSorley, who is taking over as co-chair of the Gynae DSSG, and Prof Anna Olsson-Brown, who will be taking over as co-chair of the Melanoma DSSG.

Taking on the leadership of a DSSG represents a significant commitment of time and effort. We know only too well how much of our work depends on the passion and dedication of individuals, and I want to acknowledge our colleagues' willingness to take on these additional, important responsibilities. I also want to thank the outgoing Chairs, Prof Dearbhaile Collins and Prof Fergal Kelleher. Thank you both. Your leadership and contributions have been vital.

Turning to the Clinical Trials Advisory Council (CTAC), which has already held its second meeting, I want to update members on developments. The Council has established four of its six subcommittees to implement the recommendations of the National Clinical Trials Oversight Group (NCTOG). In addition to our two seats on the Council, Cancer Trials Ireland sits on three of these subcommittees, and I am delighted to co-chair the Strategic Development subcommittee with Prof Fidelma Dunne.

An intensive work programme and meeting schedule are already underway, with the objective of establishing the new National Clinical Trials Body (as recommended by NCTOG) by the first quarter of 2028. Angela and I will keep members informed of developments as this work progresses. It is heartening to see the level of commitment and urgency being brought to the process, and also to see the seriousness with which the Minister, Government and the various departments involved are approaching this important work.

Elsewhere, I want to reflect on our international engagements this year, most recently at ESMO, where Cancer Trials Ireland participated in more than 30 meetings with pharmaceutical companies, collaborative groups and investigators. This followed a similarly busy programme of meetings at ASCO in June. The overriding message from both conferences was unmistakable: Ireland's clinical trial start-up times are paramount in attracting new trials. International sponsors and collaborative groups look at our collective performance as a country, not site by site. In that respect, we are only as strong as our weakest link.



Clinical Lead: Prof Seamus O'Reilly

Recognising this, Cancer Trials Ireland has established a National Site Start-up Timelines Working Group in Q3 2026, bringing together stakeholders to address the challenges affecting trial activation nationally. This follows on from the creation of a dedicated Start-Up Team within Cancer Trials Ireland in December 2024.

But alongside efforts to streamline processes and improve start-up performance, we must also recognise the need for clearer study prioritisation, to ensure that our collective resources are focused on the studies where Cancer Trials Ireland and our sites are best placed to deliver. That will allow us to focus on our strengths and improve our competitiveness. With that in mind, and as Angela has said, building on our Beau-RCSI / MEDSIR collaborative IIT Think Tank in May, we are piloting two DSSG mini-retreats, initially within the Breast and GI DSSGs. The aim is to bring specialists together to review their existing trial portfolios, undertake a gap analysis, and identify areas where additional studies or new approaches may be needed.

This will include examining the current research landscape, considering emerging opportunities, and identifying where our efforts and resources can be most effectively directed. Importantly, we also want to bring new voices into these discussions, including emerging investigators and clinicians returning to Ireland or reaching a stage in their careers where they are ready to become more actively involved in clinical research.

Ultimately, the objective is to develop a more strategic approach to study prioritisation. We know from our international engagements that industry places enormous value on the calibre of Irish clinicians, Principal Investigators and research sites.

Our challenge is to match that clinical excellence with the systems and performance needed to make Ireland an attractive destination for clinical trials. These mini-retreats are an important part of that wider effort, and, if successful, will be rolled out to other DSSGs.

On the subject of the next generation of investigators, I want to draw your attention to our fourth National Training Day, which will take place on Friday 29th January 2027. Hosted in conjunction with ISMO, the National Training Day provides an opportunity for trainees to present their research, and engage with a range of speakers throughout the day. These emerging investigators are entering an increasingly complex healthcare and research environment, but hopefully also one that will become more supportive of their ambitions.

This is among the many issues that we will be advocating for as the next National Cancer Strategy is developed in 2027. In this context, and in line with NCTOG recommendations, we support an evolved system that places clinical research at the heart of cancer care, with clear KPIs and targets that embed research within the health system.

New leadership appointments for Melanoma and Gynae DSSGs

Cancer Trials Ireland is pleased to announce two new leadership appointments within its Disease Specific Sub-Groups (DSSGs), with Prof Anna Olsson-Brown taking up the role of Co-Chair of the Melanoma DSSG and Dr Lynda McSorley appointed Co-Chair of the Gynae DSSG.

Prof Olsson-Brown is UPMC Professor of Cancer Clinical Trials at University College Cork and brings extensive expertise in skin cancer treatment, immunotherapy, early-phase clinical trials and the management of immunotherapy-related toxicities. She succeeds Prof Fergal Kelleher, to whom Cancer Trials Ireland extends its sincere thanks for his leadership, commitment and contribution to the Melanoma DSSG.



Prof Anna Olsson-Brown

Dr McSorley has been an active and valued member of the Gynae DSSG for several years, contributing to numerous studies across the portfolio in the roles of Principal Investigator (PI) and National Lead Investigator (NLI). She succeeds Prof Dearbhaile Collins as Co-Chair. Cancer Trials Ireland extends its sincere thanks to Prof Collins for her leadership, dedication and significant contribution to the development of the Gynae DSSG and its clinical trials portfolio.



Dr Lynda McSorley

Cancer Trials Ireland congratulates Prof Olsson-Brown and Dr McSorley on their appointments and looks forward to working with them in their new roles as the DSSGs continue to advance cancer clinical trials in Ireland.

CEO Message



CEO: Angela Clayton-Lea

Welcome to the Winter 2026 DSSG Cancer Trials Ireland Digest.

Since our Spring 2026 DSSG Digest, the Clinical Trials Advisory Council (CTAC) has been established. I am very pleased to confirm, as many of you will now be aware, that both myself and our Clinical Lead, Professor Seamus O'Reilly, were appointed to CTAC in July by the Minister of Health.

This is an important development, ensuring that Cancer Trials Ireland, and the cancer clinical trials community we represent, has a voice in discussions about the future landscape of clinical trials in Ireland. In addition, I continue to serve on the NCCP-led National Cancer Research Group, which is in the process of finalising the National Cancer Research Plan.

In May 2026 we held our annual Cancer Trials Ireland Cancer Retreat. This was an opportunity to take stock of developments across the organisation and discuss some of the challenges facing the cancer clinical research community. Among the highlights was a keynote address from Professor Benjamin Besse on the opportunities presented by treatment optimisation trials.

In collaboration with Beau-RCSI and MEDSIR, Cancer Trials Ireland hosted an IIT Think Tank in May, which brought together senior Principal Investigators from across our DSSGs, together with their trainees and mentees, to present a range of IIT proposals.

Building on the success of that event, we are now further developing the Think Tank model through a series of mini-retreats across the DSSGs. We will commence this series with mini-retreats for the Breast and then the GI DSSG – planned for Q1 2027.

In October, we had a very productive trip to the ESMO congress. Collectively, we attended over 30 meetings with industry and collaborative groups to discuss ongoing initiatives, Ireland's performance in cancer trials, and to explore new opportunities to bring more trials to Ireland. Thank you to our local Pharma partners, who greatly assisted with setting up meetings with their global teams. I also want to thank all our members who kept us informed of their involvement and their meetings at ESMO, which we made every effort to support.

Our Value of Cancer Trials 2 report, launched on 6th November, features four trials with Irish involvement presented at ESMO 2026, including DASL-HiCaP, for which Cancer Trials Ireland acted as EU and UK sponsor.

Improving cancer trial start-up times has been a major focus for me and my team this year. The Value of Cancer Trials 2 report showcases the latest figures and start-up times and includes a detailed examination of remaining challenges. Our goal is to establish parallel processes in the approval and initiation system that will further improve Ireland's start-up times. We hope this will also positively impact the number of feasibility requests we receive, which currently stand at 22 for the period of the report.

The Value of Cancer Trials 2 report also builds on our work to quantify the economic value of cancer clinical trials. Over the period examined, 38 trials involving 230 patients generated an estimated €6.51 million in standard-of-care treatment cost savings. Inward investment through investigational medicinal products, across 20 of these trials, was estimated at €6.76 million.

Beyond the economic analysis, for the Value of Cancer Trials 2 report we also conducted qualitative interviews with nine Principal Investigators. These provide valuable insights into the strengths of Ireland's clinical research system, the barriers investigators encounter, and the changes they believe are needed. The report also publishes new data arising from our fourth benchmarked public attitudes survey in six years.

Our six years of Just Ask / Let's Talk Trials campaigns have sought to improve public awareness and understanding of clinical trials and the opportunities they offer patients. One of the most encouraging findings was the substantial increase in public willingness to participate in clinical trials, rising from 48% in 2020 to 69% in 2026. Among people with cancer, the figure rises to 82%.

The survey also found that, for many patients, the main barriers are practical rather than attitudinal, including travel, additional appointments and the impact on family responsibilities. While there is always more work to do, it is encouraging to see public attitudes moving so positively over that period.

On the theme of savings, and building on Prof Besse's keynote at our May Retreat, the report also highlights the opportunities presented by optimisation trials, which have the potential to improve patient outcomes and experiences while making more effective use of resources. Other European countries are already investing in this area. In the Netherlands, ten health insurers jointly fund optimisation trials of expensive drugs, and the EU's Horizon Europe Cancer Mission runs funding calls for pragmatic trials that optimise cancer treatments.

Funding to support activity remains an ongoing challenge. Philanthropy remains an absolutely critical funding stream for Cancer Trials Ireland, particularly when it comes to supporting investigator-initiated trials (IITs). Over the Summer months, we have had significant philanthropic successes. In May, we celebrated another hugely successful Property Picnic, which raised almost €120,000, thanks to the continued generosity of Hooke & MacDonald and the wider property community.

Once again, the horse racing community has shown extraordinary support for Cancer Trials Ireland and the Pat Smullen Fund, raising more than €213,000 through the Pat Smullen Race Day in August. This support is helping to bring exciting new research and medicines to Ireland, with the prospect of making new treatments available to pancreatic patients here.

On behalf of everyone in Cancer Trials Ireland, I want to thank our community for your ongoing dedication and commitment, and our funders and philanthropic partners for your invaluable support.

Finally, I want to finish by congratulating everyone involved with the INSPIRE trial, which won Cross-border/International Collaboration of the Year at the 2026 Irish Healthcare Awards held in November. This win reflects all the hard work and commitment involved in developing and opening an IIT, and I'm sure our community will join me in celebrating this achievement.

Cancer Trials Ireland Podcast – Season 5 Coming Soon

Cancer Trials Ireland is preparing to record Season 5 of its podcast, with new episodes due for release towards the end of 2026 and into the New Year.

Season 4 explored patient experiences, the value of cancer trials, international collaboration and the future of cancer research in Ireland.

All previous episodes are available on the Cancer Trials Ireland website or wherever you get your podcasts.



Value of Cancer Trials 2: Demonstrating the value, making the case for change

On 6 November 2026, Cancer Trials Ireland launched its Value of Cancer Trials 2 report at RCSI, bringing together patients, clinicians, researchers, funders, industry representatives and policymakers. With a full room and approximately 100 participants joining online, the event highlighted the considerable benefits of cancer clinical trials and the opportunities to strengthen Ireland's research environment.

CEO Angela Clayton-Lea opened by outlining progress in clinical trial activity and start-up performance. Industry-sponsored trials commencing in Ireland increased by 44% in 2025, while Cancer Trials Ireland's Start-Up Team achieved a 65% reduction in median site agreement turnaround times. Despite this progress, Ireland remains 14th among 27 EU Member States for industry-sponsored trials per capita.

Patrick Kivlehan, Chair of Cancer Trials Ireland's Patient Consultants Committee, brought the patient perspective to the discussion. New public attitudes research shows that willingness to participate in clinical trials has risen from 48% in 2020 to 69% in 2026, reaching 82% among people with cancer. However, practical barriers, restrictive eligibility criteria and delays continue to limit opportunities for willing patients.

Prof Gerry Hanna, Vice-Clinical Lead, Cancer Trials Ireland, presented the report's economic findings. Analysis of 38 trials involving 230 patients identified an estimated €6.51 million in standard-of-care drug costs avoided, alongside €6.76 million in estimated inward investment through investigational medicines from just 20 trials. Potential hospital site-fee revenue was estimated at a further €10.5 million. These figures represent only a proportion of trial activity, suggesting considerably greater economic value nationally.

Representing industry, Samantha Humphreys, Managing Director of MSD Ireland and Chair of IPHA's Clinical Research Exchange Group, highlighted Ireland's strengths in clinical expertise and research capability, while emphasising the need for faster trial activation, national standardisation and sustainable workforce investment.

The clinical presentations demonstrated the impact of research on patient care. Dr Anne Fortune highlighted significant improvements in blood cancer survival and the importance of treatment optimisation, broader eligibility criteria and equitable access.

Prof Sinead Brennan outlined how radiotherapy trials can deliver shorter treatment courses, reduce costs and release capacity for additional patients. She also highlighted INSPIRE, the all-island prostate cancer radiotherapy trial recognised at the 2026 Irish Healthcare Awards.

Nikki Gallagher, CEO of the Irish Cancer Society, reaffirmed the Society's commitment to supporting cancer clinical research, highlighting the Beau–RCSI Lung Health Check and the importance of ensuring research opportunities are accessible to patients throughout Ireland.

The discussion reinforced the need for national coordination, sustained investment and stronger recognition of clinical research within healthcare delivery. Closing the event, Cancer Trials Ireland Chair Deirdre Somers stressed that clinical trials cannot continue to depend primarily on the goodwill and commitment of individual clinicians.

The message was clear: Ireland has the expertise, partnerships and public support to achieve considerably more. The priority now is to ensure clinical trials are recognised, resourced and embedded as an integral part of cancer care.

Read the full report:
www.cancertrials.ie/2026/11/value-of-cancer-trials-2/



L-R: Patrick Kivlehan, Dr Anne Fortune, Prof Sinead Brennan, Angela Clayton-Lea, Deirdre Somers, Nicola Cosgrove (Research Ireland)

ESMO 2026: research achievements and international partnerships



Members of the Cancer Trials Ireland team in Madrid

Cancer Trials Ireland's attendance at ESMO Congress 2026 combined support for research with strong involvement from Ireland with a structured programme of more than 30 meetings with industry partners and international collaborative groups.

Held in Madrid from 23–27 October, the Congress featured contributions from clinicians and researchers based in Ireland across oral presentations, posters, chairing and discussion roles. Cancer Trials Ireland attended and shared coverage of a wide range of sessions, highlighting research spanning treatment advances, supportive care, patient experience and cancer genetics.

A particular highlight was Prof Jarushka Naidoo's invitation to serve as the first Irish Presidential Discussant. In Presidential Symposium III, she provided an independent expert assessment of the French phase III MOIO trial. Her presentation, "Doing less, Proving more? Lessons in De-escalation in Oncology", examined the findings and limitations of less frequent immunotherapy and highlighted the need for approaches tailored to specific cancers and clinical settings.

Four international trials illustrated the contribution of patients, researchers and sites in Ireland to evidence presented at the Congress. DASL-HiCaP, for which Cancer Trials Ireland acted as EU and UK sponsor, reported that adding darolutamide to standard treatment reduced the risk of metastasis or death in very high-risk prostate cancer. Long-term PEACE-1 findings reinforced the survival benefits of adding abiraterone to treatment for prostate cancer that had spread at diagnosis.

In breast cancer, NATALEE reported sustained reductions in recurrence and encouraging overall survival findings, while the final NSABP B-42 analysis demonstrated lasting reductions in recurrence with extended letrozole treatment, without a statistically significant overall survival benefit. Together, these studies underline the importance of maintaining research participation and follow-up over many years.

Alongside the scientific programme, the team's partnership meetings focused on renewing relationships, forming new connections and discussing ongoing studies and future research opportunities. This work supports Cancer Trials Ireland's objective of attracting more clinical research to Ireland and expanding trial opportunities for patients.

The delegation included Prof Seamus O'Reilly, Clinical Lead; Prof Gerry Hanna, Vice Clinical Lead; Angela Clayton-Lea, CEO; and Jacinta Marron, Head of Operations, alongside colleagues working across trial delivery and clinical operations. Head of Marketing Claire Hopkins coordinated coverage during and after the Congress, supported by a dedicated webpage highlighting contributions from Ireland.

The visit brought together two connected priorities: recognising the research community's contribution to international evidence and developing the partnerships needed to support future studies.



Prof Naidoo in the ESMO Presidential Symposium

INSPIRE wins Cross-border / International Collaboration of the Year



Representatives of the INSPIRE team at the awards

The INSPIRE prostate cancer radiotherapy trial has won Cross-border / International Collaboration of the Year at the Irish Medical Times Irish Healthcare Awards 2026, held at the Aviva Stadium in Dublin on 3 November.

Sponsored by Cancer Trials Ireland, INSPIRE (INnovative SABR for Prostate cancer all IREland) is the first radiotherapy trial to bring together radiation oncology teams from across the island of Ireland. Led by Co-Chief Investigators Prof Suneil Jain (Queen's University Belfast) and Prof Brian O'Neill (St Luke's Radiation Oncology Network), the study marks an important milestone in cross-border cancer research.

INSPIRE uses advanced imaging, precision planning, gold fiducial markers and rectal spacers to investigate whether prostate radiotherapy can be delivered with fewer urinary, bowel and sexual side effects while maintaining excellent cancer control. Patient contributors Martin Sweeney and Ken McBride, from North and South, were closely involved in shaping the trial's design.

With 27 patients now enrolled, the award recognises the collective efforts of clinical teams, patient contributors, Cancer Trials Ireland, the Irish Research Radiation Oncology Group (IRROG), and partners across Ireland, Northern Ireland and internationally.

Find out more: www.cancertrials.ie/inspire-innovative-sabr-for-prostate-cancer-all-ireland/





Climate and Cancer Care: London Global Cancer Week 2026

On 2 November 2026, Cancer Trials Ireland collaborated with Oncology Advocates United for Climate and Health – International (OUCH-Int'l) to present Climate and Cancer Care: The Oncologist's Perspective on Biology, Equity, and a Sustainable Future, as part of London Global Cancer Week.

Chaired by Dr Susannah Stanway, the webinar brought together oncology experts and a patient advocate from across the world to explore how climate change is affecting cancer risk, tumour biology, access to treatment and health inequalities.

Prof Seamus O'Reilly, Clinical Lead, Cancer Trials Ireland, discussed practical approaches to more sustainable oncology services and clinical research, including reducing unnecessary interventions and designing greener clinical trials.

The discussion also highlighted the importance of patient involvement in developing climate-resilient healthcare and the role of oncology professionals in driving change through research, education and advocacy.

Watch the full webinar recording: https://youtu.be/gDW19a9wdVU

Breast Updates - open to accrual

SHAMROCK Study (CTRIAL-IE 22-01)

The 'Single arm phase 2 trial of neoadjuvant trastuzumab deruxtecan (T-DXd) with response-directed definitive therapy in early-stage HER2-positive breast cancer: a standard chemotherapy-sparing approach to curative-intent treatment – SHAMROCK study' was placed on hold in May 2024 and subsequently underwent substantial protocol amendments. Following regulatory approval of the revised study design, the study reopened to accrual on 1 May 2026.

Since reopening, eight patients have been enrolled at Beaumont Hospital so far. The SHAMROCK study is also open to accrual at Cork University Hospital, St. James's Hospital, and University Hospital Limerick. University Hospital Galway is expected to join the study following approval as a participating site.

According to the amended study protocol patients will receive T-DXd 5.4 mg/kg intravenously every three weeks for four cycles. A mandatory repeat tumour biopsy is performed at Cycle 2 Day 14 to assess the RNA Disruption Index (RDI), a biomarker designed to evaluate tumour response to treatment.

Following completion of four cycles of T-DXd, patients undergo repeat breast imaging. Patients who achieve an imaging complete response (iCR), defined as the resolution of all previously identified suspicious abnormalities, proceed directly to surgery and may avoid standard cytotoxic chemotherapy. Patients who do not achieve an iCR receive four additional cycles of neoadjuvant paclitaxel, trastuzumab and pertuzumab (THP) prior to surgery. A second mandatory tumour biopsy is performed after initiation of THP to further assess RNA disruption and treatment response.

The primary objective of the study is to evaluate the efficacy of neoadjuvant T-DXd using imaging complete response after four cycles of treatment as the primary endpoint. Secondary objectives include assessment of pathological complete response (pCR), event-free survival (EFS), overall survival (OS), safety and tolerability, and the predictive performance of the RNA Disruption Index.

The study also incorporates several translational research programmes aimed at understanding tumour evolution during treatment and developing biomarker-based strategies to better predict treatment response and pathological complete response.

The study is led by Prof Bryan Hennessy, with Cancer Trials Ireland acting as sponsor. The SHAMROCK study is funded through a grant from Breast Cancer Ireland. AstraZeneca and Daiichi Sankyo, the co-developers of trastuzumab deruxtecan, are supporting the study by providing the investigational medicinal product.

NOAX (CTRIAL-IE 25-72)

This international randomized 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 the incidence of breast cancer-related lymphoedema while maintaining excellent oncological outcomes.

The trial is jointly sponsored by University Hospital Basel and Cancer Trials Ireland. The study opened to accrual at University Hospital Galway on 15 July 2026, and Prof Aoife Lowery has already enrolled two patients.

Additional Irish sites are expected to open shortly, including St. Vincent's University Hospital, St. James's Hospital, and the SLRON Network. Cork University Hospital is planning to join the study in 2027.

The OPBC-10/NOAX study will recruit 295 patients internationally, with a target of enrolling 50 patients across Irish sites.

Breast Updates continued

ASCENT-05 (CTRIAL-IE 24-36)

ASCENT-05 is an international, randomised, open-label phase III trial sponsored by Gilead Sciences. The study is evaluating whether adjuvant sacituzumab govitecan in combination with pembrolizumab can improve outcomes compared with treatment of physician's choice (TPC) in patients with high-risk early triple-negative breast cancer (TNBC) who have residual invasive disease following neoadjuvant therapy and surgery.

The trial is enrolling patients with TNBC who have received neoadjuvant chemotherapy, with or without immune checkpoint inhibitor treatment, and have residual invasive disease in the breast and/or axillary lymph nodes at surgery. Patients are randomised to receive either sacituzumab govitecan plus pembrolizumab or treatment of physician's choice, consisting of pembrolizumab with or without capecitabine, according to local standard practice.

The primary objective of the study is to compare invasive disease-free survival (iDFS) between the two treatment strategies. Secondary objectives include evaluation of overall survival, distant relapse-free survival, safety, tolerability, and patient-reported outcomes.

The study plans to enrol 1,514 patients globally, with a target of 25 patients across Irish sites. Four Irish centres are currently open to accrual: St James's Hospital (PI: Dr Niamh Coleman), Beaumont Hospital (PI: Prof Patrick Morris), Mater Misericordiae University Hospital (PI: Dr Shahid Iqbal), and Cork University Hospital (PI: Prof Seamus O'Reilly).

To date, 15 patients have been randomised in Ireland, with active screening continuing across participating sites. Due to strong international recruitment, global enrolment is progressing ahead of expectations, and accrual is now anticipated to close earlier than originally projected, with study completion of recruitment expected in January 2027.





L-R: Prof Bryan Hennessy & Dr Niamh Coleman

Melanoma Update

MSLT-3 Study Progresses to Start-Up Following Funding Award

The MSLT-3 (Multicentre Selective Lymphadenectomy Trial 3) study is progressing through start-up in Ireland following the award of funding from the Irish Cancer Society in November 2026.

Sponsored internationally by Melanoma Institute Australia, this Phase III trial will investigate whether patients with stage III melanoma who respond particularly well to immunotherapy before surgery can safely undergo less extensive lymph node surgery without compromising treatment outcomes.

The study aims to determine whether this approach could reduce surgical complications, including lymphoedema, and improve patients' quality of life.

Ms Amy Gillis and Melanoma DSSG Co-Chair Prof Shirley Potter are leading the study's development in Ireland. Site feasibility work is being progressed, with ethics submissions targeted for early 2027.





L-R: Ms Amy Gillis & Prof Shirley Potter

GI Updates

The GI clinical research portfolio has continued to gain momentum since the last DSSG Digest was published in March, with a broad range of studies advancing through development and activation. New projects span multiple disease sites and research themes, reflecting the strength and diversity of the programme. These include the **DOSe eScalated Hypofractionated Radiotherapy in Rectal Cancer** study led by Dr Sean O'Cathail and Dr Catherine Hanna, the **MACHINE** hepatocellular carcinoma study led by Prof Grainne O'Kane, and the **OGHAM** oesophageal cancer study under Dr Jessie Elliott. The portfolio is also expanding into supportive care and survivorship research through initiatives such as **KEYP-ICI**, **Support GI**, and **Minigo**, alongside translational and precision oncology studies including **PANC-IRE**, **PPD**, and **APEX.**

Recruitment remains strong across the open portfolio. In upper GI cancer, **SARONG-II** has recruited 130 of its target 310 participants across three Irish sites, while the international **CARDIA** trial has surpassed 220 global inclusions. Colorectal cancer research continues to be a major focus, with **MOUNTAINEER-03**, **BOLD-100-001**, and **Mercury 3** currently recruiting, supported by a further three studies in development.

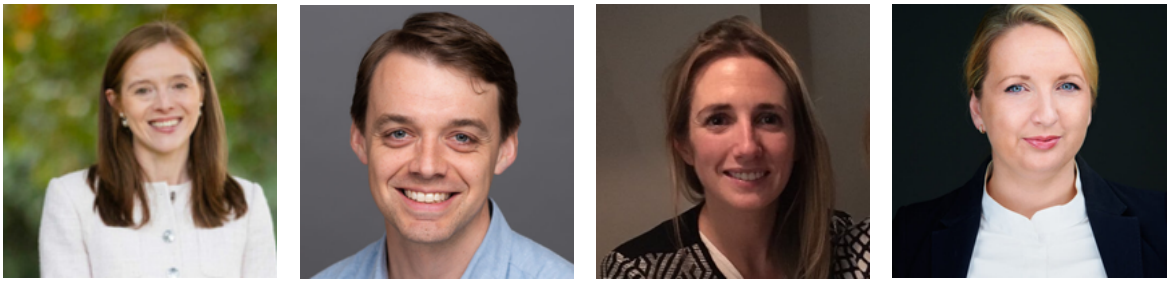
The hepatobiliary programme is also growing, with the **ZW251** Phase I study actively recruiting patients with advanced solid tumours, including hepatocellular carcinoma. In biliary tract cancer, development is underway for the **SAFIR IMPACT BTC** study, an international precision medicine platform evaluating biomarker-directed adjuvant therapies in resected cholangiocarcinoma.

Pancreatic cancer remains one of the largest areas of activity within the portfolio. Current studies include the **FEED Study**, the **DP-IMRT Pancreas Study**, and **MountainTAP-30**. Upcoming studies include **LAP100**, a Phase III radiotherapy trial in locally advanced pancreatic cancer, a pilot study evaluating universal germline testing for all newly diagnosed pancreatic cancer patients, and **CAREFNDR**, a study assessing Paltusotine for neuroendocrine tumour-associated carcinoid syndrome.

The Molecular Targeted Therapy programme continues to expand, with five early-phase studies currently open at the Mater Hospital. These include **MOONRAY-01, STX-478-101, BMS CA240-0005, IAM1363**, and **APEX**, providing access to innovative therapies targeting KRAS, PI3Kα, HER2, MTAP deletion, and other molecular alterations. A further three pan-solid tumour studies are also recruiting, broadening treatment opportunities for patients with advanced cancers.

In addition to disease-specific studies, the portfolio includes ongoing expansion studies such as **CAReS**, investigating interventions for cancer-associated anorexia and weight loss, and **KEYNOTE-587**, a long-term pembrolizumab extension study.

Overall, the portfolio is experiencing significant growth, with a strong balance of investigator-led, translational, academic, and industry-sponsored research. The continued expansion of studies across gastrointestinal cancers and molecularly targeted therapies is increasing opportunities for patients to access innovative treatments and participate in cutting-edge clinical research.



L-R: Prof Grainne O'Kane, Dr Sean O'Cathail Dr Catherine Hanna, Dr Jessie Elliott

Lung Updates

CTRIAL-IE 24-15 OPTIMISE Lung SABR

The OPTIMISE Lung SABR study is now open for recruitment at SLRON (SLH & SJH).

This investigator-initiated study was devised by Chief Investigators Prof Pierre Thirion and Dr Lorna Keenan. The study is a phase II, randomised, multi-centre study, independently evaluating conventional five-fraction image-guided (IG)-SABR and Investigational optimised-dose-painted three-fraction IG-SABR for patients with a peripherally located NSCLC tumour (T1-T2 and selected T3 and T4), or a peripherally located single pulmonary oligometastatic lesion.

The primary endpoint of the study is to prospectively determine the safety of two SABR fractionation schedules: conventional five-fraction SABR and optimised dose-painted three-fraction SABR. Patients will be followed for 5 years, and the primary endpoint will be assessed based on patient safety after 2 years of follow-up.

The study will recruit ~208 patients, with the first patient being recruited in October 2026. The study is also planned to open at the following hospital sites in due course: Cork University Hospital, University Hospital Galway, Bon Secours UPMC Hospital Cork, UPMC Whitfield Hospital Waterford, and Belfast City Hospital.

CTRIAL-IE 25-24 ETOP ARCH

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.

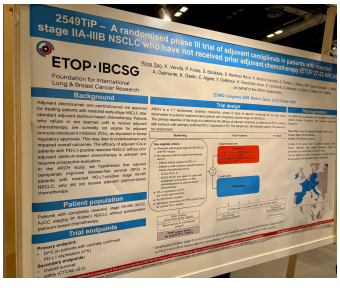
As a result, these patients are currently unable to receive immunotherapy after surgery. Presently, we don't know if immunotherapy on its own can help lower the risk of lung cancer coming back after surgery in people who cannot have chemotherapy. The ARCH study is designed to answer this question. It 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. Since activation, both sites have enrolled their first patient. A total of 2 patients has been enrolled to the study in Ireland. 2 additional sites have been approved for participation, Cork University Hospital and St. Vincent's University Hospital with activation of both sites planned for Q4 2026. The addition of new sites will support our recruitment efforts across Ireland with the aim of reaching a total of 50 participants.





L-R: Prof Pierre Thirion and Dr Lorna Keenan





L-R: ETOP ARCH poster at ESMO, Prof Patrick Forde

Gynae Updates

The Gynae DSSG has experienced considerable growth and development throughout 2026. The portfolio currently comprises studies across all gynae areas: 15 in ovarian, 3 in endometrial, 2 in cervical, and 2 in vulvar. Additionally, research in translational, surveys, surgical, registry and nutrition are all available, or will be available, to gynae patients in 2027.

The group has made significant progress towards opening studies across all areas of gynaecological oncology and at numerous sites across the country, reflecting one of the core objectives of the PCC members. With an exciting year ahead, the focus remains on expanding access to clinical trials and research opportunities for patients nationwide.

The DSSG would also like to thank Prof Dearbhaile Collins for her time as co-chair of the Gynae DSSG, and welcome Dr Lynda McSorley into the co-chair position. We look forward to working with Dr McSorley. The DSSG also celebrates Lucy Murphy (Ops Lead)'s well-deserved appointment as the new chair-elect of the GCIG harmonisation operations committee.

NEW STUDIES OPEN IN IRELAND

25-61 ENGOT ov97 FRAmework 01
Led by Prof Karen Cadoo, this is a three-Part Phase 3 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 is now open in SJH and plans to open in SVUH later this year.

This study has 3 arms: A) Platinum Resistant; B) Platinum Sensitive; and C) Platinum Sensitive PARPI-naïve. Accrual to Arm A is nearly complete; therefore, referrals for the other arms are highly welcomed.

24-41 ENGOT ov84 Trofuse-022
Led by Prof Karen Cadoo, this is a phase 3 study evaluating the efficacy and safety of Sacituzumab Tirumotecan maintenance treatment with or without Bevacizumab versus standard care in participants with platinum-sensitive recurrent ovarian cancer.

This study is now open in Ireland at St. James's Hospital and is due to open shortly at St Vincent's University Hospital. 6 patients planned to be enrolled onto this study in Ireland.

24-42 ENGOT ov85 Trofuse-021
Led by Dr Lynda McSorley, this is a phase 3 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 now open in Ireland at SJH and is due to open shortly at CUH and SVUH. 11 patients are expected to be enrolled onto this study in Ireland.

25-37 TroFuse-036 /ENGOT cx22
Led by Prof Dearbhaile Collins, this phase 3 study evaluates 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).

This study is now open in Ireland and activated in all approved Irish sites, including Mater Hospital, Cork University Hospital and St. James's Hospital. To date, 2 patients have been enrolled on the study, and we aim to enrol a total of 10 patients across our Irish sites.




L-R: Prof Dearbhaile Collins & Prof Karen Cadoo

Gynae Updates continued

GYNAE STUDIES - further updates:

24-68 ENGOT-ov83_NOGGO_TORL
Led by Prof Austin Duffy, this phase 2 study evaluates 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 opened at all approved Irish sites, including START Dublin, St. James's Hospital, University Hospital Galway and Cork University Hospital. There were tremendous recruitment efforts in this study, with a total of 10 patients enrolled in Ireland. Both START Dublin and Cork University Hospital enrolled their first patient, with START Dublin exceeding its target recruitment, enrolling 8 patients.

26-23 ENGOT ov106 MAESTRA3
This is a phase 3 Study of INCB123667 plus bevacizumab versus bevacizumab alone as first-line maintenance therapy in participants with ovarian cancer who are overexpressing cyclin E1.

Submission of the study under the EU CTR and IVDR was completed in Sep 2026, with approvals expected towards the end of this year/early 2027.

Unfortunately, the sponsor has decided to discontinue the ENGOT ov106 MAESTRA-3 trial.

This study will no longer proceed.

SIGNIFICANT RECRUITMENT MILESTONE:
25-16 RAMP 301
Open in St. James's Hospital and led by Prof Karen Cadoo, RAMP-301 is a phase 3, randomized, 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).

St. James's Hospital has exceeded their recruitment target of 3 patients and currently has 4 patients enrolled to the study. This is a huge achievement given that this study is for patients diagnosed with LGSOC which is considered a rare cancer. A big part of this success has been the teamwork across the Irish sites' referral pathways, which helped identify and refer eligible patients.

Screening/enrolment remains open for the moderate hepatic impairment (MHI) cohort only. This cohort invites patients with recurrent LGSOC who have progressed on a prior platinum-based therapy and have moderate hepatic impairment.

The study is due to close to recruitment towards end of 2026.




L-R: Prof Austin Duffy & Dr Sharon O'Toole

Gynae Updates continued

26-49 ENGOT ov109 ASPENOVA
Led by Dr Razia Aslam, this randomised Phase 3 trial evaluates the efficacy and safety of azenosertib compared with the investigator's choice of chemotherapy in subjects with platinum-resistant ovarian cancer whose tumours are positive for cyclin E1 protein expression.

A significant milestone has been achieved with the successful approval in Oct 2026 of the wave 1 site submission under the EU Clinical Trials Regulation (EU CTR). The study is due to open in the coming months at SJH and CUH.

The Mater, Beacon, and UHW are planned to be submitted as part of the wave 2 submission under the EU CTR towards the end of the year, with the hope of activating the sites in early 2027.

26-22 ENGOT ov101 NAPISTAR-3-01
Led by Prof Conleth Murphy, this is a Phase 3 study to investigate TUB-040 monotherapy when compared to physician's choice of therapy in patients with high-grade, serous or endometrioid platinum-resistant ovarian cancer.

The study is currently being transitioned to a new sponsor, Gilead, and site engagement is still underway. We hope to open this study at 5 sites: Bons, CUH, UHW, Mater & SVUH.

24-70 Expression IX
Led by Dr Sharon O'Toole, Expression IX is a study looking at long-term survival in patients with any gynaecological cancer by survey. It is expected to collect 150-200 surveys per country, with a target of 1500 surveys. The study is expected to be completed in approximately 2028.

Local ethics submissions have commenced, with submissions made to SVUH, Mater, Sligo UH and SJH. Submissions to SLRON and Tullamore are planned in the coming months.

While start-up activities are ongoing, we hope to activate this study in Ireland in Q4 2026. We encourage all sites to open this study, so please contact the gynae DSSG team if your site is interested.

26-68 ANVU
Led by Mr Feras Abu Saadeh, this is a surgical study in early-stage vulval cancer. This study has recently been approved into our portfolio and start-up activities have commenced.

The ANVU clinical trial aims to assess a less invasive approach to the management of early-stage vulval cancer. Standard treatment typically involves surgical removal of the tumour along with groin lymph node dissection, a procedure associated with significant short- and long-term morbidity.

The aim of this trial is to reduce the need for invasive groin surgery by using regular ultrasound surveillance of the groin lymph nodes instead of upfront lymph node dissection. Surgical intervention to the groin lymph nodes would only be required if cancer is detected during ultrasound monitoring.

The ANVU trial will assess whether this approach is a safe and effective alternative for women with early-stage vulval cancer, while potentially reducing treatment-related side effects and improving quality of life.

This study is planned to open at SJH, and referrals will be welcome.




L-R: Prof Conleth Murphy & Dr Razia Aslam

GU Updates

CTRIAL-IE 24-32 De-Escalate: Open

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 across 9 sites; Tallaght University Hospital, Cork University Hospital, University Hospital Limerick, St James's Hospital, Beaumont Hospital, Mater Misericordia University Hospital, Beacon Hospital, St. Vincent's University Hospital and University Hospital Galway.

Since recruitment commenced in Ireland in December 2025, 34 patients have been registered to date, with recruitment continuing at a steady pace. 7 sites have enrolled their first patient, demonstrating strong study engagement.

Globally, the study has surpassed the 25% recruitment milestone, with over 500 patients registered to date

This is a fantastic start to recruitment both in Ireland and at a global level.







L-R: Prof Ray McDermott & Dr Lynda Corrigan

Radiotherapy Updates

Database lock for CTRIAL-IE 08-17 IMRT Prostate study
Study Title: A Prospective Phase II Dose Escalation Study using IMRT for High Risk N0M0 Prostate Cancer. CI: Prof John Armstrong (SLRON).

The database for this long running study was locked on 28-Aug 2026. The study commenced accrual in 2009, with 252 patients being enrolled at SLRON, Beacon and CUH between 2009 and 2016.

The Primary objective for the study is to determine if dose escalated IMRT for high risk localised prostate cancer can provide Prostate Specific Antigen (PSA) relapse-free survival similar to that reported by Memorial Sloan Kettering (Alicikus et al 2011) by analysing PSA results.

Sites are currently being closed out, and the study manuscript is in preparation.

There have also been a significant number of publications on the translational sub-study data including papers published in 'International Journal of Molecular Sciences', 'Translational Biophotonics', 'Cancers', 'The Royal Society of Chemistry', 'International Journal of Radiation Biology', 'Journal of Biophotonics', and most recently in 'Frontiers in Oncology' by Dr Meade and Prof Lyng. The study was also presented as a poster at ASTRO in 2023.

CTRIAL-IE 24-35 PRESERVE Breast
PRESERVE Breast (CTRIAL-IE 24-35) opened to accrual in Ireland at SLRON, UHG and CUH in September 2026. The first patient was recruited to this study in October 2026. As global accrual is expected to reach completion shortly, Cancer Trials Ireland would like to recognise the significant collaborative effort from all parties to get this study open and recruiting at all planned sites in Ireland. All sites welcome referrals for potential patients for this study.

PRESERVE Breast is a phase II radiotherapy study for women with localised recurrent or new primary breast cancer and who have undergone breast-conserving surgery followed by radiotherapy in the past. Generally, patients with this form of cancer are offered treatment with surgery (mastectomy) followed by courses of radiotherapy lasting 3 – 5 weeks. The goal of this study is to find out if a shorter, 1-week course of radiotherapy can be offered as an alternative option for the current standard of care treatment (i.e. a longer course of radiotherapy).

The primary objective of this study is to evaluate the risk of adverse events at 1 year with a 1-week course of partial breast radiotherapy following breast conserving surgery as treatment for localised, recurrent or new primary breast cancer. This study is jointly sponsored by University Health Network, Canada and Cancer Trials Ireland.




L-R: Prof John Armstrong & Prof Frances Duane




L-R: Prof Aisling Barry & Prof Joseph Martin

Radiotherapy Updates continued

CTRIAL-IE 25-72 NOAX
NOAX (CTRIAL-IE 25-72) opened to accrual in Ireland at University Hospital Galway in July 2026, and 2 patients have been accrued to date to this study. This study will also open at SLRON, St James's Hospital, St Vincent's University Hospital and CUH.

NOAX is a randomised study for patients with breast cancer that has spread to the lymph nodes in the armpit and who are undergoing surgery without prior chemotherapy. This study aims to find out whether less invasive surgery of the armpit in combination with radiation therapy leads to a better quality of life and less painful swelling of the arm (lymphoedema) than the current standard treatment, which is extensive surgical removal of the armpit.

In this study, the affected lymph nodes and sentinel lymph nodes (i.e. the 'first-stop' lymph node to which cancer cells are likely to spread from a primary tumour) are first removed in all participants ("less invasive axillary surgery"/"tailored axillary surgery").

Subsequently, in some of the patients, all lymph nodes in the armpit are also surgically removed (the current standard treatment), while in others, the armpit is treated with radiotherapy in addition to the routine irradiation of the breast or chest (the experimental treatment).

This study is jointly sponsored by University Hospital Basel and Cancer Trials Ireland.



L-R: Prof Suneil Jain & Prof Brian O'Neill

INSPIRE is now open in Ireland
INSPIRE (CTRIAL-IE 24-72) opened in Ireland at Bon Secours Radiotherapy Cork in Partnership with UPMC Hillman Cancer Centre in April 2026, followed by UPMC Whitfield Hospital in June; 27 patients have been recruited to date. The Co-Chief Investigators are Prof Suneil Jain (Belfast City Hospital) and Prof Brian O'Neill (SLRON).

INSPIRE (INnovative SABR for Prostate Cancer All IREland) is an investigator-initiated, all-island, multi-centre, prospective, single-arm phase 2 trial of "next-generation" prostate Stereotactic Ablative Radiotherapy (SABR), which includes several strategies to reduce toxicity. It is planned to open at 10 radiotherapy centres in the Republic of Ireland (ROI) and Northern Ireland, with a planned enrolment of 136 participants, including eligible patients with low-, intermediate- and high-risk prostate cancer.

This study uses novel planning methods to boost the radiation dose to the part of the prostate containing the dominant tumour, rather than delivering a high dose to the whole prostate gland. The treatment preparation also involves tiny markers, called fiducial markers, inserted into the prostate gland, improving the accuracy of SABR treatment. In addition to the fiducial markers, a gel device called a rectal spacer is placed between the prostate and rectum to help protect the rectum. The SABR treatment involves 5 sessions given on alternating days over about two weeks.

The primary objective of the study is to demonstrate that next-generation prostate SABR rates of late genitourinary (GU) toxicity are superior to standard-of-care prostate cancer SABR rates at 2 years after the last radiotherapy treatment.

The study is expected to open additional sites in the Republic of Ireland later this year, with further centres opening in Northern Ireland in early 2027.

Lymph & Haem Updates

CLLRT2 opens in Ireland and welcomes referrals
CLLRT2 (CTRIAL-IE 24-44) has recently opened in Ireland at Beaumont Hospital and University Hospital Galway in August 2026. Both sites are now open for recruitment and welcome referrals for eligible patients.

CLLRT2 is a randomised phase III trial evaluating the combination of pirtobrutinib and epcoritamab compared with standard-of-care R-(mini)-CHOP in patients with previously untreated Richter Transformation (RT). Richter Transformation is an aggressive lymphoma that can develop in people with chronic lymphocytic leukaemia (CLL).

Patients with Richter Transformation currently receive intensive chemoimmunotherapy, most commonly R-CHOP or R-mini-CHOP. While these regimens can be effective, outcomes remain poor for many patients and treatment-related toxicity can be significant.

CLLRT2 is investigating whether a chemotherapy-free approach using pirtobrutinib, a highly selective BTK inhibitor, together with epcoritamab, a bispecific antibody that helps the immune system identify and destroy lymphoma cells, can improve outcomes for patients newly diagnosed with RT.

Participants are randomised to receive either the investigational combination or standard chemoimmunotherapy. The study will assess progression-free survival, response rates, overall survival and safety, helping to determine whether this novel targeted and immunotherapy-based approach could become a new treatment option for Richter Transformation.

The study is sponsored by the DCLLSG (German CLL Study Group), with Prof Patrick Thornton serving as Principal Investigator in Ireland. The global recruitment target is 116 patients, including eight patients in Ireland.

EMN 41 (TRIlogy-6) to evaluate a novel frontline treatment approach in transplant-eligible multiple myeloma
EMN 41 (TRIlogy-6) is expected to open in Ireland in 2027 at six Irish sites. The study will evaluate whether a novel combination of ramantamig and daratumumab can improve outcomes for patients with newly diagnosed multiple myeloma who are eligible for stem cell transplantation, compared with the current standard induction regimen of daratumumab, bortezomib, lenalidomide and dexamethasone (D-VRd).

EMN 41 (TRIlogy-6) is a randomised phase III trial comparing an investigational regimen containing ramantamig and daratumumab with the current standard-of-care D-VRd regimen in transplant-eligible patients. The study will assess whether this novel immunotherapy-based approach can further improve disease control and long-term outcomes in the frontline setting.

Participants will be randomly assigned to receive either the investigational treatment or standard therapy. Researchers will evaluate treatment efficacy and safety in a large international study expected to enrol approximately 1,000 patients worldwide.

EMN 41 forms part of the wider TRIlogy clinical research programme, which is exploring innovative treatment approaches for patients with multiple myeloma. The results will help determine whether this investigational strategy could become a future treatment option for patients newly diagnosed with transplant-eligible disease.



L-R: Prof Patrick Thornton & Dr Janusz Krawczyk

Academic Publications from Cancer Trials Ireland Investigators

Basket 01

CTRIAL-IE 15-42: LOXO-TRK-15002

"Larotrectinib in TRK-fusion differentiated thyroid carcinoma: updated trial data." Waguespack SG, Brose MS, Lin JJ, McDermott R, Almubarak M, Bauman J, Casanova M, Kummar S, Lee S, Rieke DT, Oh D, Qi C, Neu N, Burcoveanu D, Mussi CE, Drilon A, Hong DS, Cabanillas ME. ***Endocr Relat Cancer.*** 2026 Aug 1;33(8):e250531. PMID: 42454511 • DOI: 10.1530/ERC-25-0531

Breast 02

CTRIAL-IE 14-11: PENELOPE-B

"Clinical and Molecular Evaluation of HER2-Low and Ultralow Breast Cancer in the PENELOPE-B Clinical Trial Cohort." Denkert C, Rachakonda S, Pehl A, Marmé F, Martin M, Karn T, Untch M, Bonnefoi H, Kim S, Hirmas N, Bear H, Witkiewicz AK, Im S, DeMichele A, Veer LV, McCarthy N, Stiewe T, Jank P, Gelmon KA, García-Sáenz JA, Westhoff C, Kelly CM, Reimer T, Olivé MM, Knudsen ES, Mackelenbergh M, Rojo F, Frickel N, Fasching PA, Teply-Szymanski J, Toi M, Rugo HS, Gnant M, Makris A, Felder B, Nekljudova V, Loibl S. ***Mod Pathol.*** 2026 Jun;39(6):101006. PMID: 42025846 • DOI: 10.1016/j.modpat.2026.101006 – Epub 2026 Apr 21.

CTRIAL-IE 25-71: SENOMAC-ULTRA trial

"Omission of axillary lymph node dissection in ultrasound-detectable axillary metastases in primary breast cancer treated by upfront surgery: prospective randomized SENOMAC-ULTRA non-inferiority trial." Boniface J, Meretoja T, Rydén L, Sund M, Karlsson P, Huang C, Kim HJ, Ryu JM, Nash S, Offersen B, Nissen HD, Wieslander E, Maggi N, Swedin L, Kuo S, Tramm T, Dembrower K, Terata K, Nishibuchi I, Tomás MAL, Ciérvide R, Lowery A, Skjerven HK, Ejlertsen B, Valachis A, Szulkin R, Spanic T, Shien T, Tvedskov TF, Alkner S. ***BJS Open.*** 2026 Jul 3;10(4):zrag083. PMID:42551036 • DOI: 10.1093/bjsopen/zrag083

CTRIAL-IE 16-20: IBCSG 48-14 POSITIVE/BIG 8-13 (POSITIVE)

"Updated Results of the POSITIVE (Pregnancy Outcome and Safety of Interrupting Therapy for Women with Endocrine Responsive Breast Cancer) Trial." Pagani O, Niman SM, Ruggeri M, Peccatori FA, Azim Jr HA, Colleoni M, Saura C, Shimizu C, Sætersdal AB, Kroep JR, Warner E, Amant F, Mailliez A, Moore HC, Ruiz-Borrego M, Walshe JM, Borges VF, Gombos A, Kataoka A, Rousset-Jablonski C, Borstnar S, Takei J, Lee JE, Saunders C, Bjelic-Radisic V, Susnjar S, Cardoso F, Klar NJ, Ferreiro T, Ribi K, Ruddy KJ, Kammler R, El-Abed S, Viale G, Piccart M, Korde LA, Goldhirsch A, Gelber RD, Partridge AH; International Breast Cancer Study Group; POSITIVE Trial Consortium. ***Ann Oncol.*** 2026 Sep;37(9):1230-1241. PMID: 42214557 • DOI: 10.1016/j.annonc.2026.05.699 – Epub 2026 May 28.

CTRIAL-IE 15-49: NEO TRIP

"Longitudinal transcriptomic profiling identifies predictors of response to neoadjuvant chemoimmunotherapy in triple-negative breast cancer: results from the NeoTRIPaPDL1 trial." Dugo M, Huang CS, Egle D, Bermejo B, Seitz RS, Nielsen TJ, Zamagni C, Thill M, Antón-Torres A, Russo S, Sevillano E, Ciruelos EM, Schweitzer BL, Galbardi B, Greil R, Semiglazov V, Colleoni M, Kelly CM, Del Mastro L, Mariani G, Viale Gi, Győrffy B, Ali HR, Pusztai L, Viale G, Callari M, Gianni L, Bianchini G. ***Ann Oncol.*** 2026 Sep;37(9):1278-1292. PMID: 42162664 • DOI: 10.1016/j.annonc.2026.05.694 – Epub 2026 May 19.

"To stop or not to stop? International physician survey on HER2 targeted therapy for metastatic breast cancer patients in remission." Lee HY, Ong WS, Tjan-Heijnen V, Lambertini M, Lu YS, Park KH, Sagara Y, Vidal M, Urruticoechea A, Oliveira M, Ciruelos E, Zdenkowski N, Bedard PL, Ignatiadis M, Lee SC, Sohn J, Zaman K, Werutsky G, Curigliano G, O'Reilly S, Tsang J, Kim S, Saji S, Ohno S, Adam V, Arahmani A, Caballero C, Yap YS. ***Breast.*** 2026 Oct 12:90:104935. PMID:42950386 • DOI:10.1016/j.breast.2026.104935 – Online ahead of print.

CNS 03

CTRIAL-IE 15-41: ROAM

"Radiotherapy versus observation following surgical resection of WHO grade 2 atypical meningioma (ROAM/EORTC-1308): an international, multicentre, open-label, phase 3, randomised controlled trial." Jenkinson MD, Rosala-Hallas A, Sahm F, Andratschke N, Ashkan K, Balestrini D, Bulbeck H, Comas S, Culeddu G, Das K, Fariselli L, Fowkerer K, Francis P, Gkioni E, Golfinopoulos V, Gorlia T, Haghighi N, Haylock BJ, Hughes DA, Javadpour M, Martinive P, Mayles HMO, Moore P, Rhun E, Rosenfelder N, Ryan G, Weller M, Gamble C, Preusser M, Weber DC; ROAM/1308 Study Collaborators. ***Lancet.*** 2026 Sep 25: S0140-6736(26)01804-0. PMID:42790456 • DOI:10.1016/S0140-6736(26)01804-0

Lymph and Haem 04

CTRIAL-IE 16-60: CLL13

"Venetoclax combinations in untreated CLL: 5-year results and patient-reported outcome analysis of the CLL13/GAIA trial." Fürstenau M, Niemann CU, Robrecht S, Rotbain EC, Eurelings LM, Giza A, Tresckow J, Zhang C, Gregor M, Thornton P, Staber PB, Tadmor T, Lindstrom V, Juliusson G, Janssens A, Cunha-Bang C, Schneider C, Herishanu Y, O'Shea D, Baumann M, Widmer AA, Nösslinger T, Poulsen CB, Frederiksen H, Lotfi K, Ranti J, Enggaard L, Velders GA, Vekemans MM, Heer K, Snijders T, Siemes C, Wendtner C, Knauf WU, Kroeber A, Zahn M, Illmer T, Schöttker B, Simon F, Fink A, Fischer K, D'Brot R, Holmes EE, Kreuzer K, Ritgen M, Brüggemann M, Tausch E, Stilgenbauer S, Levin M, Hallek MJ, Kater AP, Eichhorst BF. ***Blood.*** 2026 Jun 18;147(25):3025-3038. PMID:41911073 • DOI:10.1182/blood.2025032160

CTRIAL-IE 16-60: CLL13

"Telomere length in chronic lymphocytic leukemia treated with venetoclax-based regimen in GAIA/CLL13 and CLL2-GIVe trials." Jebaraj BMC, Tausch E, Yosifov DY, Schneider C, Fürstenau M, Zhang C, Robrecht S, Cunha-Bang C, Levin MD, Staber PB, Huber H, Tadmor T, Thornton P, Gregor M, Fink AM, Fischer K, Kreuzer KA, Ritgen M, Hallek MJ, Kater AP, Niemann CU, Eichhorst BF, Stilgenbauer S. ***Blood.*** 2026 Oct 6:blood.2025032302. PMID:42837320 • DOI: 10.1182/blood.2025032302

Gynaecology 05

"Consensus statements from the first Gynecologic Cancer InterGroup Cervical Cancer Consensus Conference in Clinical Research." Kataria B, Mukhopadhyay A, Oaknin A, O'Donnell DM, Tan DSP, Cibula D, Bleeker MCG, Plante M, Chargari C, Brand A, Lorusso D, Mayadev J, Leary A, Hasegawa K, Kohn EC, Mendez LC, Maguire PJ, Garcia-Duran C, Hanly K, Malhotra P, Emery L, Happy M, Nout RA, Lecuru F, Covens A, Stuart GCE, Oza AM, Bookman MA; participants of the 2024 Gynecologic Cancer InterGroup Cervical Cancer Consensus Conference in Clinical Research. ***Lancet Oncol.*** 2026 Aug;27(8):e379-e391. PMID: 42508438 • DOI: 10.1016/S1470-2045(26)00215-9

CTRIAL-IE 22-02: ENGOT en15 KEYNOTE-C93

"First-line pembrolizumab versus carboplatin plus paclitaxel in participants with mismatch repair-deficient advanced or recurrent endometrial cancer (KEYNOTE-C93/GOG-3064/ENGOT-en15): interim analysis of a multicentre, open-label, randomised, active-comparator controlled, phase 3 trial." Slomovitz BM, Zhu J, Yin R, Backes F, Bidziński M, Gilbert L, Willmott LJ, Hasegawa K, Kim J, Kroep JR, Romero I, Gultekin M, Wang P, Baron-Hay S, Klát J, Rosengarten O, Polignano M, Berrios M, Cadoo K, Lassus H, Maćkowiak-Matejczyk B, Lorusso D, Reyners AKL, Burton ER, Makker V, Yao L, Meng R, Orlowski R, Pignata S. ***Lancet.*** 2026 Oct 26:S0140-6736(26)02095-7. PMID: 42933458 • DOI: 10.1016/S0140-6736(26)02095-7 – Online ahead of print.

Genitourinary 06

CTRIAL-IE 15-31: MK-3475-045/ KEYNOTE-045

"Pembrolizumab Plus Lenvatinib in Participants with Docetaxel-pre-treated Metastatic Castration-resistant Prostate Cancer: Results from KEYNOTE-365 Cohort E." Augustin M, Laguerre B, Baldini C, Zedan AH, Gonzalez-Billalabeitia E, Fong PC, Zukov R, Hammerer P, Prentice M, Shore N, Necchi A, Todenhöfer T, Kessler ER, Kose F, Gurney H, Valderrama BP, Zhu P, Imai K, Liu Y, McDermott R. ***Eur Urol Oncol.*** 2026 Oct;9(5):1039-1045. PMID: 42070919 • DOI: 10.1016/j.euo.2026.03.026 – Epub 2026 May 2.

Genitourinary 06

CTRIAL-IE 16-21: PEACE III

"Alkaline Phosphatase and Prostate-specific Antigen Response in Metastatic Castration-resistant Prostate Cancer Treated with Enzalutamide Alone or in Combination with Radium-223: Ad Hoc Analysis of the PEACE-3 Consortium Trial." Soares A, Gillessen S, Choudhury A, Saad F, Gallardo E, Loriot Y, McDermott RS, Rodriguez-Vida A, Velho PI, Nolè F, Cruz FM, Roumeguère TA, Daugaard G, Yamamura R, Poncet C, Coens C, Fournier B, Tombal BF. ***Eur Urol Oncol.*** 2026 Aug 28:S2588-9311(26)00228-2. **PMID: 42665513 • DOI: 10.1016/j.euo.2026.08.001** – Online ahead of print.

CTRIAL-IE 18-02: NRG GU005

"Stereotactic Body Radiotherapy vs Moderately Hypofractionated IMRT for Localized Intermediate-Risk Prostate Cancer: A Randomized Clinical Trial." Ellis RJ, Pugh SL, Yu JB, Feng FY, Konski AA, Grubb 3rd RL, Wallace RE, Gladstone DJ, Ménard C, Miccio JA, Frazier AJ, Pennington JD, Michalski JM, Spratt DE, Martinez A, Morgan SC, Mihai A, Solanki AA, Amjad A, Straza MW, Delouya G, Schroeder TM, Marshall DT, Kapadia N, Patel AN, Cescon TP, El-Gayed A, Yoon HA, Paulus R, Sandler HM; NRG-GU005 Collaborative Authors. ***JAMA.*** 2026 Sep 22;336(12):1029-1038. **PMID:42593775 • DOI: 10.1001/jama.2026.12627**

CTRIAL-IE 14-07: ENZARAD

"ENZARAD (ANZUP1303): Phase 3 Trial of Enzalutamide With Androgen Deprivation Therapy and Radiation Therapy in High-Risk Localized or Locally Advanced Prostate Cancer." Williams S, Sweeney CJ, Thomas H, Mak B, Zhang A, Lim TS, Jose C, Martin J, Patanjali N, Pryor D, Tran P, Mangar S, Mihai AM, Thomas C, Gampenrieder S, Yip S, Cheung L, Lee S, Goodwin A, Haworth A, Walsh A, Kelly PJ, Hughes S, Martin A, McDermott R, Stockler M, Davis ID, Nguyen PL. ***J Clin Oncol.*** 2026 Oct 24:101200JCO2601794. **PMID: 42921729 • DOI: 10.1200/JCO-26-01794** – Online ahead of print.

CTRIAL-IE 26-30:MK-6482-033 LITESPARK-033

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CTRIAL-IE (ICORG) 15-46: PACE B/ PACE C

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PCC Progress Update – November 2026

Since our last update in March, the Patient Consultants Committee (PCC) has continued to strengthen its involvement across Cancer Trials Ireland, with 2026 bringing exciting developments in research, patient advocacy and collaboration. From international conference presentations and research publications to shaping new studies and advocating for better access to clinical trials, PCC members continue to demonstrate the value of bringing lived experience into cancer research.

From Patient Involvement to Research Impact

One of the most encouraging developments this year has been the growing number of tangible research outputs supported and shaped by patient contributors.

Following its oral presentation at the European Association of Urology Congress in March, the patient-led PRO-ACT study, exploring sexual wellbeing following prostate cancer treatment, has continued to progress, with a manuscript for the World Journal of Urology and a further abstract submitted to ASCO GU. PRO-ACT remains a wonderful example of patients being involved throughout the research journey, from identifying the questions that matter to sharing findings with international clinical audiences.

Patient partnership at Cancer Trials Ireland was itself showcased at ASCO 2026, through a poster developed in collaboration with the Irish Cancer Society. With four PCC members among its authors, the presentation explored how patient involvement has evolved within our national clinical trials network. This work has also progressed towards publication in Current Oncology, helping to share our experiences with the wider research community.

Closer to home, PCC members have contributed to new study proposals and funding applications, including the Irish Cancer Society Seed Funding Call, helping to shape research questions, study design and plans for meaningful patient involvement.

The committee has also supported the review of patient-facing materials, including the PRISM study Patient Information Leaflet and a wider review of readability in breast cancer trial information materials. The latter has highlighted important opportunities to improve how research information is communicated to patients, with findings being developed for publication.

Patient Voices Driving Change

PCC members continue to bring forward ideas and identify issues that extend beyond individual clinical trials.

Within the CNS Disease Specific Subgroup, patient contributors have raised important questions about pathways to clinical trials for people living with glioblastoma, particularly following recurrence. These discussions have highlighted the need for clear information, timely access to molecular testing and greater awareness of research opportunities in Ireland and internationally.

Patient advocacy has also reached wider audiences. PCC member Laura Ryan shared her experience of living with glioblastoma in The Irish Times, raising awareness of the realities of brain cancer and the importance of access to research.

PCC member Jed van de Poll and his wife Pam also played a central role in Cancer Trials Ireland's 10-minute documentary, ‘Life of a Trial’, following the Isa-RVD Multiple Myeloma trial. Welcoming the production team into their home, they generously shared their personal experiences, bringing an important human dimension to the film. Now viewed more than 2,100 times on YouTube, the documentary has resonated with audiences, helping to illustrate the impact of clinical trials not only on individual patients, but also on their families.

PCC Updates continued

Meanwhile, patient-led initiatives continue to develop, including Brothers in Arms, exploring peer support for men receiving androgen deprivation therapy, and a new project examining the language used around cancer. Both reflect the importance of creating opportunities for research ideas to emerge directly from patient experiences.

PCC members have also supported wider engagement activities, including the INSPIRE prostate cancer study launch, Cancer Trials Ireland's annual Retreat and the Value of Cancer Trials 2 report, where patient contributions helped ensure lived experience was reflected in both the publication and its launch.



Séamus Conaty presenting at the Cancer Retreat

Supporting Our PCC Community
Meaningful patient involvement depends not only on opportunities to contribute, but also on ensuring that contributors feel supported and confident in their roles.

In March, PCC members attended a dedicated media training workshop at RCSI, facilitated by journalist Clare O'Connell. The interactive session was very positively received and formed part of a broader training programme informed by feedback from PCC members themselves. Further priorities include clinical trial education, reviewing patient information materials and building confidence in research discussions.



Jed van de Poll played a central role in 'Life of a Trial'

The PCC has also been involved in discussions around research priorities and portfolio gaps within the Disease Specific Sub-Groups, encouraging contributors to consider where research opportunities may be missing and how lived experience can help shape future priorities.

Our collaboration with the Irish Cancer Society remains an important part of this work, with PCC members helping to strengthen relationships, support shared initiatives and identify new opportunities for engagement.



PCC members attended media training at RCSI

A Special Thank You to Patrick Kivlehan

As 2026 draws to a close, we want to take this opportunity to recognise and sincerely thank Patrick Kivlehan, who is concluding his tenure as Chair of the Patient Consultants Committee.

Patrick has been an extraordinary advocate for patient involvement in cancer research, bringing not only his experience and insight, but an enormous amount of himself to the role. Throughout his time as Chair, he has been a familiar voice and face in the media, generously sharing his own cancer experience to raise awareness of clinical trials and advocate for greater research opportunities for patients across Ireland.

He has never shied away from difficult conversations, particularly when it comes to barriers that can prevent patients from accessing research. Patrick has been a strong and vocal advocate on the challenges arising from the interpretation of GDPR in Ireland and the impact these can have on cancer clinical trials. His willingness to challenge established thinking, while keeping patients at the centre of the conversation, has been an important part of his contribution.

Patrick has also spoken openly about the importance of timely access to clinical trials, drawing on his own experience of how life-changing these opportunities can be. He understands that, for some patients, the difference between accessing a trial and missing that opportunity can simply be a matter of timing. His advocacy is a powerful reminder that delays in opening clinical trials are not just administrative challenges; they can have very real consequences for patients who may become too unwell to participate while waiting.

But Patrick's contribution has not been limited to the public stage. Within the PCC, he has been a welcoming and encouraging presence, particularly for new members finding their feet in an unfamiliar and sometimes complex research environment. He has been a valued ally to many who have joined the committee during his tenure, helping them find their confidence and recognise the value of their experiences.

Under Patrick's leadership, the PCC has continued to grow in both membership and influence, with patient contributors now actively involved across all adult Disease Specific Sub-Groups and contributing to research development, governance, advocacy and dissemination. He has helped foster a culture of collaboration, mutual respect and genuine partnership that will remain an important part of his legacy.
On behalf of everyone at Cancer Trials Ireland, thank you, Patrick, for your generosity, courage, leadership and extraordinary commitment to improving cancer research for others. You have given so much of your time, your experience and yourself, and we are enormously grateful.







Patrick in action at the 2026 Cancer Retreat, the recent launch of the Value of Cancer Trials 2 report, and a GDPR event in 2024

National Training Day 2027 – Save the Date

Following the success of recent years, Cancer Trials Ireland's National Training Day will return on Friday, 29 January 2027, at The Gibson Hotel, Dublin, once again held in partnership with the Irish Society of Medical Oncology (ISMO).

The 2026 event, held at O'Reilly Hall, UCD, welcomed more than 250 attendees from across the cancer trials community. The programme combined research presentations, expert discussions and networking opportunities, with a focus on professional development, collaboration, wellbeing and shared learning across oncology disciplines.

Building on this success, the 2027 National Training Day will bring together trainees, clinicians, researchers, CTRU staff, industry partners and patient representatives for another day of learning, discussion and connection.

The event provides an important opportunity to share experiences, strengthen professional networks and explore the opportunities and challenges facing cancer clinical trials in Ireland.

A call for abstracts will once again invite non-consultant hospital doctors (NCHDs) to submit their research for consideration for oral or poster presentation. These sessions provide an opportunity for early-career researchers to showcase their work to the wider cancer trials community, with prizes awarded for the best oral presentations and research posters.

Save the date – Friday, 29 January 2027. Further details, including the programme, abstract submission guidelines and registration information, will be announced soon.



Prof Brendan Kelly addresses the room at the National Training Day in January 2026

Cancer Retreat 2026: Report Published

Cancer Trials Ireland has published its Cancer Retreat 2026 Report, bringing together the presentations, discussions and key findings from this year's event and identifying priorities for strengthening cancer clinical trials in Ireland.

A central focus of the Retreat was progress across three areas: studies, streamlining and succession.

Presentations highlighted continued growth in cancer research participation, with 4,926 people enrolled in cancer studies in 2025, alongside efforts to reduce trial start-up times and support the next generation of clinical research leaders.

The scientific programme explored treatment optimisation and de-escalation, examining how reducing treatment doses or duration could maintain effectiveness while minimising side effects, improving quality of life and reducing healthcare costs. Patient involvement was another important theme, with a dedicated panel marking ten years of Cancer Trials Ireland's Patient Consultants Committee and highlighting the growing impact of patient-led research.

Interactive breakout discussions explored the challenges and opportunities facing Ireland's clinical trials community, including sustainable funding, workforce development, international collaboration and improving patient access to research.

The report captures both the progress being made and the work still needed to strengthen Ireland's position as a leading location for cancer clinical trials.

Read the full Cancer Retreat 2026 Report for a detailed account of the presentations, discussions and recommendations: www.cancertrials.ie/Cancer-Retreat-Report.pdf



Miriam Staunton (PCC) leading a group discussion



PPI Panel with Nikki Warner from the Irish Cancer Society



Members of Ireland's cancer trials community gathered at RCSI to attend the Retreat in person

Fundraising News

Pat Smullen Fund
The annual Pat Smullen Race Day took place at the Curragh in late August, raising an incredible €213,980 for Cancer Trials Ireland and the Pat Smullen Fund. The support received from the horse racing community over the past seven years has been staggering, with more than €4 million raised to support pancreatic cancer research.

This year, supporters were delighted to receive an update from Professor Gráinne O'Kane, the Pat Smullen Chair in Pancreatic Cancer at UCD, on exciting developments in pancreatic cancer treatment, particularly around the KRAS mutation and the emergence of promising new treatments. Our enormous thanks to everyone involved in the event, and to the wider horse racing community for their extraordinary and continuing support.



Nina Carberry MEP won the 2026 Pat Smullen Charity Race



Staff of Gresham House on their Harbour 2 Harbour walk challenge

Property Picnic
This year's Property Picnic raised almost €120,000 for Cancer Trials Ireland. The event, which was led this year by Hooke & MacDonald, has become an important fixture in our fundraising calendar, and we are hugely grateful to everyone involved.
The Property Picnic was established in memory of Louise Creevy, and her legacy continues to inspire fundraising efforts on behalf of Cancer Trials Ireland.

Louise's husband, Andy Creevy, subsequently helped raise funds through the staff charity at Nestlé Ireland, while in recent weeks, Today FM DJ Shauna O'Reilly, a close friend of Louise's, took part in a fundraising event in the west of Ireland, with half the proceeds going to Cancer Trials Ireland. At the time of writing, Shauna had raised more than €5,000 in total.

Another connection through the Property Picnic saw the staff of Gresham House undertake a Harbour 2 Harbour Walk in tough weather in October, raising a further €10,000 for Cancer Trials Ireland. Gresham House plans to run a further fundraiser, a coffee morning, before the end of 2026. Our thanks and best wishes to them on that venture, and our sincere thanks to everyone involved in all of these initiatives.



Hooke & MacDonald took on the 2026 Property Picnic

Fundraising News continued

Marathons & Events
Cancer Trials Ireland continues to receive tremendous support from the running and fitness community.

Among this year's outstanding fundraisers was Ashley Murray, who raised an incredible €13,193 in honour of her mother. Her achievement follows the €18,809 raised in 2024 by her brother Rob and his friend, Lena Quinn, who climbed Kilimanjaro in support of Cancer Trials Ireland.

Other marathon runners have also made significant contributions. Craig Doyle, who completed the Barcelona Marathon, raised €3,361, while Sonia Mullen raised €4,345 at the Rome Marathon. At the recent Dublin Marathon, Josh Wood raised €1,257, with other runners contributing a further €1,025.

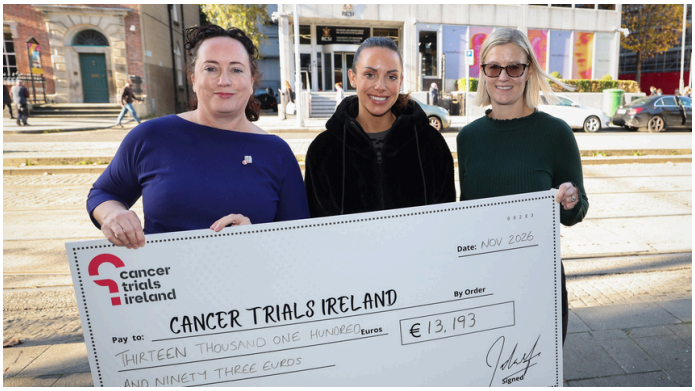
We also want to pay particular tribute to siblings Hannah and Daniel Ryan, who took part in a TRYKA fitness event earlier this year, raising a wonderful €12,500 in memory of their mother, a much-loved teacher in Newbridge, County Kildare.

Our thanks to all those who have taken on these challenges, and to the families, friends and communities who have supported them.

Moving away from fitness, but remaining in the arena of sports, our thanks go to the Wednesday Hotshots Golf Society, who raised an incredible €6,000 for Cancer Trials Ireland in October. This contribution came through a connection with the Friends of Cancer Trials Ireland, whose members have been such valued supporters of our work over the years. It is particularly heartening to see those connections continue to generate such generous support.

Other Fundraising
We are once again grateful to the Ballyfoyle Agricultural Show, which donated a further €2,000 to Cancer Trials Ireland this year. The show has been a longstanding supporter of our work, and its continued generosity is very much appreciated.

We also wish to acknowledge in-memoriam donations received via RIP.ie relating to John Michael Beck, Jimmy Guinan and Paddy Griffin. Cancer Trials Ireland received €2,657.08 in their memory, and we are very grateful to their families and friends for choosing us.



Ashley Murray (centre) ran the Dublin Marathon for CTI



Hannah & Daniel Ryan at their TRYKA event.



Josh and Hannah Wood in action at the Dublin Marathon

cancer trials ireland

Together, we're finding answers to cancer.

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