2026

CANCER RETREAT REPORT

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Executive Summary

The 2026 Cancer Retreat opened with Prof Seamus O'Reilly marking Angela Clayton-Lea's first full year as CEO and framing the organisation's ambition to become an indispensable part of cancer care in Ireland, underpinned by the longitudinal funding relationships he identified as essential to progress. In her CEO welcome, Ms Clayton-Lea structured five years of development around three themes: studies, streamlining, and succession. She reported the headline metrics which anchored the day's presentations and discussions.

On studies, the accrual trajectory was the highlight. Patient accruals grew from 1,470 in 2022 to 3,169 in 2025, a 215% increase, with a further 1,757 people at high risk of developing lung cancer enrolled in the Irish Cancer Society-funded Beaumont-RCSI Lung Health Check Pilot, bringing total accruals in 2025 to 4,926. Twelve per cent of patients diagnosed with invasive cancer participated in a cancer study in 2025, and participation in interventional trials rose to 2.9% (715 individuals), up from 1.3% in 2022. Both figures remain short of the national cancer strategy target of 6% and the OECI targets of 10% or higher, a gap that framed much of the streamlining and funding agenda that followed.

Time to first patient (streamlining) was the central operational theme. Emer Mulvaney stated that, per the IPHA Clinical Trials Activity Comparison Report published in 2025, Ireland ranked as the slowest EU member state for the time from EU CTR approval to first site ready, with a median of 213 days, compared with the NCTOG recommendation of 42 calendar days. Progress is real and measurable: the time from site agreement issued to executed fell 45% between Q4 2025 and Q1 2026, from a median of 73 days to 40 days, with some sites turning agreements around in as little as two days. One area has worsened: the time from ethics approval to site activation increased by 21%, and Ms Mulvaney identified this window as Cancer Trials Ireland's key focus for the second half of the year, proposing a pilot of earlier parallel preparation across one to three sites and studies.

On succession, Ms Clayton-Lea outlined Cancer Trials Ireland's investment in strengthening and expanding the national investigator base, with emphasis on succession planning and the development of the next generation of principal investigators across tumour streams and institutions. Through the work of Cancer Trials Ireland's DSSGs, she described ongoing efforts to build nationally coordinated research leadership, supporting collaboration, mentorship, and engagement from emerging clinical researchers. That investment was visible across the day's scientific programme: proposals at the investigator-initiated think tank came from Dr Emer Lynch, described by Prof Naidoo as a new academic clinical trialist supported through UCC, and from her own PhD student David O'Reilly, while Precision Oncology Ireland 2 will train between 40 and 50 PhD students, its first tranche of 12 to 15 positions attracting 320 applicants.

The value case for trials was made in concrete terms. Angela Clayton-Lea's presentation on cost savings at sites reported that one site identified potential annual savings of €1.62 million if it could join four trials, currently blocked by the absence of a clinical trial pharmacist (an approximately €90,000 salary blocking €1.62 million in annual savings). Further sites reported inward IMP investment of €1.136 million, combined savings and investment of €577,443, and €299,533 in a single quarter. She estimated the data collected likely falls far short of total network savings. These figures build on the published Value of Cancer Clinical Trials report, which estimated €14.8m in State savings from a sample of 18 trials involving 249 patients over 2021–2025. A structural barrier was flagged: voluntary hospitals can reinvest trial savings, whereas in HSE hospitals, end-of-year drug savings are reabsorbed into the broader HSE budget.

Executive Summary, continued

The scientific programme centred on optimisation and de-escalation. Prof O'Reilly and, remotely, Prof Benjamin Besse made the case that lower doses, shorter durations, and reduced schedules can maintain efficacy while cutting toxicity and cost (Prof O'Reilly citing the PLANET trial's drug-cost savings of roughly €35,000 per pair of patients enrolled, and Prof Besse citing an Indian ultra-low-dose trial with cost savings exceeding 86%). Both identified the regulatory and payer system, and not science, as the binding constraint. Prof Jarushka Naidoo presented the MEDSIR partnership and the investigator-initiated trials think tank, noting that IITs now account for 8% of Cancer Trials Ireland's accrual, or 50% in the past year with the Lung Health Check pilot included. Prof Donal Brennan presented Precision Oncology Ireland 2, at €27 million, the largest cancer research investment in the history of the State.

Dr Claire Kilty confirmed the Irish Cancer Society's renewed partnership with Cancer Trials Ireland (€1 million per year for a further three years) and called for sustained, predictable, rolling, long-term funding across the full spectrum of trial types. The PPI panel marked ten years of the Patient Consultants Committee, now grown from three to 33 members. Afternoon breakout groups and industry representatives converged on a consistent message: Ireland's quality is established; what remains is to communicate it, streamline activation, and secure the multi-year funding on which everything else depends.

Dr Claire Kilty - Head of Research, Irish Cancer Society

Dr Claire Kilty began her address by acknowledging Cancer Trials Ireland's leadership, expertise, and commitment to cancer clinical trials in Ireland, and by recognising the range of people working across the cancer research community: clinicians, researchers, nurses, trial staff, policymakers, and patient partners, whose work directly improves outcomes for patients.

She outlined the Irish Cancer Society's goal: that everyone affected by cancer in Ireland has access to world-class cancer research, care, and support. She also expressed the Society's conviction that improving outcomes and survival rates result from research, and that cancer clinical trials are at the heart of that research.

Partnership with Cancer Trials Ireland

Dr Kilty highlighted the Irish Cancer Society's partnership with Cancer Trials Ireland, (€3 million investment over three years at €1 million per year) as built around a shared ambition to improve the landscape of cancer clinical trials in Ireland: bringing more trials to the country, increasing patient accruals, and broadening the range of trial types available to patients. She was explicit that this encompasses not only IMP and drug trials, but also non-IMP trials such as radiotherapy and surgery, and non-interventional trials including patient-led and translational research. The shared goal, she said, is a system where more patients can access the right trial for them at the right time.

She welcomed the accrual figures detailed by Angela Clayton-Lea and highlighted the Irish Cancer Society's €4.9 million partnership with Beaumont Hospital and RCSI to deliver a lung cancer screening pilot in Ireland. Results remain provisional, but as of March 2026, over 2,100 people had been screened, 32 lung cancers had been detected in asymptomatic patients, and 17 curative surgeries had taken place. She outlined the breadth of collaboration involved, from Beaumont and RCSI clinical partners, to patient partners Seamus Cotter and Anne-Marie Baird, GP practices, GAA clubs who hosted the mobile unit. She also praised Alliance Medical who operated the trial, all of which illustrates how progress in cancer research depends on partnership and breaking down silos.

She identified patient partnership as an area in which Ireland is demonstrating genuine international leadership, drawing on her involvement in international forums to support this assessment. She encouraged greater and louder communication on this topic as well. Kilty acknowledged the work of the Cancer Trials Ireland Patient Consultants Committee in driving patient-led research in areas of unmet need, and cited the Society's support for Siobhán Gaynor's patient-led trial — the first of its kind at Cancer Trials Ireland.

She described the Society's current support for Martin Sweeney's PRO-ACT study as groundbreaking work, also acknowledging Jacqueline Daly's contribution to the partnership dimension of that study. She described this body of work as a clear blueprint for how cancer trials should be directed and conducted going forward.

Dr Claire Kilty - Head of Research, Irish Cancer Society, continued

Renewed Partnership

Dr Kilty underscored the renewal of the Irish Cancer Society's partnership with Cancer Trials Ireland, formalised in April. The renewed agreement continues the €1 million-per-year investment for a further three-plus years. It will include continued support for academic and collaborative trials addressing unmet need, support for Cancer Trials Ireland's start-up team in reducing trial timelines and continued support for and advocacy around patient-led research.

Challenges

Dr Kilty identified significant challenges facing the clinical trials community, particularly around the future-proofing of trial funding, and she described the current period as one of real uncertainty. She welcomed the publication of the NCTOG report at the end of last year and commended Prof Donal Brennan and the group's members for their work and recommendations. She expressed support for establishing CTAC (Clinical Trials Advisory Council) and implementing the report's measures, while also issuing a specific call to ensure that non-IMP studies, and academic-led trials and research in particular, are not overlooked.

Dr Kilty stressed the importance of equitable access, including through more decentralised trial models, and cited a patient from her own partnership panel who described an eight-hour round trip to access a trial in Dublin as illustrative of why bringing trials closer to patients' homes matters. Her call to action was for sustained, predictable, rolling, long-term funding covering the full spectrum of trial types, IMP, non-IMP, interventional, and non-interventional, and she identified the development of the next national cancer strategy as an opportunity to embed research as a core pillar of cancer care.

She closed with the words of Aoife from County Louth, a patient diagnosed with ovarian cancer, who spoke about her belief that all types of cancer will eventually be manageable, and reflected that it is only through a cancer diagnosis that most people come to realise the extent of the research happening behind the scenes. Dr Kilty called for greater public awareness of clinical trials so that they are understood, valued, and trusted from the outset, not encountered for the first time in the midst of a diagnosis.

Prof Donal Brennan – Precision Oncology Ireland

Prof Brennan began by noting that, launched in October 2025, Precision Oncology Ireland 2 (POI2) is the largest investment in cancer research in the history of the State. It is a €27 million investment, with 50% provided by the state through Research Ireland and 50% by partners. It builds on Precision Oncology Ireland 1 (POI1), led by Prof Walter Kolch and Prof Liam Gallagher, which he described as immensely successful and as being the first time academia, charities, and industry had come together in this way in Ireland. He acknowledged there were teething problems at the outset, but said the consensus is that POI1 proved very successful.

He outlined the ambition of POI2 as moving further towards the clinic, and enabling people across settings (hospital, GP practice, and university laboratory) to feel part of a translational research environment. He situated this within a broader landscape of developments in Irish cancer research, including the accelerated research commercialisation hubs and new Research Ireland centres due to be launched on 10 June 2026, with a focus on areas including cellular therapy. He also referenced ongoing work on a National Cancer Research Strategy, with the aim of having an agreed research plan in place before the next national cancer strategy.

The Case for Personalised Medicine

Prof Brennan reflected on the long-standing aspiration for personalised medicine in cancer, arguing that outside of haematological malignancies, truly personalised medicine remains limited in solid organ cancers, with the exception of HER2, certain advances in lung cancer, and markers such as mismatch repair deficiency. His view is that the field has spent too much time focused on the tumour and not enough on the person, and that POI2 aims to combine tumour-profiling technologies with a deeper understanding of how an individual patient may alter the impact of treatment.

POI One: Legacy and Return on Investment

He described POI1's original investment of €11.1 million as having delivered a return he estimated had at least tripled and probably quadrupled, crediting both individual investigators and the collective direction of travel. He identified the single most important legacy of POI1 as being the community it built, that is, people committed to translational research in Ireland, along with the training of a significant number of PhD students and postdocs.

A key strategic ambition for POI2 is to build alliances that span from blue-sky basic research through to the delivery of clinical trials, and he emphasised that this is directly relevant to clinicians working in trials, not merely a translational research exercise. He noted that engagement with the Cancer Trials Ireland DSSGs was one of the key interactions during the development of POI2, describing the response from clinical trialists who had not previously participated in translational research as genuinely striking, and that it helped develop important ideas for the programme.

Following an interim review of POI1, the group received a clear indication from Research Ireland that they should apply for further funding, which Prof Brennan described as unusual, since the expectation for such strategic partnership groups is that they would become self-sustaining. The group made a successful case for a second round.

Prof Donal Brennan - Precision Oncology Ireland, continued

Industry Partnerships and Clinical Translation

He gave a concrete example from his own POI1 work package: a collaboration with AstraZeneca focused on improving immune checkpoint inhibitor therapy in ovarian cancer. This resulted in formal research agreements with AstraZeneca, with compounds now progressing in Phase 1/2 trials, including bispecific antibodies, novel immune checkpoint inhibitors, and T-cell engagers. The work was subsequently presented to the Cancer Trials Ireland DSSG group, leading to a project focused on the treatment of peritoneal carcinomatosis, regardless of organ of origin.

Cancer Trials Ireland now has two active AstraZeneca projects, one with AstraZeneca UK in Cambridge and one with AstraZeneca Dublin's Personalised Medicine Group, reflecting AstraZeneca's significant investment in its Blanchardstown site. He also mentioned a separate project with GSK (outside POI2) and noted that pharma's willingness to fund translational research at Irish universities has changed substantially.

A central vision for POI2 is to complete the full circle, namely to bring advances in basic research to patients and to bring clinical questions back to the lab in Ireland, so that clinicians do not feel the need to return to labs in San Diego or San Francisco. He described this as an explicit goal: to build a community of scientists in Ireland willing and able to do this work.

POI2: Expanded Scope and Structure

POI2 has expanded significantly from its predecessor. The number of charity partners has grown from six to nine, and the number of industry partners from seven to ten; DCU has joined as a new university partner, bringing five of the six academic partners within the regional health group system.

Seven hospital foundations have also been brought in, which he identified as valuable for communicating directly with patients on the ground. The programme includes 38 investigators, 31 projects, and a dedicated patient and public engagement programme with a budget of over €1.5 million, the first time a full PPE programme has been embedded within POI. He noted that POI1's PPE work, led largely by Prof Liam Gallagher, Dr Claire Kilty, and colleagues at the Irish Cancer Society, was strong, but that POI2 now has a formalised programme with dedicated leadership.

Between 40 and 50 PhD students will be trained under POI2. The first tranche of 12 to 15 positions attracted 320 applicants, which he described as reflecting exceptionally high standards.

Digital Twins and Multi-Omic Research

Prof Brennan outlined the digital twin model as a central methodological approach within POI2. The model involves an integrated multi-omic analysis, drawing on transcriptomics, proteomics, and other data, to identify tumour regions specifically suitable for treatment, followed by mechanistic modelling and targeted perturbations. He referenced the C-STAR method published by Walter Kolch and Boris as a tool for analysing this data and identifying nodes of interest.

Prof Donal Brennan - Precision Oncology Ireland, continued

He noted that AI has dramatically accelerated the process: building a digital twin that previously took two years can now be achieved in approximately two weeks. He described Ireland's strength in computational biology as one of its major assets and said the digital twin approach is the programme's overarching framework for managing multi-omic data sets.

He also highlighted Ireland's position in molecular profiling of childhood cancers. All childhood cancers in Ireland, through a collaboration between POI, Children's Health Ireland, and the Children's Health Foundation, are now being offered whole genome and whole transcriptome sequencing. The first 60 cases have been analysed, initially in haematological tumours, with the pipeline now moving towards CNS tumours. He described the pipeline as working well and said the programme is close to a point where it can assess whether this approach can be made to work clinically.

Structure, Leadership, and Training

POI2 spans multiple work packages across multiple tumour types, with a particular focus on early-onset lung and gastrointestinal cancers, the latter reflecting what he described as an epidemic of early-onset GI cancer. The molecular tumour board partnership with Cancer Trials Ireland was identified as serving a dual purpose: benefiting patients directly while also functioning as a training forum for PhD students and postdocs, allowing them to see how translational research connects to clinical reality. He noted that PhD students and postdocs attending surgery for ovarian cancer, for example, gain insights that are difficult to convey in any other way.

Leadership across all work packages is multidisciplinary, with clinical and non-clinical leads throughout. The training work package, led by Prof Leonie Young, Prof Darran O'Connor and Prof Jacintha O'Sullivan,
was identified as a significant element, supported by investment from Trinity and RCSI. The PPE programme is led by Yvonne O'Meara and Laura Rice. He described POI2 as both a large technical experiment and, in Prof Kolch's framing, a large social experiment and expressed confidence that if it builds on the community created by POI1, it will deliver strong outcomes.

Prof Jarushka Naidoo - Investigator-Initiated Trials: The MEDSIR Partnership

Prof Jarushka Naidoo presented on an initiative that arose from a strategic partnership between Beaumont RCSI Cancer Centre and MEDSIR, an academic clinical research organisation based in Barcelona. She described a clinical trials think tank held in early May, outlined what was learned from it, and then opened the discussion to the wider group on where such an initiative could go and how it might strengthen the Irish cancer trials ecosystem.

Why Investigator-Initiated Trials Matter

She began by framing the global importance of investigator-initiated trials (IITs) and their importance for Ireland specifically. IITs allow investigators to develop their own clinical trial hypotheses and to answer questions that commercial trials cannot and will not address, including de-escalation studies focused on safety, studies in rare or neglected cancers, trials focused on patient-centred outcomes, and translational discoveries.

Prof Naidoo identified what sets Ireland apart as the networks already in place: the Cancer Trials Ireland infrastructure, the POI2 network, and the system by which clinical leaders across cancer centres interact and discuss trials. With 19 centres across the Cancer Trials Ireland network and 137 clinical trials open in recent years, she described Ireland as having scaffolding that very few countries in Europe or internationally possess.

She noted that currently 8% of Cancer Trials Ireland accrual comes from investigator-initiated trials, and that in the past year, with the inclusion of the Lung Health Check pilot, 50% of Cancer Trials Ireland accrual came from an investigator-initiated trial, illustrating what strategic focus on IITs can achieve. Her framing was that IITs are the lever that turns existing infrastructure into original scientific leadership.

What is MEDSIR?

MEDSIR is an academic CRO that originated as a spin-out from the work of renowned breast cancer oncologist Prof Javier Cortés in Barcelona, who developed his clinical trials unit over 20 to 30 years into what she described as a machine for conducting IITs, before establishing it as a standalone company.

MEDSIR's role is to bridge the gap in academic clinical trial development: helping investigators refine their hypotheses, aligning those hypotheses with funder priorities, supporting protocol development, and — critically for a small country like Ireland — enabling trials to scale across other countries with aligned interests, to reach the patient numbers needed to make a trial feasible. She noted that many excellent IIT ideas fail at the point of aligning with funder priorities or achieving the scale necessary for success, and that MEDSIR addresses both.

Since its establishment in 2012, MEDSIR has led several large-scale investigator-initiated trials (IITs), including studies published in Nature Medicine and other leading journals, covering areas such as trastuzumab deruxtecan (T-DXd) for brain metastases in metastatic breast cancer and novel therapies for rare lung cancers, including thymic tumours. Evidence from some of these trials has contributed to regulatory approvals.

Prof Jarushka Naidoo - Investigator-Initiated Trials: The MEDSIR Partnership, continued

Beaumont RCSI Cancer Centre signed a memorandum of understanding with MEDSIR with the goal of developing and funding at least one to two academic clinical trials per year. Prof Naidoo was explicit that the ambition is to democratise this opportunity beyond a single cancer centre and extend it nationwide.

The Think Tank: Format and Process

The think tank, held on 5 May, was structured around an open call for proposals to investigators across the country. Submissions were assessed and separated into those suitable for a brief one-slide overview and those ready for a full proposal.

Prof Naidoo, Angela Clayton-Lea, and others all selected proposals to align with MEDSIR's current areas of focus (breast, lung, GU, and GBM), reflecting where sponsors are currently approaching MEDSIR for trial opportunities. Full proposals were presented by PIs with dynamic discussion and critical feedback from other PIs across the country. MEDSIR's scientific coordinator, Federica Turrisi, addressed the group on what makes a successful partnership and the value of these brainstorming sessions as a grassroots mechanism for developing trial concepts with genuine buy-in from relevant stakeholders.

Proposals Presented

Five full proposals were presented at the think tank:
The first was presented by Dr Emer Lynch, a new academic clinical trialist supported through UCC, on a liquid biopsy study in breast cancer building on the previous PLAN Trial in lung cancer. Given the growing number of genomic targets relevant to breast cancer patients, the proposal was seen as an opportunity for a junior investigator to develop a translational intervention. The study is currently in development and is supported by UCC. It was discussed by Prof Leonie Young.

The second was Adapt RAS, developed by Prof Naidoo's PhD student David O'Reilly. Situated within what she described as the RAS revolution (an expanding landscape of targeted therapies for KRAS mutant cancers including pancreatic, GI, and lung), the proposal aimed to rationalise which patients with RAS mutant lung cancer might benefit most from available therapies. The approach uses upfront chemo-immunotherapy, with patients who show persistent disease identified through circulating tumour DNA then prioritised for a pan-RAS inhibitor. She noted that MEDSIR subsequently made contact expressing interest in the proposal, and that sponsors also appear interested.

The third involved a study in melanoma, developed by Dr Sarah Lochrin. The proposal addressed the question of optimal duration of adjuvant immunotherapy following neoadjuvant treatment and surgery in melanoma patients, adapting an approach used in lung cancer — where tumour response guides duration of treatment. She described it as a pragmatic clinical trial well suited to government and general funder interest, addressing a question where clinical leadership in Ireland is strong.

Prof Jarushka Naidoo - Investigator-Initiated Trials: The MEDSIR Partnership, continued

The fourth was a GU study presented by the Beaumont RCSI team led by Dr Min Yuen Teo, discussed by Prof Ray McDermott at St Vincent's, proposing neoadjuvant immunotherapy in locally advanced penile cancer. Beaumont is a national centre for penile cancer surgery and sees a critical mass of patients annually. The study would begin with 12 patients, potentially expanding to 37, and would yield surgical specimens offering significant translational research potential through pre- and post-treatment comparison.

The fifth, presented by David Fitzpatrick and the radiation oncology group, addressed glioblastoma — an area where she noted there has not been an IIT in Ireland for at least 10 to 15 years. The study proposes evaluating hyperfractionated accelerated radiation as an alternative to standard chemoradiation, described as a pragmatic trial addressing a significant unmet clinical need.

Key Learnings and Challenges

Prof Naidoo identified several key takeaways from the think tank. The quality of ideas demonstrated that Irish investigators have the capacity to develop high-quality IIT proposals that can originate at a single site, scale nationally, and through MEDSIR scale across Europe to achieve the patient numbers needed for feasibility.

The process also clarified where Ireland's strengths lie: in radiation oncology, immunotherapy, and clinical leadership, and Naidoo argued it is more effective to build on existing strengths than to start from a low base in areas where capacity is underdeveloped. She also noted the volume of supportive care proposals, and questioned whether the DSSGs currently have sufficient dedicated expertise in this area, suggesting consideration of a dedicated supportive care and patient-reported outcomes track.

She observed that the real-time critical feedback from senior clinicians in the audience, people who may no longer be writing trials themselves but have deep expertise, was extremely valuable for PIs refining their proposals. She reflected that while the Cancer Trials Ireland DSSGs serve multiple purposes well, they may have limited capacity for the depth of critical appraisal that a dedicated forum like this can offer. She proposed that a competitive format (a "dragon's den" model for IIT funding) could further raise the quality of proposals and engage teams more broadly.

She acknowledged that prioritisation of proposals will be a significant challenge, given that funding will not be available for all ideas submitted. MEDSIR has expressed interest in running the think tank as an annual event. She invited the wider group's thoughts on format, selection process, alignment with Cancer Trials Ireland structures, and next steps.

She closed by thanking Angela Clayton-Lea and the Cancer Trials Ireland organisation for organising the event, and Keith Egan, Patrick Morris, and Leonie Young of the Beaumont RCSI Cancer Centre for developing and administering the MEDSIR partnership.

Prof Jarushka Naidoo - Investigator-Initiated Trials: The MEDSIR Partnership, continued

Arising in the Q&A

In Q&A, the question of supportive care was explored further. Prof Naidoo acknowledged that supportive care research, which typically involves health services research and patient-reported outcomes, requires a distinct skill set that most clinical trialists, including herself, are not trained to critique reliably. She expressed the view that developing a dedicated supportive care track would require bringing in researchers who are specifically skilled in this area, but noted the interest is clearly present across the investigator community.

On de-escalation trial funding, raised by Miriam Staunton, Prof Naidoo acknowledged this as a known and significant difficulty. She noted that the keynote speaker, Prof Benjamin Besse, would address this directly in his session, including a government-funded de-escalation study underway in France. She observed that, currently, the only avenue for government funding of IITs in Ireland would cover approximately 10 patients in a trial, far short of what is needed, and that recycling drug cost savings back into trial funding, while creative, would require government buy-in.

On the matter of European funding opportunities, which was raised by Prof Liam Gallagher, she confirmed that Horizon EU has a €9 million call for pragmatic clinical trials, and that she and Patrick Forde, among others, are actively writing for the digital twins strand of that call. She agreed that targeted workshops towards such funding opportunities, with a view to coordinating a European collective led by Irish investigators, would be a valuable complement to the bottom-up think tank model.

On MEDSIR's model and regional reach, she noted that MEDSIR's investigator base has to date been concentrated in Spain and continental Europe, reflecting their origins, with growth in breast and lung cancer areas tracking where sponsor funding has been strongest. Their approach is to engage investigators with a track record in relevant areas, which is why they approached the Irish group.

Prof Naidoo clarified that under MEDSIR's model, the PI and site own the concept; MEDSIR does not. A PI can develop a concept with MEDSIR and subsequently take it directly to pharma without using MEDSIR as a sponsor, something that has happened previously. She identified Ireland's opportunity as primarily in developing de novo ideas rather than joining studies initiated elsewhere, given the country's smaller population.

Prof Seamus O'Reilly closed the session by welcoming the idea of an annual incubator event and noting the potential synergy with Precision Oncology Ireland.

Prof Benjamin Besse - De-escalation in Oncology: The Case for Optimisation Trials

Prof Benjamin Besse, speaking remotely from Gustave Roussy in France, addressed the case for de-escalation/optimisation in oncology.

He argued that de-escalation is not a new concept, illustrating this with the LUNG ART trial, which tested whether adjuvant radiotherapy after resection of N2-positive non-small cell lung cancer added benefit. At the time the trial was designed, roughly half of physicians routinely gave adjuvant radiotherapy and half did not. The trial was negative for overall survival (showing better local control but no survival benefit), meaning that for those who had been giving adjuvant radiotherapy routinely, it constituted a de-escalation finding. He used this to establish that de-escalation is embedded in everyday clinical questions, even when not labelled as such.

Dose De-escalation: The Academic Community's Missed Opportunities

He argued that the academic community has, in his view, been too passive in questioning drug doses, and that this passivity has had significant financial consequences for health systems.

He cited bevacizumab in lung cancer, which was developed and approved at two doses (7.5 and 15 mg/kg) with no randomised trial clearly demonstrating superiority of the higher dose. The only randomised trial comparing the two doses used biomarker interaction as its primary endpoint, rather than dose comparison, meaning it cannot formally support a conclusion that the lower dose is sufficient. He described the situation as remarkable: an expensive drug approved with a label effectively inviting clinicians to make their own choice.

Prof Besse also cited the case of pemetrexed, which was tested at 500 mg/m² versus 900 mg/m² with identical survival and identical toxicity across both arms, a consequence of the drug's active transport mechanism, which delivers the same effective dose to cancer cells regardless of the administered dose. He noted the opportunity to test lower doses was not taken.

Regarding immunotherapy, he presented PD-1 occupancy data showing that 0.1 mg/kg and 10 mg/kg of nivolumab — a hundredfold difference — yield identical lymphocyte PD-1 occupancy. The drug was developed at 3 mg/kg, thirty times higher than the lowest dose that appears biologically active. Phase 1 melanoma data showed response rates of 29% at 0.1 mg/kg, 41% at 3 mg/kg, and 20% at 10 mg/kg, suggesting the approved dose may be at or above the plateau of efficacy. In renal cell carcinoma, a Phase 2 trial comparing 0.3, 2, and 10 mg/kg showed identical survival across a 33-fold dose range.

He also addressed the move to flat dosing, noting that nivolumab's flat dose assumes a patient weight of 80 kg, and pembrolizumab's assumes 100 kg, which he described as high, particularly for European populations. His own analysis at Gustave Roussy found that the average weight of women diagnosed with metastatic non-small cell lung cancer eligible for first-line immunotherapy is 50 kg, meaning the standard 200 mg pembrolizumab flat dose is approximately twice the dose at which the drug's efficacy was originally demonstrated.

Prof Benjamin Besse - De-escalation in Oncology: The Case for Optimisation Trials, continued

Evidence for Ultra-Low Dose Immunotherapy

He described work from India, where immunotherapy is unaffordable for more than 97% of patients. A trial in head and neck cancer randomised patients after first-line failure between palliative chemotherapy and palliative chemotherapy plus ultra-low dose nivolumab. This meant 20 mg per injection, compared to the standard flat dose of 240 mg, so one vial treated 12 patients rather than 1. The trial showed improvements in both progression-free survival and overall survival. He noted that the shapes of the survival curves in this ultra-low-dose trial are strikingly similar to those of the registration trial at the standard dose. A Phase 3 trial in India has followed, showing improved overall survival as the primary endpoint, with cost savings exceeding 86%.

Schedule De-escalation

He explained the pharmacological rationale for schedule de-escalation: a single injection of nivolumab produces PD-1 saturation on circulating lymphocytes for approximately 100 days, yet the drug is cycled every 21 days. He described the standard cycling interval as pharmacologically irrational given the drug's half-life and noted that almost all PD-1/PD-L1 blockers in current use have very long half-lives.

In the UK, the REFINE-lung trial is testing pembrolizumab at 400 mg every six weeks versus every twelve weeks, with a non-inferiority design, and plans to extend to 18-week intervals if the initial analysis is positive.

In France, Prof Besse is running the PULSE trial in non-squamous non-small cell lung cancer, randomising patients in the maintenance phase between standard pembrolizumab at 200 mg every three weeks and 200 mg every six weeks. He presented the economic modelling of this strategy: in France, with approximately 40,000 new lung cancer cases per year, the projected cost saving from halving the frequency of pembrolizumab administration in the metastatic maintenance population amounts to €1 billion every three years.

He also described a trial of intermittent versus continuous BRAF-MEK inhibition in melanoma with a BRAF mutation, in which a four-weeks-on, two-weeks-off schedule was tested against continuous treatment. The intermittent regimen performed significantly worse, with no reduction in grade 3 or higher toxicity, a caution that not all de-escalation hypotheses supported by preclinical data translate into clinical benefit.

Duration De-escalation

On treatment duration, he cited the CheckMate 153 sub study, which showed a benefit to continuing nivolumab beyond one year, though he noted the quality of evidence is weak as it was a secondary endpoint. He then presented retrospective real-world data: a US dataset of 14,000 patients starting immunotherapy showed that 7.5% remained on treatment at two years. Of those who stopped at two years versus continued, overall survival was similar. A French national database analysis of 43,000 patients who started pembrolizumab for lung cancer between 2019 and 2023 found that 7.4% were still on treatment at 29 months. Of these, roughly 1,000 continued and 1,000 stopped — and overall survival was strictly similar. He has updated this database and found identical results. His conclusion is that two years of immunotherapy appears sufficient.

Prof Benjamin Besse - De-escalation in Oncology: The Case for Optimisation Trials, continued

He described the French IFCT trial DICIPLE with ipilimumab plus nivolumab, asking whether six months or longer is needed in metastatic lung cancer. A stop-and-go strategy (six months of treatment, with rechallenge on recurrence) showed no detrimental effect and significantly less toxicity in a small population, though the trial was stopped early when ipilimumab plus nivolumab was not approved in Europe. The IFCT is now running the DIAL trial, randomising metastatic non-small cell lung cancer patients at six months between observation, pemetrexed alone, or continuation of their full regimen up to two years.

On neoadjuvant versus perioperative therapy, he noted there is only one purely neoadjuvant study versus five perioperative studies, and that comparisons between them are methodologically compromised because the perioperative trials enrolled only patients who were able to receive at least one cycle of adjuvant therapy post-surgery, i.e. a selected, higher-performance-status population. Two ongoing trials (ADOPT-Lung ETOP study and the Insight SWOG study) are directly comparing perioperative versus neoadjuvant-only approaches.

The Regulatory and Policy Barrier

Prof Besse then closed his presentation with what he described as the fundamental structural problem facing de-escalation research: Even if a large, well-designed academic non-inferiority trial demonstrates that a lower dose or shorter duration is equivalent, it cannot change the drug label, because the European Medicines Agency only allows pharma companies to request their own label changes.

He expressed the view that academic researchers should be able to engage with regulatory agencies to validate trial designs in advance, with a commitment to label change if the trial is positive, but Prof Besse acknowledged this is not currently possible.

He described the situation in which payers and health systems fail to act on available evidence (for example, France's national database showing two years of pembrolizumab is sufficient, yet no system-level limit has been imposed) as a failure of institutional courage. He cited Denmark as one of few exceptions, having formally limited immunotherapy duration to two years for patients starting chemo-pembrolizumab.

He also described a Netherlands-based osimertinib de-escalation trial, initiated after the Dutch health insurance system issued a call for physicians to design such a trial and committed to funding it from projected drug cost savings. The trial, led by Anne-Marie Dingemans, randomises patients who have had no progression after six months on standard-dose osimertinib between standard dosing and an every-other-day schedule, a design chosen because the 40 mg and 80 mg tablets are identically priced, making a simple dose-reduction approach cost-neutral. The every-other-day schedule effectively halves drug consumption and therefore cost.

Prof Besse concluded that de-escalation is not optional — it is necessary — but that financial toxicity will only be meaningfully addressed if regulators and payers are willing to act on the evidence.

Prof Benjamin Besse - De-escalation in Oncology: The Case for Optimisation Trials, continued

Additional Q&A: Prof Benjamin Besse

Prof Naidoo asked Prof Besse about the political levers that can be pulled to achieve the kind of health-system-led de-escalation funding model seen in the Netherlands. Prof Besse clarified that the starting point in the Netherlands was not the investigator but the health insurer, which issued a call for de-escalation trial proposals and committed to funding them on the basis that reduced drug use would generate cost savings.
He described this as the ideal model, the payer identifying excessive expenditure and commissioning a trial to address it. He noted that EORTC had worked with a company to develop software modelling the potential savings from de-escalation across European countries, but that despite concrete projections, no other country had taken political action beyond expressing interest.

He expressed cautious optimism that fiscal pressure across European governments may open doors that have previously been closed, noting that the existence of the Netherlands trial proves the model is achievable.

Prof Naidoo asked Prof Besse about the design of the IFCT DIAL trial, specifically how the decision about when to de-escalate is made and why six months was chosen as the decision point.

Prof Besse explained that the trial uses no specific criteria for de-escalation, patients who have not progressed at six months simply stop treatment. He described it as a brave design. He also noted that the PULSE trial, which he is running, takes a different strategic approach, reducing frequency rather than stopping treatment entirely, and expressed the view that generating data from both approaches is valuable. He observed that approximately 20% of patients achieve complete pathological response in the neoadjuvant setting, and that these may represent the very long-term responders, providing some rationale for a stopping strategy in the metastatic setting.

He also emphasised the importance of involving patients from the very beginning of trial design in de-escalation studies, not just in informed consent review at a late stage. He noted that some investigators still treat patient involvement as a late-stage administrative step, which he described as a mistake in the context of trials that ask patients to accept less treatment than the approved standard.

He described an initiative at EORTC to include QR-coded videos of patients explaining, in their own words, why they participated in a de-escalation trial, making these available to investigators at recruitment sites. He observed that when patients speak to patients, the dynamic is entirely different from when an investigator, who may not be personally convinced of the de-escalation rationale, attempts to explain the trial, and that this kind of patient-to-patient communication is an innovation the field should pursue.

Prof Seamus O'Reilly - Advancing Optimisation Trials in Ireland

Prof O'Reilly opened by situating the discussion in a broader historical context, noting that monoclonal antibodies were invented 50 years ago by Milstein and Köhler, who received the Nobel Prize for the discovery.

He charted the subsequent therapeutic growth of monoclonal antibodies, noting the emergence of bispecific antibodies and observing that trispecific and tetraspecific antibodies are now in clinical development. He used a striking illustration (imagining bevacizumab, pembrolizumab, trastuzumab, deruxtecan, and sacituzumab govitecan combining to produce a next-generation therapeutic) to convey the complexity and power of the drugs now dominating the clinical landscape. He noted that more than half of the top 15 trials selected for presentation at ASCO had monoclonal antibodies at their core, and that 160 antibody-drug conjugates are currently in development in lung cancer alone.

The Human Cost of Non-Personalised Therapy

He introduced a patient case to illustrate why dose optimisation matters. A woman with early-stage breast cancer received chemotherapy and pembrolizumab on a standard Keynote regimen, and had surgery, at which point she achieved a complete response. However, she then continued on pembrolizumab regardless of the surgical result. She subsequently developed progressive crater-like skin lesions on both arms, her legs, and her buttocks.

Biopsy confirmed lipodystrophy. She was placed on steroids and has slowly improved, but recovery is not guaranteed. He framed this as illustrating the human cost of non-selected, non-personalised therapy, and posed the question directly: Why was treatment not adjusted after the complete response was confirmed at surgery?

Prof O'Reilly then presented an analysis of FDA randomised trials over a 20-year period, showing the dominant direction of travel has been escalation. Only two outlier de-escalation trials reached the FDA during that period, one in basal cell carcinoma, a tumour type where surgery is usually the primary treatment, and one involving dose reduction of cabazitaxel in prostate cancer.

He noted that industry's aversion to de-escalation is structural: a failed trial can cost up to $50 billion, and companies have duties to shareholders. He also acknowledged the complementary roles of academic and industry trials.

The Case for De-escalation

He argued that if a drug is approved at a certain dose, the natural assumption is that regulatory agencies have established the correct dose and there is no need to revisit it. He challenged this, citing several reasons: trial populations may not be representative of real-world patients; age and comorbidities may alter benefit and risk; emerging biomarkers may modify appropriate treatment selection; and affordability is a genuine clinical and societal concern.

He outlined the benefits of de-escalation for patients: less toxicity, reduced financial toxicity, reduced time toxicity (noting that the average round-trip to the oncology day ward in Cork is 120 km), and reduced climate impact, given that healthcare accounts for approximately 5% of global emissions.

Prof Seamus O'Reilly - Advancing Optimisation Trials in Ireland, continued

He was careful to extend the patient cost picture beyond the visible: de-escalation also addresses the hidden burdens of prolonged treatment, including relationship strain, financial hardship due to inability to work, and quality-of-life impacts not captured by clinical endpoints.

Physician and Patient Mindsets

Prof O'Reilly described work from a French group on the OPTIMA YOUNG trial examining barriers and facilitators to de-escalation trials, which shows that the physician mindset and the patient mindset are markedly different. He noted that the moment at which de-escalation is discussed with a patient (typically shortly after the shock of diagnosis) is often the worst possible time for such a conversation, when patients are terrified of recurrence and instinctively resistant to any suggestion of reducing a regimen that has been approved by a regulatory body.

He extended the financial argument to the system level: if resources are consumed by the existing generation of approved agents, there will be insufficient funding to evaluate and access the next generation of trispecific and tetraspecific antibodies, which may prove as transformative as pembrolizumab and trastuzumab. He cited data on pembrolizumab showing a cost of approximately $3 million per relapse event prevented, noting that halving that cost through de-escalation would generate significant societal savings and expand treatment access.

He argued that de-escalation is not a new concept in Irish oncology practice, pointing to two examples. The first was the transition from 12 months to six months of CMF adjuvant chemotherapy in early breast cancer, established through a randomised trial showing equivalence.

The second was the implementation of the TAILORx trial findings in Ireland, led by Prof Janice Walsh, which demonstrated using genomic platforms that chemotherapy could be safely omitted in certain early breast cancer patients, resulting in a 53% reduction in chemotherapy prescriptions in that group nationally. He noted the significance of the TAILORx design: physicians had to believe the patient needed chemotherapy in order to randomise them, making the de-escalation finding all the more practice-changing.

Prof O'Reilly also referenced the OPTIMAL trial, led globally by Marlene Koch and by Roisín Connolly in Cork, examining whether tumour-infiltrating lymphocytes, assessed by standard H&E staining without genomic platforms, can identify triple-negative breast cancer patients who do not need adjuvant chemotherapy.

He highlighted the FAST FORWARD trial in radiation oncology, one of the largest practice-changing studies in the field, which demonstrated equivalence between one week and three weeks of radiotherapy. Results became available at the onset of the COVID pandemic in 2020 and practice changed overnight in many cancer centres.

International Collaboration and Irish Priorities

Prof O'Reilly described the impetus for the current focus on optimisation trials as arising from a meeting at the Netherlands Cancer Institute, which has been involved in significant de-escalation work including the SONYA trial. The meeting was attended by NCCP representatives and produced recognition for EU-wide collaboration to facilitate trial conduct. He emphasised that rapid accrual is essential for de-escalation trials. The larger the network, the faster a trial can generate evidence before current practice becomes entrenched.

Prof Seamus O'Reilly - Advancing Optimisation Trials in Ireland, continued

He described a specific trial of interest to Cancer Trials Ireland, the PLANET trial, which randomises patients who have surgery after receiving the keynote neoadjuvant regimen for triple-negative breast cancer to either continue chemotherapy plus pembrolizumab or receive chemotherapy alone. The rationale is that patients who achieve a complete pathological response at surgery may not require continued pembrolizumab.

The trial aims for 1,000 patients. Cancer Trials Ireland has discussed the study at its breast DSSG with 100% clinician buy-in. Data management costs are approximately €3,000–4,000 per patient; drug cost savings in the control arm are approximately €70,000 per patient, yielding savings of roughly €35,000 per pair of enrolled patients.

He also described the VIPER trial from the Netherlands, which uses pharmacokinetic-adjusted dosing to optimise venetoclax and ibrutinib in haematological malignancies, achieving significant drug cost savings. Cancer Trials Ireland is planning to introduce this approach in collaboration with the Hovon Group through its haematological DSSG.

He also noted that Sarah Lochrin had presented not one but two pragmatic melanoma trials at the investigator-initiated think tank, emphasising the strength of Ireland's clinical leadership in this tumour type.

A platform trial is also in development at Cancer Trials Ireland in association with GEICAM, an international group, integrating genomic platforms for node-positive breast cancer, building on work already done in low-risk, node-negative disease. This will be a global Phase 3 study for which funding is being sought.

Key Facilitators

He identified four key facilitators for advancing optimisation trials in Ireland: public funding; early patient and public involvement (noting that the Cancer Trials Ireland/Irish Cancer Society/Breast International Group PPI project had been presented at ASCO, by Emer Mulvaney); a strong cooperative group infrastructure with global reach (as Ireland's patient population is insufficient alone to power the large practice-changing de-escalation trials needed); and a clinical champion to lead the effort.

Q&A

One audience member asked both Prof O'Reilly and Prof Naidoo whether the definition of optimisation has changed in the context of AI, specifically whether adaptive trial designs, such as dropping underperforming arms during a trial, changing randomisation ratios based on interim data, or adopting digital biomarkers as secondary endpoints, are now part of how optimisation trials are being conceived.

Prof O'Reilly confirmed that his final slide addressed novel, smarter trial designs, including Bayesian adaptive designs and AI-enhanced approaches such as AI-generated control arms, which are potentially relevant for rare tumour types where patient numbers are limited.

Emer Mulvaney - Trial Start-Up Times: Progress and the Road Ahead, Cancer Trials Ireland

Emer Mulvaney, who works across contracts, start-up, and patient engagement at Cancer Trials Ireland, focused her address on a specific segment of the clinical trial pathway: the period between trial approval and site activation, which she described as both a major challenge and a major opportunity for Ireland.

The Current Picture

Ms Mulvaney set the context with a striking data point:
According to the IPHA Clinical Trials Activity Comparison Report published in 2025, Ireland ranked as the slowest EU member state for the time from EU CTR approval to first-site readiness, with a median activation time of 213 days.

While she acknowledged that the trend is improving, she noted that Ireland remains far short of the NCTOG recommendation of 42 calendar days. She described the consequences of this delay as directly impacting patient access, site competitiveness, sponsor confidence in Ireland, and future research opportunities.

Progress Made

She outlined the work Cancer Trials Ireland has been doing over the past 18 months to streamline clinical trial set-up processes across contracts, budget negotiations, ethics coordination, data protection, governance, site activation and readiness, and early engagement and issue resolution.
One metric she highlighted specifically:

The time from site agreement issuance to execution dropped by 45% between Q4 2025 and Q1 2026, falling from a median of 73 days to 40 days, with some sites turning agreements around in as little as 2 days.

She acknowledged the collaborative work underpinning this improvement and specifically thanked Dr Claire Brady from Cork for liaising with Cancer Trials Ireland and the HSE to design a template agreement for non-regulated studies, which means template agreements are now available across all study types.

A Persistent Problem

However, she was direct about one area where performance has worsened:

The time from ethics approval to site activation has increased by 21%.

She described the volume of tasks that must be completed in this window (contact, training, document collection, local approvals, site initiation visits, and more) as illustrative of why this period is so difficult to compress. She identified it as the key focus for Cancer Trials Ireland in the second half of the year.

Emer Mulvaney - Trial Start-Up Times: Progress and the Road Ahead, Cancer Trials Ireland, continued

The Ask: A Pilot

She proposed that Cancer Trials Ireland pilot an earlier parallel preparation approach with one to three interested sites across one to three studies. The model would involve sites beginning to progress draft contracts, plan for activation, prepare study documentation, and schedule site initiation visits earlier, running in parallel with the ethics review period rather than waiting for ethics approval before beginning these steps. She acknowledged that Cancer Trials Ireland has its own work to do in this area, that site capacity and operational pressures are real, and that the approach will not suit every study. However, she argued that even incremental reductions in activation timelines would improve patient access, strengthen Ireland's competitiveness, and enhance sponsor confidence.

Q&A

When asked how challenging it had been to bring the metrics down, Ms Mulvaney said the experience shows that small operational tweaks can make a very significant difference, and expressed the view that Cancer Trials Ireland has good ideas for further improvements in the final section of the activation timeline. She described the current environment as a good moment to drive change, given the level of investment from all parties.

A question from a sponsor representative asked what sponsors could do better to improve timelines.

Ms Mulvaney identified the multiplicity of systems and training platforms that different sponsors bring to sites as a significant problem, noting that every study arrives with different programmes and processes.

She also highlighted a structural barrier: in Ireland, sites cannot begin sponsor-required training and system set-up until contracts are signed, and contracts cannot be signed until ethics approval and appropriate insurance cover are in place. This prevents parallel work progression that, in other systems, can occur simultaneously.

PPI Panel – Chaired by Emer Mulvaney
Panellists: Patrick Kivlehan, Niki Warner, Martin Sweeney

Emer Mulvaney chaired the panel in her capacity as PPI Programme Manager at Cancer Trials Ireland, noting the occasion marked ten years since the establishment of the Patient Consultants Committee.

Patrick Kivlehan – Evolution of the PCC

Patrick Kivlehan, chair of the PCC and a board member of Cancer Trials Ireland, described the arc of the committee's development. It was established in 2016 with three patient representatives and grew to five by 2018. COVID had a significant negative impact on activity starting in 2020. The pivotal moment came in 2022, when Cancer Trials Ireland allocated dedicated funding for a PPI coordinator role, which he described as a genuine game-changer. Two subsequent online recruitment processes have been highly successful, and membership now stands at 33. Patient representatives are now embedded in all DSSGs, which he identified as a key original objective.

He acknowledged that some members have left to pursue other advocacy roles, and that some have passed away, and paid tribute to all past and present contributors. He described the range of available involvement, from reviewing patient information leaflets and assisting with grant applications to sitting on panels and leading patient-initiated research, and encouraged anyone considering involvement to make contact. He identified the absence of formal pathways into patient advocacy as a significant gap, arguing that considerable patient knowledge and experience is being missed as a result.

Niki Warner – Irish Cancer Society Partnership and Accountability in PPI

Niki Warner, Research Programme Manager at the Irish Cancer Society, welcomed the renewed three-year partnership with Cancer Trials Ireland at €1 million per year, and described the Society's shared ethos around patient partnership. She emphasised that the Irish Cancer Society embeds patient partners directly in funding decisions, including reviewing applications and sitting on interview panels, and that meaningful involvement requires more than having patient partners present at a table. It requires creating an environment where they feel safe and comfortable to share views that may differ from those of researchers or funders, and ensuring those views are genuinely heard.

She identified public awareness of PPI as a key challenge, noting that while Ireland has pockets of excellent practice (including ten years of the PCC at Cancer Trials Ireland and a comparable history at the Irish Cancer Society), the concept is not widely understood among the general population. She described building that understanding as a priority for the Irish Cancer Society, drawing on its communications and advocacy teams, and noted that Claire Kilty would be attending ASCO to speak about PPI, with the Irish Cancer Society intending to use the opportunity to amplify the message more broadly.

Martin Sweeney – Patient-Led Research and the Future of PPI

Martin Sweeney, co-principal investigator of the PRO-ACT study and a member of the PCC, reflected on the growing impact of patient involvement on research. He credited Siobhan Gaynor with starting the patient-led research journey at Cancer Trials Ireland through her study on the impact of metastatic breast cancer beyond the oncological setting, and noted that the themes Prof O'Reilly raised earlier in the day: financial toxicity, climate impact, transport costs, all reflect the kind of issues that emerge naturally from patient involvement, when people with lived experience of cancer are genuinely at the table.

PPI Panel – Chaired by Emer Mulvaney
Panellists: Patrick Kivlehan, Niki Warner, Martin Sweeney

He described the trajectory of the PRO-ACT study on the sexual experience of patients and partners after prostate cancer as illustrative of what patient-led research can achieve. The data has been collected, and the team is now working with the NCCP to review clinical guidelines for prostate cancer in light of the findings.
He also described how PRO-ACT data directly informed a protocol change in the INSPIRE trial, with a patient-initiated question added as a result of the findings. He used this to argue that PPI should not be treated as a box-ticking exercise or an optional add-on, but should be embedded in research, in the same way as ethics, making patient involvement a formal requirement rather than something researchers opt into.

He paid tribute to Patrick Kivlehan's role in growing the PCC from three to 33 members, describing it as an incredible achievement, and observed that the results of genuine patient involvement are already evident: research becomes more relevant, and a sense of urgency is introduced that researchers alone may not naturally bring.

On diversity, he was direct: PPI in Ireland currently skews towards a particular age cohort, socioeconomic background, and gender profile, predominantly older and predominantly women. He identified the core structural barrier as the absence of meaningful reimbursement or compensation for patient involvement, which effectively excludes those who cannot afford to give their time.

He described this as a systemic issue requiring systemic action, not something Cancer Trials Ireland alone can solve, while acknowledging that the organisation goes above and beyond in its efforts to address it. He argued that the voices of people who are actively struggling with a cancer diagnosis, including those facing quality of life challenges beyond the cancer itself, are precisely the voices most needed in research, and that the current model makes it difficult to include them.

Patrick Kivlehan added that future growth should prioritise younger members and people with more recent clinical trial experience, noting that the oncology landscape has changed significantly even since he began his own trial in 2013. He also highlighted the broadening of the PCC's membership criteria, originally limited to people with direct clinical trial experience, now extended to those with lived cancer experience and carers, as an important development that has widened the pool and the range of perspectives available.

Ashley Bazin - FDA Inspection, Tallaght University Hospital

Prof O'Reilly introduced Ashley Bazin by framing the account of a recent FDA audit as an exemplar of the rigour and accountability built into clinical trial conduct, and of the trust that underpins the entire enterprise.

Ashley Bazin, a trials professional at Tallaght University Hospital, described the hospital's experience of an FDA inspection in April 2026. The study under inspection was a second-line renal cancer trial in which the site had recruited 17 patients over 17 months — a complex, open-label, toxicity-managed study with over 20,000 data points per patient. Notification arrived on 3 February that an inspector would arrive on 13 April for a five-day visit.

She described the preparation process: immediate notification of hospital management and the sponsor company; a pre-inspection visit from five members of the MSD pharma team three weeks before the FDA arrived, which she described as nearly more stressful than the inspection itself; a full review of all SOPs and processes across the team; a review and tidy-up of all 17 patient charts; preparation of deviations; detailed research into FDA inspection expectations; and an investigator education session covering potential interview questions, given that any team member could be called for interview.

She noted that the received wisdom about FDA inspections — that they focus on process rather than detail — was not borne out in practice. The inspector was highly experienced, with 85 previous inspections and a 34% rate of issuing 483 notices — formal citations for regulatory violations — which prompted considerable anxiety within the team. In the event, the inspector's primary focus for the first day and a half was site files and amendment implementation rather than consent forms or eligibility, as the team had anticipated. She examined almost all 17 patient charts in detail, with particular attention to source documentation, adverse event recording, toxicity management, and evidence of principal investigator oversight.

The close-out meeting was attended by the full trials team. The inspector opened by stating she loved the site's source documentation, describing it as among the top five she had encountered across 85 inspections. The outcome was no action indicated — the best possible result. She noted that the site will receive a formal inspection report in nine to fourteen months, and flagged an open question about whether the HPRA should be proactively informed of the outcome, given that no automatic notification mechanism appears to exist.

Key lessons she identified for future inspection readiness: maintaining ongoing inspection readiness rather than preparing reactively; documenting rationale for clinical decisions at the time they are made, since charts from several years ago cannot be reliably reconstructed from memory; standardising the documentation of PI oversight; keeping source documentation simple, traceable, and trial-specific; and implementing an internal audit system. She also flagged the delegation log — at 30 pages for this study — as an area of practice they will change.

Ashley Bazin - FDA Inspection, Tallaght University Hospital, continued

In Q&A, she noted the inspection was site-specific, conducted separately from any sponsor inspection, though the global inspection lead from the pharma company was present as an observer throughout. Asked to compare it to other regulatory inspections, she described it as slightly easier than an HPRA inspection, but not dramatically so — contrary to what she had been led to expect — given the inspector's thoroughness on source documentation detail.

Later on in Q&A, Ashley Bazin returned to the theme of selling Ireland's capabilities, describing the reaction of a Nordic quality manager who had visited Tallaght as part of the pre-inspection process and had been genuinely surprised by the sophistication of the site's setup — noting that in Denmark, research nurses carry out many functions that in Ireland are handled by specialised data managers, sampling managers, and dedicated trials teams.

She argued that Ireland needs to communicate this depth of specialisation and experience more actively and confidently, alongside the work being done to address start-up timelines.

Angela Clayton-Lea - Cost Savings at Sites

Ms Clayton-Lea opened her presentation by framing it as part of an ongoing, year-on-year endeavour to communicate the true value of cancer clinical trials. She referenced Cancer Trials Ireland's Value of Cancer Trials Report published in November 2025, which included the observation from patient advocate, Seamus Cotter, that the proven benefits of trials are, sadly, not sufficient on their own to make the case for government action, and she reiterated Cancer Trials Ireland's call to the community to make the strongest possible collective case for increased government funding in the future.

Recent Data

Cancer Trials Ireland has been working with 19 sites across Ireland to gather data on actual treatment cost savings arising from trial activity. The figures presented at the Cancer Retreat span Q4 2025 to Q1 2026 and represent only a fraction of the full picture.

Ms Clayton-Lea estimated that the data collected may represent less than two-thirds of the total savings across the network, as data is still coming in. Reported savings are shown in the table below:

Beyond treatment cost savings, she cited several other data points:

- One site identified potential annual savings of €1.62 million if it could join four trials; however, it is currently unable to open any IMP trials because the hospital has not hired a clinical trial pharmacist.
  - Ms Clayton-Lea noted that an annual salary investment of approximately €90,000 is blocking €1.62 million in annual savings.
- A second site estimated the inward investment value of experimental IMP at €1.136 million between September 2025 and April 2026.
- A third site reported combined savings and inward investment of €577,443 between October 2025 and March 2026.
- A fourth site reported combined savings and investment of €299,533 in Q1 2026 alone.

She noted that two further sites and IRROG are contributing data to the forthcoming second Value of Cancer Trials report.

Value of Cancer Trials 2026 Report

The Cancer Trials Ireland follow-up report is planned for publication in late October/early November 2026. The upcoming report will cover a one-year period and is intended to involve more sites than last year's report. The 2026 report will also take a forward-looking approach, identifying trials that Ireland could and should be opening and quantifying the financial cost of not opening these trials. The upcoming report will also include benchmarked data on public attitudes to clinical trials and a deep dive on patient perceptions around the myths associated with trial participation.

Angela Clayton-Lea - Cost Savings at Sites, continued

Advocacy

Ms Clayton-Lea ended her presentation by describing the range of advocacy activity underway. Updates included:

- The 2025 Value of Cancer Trials Report was shared with the Minister of Health
- Ms Clayton-Lea, along with Dr Veronica McInerney (representing HSE sites), joined the Joint Oireachtas Committee on Further and Higher Education, Research, Innovation and Science in March 2026 to discuss the topic of Sectoral Skills Gaps and Critical Skills. They emphasised the need for ring-fenced whole-time equivalent posts in HSE hospitals and the conversion of specified-purpose contracts to permanent research posts
- Ongoing engagement with the Minister for Health and the Oireachtas Health Committee on the soon-to-be-formed Clinical Trials Advisory Council (CTAC)
  - Ms Clayton-Lea confirmed that both she and Prof Seamus O'Reilly have submitted applications for Cancer Trials Ireland representation on CTAC
- Participation in the development of the Life Sciences Strategy and engagement with the Biotech Act
- Working as a member of the NCCP's National Cancer Research Group to assist in the development of the National Cancer Research Plan
- And finally, a growing collaboration with the Irish Cancer Society advocacy team.

Prof Gerry Hanna - Introducing the Breakout Groups

Prof Gerry Hanna, Vice Clinical Lead at Cancer Trials Ireland, introduced the afternoon's interactive breakout session, describing it as an opportunity for the community to discuss where Cancer Trials Ireland will go over the next one to two years.

Four groups were formed, each given a specific question:

- Group One was asked how the cancer trials community, and Cancer Trials Ireland specifically, can collectively support the work of CTAC, noting the NCTOG recommendations to establish CTAC by Q1 2026 and to have it oversee the transition to a national clinical trials body by Q3 of the following year.

- Group Two was asked what capabilities Cancer Trials Ireland must strengthen or build over the next three years, including greater internal collaboration across sites, a stronger government voice, expanded PPI, sustained multi-year funding, or a combination of these.

- Group Three was asked how Ireland can strengthen its position as a high-quality, high-trust clinical trials destination, covering time to first patient, process predictability, robustness, and a unified research policy, as well as the lessons illustrated by the FDA inspection earlier in the day.

- Group Four was asked how Ireland can expand national research capacity and embed patient-focused innovation across care pathways, including through PPI and patient-led research, workforce planning, and decentralised trial models that reduce the need for patients to travel.

Prof Hanna noted the energy and depth of the discussions before inviting each group to report back.

Breakout Groups Reports

Group One: Supporting the Work of CTAC
Reported by Moira Handbidge

Group One focused on how the cancer trials community can collectively support the Clinical Trials Advisory Council's work. Discussion centred on three themes.

To promote value and incentivise activity, the group identified start-up processes as a priority, calling for standard national templates for budget planning to ensure staff costs are accurately predicted and planned. The group also raised the importance of national representation of trial activity and a collective, all-island approach to attracting and managing trials, including stronger engagement with industry.

On creating agile and responsive systems, the group echoed the importance of hard data and metrics as the foundation for attracting trials from abroad, drawing on the work presented by Emer Mulvaney earlier in the day.

On strategic workforce development, the group identified three interconnected issues:

- funding for permanent roles, including permanent contracts for research nurses and the development of clear education and career pathways for people working in clinical trials;
- protected time for consultant investigators, without which clinical leadership cannot be sustained; and
- data infrastructure, specifically the absence of a unique all-Ireland health record number, which the group identified as a significant barrier to building a central patient database or registry that would enable interrogation for trial eligibility.

The group also emphasised the importance of referral pathways between hospitals, so that patients attending sites with limited trial activity can be connected to sites where appropriate trials are running, and highlighted feasibility assessment as a process that should occur earlier in the trial selection timeline.

Group Two: Capabilities Cancer Trials Ireland Must Strengthen or Build
Reported by Jed van de Poll

Group Two examined what Cancer Trials Ireland needs to strengthen or build to reach its potential by 2027–2030. The group focused on four areas.

Regarding greater international collaboration, the group identified GDPR implementation as a significant barrier to attracting pharma trials to Ireland compared with countries such as Denmark — which, despite a similar population, conducts approximately 10 times as many cancer trials. The group noted that a delegation from Denmark had visited Ireland and had expressed genuine admiration for the quality of Cancer Trials Ireland's work and trial conduct, but that Denmark has clearly found ways to overcome the GDPR and funding barriers that Ireland has not. The group called for Cancer Trials Ireland to strengthen collaboration with Denmark specifically, to understand how those barriers have been addressed there.

Breakout Groups Reports, continued

On strengthening the voice to government, the group reflected on the difficulties of advocacy at the national level, noting that a ministerially appointed Cancer Patients Advisory Committee had effectively stalled following repeated changes in responsible civil servants. The group suggested redirecting advocacy efforts to the local level — TDs and county councils — on the grounds that cancer affects half the population and that elected representatives have a direct constituency interest in addressing it. International Clinical Trials Day was proposed as an annual focal point for this kind of local engagement and, potentially, fundraising, drawing an analogy to the Irish Cancer Society's Daffodil Day.

On public and patient involvement, the group highlighted the power of putting patients directly in front of TDs and councillors as advocates. Reference was made to a short documentary in development, focused on one patient's experience of a clinical trial, as an example of the kind of personal storytelling that can shift understanding among decision-makers.

On sustained multi-year funding, the group identified this as fundamental, noting that without predictable, long-term funding, the structural improvements being sought cannot be delivered.

The group also raised the lack of response from Ireland's EU representatives to approaches regarding clinical trial funding, and called on Cancer Trials Ireland to advocate more actively for EU-level investment, on the basis that improving cancer outcomes for half the population should be among the most compelling cases for public expenditure.

Group Three: Ireland as a High-Quality, High-Trust Clinical Trials Destination
Reported by Seamus Conaty, with support from Rachel O'Rourke

Group Three discussed what it means for Ireland to be a high-quality, high-trust destination for clinical trials, framing the question primarily from a sponsor perspective — given that sponsor confidence, once lost through underperformance, is very difficult to regain.

The group identified streamlining processes as the central priority, acknowledging that, as a heavily regulated environment, there are few steps that can be skipped, but arguing that work which does not strictly require a prior step to be completed — particularly during the ethics review period — should be progressed in parallel, as Emer Mulvaney had described.

Breakout Groups Reports, continued

Protected time for clinicians to develop and conduct research was also identified as a key enabler, with the group noting the tension that can arise when time spent on research is perceived as time taken away from patient care, and calling for formal recognition of research as a core clinical activity.

On site selection, the group raised a strategic question: adding sites to a multi-site trial to improve patient access is valuable, but only if those sites can realistically recruit to target. A site that fails to meet its recruitment commitments damages sponsor confidence in the whole network. The group suggested a more rigorous upfront feasibility assessment and raised the possibility of routing patients to nearby sites that can deliver care while allowing them to continue routine care at their local hospital.

On cross-site collaboration, the group proposed that sites regularly compare their timelines for key process steps, share lessons learned when one site is performing particularly well, and use that information collectively to reduce activation times across the network.

On communication, the group cited an example where regulatory approval had been granted in January, but the site was not informed for several months — a simple process failure with significant consequences for time to first patient and sponsor perception.

Group Four: Expanding National Research Capacity and Embedding Patient-Focused Innovation
Reported by Martin O'Sullivan

Group Four discussed how Ireland can expand national research capacity and bring clinical trials closer to patients. Three themes dominated.

On leveraging technology, the group identified the National Shared Care Record as a future enabler of trial enrolment, while acknowledging it is not yet fit for this purpose. The Individual Health Identifier was raised as a resource many people are unaware they have, and the group suggested that wider public awareness of the IHI — and of the fact that hospital records will increasingly be accessible across sites — would support both trial enrolment and continuity of care. The group also called for a hub-and-spoke model for research delivery, allowing patients to participate in trials as close to home as possible rather than requiring travel to major centres for every visit.

On core funding, the group was unequivocal: without agreed, multi-annual, ring-fenced core funding, sustainable capacity cannot be built. A system dependent on annual allocations or the priorities of individual ministers cannot support the long-term infrastructure investment the sector requires.

Breakout Groups Reports, continued

Open Discussion: Industry Perspectives

Three industry representatives offered perspectives from the floor.

Deirdre Smith of AstraZeneca welcomed the data-generation work described during the day and encouraged clinical investigators to engage proactively with pharma medical affairs teams to identify unmet patient needs and populations where trials are particularly needed. She emphasised that demonstrating site-specific unmet need strengthens the internal business case when pitching Ireland for a global trial. She also underlined that once a trial is open, consistent on-target recruitment is one of the most important signals to global teams when assessing whether to return to a site.

Ciara O'Dwyer of Bristol Myers Squibb noted that her team is developing a pitch deck to support selecting Ireland for global trials — an effort that has historically been hampered by a lack of strong supporting data. She expressed interest in incorporating the FDA audit outcome and other quality indicators into that pitch and invited engagement from those willing to help make the case for Ireland globally.

Gwen Morley of IQVIA described the company's concept of a "prime site" — a designation that brings with it preferential access to studies, technology support, and training. She acknowledged that individual Irish sites are unlikely to meet the threshold for prime site status on their own, but proposed that, if the Irish network operated as a collective, it could achieve equivalent recognition and benefit. She drew on the examples of Denmark and Spain, where clinical trial volume was significantly driven by public-private partnerships, and argued that leveraging commercial infrastructure and funding to support investigator-led studies is a model Ireland should actively pursue.

Further Discussion from the Floor

Martin O'Sullivan raised the question of how trial results are communicated once studies conclude, using exercise during chemotherapy as an example: knowing that exercise improves outcomes is useful, but what patients and clinicians need is specific, actionable guidance — type, duration, intensity — that can be built into programmes. He also suggested that ongoing data collection after trial completion, tracking patient exercise patterns and outcomes, could allow further refinement of recommendations over time. He welcomed the de-escalation data presented during the day, noting that the finding that reducing doses does not reduce efficacy would be very welcome to most patients — reducing both toxicity and time burden — and offered a candid observation that the cost savings from dose reduction are unlikely to be captured in manufacturing costs, which are minimal, but should materialise in reduced administration costs: fewer nursing hours, fewer hospital visits, fewer associated overheads.

Breakout Groups Reports, continued

Ashley Bazin returned to the theme of selling Ireland's capabilities, describing the reaction of a Nordic quality manager who had visited Tallaght as part of the pre-inspection process and had been genuinely surprised by the sophistication of the site's setup — noting that in Denmark, research nurses carry out many functions that in Ireland are handled by specialised data managers, sampling managers, and dedicated trials teams. She argued that Ireland needs to communicate the depth of its specialisation and experience more actively and confidently, alongside the work underway to address start-up timelines.

Angela Clayton-Lea added that data shows Ireland ranks 36th in Europe by population but 13th for clinician and research expertise, and agreed that this comparative strength needs to be communicated far more actively. She also responded directly to Martin O'Sullivan's question on exercise, sharing findings from an ExWell presentation at a Myeloma Ireland conference the previous week, which indicated that the current evidence-based recommendation is approximately two one-hour exercise sessions per week, supplemented by three ten-minute walks on the remaining days. She identified a potential role for Cancer Trials Ireland and the Irish Cancer Society in promoting ExWell's work and raising awareness of the evidence base for exercise in cancer care.

Conclusions

Members & Clinical Oncology Community: metrics, streamlining and accruals

- Accruals are rising, but interventional participation remains below target. Total accruals reached 4,926 in 2025, and interventional participation more than doubled to 2.9% since 2022, but this remains short of the 6% national cancer strategy target and OECI targets of 10%+.

- Start-up gains are concentrated in contracting; the ethics-to-activation window is the live problem. The 45% reduction in site-agreement execution time (from 73 to 40 days) shows that small operational tweaks can make a very significant difference. But the 21% increase in ethics-approval-to-activation is the countervailing signal, and Cancer Trials Ireland has named it the priority for the second half of the year.

- The parallel-preparation pilot is the concrete next step on time to first patient. Progressing draft contracts, documentation, and site initiation visits during the ethics review period, rather than sequentially after it, is the mechanism proposed. Its success depends on the selection and support of one to three pilot sites in the near term.

- Start-up time is the metric sponsors watch most. Industry representatives were explicit that recruitment reliability, more than any single quality indicator, drives the decision to return to a site, making feasibility assessment a metric-critical process rather than an administrative one.

- The FDA "no action indicated" outcome at Tallaght is a reusable quality asset. Bristol Myers Squibb asked to incorporate it into its global pitch for Ireland. Members could consider treating inspection outcomes and specialisation depth as data to capture and share.

- Workforce and data infrastructure are the recurring structural constraints. Permanent research-nurse contracts, protected time for investigators, and the absence of a unique all-Ireland health record number were raised across multiple discussion groups as limits on what metrics alone can deliver.

Conclusions, continued

For External Audiences: value, investment and the case for funding

- Cancer trials deliver measurable savings to the State, and the reported estimate is very likely an undercount. Site-level data showed savings and inward investment ranging from hundreds of thousands of euros to more than €1 million per site, with the collected data estimated to represent less than two-thirds of the total network savings. This sits on top of the published finding of an estimated €14.8 million in savings to the State from 2021–2025, based on a sample of just 18 trials.

- A €90,000 post is blocking €1.62 million in annual savings at one site. This single ratio is the sharpest illustration of the argument: modest, targeted investment in trial infrastructure unlocks disproportionate return.

- A structural inequality prevents HSE hospitals from realising the value of trials. Because end-of-year drug savings are reabsorbed into the broader HSE budget, HSE sites cannot reinvest as voluntary hospitals can. Recognising trial value at corporate and system level is therefore a policy change, not merely a funding increase.

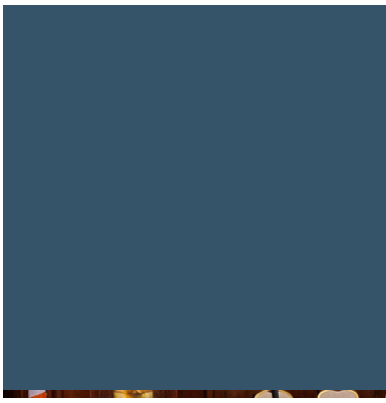
- Optimisation and de-escalation represent a large, unrealised savings opportunity, gated by regulation and payer courage rather than science. The PLANET trial's ~€35,000 savings per pair of enrolled patients, along with international precedents (Denmark's two-year immunotherapy limit; the Netherlands' savings-funded trials), show the model works when payers act. Ireland has not yet built this mechanism.

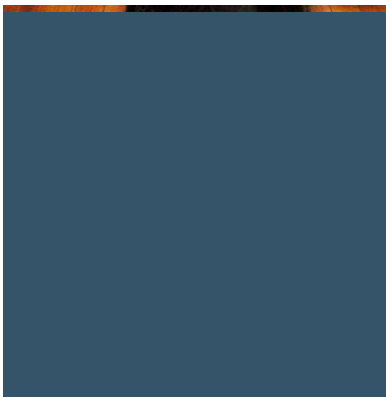
- Sustained, multi-year, ring-fenced funding is the precondition every strand returned to. The Irish Cancer Society's renewed €1 million per year commitment and the €27 million POI2 investment show co-investment is available; breakout groups were unanimous that annual, minister-dependent allocations cannot support long-term infrastructure.

- The advocacy case rests on a population-scale argument. Cancer affects half the population; Ireland ranks 36th in Europe by population but 13th for clinician and research expertise. The consistent conclusion across the day was that Ireland's quality is proven and its remaining task is to communicate that value and convert it into a durable government funding commitment through CTAC, the next national cancer strategy, and coordinated engagement at the local, national and EU levels.

cancer trials ireland

Together, we're finding answers to cancer.





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