



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

# REPORT

## CANCER RETREAT

10.05.2024



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# KEY ACTION POINTS ARISING

- Work with DPC and DPOs on the interpretation of GDPR to reduce the timeline to the first patient.
- Engage with the newly appointed Regional Executive Officers and encourage them to put research firmly on their agenda and commit financially.
- Achieve reduced and reliable startup timelines to move Ireland from the bottom third of the European timelines table to the top 10%.
- Seek to develop a program for innovative cellular therapy-based treatments (CAR-T treatments).
- Advocate for increased investment in translational, nurse-led, allied health and lifestyle trials.
- Continue to build meaningful patient involvement in everything we do as a community.
- Improve communication and referrals across sites and specialities to provide maximum opportunities for patients.



# EIBHLIN MULROE, CANCER TRIALS IRELAND CEO

## People and Funding. That's what makes things work.

The Retreat was opened by Eibhlin Mulroe, CEO of Cancer Trials Ireland, who was warmly welcomed back after a period of absence. In her address, Ms Mulroe likened Cancer Trials Ireland to a family, “a family that is striving to deliver the best treatments and the best opportunities for our cancer patients.”

Ms Mulroe explained that Cancer Trials Ireland has a clear mission and vision. The organisation aims to maximise cancer trial access and outcomes to prolong patient lives and expand cancer research in Ireland.

Its vision is an indispensable all-island hub for cancer trials globally recognised for excellence in governance, collaboration, and innovation in clinical research. The strategy, which Chair of the Board Deirdre Somers will speak to later, has five main themes:

- Maximise contribution to the National Cancer Strategy
- Optimal, stable and scalable TALENT to serve growth
- Clinical Research is fundamental to clinical care through Leadership, Advocacy and Influence
- A compelling 'All-Island' cancer trials proposition
- Financially Stable and Funded for Growth



Ms Mulroe emphasised that of the strategic objectives, the most critical is maximising the contribution to the National Cancer Strategy. Established in 2017, the strategy aims to have 6% of cancer patients in clinical trials, a target that has not been achieved.

The second strategic objective speaks to the importance of the people in the Cancer Trials Ireland community, the staff in the central office and the people at the sites.

The third strategic objective is to advocate for the community with the government, stakeholders, the HSE, and the Department of Health, highlighting the importance of clinical research and its fundamental role in providing patients with a high standard of clinical care.

The all-island cancer trials proposition is taking shape, and significant progress has been made over the last few years, particularly with the AICRI, which has done sterling work.

The final strategic objective concerns financial stability. Ms Mulroe noted that as a charity, CTI must be incredibly mindful of funding, where it comes from, and how it is spent.

Moving away from strategy, Ms Mulroe shared a personal story about her recent cancer journey.

# EIBHLIN MULROE, CANCER TRIALS IRELAND CEO

After being diagnosed in November and undergoing treatment, Ms Mulroe is keen to share the learnings she gathered from a patient perspective and use these to help inform the work.

Time away from work while undergoing treatment also gave her time to reflect. “I thought a lot about us and what we do, and I thought back to 2015 when I took this job and the difference between where we were then and where we are now.”

In 2015, the Cancer Trials Ireland office had 26 staff members, and it now has 60. The HRB grant was cut by 20% in 2015 and is now a five-year commitment. The Irish Cancer Society provided €360K of funding back in 2015, and that has now grown to €1 million per year committed for three years.

Philanthropy is another area that has seen significant growth. In 2015, very little funding came in through this route, whereas today, this is 14% of the revenue. Events such as the Pat Smullen race day and Property Picnic are incredible fundraising opportunities for Cancer Trials Ireland.

Ms Mulroe emphasised the key elements: people and funding. These are the essential components that drive success. Securing the necessary financial resources and engaging with the community are critical.

She also highlighted the community's positive culture and emotional connection, which significantly contribute to the work. Sharing some success stories from the first quarter of 2024, Ms Mulroe briefly discussed twelve new trials that have opened. This is a testament to the hard work of so many PIs, site staff, and members of the Cancer Trials Ireland team.

The all-island collaboration and the great work achieved in resigning the MOU with NCI were also stressed, alongside newer developments such as the HRB All Island Grant and the PEACE PLUS application for all-island clinical trials.

Ms Mulroe finished her address by thanking her team and the community and offering a message to the attendees to look after their health and “make the time to mind yourself.”



# PROF MAEVE LOWERY, TRINITY ST JAMES'S CANCER INSTITUTE

Prof Maeve Lowery was excited to share information about a grant application submitted jointly with Cancer Trials Ireland for a project related to the equity of access to cancer clinical trials, drugs, and molecular diagnostics. The background is a family of studies called DRUP-like studies or drug repurposing studies.

These trials aim to improve access to patients with rare subtypes of common or rare cancers to ensure they can access personalised, targeted therapy appropriate to their mutational profile through somatic mutational profiling. A patient with advanced cancer has molecular profiling done, determining what treatment they're allocated within several different baskets available on the clinical trial. All the drugs available on the trial are approved for another indication, so the side effect profile is already well understood, but they're not reimbursed or available to a patient.

“To date, these trials have been opened across the Netherlands, Scandinavian countries, France, Portugal and the UK, all with similar endpoints and protocols,” said Prof Lowery. In addition to delivering the correct drug to the patient, this trial design also develops a National Framework around novel access to drugs and access to novel methods of drug reimbursement. Following the publication of the initial study in the Netherlands, a network of ‘sister trials’ was developed, sharing endpoints, protocols, and data.

Prof Lowery highlighted one study in particular: the DETERMINE study in the UK, led by a team in Manchester. It is currently open in Belfast but not in the Republic of Ireland. In attempting to refer patients to the trial, Prof Lowery discovered that “cross-border access to clinical trials is an issue.”

She elaborated that this is not only an issue for the island of Ireland but also across Europe, as the EU directive that covers cross-border access to healthcare does not cover cross-border access to clinical trials.

The issues include financial responsibility, who pays when a patient gets sick as in their jurisdiction, issues of access, and issues of legislation and regulation.



Prof Lowery spoke about two European collaborations that Ireland was invited to join in more detail. The first is the European collaborative group PCM4EU. The goal was to provide recommendations, share capacity across various aspects of the pathway, and facilitate cross-border European access to genomic testing and the precision medicine aspect of the trials.

The second collaborative group was the PRIME-ROSE Consortium, building on the work of the PCM4EU group by developing novel and pragmatic clinical trial designs and using synthetic controls or artificial intelligence to build cross-country collaboration meaningfully.

Participating in these projects led to the desire to develop a DRUP-like study for Ireland, and the structure of PCM4EU & the PRIMEROSE consortium is such that they provide a framework to help create a protocol relevant to our national framework. The support covers all aspects, from diagnostics to discussing reimbursement with the government.

Prof Lowery shared that, with CTI's help, an initial protocol framework has been developed. Support has been secured from Roche Ireland to supply drugs for two indications, and Cancer Trials Ireland has agreed to add to the study sponsor, which is a huge step forward. The study has been designed to be a sister trial to the DETERMINE study to avoid having competing trials on the island of Ireland.

The studies will open complementary arms, so a patient in Belfast could travel to Galway or Cork for that trial. Similarly, a patient in Dublin could travel to Belfast for an arm of the study that wasn't open in the Republic of Ireland.

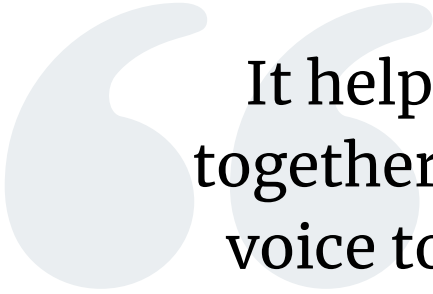
Prof Lowery notes that this again raises the question of cross-border referral pathways that do not currently exist for cancer clinical trials. She shared details of the ALIGN consortium which was established to create a framework for governance around public-private engagement to accelerate precision oncology in Ireland.

Led by Prof Lowery, ALIGN has applied for €7.2 million of PEACE-PLUS funding to deliver three work packages, the first of which is establishing a cross-border referral pathway for cancer clinical trials.

The second work package concerns developing an online and precision medicine platform. The idea is to provide patients without access to comprehensive genomic profiling with 500 gene panels that would then be available as a report to screen patients for inclusion to either DETERMINE or PROGRESS.

In a broader sense, this also facilitates the sharing of data and samples across the border, which is crucial.

Work package three is the trial itself, which follows the typical protocol of a DRUP-like study with five arms, the same as the DETERMINE study. It has an adaptive design, with cohorts of up to 30 and sub-cohorts that can be identified from within.



It helps to come together with one voice to improve access for all patients.

Prof Lowery shared that the group hopes to hear if the funding application will succeed by the end of the year and thanked CTI for their work on the application. She reflected that “even if we are not successful in that grant, the work has been done in establishing the needs analysis, developing potential solutions, and looking at the framework needed to address some of the issues” had been very valuable.

In closing, Prof Lowery expanded on the ALIGN consortium, which is modelled on the Norwegian ‘CONNECT’ Consortium in that it seeks to identify an arena for all shareholders to come together and work across public and private partnerships to address the obstacles that have been identified and develop novel solutions.

# DEIRDRE SOMERS, CHAIR OF THE BOARD



**“It is an honour and a pleasure for me to chair this board of this incredible organisation and to work with the most passionate, committed and talented management team that I’ve had the pleasure of working with throughout my entire career,” said Deirdre Somers, Chair of the Cancer Trials Ireland board.**

Providing context and an insight into how the board of Cancer Trials Ireland is run, Ms Somers shared that the board members have backgrounds and experiences that span commercial, medical, research, stakeholder, legal, and accountancy. She noted the importance of easing the compliance and stewardship obligations for those managing charitable organisations in Ireland to allow them to navigate the inherent complexities of the current environment more effectively.

She continued by saying that the board is gifted with diverse views and an extraordinary backlog of experience from every perspective. Cancer Trials Ireland is a multi-stakeholder environment; progress is only possible if all the cogs of the wheel are in harmony and feel that working together is essential.

Ms Somers noted that the organisation must be clear on short-term goals due to the tight funding schedule and limited resources. “Having a set strategy enables us to direct those limited resources most effectively year on year”. She gave some insight into the Cancer Trials Ireland strategy day held at the start of the year, which was focused on reducing the overall time to first patient. Topics covered included clinician engagement, funding, attracting trials, and operational effectiveness. One issue raised repeatedly was GDPR, specifically how it is interpreted and implemented in Ireland. Hold-ups resulting from this increase the time to the first patient, reduce the attractiveness of Ireland for trials, increase the costs of trials, and reduce our ability to obtain new funding sources.

It reduces clinician incentive and engagement and increases patients' challenges and difficulties in participating in trials. Ms Somers continued, saying that the board had prioritised this for the next year. It is very much an operational focus and may seem narrow, but it is a significant roadblock. Another objective to reduce the time to the first patient is to implement LEAN to ensure that Cancer Trials Ireland operates internally with as little operational friction as possible. After that, new funding sources need to be identified. Ms Somers acknowledged the very welcome support of the Irish Cancer Society for the funding they provide to Cancer Trials Ireland, stating that academic research and investigator-led trials would simply not happen without their support.

Ireland has one of the largest clusters of pharmaceutical companies in Europe. Yet, they are not leveraged for the domestic research or clinical trial agenda as other countries, such as Switzerland. Ms Somers noted that the board is keen to engage with companies and explore how to leverage these relationships.

“The secret sauce of clinical trials in Ireland is the clinicians”, Ms Somers continued. “We have clinicians who have been trained internationally, have international credibility, have international networks, and come back to Ireland with all the passion, commitment, and international perspective that results from these experiences. Ensuring that they are engaged, incentivised, valued, visible, and supported is a huge part of what Cancer Trials are all about.”

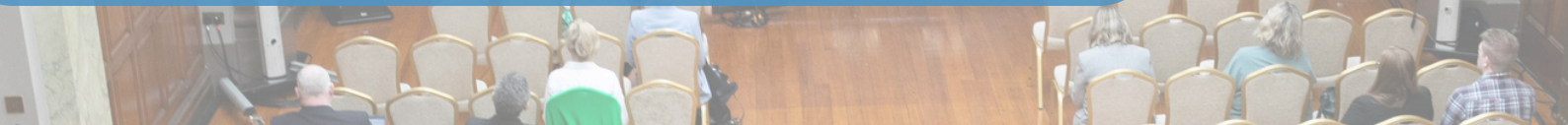
She noted the new generation of oncologists who have returned to Ireland and are highly engaged and enthusiastic about research. They will be the ones to replace the generation of clinicians who founded Cancer Trials Ireland and created this network. Cancer Trials Ireland must support those clinicians as we move forward, said Somers.

The final point Ms Somers made was communicating the value of Cancer Trials Ireland and the importance of raising the organisation's profile across government, media, the public sector, pharma, clinicians, and researchers.

As she left the podium, Ms Somers paid tribute to her late sister-in-law, stating that she is why Ms Somers joined the board and ultimately became Chair of Cancer Trials Ireland. These personal connections that so many of us share give meaning to this vital work.



# ANGELA CLAYTON-LEA, CANCER TRIALS IRELAND COO



**“If it makes a difference to patients, I want to make it happen”, opened Angela Clayton-Lea, COO of Cancer Trials Ireland.**

Continuing the theme of the future and strategic priorities, Ms Clayton-Lea focussed on action and the practical steps to move forward with the strategy described by Ms Mulroe and Ms Somers.

Building on comments made by the Chair of the Board, Ms-Clayton-Lea reiterated that GDPR is a crucial priority for the coming year. “The overall objective is to harmonise legislative interpretation.”

She shared the results of a recent benchmarking exercise provided to CTI that compared the timelines involved from the point of a final protocol being developed to initiating the first site. In Ireland, that combined timeline is currently eleven months.

The best in Europe is doing this within five and a half months, working under the exact same legislation. Most of this time difference is due to the interpretation of that legislation in Ireland.

Ms Clayton-Lea explained the actions that Cancer Trials Ireland plans to take. The goal is to reach a consensus with the DPC and DPOs on the interpretation of GPDR and harmonise the templates used to reduce the timeline to the first patient. CTI, with the assistance of its board, is seeking a Senior Counsel review of the interpretation within Ireland and benchmarking that with Europe.

CTI is examining the structures in place at the EU level and reviewing what good practice looks like. In addition, a survey planned for the summer will gather public feedback on how people feel about GDPR in relation to research and health data, as well as their worries and concerns.

The CTI PCC will provide a valuable patient perspective on the same issues. The insights gathered through these actions will be used to compile a position paper with stakeholders and engage policymakers on this crucial issue to drive change.



Moving on to the issue of funding, Ms Clayton-Lea once again kept the focus on actions. “The objective is to maximise our funding opportunities.” Although Cancer Trials Ireland is a not-for-profit, Ms Clayton-Lea noted that developing the business model to attract more funding by charging for the provided CRO service would help secure the funding base. In addition, there are plans to maximise incoming funds from EU grants, pharma, and the six newly formed Health Regions.

The action here is to meet the newly appointed Regional Executive Officers and encourage them to put research firmly on their agenda and make a financial commitment. Finally, regarding funding, the HRB grant is critical, and coming together as a community to ensure that learnings are shared from the current grant and that a robust approach is taken in the next round of the HRB grant funding is essential.

Ms Clayton-Lea stated, “Ultimately, we aim to increase our funding and to make Ireland the ‘go to’ country for cancer clinical trials”.

The results from the previously mentioned benchmarking showed that Ireland is currently 33rd out of 35 European countries regarding timelines from final protocol to initiating the first site. Ireland must shave six months off the current timelines to become more competitive. With this in mind, Ms Clayton-Lea shared that CTI is prioritising maximising operational efficiency through the implementation of 'Lean' principles.

This includes a combination of working through some of the external barriers, such as GDPR and other regulatory issues and becoming leaner internally. In-house training has started to assist in implementing internal improvement initiatives that have been identified to minimise any avoidable delays.

Providing “reduced and reliable start up timelines” is critical to moving Ireland from the bottom third of that European table of timelines to the top 10%. Ms Clayton-Lea reiterated that if this ambitious change is achieved, more studies will come to Ireland, and patients will ultimately benefit.

The final point Ms Clayton-Lea addressed was clinician engagement. She recognised the dedicated clinicians on teams working across all the sites around the country. She addressed them directly, saying, “We want to get your studies open and in a timely fashion.”

Cancer Trials Ireland is working closely not only with clinicians but also with team leaders and research nurses who are highly supportive. It was noted that many staff working in research units around the country do not have permanent contracts, which harms those people regarding job security.

“We will lobby on behalf of site teams to say to the Department of Health and the Health Executive Officers that we need permanent contracts for our research staff.” It is the only way to retain dedicated staff and attract new talent to that area.

“We want to get your studies open and in a timely fashion.”

Engaging surgeons is another aspect that Ms Clayton-Lea is passionate about. Ireland opens fewer surgical studies than comparable countries and should look to do more. The GI DSSG recently welcomed a new surgical co-chair, Mr Michael Kelly, and there are also plans to engage with RCSI to develop cancer surgical trials.

The Cancer Trials Ireland National Training Day held in January was mentioned, particularly the implementation of the actions from that day. One such action is the creation of an ‘Expertise Atlas’, which will show in a visual way which sites around the country are specialising in which types of trials, their areas of expertise, and highlight who sites can refer to.

It is envisioned that this will be particularly useful for new clinicians returning to the country. Other resources being developed with a similar approach are a mentoring program and an induction or onboarding document, which Cancer Trials Ireland is working on with ISMO. The idea behind this is to create a “one-stop document” for anyone within the community who has newly returned to Ireland to help them quickly and easily understand the landscape, who they can speak to, and what they need to do if they have an idea for a study.

In summary, Ms Clayton-Lea reminded the audience of the day's theme, ‘Securing our Futures’. “We want to secure our future through more collaboration and support”.

# AVERIL POWER, CEO IRISH CANCER SOCIETY

**“Every 3 minutes, someone in Ireland hears the words ‘you've got cancer’, and in the blink of an eye, their world is turned upside down.**

Time stands still as they try to process what that means for them. Thanks to research for most people, Cancer is no longer the death sentence that it once was”.

“Over 6 in 10 Irish people are now alive five years after a cancer diagnosis, and over 9 in 10 survive breast, prostate, and testicular cancer. Today, a simple vaccine can prevent people from ever getting cervical cancer and other HPV-related cancers. Cancer Research has improved how we deliver chemotherapy and helped us predict which patients don't need it.

It has made radiotherapy far more targeted and proven that our immune systems can be trained to seek out and kill cancer cells. This has only been possible thanks to the people in this room and your colleagues in the global Cancer community”.

An investment in Cancer Research is the only way to turn hope for a cure into reality, and that is why the Irish Cancer Society has been proud to fund Cancer Trials Ireland since its establishment in 1996 and to double its funding for the organisation in recent years.

“It's why we're the most significant voluntary funder of Cancer Research in Ireland, and it's why we are investing both in today's Cancer leaders through buy-out for research and helping to create the leaders of tomorrow through funding for summer scholarships and PhDs. It's why we provided seed funding for bowel screening, €7.5 million for Breast Predict, and foundational investment in the All-Island Cancer Research Institute.”

Ms Power stated that the Irish Cancer Society is proud of what their research investments have achieved and optimistic about the possibilities offered by new advances in areas such as precision, oncology, AI, machine learning and digital health.



However, there is also frustration that the National Cancer Strategy has only been adequately funded in two of the seven budgets since it was published and that the very modest target of 6% participation in Cancer Trials set out in that strategy is not being met due to many of the obstacles that have already been mentioned and that the number of clinical trials in Ireland is only half of that in similarly sized Denmark.

There is frustration that bowel screening is not expanded as planned, that Ireland is a laggard in e-health and that infrastructure is struggling. Underinvestment, missed targets, and delays affect real people; they affect the quality of care clinicians can provide and limit researchers' progress.

Ms Power shared that, alongside Professor John Kennedy, she recently presented these frustrations to the Oireachtas Committee on Health. The presentation celebrated the improvements that have been made in Ireland's cancer outcomes because of previous investments but also highlighted that in 2019, which is the latest year for which comparable data is available, Ireland had the third highest cancer mortality in Western Europe.

It is yet to be seen if Ireland's relative position has improved since then. However, improvements in cancer research and treatment have been made in the last five years. Thanks to research, our understanding of Cancer has improved significantly and is improving all the time. In recent years, new diagnostic techniques have been introduced, and new treatments, such as CAR-T-cell therapy and immunotherapies, are now available to Irish patients.

Continuing the theme from earlier talks, Ms Power pointed out that the pace of progress in Ireland and the timelines involved is problematic. It is slower to set up Cancer Trials here than elsewhere, and Irish patients are not getting access to new medicines as fast as their counterparts in other countries.

Ms Power expressed her gratitude to the clinicians and researchers, some of whom were in attendance, who co-signed the letter to the Taoiseach, calling on him to secure proper funding for the National Cancer Strategy. She stressed the importance of using our collective voice as a community to ensure we can deliver greater investment and practical support in the next budget and for the next five years.

From vaccines to treatments to radiotherapy - research has positively impacted cancer patients

Ms Power also thanked those in the room who have contributed to an independent scoping review, initiated by the Irish Cancer Society, of the cancer clinical trial landscape in Ireland, including the barriers and obstacles to trial access. By undertaking that review, the ICS hopes to have a series of practical recommendations on how we in the community can plan and improve the cancer clinical trial ecosystem.

These recommendations, together with all the work done by Cancer Trials Ireland, will help to inform our collective advocacy about what we need to do to move Ireland into that top 10%.

Ms Power concluded by thanking everyone at the Retreat for their work in improving how we prevent, detect, and treat cancer. She reiterated the Irish Cancer Society's determination to help the community through funding advocacy and public communications "because together, we can turn potential into real-world progress, and together, we can turn today's terminal cancers into tomorrow's treatable and survivable ones".



# Members Workshop: The HRB Cancer Network Grant



**In this session, Chaired by Prof Seamus O'Reilly & Ms Eibhlin Mulroe, CTI members discussed the HRB Cancer Network Grant. Reflections arising from that discussion included:**

- This grant cycle has created closer relationships between academic institutions and hospital sites, which has been positive. Many in the room echoed this, praising the strong connections built between hospitals and academics. Others felt that the relationship between the group and the academic institution, while valuable, could be clearer.
- The ability to leverage the co-investment from the hospital and the university by formally agreeing on what was to be funded and what commitments were being made was noted as a significant benefit. It was pointed out, however, that because the grant didn't come with additional funding, it had not enabled extra positions to be created. In the experience of many in the room, the grant had been used to fund hospital-based positions rather than as an enabler to hire university staff to work on the grant. It was suggested that the relationship may have become more easily embedded if university staff had worked directly on the grant.
- Participants shared views and experiences on hiring staff through the university partners versus hiring through the HSE. A common approach is to collaborate with the university to pay salaries, which is effective because it means that nursing staff are not compelled to leave a permanent post to take a temporary university one. However, this was seen by some as a less collaborative approach, where the relationship with the university is somewhat transactional.
- The more robust translational research component seen in this grant cycle, alongside the clinical research and with allied health professionals, was welcomed.
- The importance of the role of a Project Manager was noted as a vital benefit of this grant cycle. Participants shared that this valuable role has assisted with following up actions from meetings, ensuring that things happen, and in thinking more broadly and breaking down silos.
- Participants discussed the challenges of navigating the HSE recruitment embargo to ensure that essential team members can be hired. They shared various solutions, including using philanthropic funding to pay salaries via the university and using agency staff, but all agreed that the situation was complicated. There is no straightforward means of enabling a permanent staff member in a hospital who wants to become involved in clinical trials.
- The HSE Health Regions were discussed as a potential opportunity to move towards a blended model. Combined with HRB funding, the regions could create a permanent headcount to drive research and open trials nationwide. This would address the problem that sites are currently experiencing, where they are being asked to take on more studies but do not have the resources. This impacts accruals, which creates a weaker position from which to lobby for additional funding, creating a 'Catch 22' scenario. Sites should be provided with the resources they need and given some flexibility so that the 6% target can be achieved.

# Members Workshop: The HRB Cancer Network Grant

- The HSE Health Regions were further discussed in the context of funding. It was suggested that they could become co-applicants on each of the grant applications, as this would see them commit a budget and a headcount to research. They were also discussed regarding potential changes to relationships, as some sites that had previously worked very closely together will now be in separate regions, potentially working with different partners.
- The issue of a potential disconnect between the HSE Health Regions, who will hold the budget, and the plan put forward by the NCCP and the need for these to be in sync was discussed. Establishing the HSE Health Regions was again suggested as an opportunity to rethink how funding works nationally. It was noted that this will need to be considered carefully for groups outside of a geographic site, such as IRROG.
- Many shared a key frustration with the current funding model in that it supports the idea that Cancer Trials units are 'add-ons' rather than fundamentally integrated parts of the oncology and haematology services within hospitals. Due to the lack of security about what funding will come in from each grant call, it is challenging to put staff in place to deliver the work packages successfully. It was suggested that it is time to begin advocating for a research budget with the HSE Health Regions, which should be linked in some way to the future HRB grant.
- Other features of the current grant that have been challenging, such as laborious reporting requirements and, in particular, Research Fish, were discussed. It was observed that this is a time-consuming tool, and the staff filling it in are already extremely busy. The quality and depth of the feedback in response to submitted reports was also critiqued. The reporting requires gathering large amounts of data and takes much time and consideration.
- Translational research was another topic that was front of mind for the audience. It was felt that, at a high level, translational and observational trials are less appreciated and valued than other trials. They do not make up part of accreditation systems for cancer centres like the OEIC, and until that changes, there is unlikely to be a national investment program. It was noted that the charity sector in Ireland is now largely funding translational trials.
- It was noted that some duplication exists within the clinical trial sector, particularly in data processing and project management, and suggested that Cancer Trials Ireland can play a role in identifying where central resources can be provided to create a web.
- Looking to the future, the importance of developing a program for innovative cellular therapy-based treatments (CAR-T treatments) was highlighted. The first patient was treated in 2012, and up until now, there has been no academic clinical trial in Ireland, placing Ireland at risk of falling behind in this innovative area. Including this in the grant proposal would increase the possibility of Irish patients accessing CAR-T and other cell therapy trials.
- Referral pathways were also raised, and a need was expressed to increase the ease with which patients can be referred between sites. Currently, referring a patient from a more remote centre like Galway to a site in Dublin is difficult because there are no agreements for data transfer.
- It was suggested that the current grant cycle could be more focused on patient impact. The patient voice should be woven into examining, valuing, and prioritising our work. The value to patients should be an essential metric and consideration and is not currently reflected in the grant.

# Members Workshop: The HRB Cancer Network Grant

The patient voice should be woven into how we examine, value, and prioritise things.

Due to the lack of security about what funding will come in from each grant call, it is challenging to put staff in place to deliver the work packages successfully.

Greater integration between universities and hospitals has been a positive outcome of this grant cycle.

Research Fish is a time-consuming tool, and the staff filling it in are already extremely busy.

Having a Program Manager has been the single most helpful thing to have someone to coordinate us to pull together.



Many investigator-initiated clinical trials, including the SHAMROCK trial, are based on translational projects.

We should look at developing a program to bring innovative cellular therapy-based treatments (CAR-T treatments) to Irish patients.

Sites should be provided with the resources they need and given some flexibility so that the 6% target can be achieved.

Referring a patient from a more remote centre like Galway to a site in Dublin is difficult because there are no agreements for data transfer.

There is no straightforward means of enabling a permanent staff member in a hospital who wants to become involved in clinical trials

# Panel Discussion: The future for Non-drug trials

- Professor Bill Watson, Professor of Cancer Biology, UCD (Chair)
- Ms Katie Johnston, Clinical Cancer Research Dietitian, UCC
- Dr Veronica McInerney, UoG / University Hospital Galway and Saolta Cancer Network
- Ms Emma Noone, Research Project Manager, St Luke's Radiation Oncology Network
- Professor Leonie Young, RCSI University of Medicine and Health Sciences
- Ms Siobhan Gaynor, Patient Consultants Committee, Cancer Trials Ireland
- Ms Kate O'Connell, Research Support Officer, UCC



**“We need to remember that Cancer Trials Ireland is Cancer Trials Ireland and not Cancer Drug Trials Ireland – the remit is much broader than just drug trials”, opened Professor Bill Watson, facilitating this panel session on the future of non-drug trials.**

Clinical trials are the primary mechanisms for evaluating and advancing all new cancer treatments, including drugs, radiation, and surgical treatments. Prof Watson praised Cancer Trials Ireland's efforts to increase surgical involvement in the DSSGs. He also reflected that diet and exercise will potentially be treatments in the future.

Prof Watson further emphasised the importance of assessing patient-reported outcomes alongside clinical outcomes. While a therapy may be effective against a particular cancer, it must also be acceptable to the patient receiving it. Translational studies increase biological understanding of cancer and help researchers understand why studies work and, ultimately, why they fail. Studies can then be modified to have better outcomes in the future.

Dr Veronica McInerney spoke to the audience about nurse-led trials and the need to focus on cancer prevention, survivorship, and other aspects of care, all of which are conducive to nurse-led trials.

While most cancer nurses would have been involved in observational research, the official figures show that the number of nurse-led cancer trials trails behind comparable countries. For example, Denmark is a similarly sized country with 75 registered nurse-led cancer trials, while Ireland has just seven. Dr McInerney ventured that this is due to factors including a tendency to disregard non-drug treatments, including lifestyle and surgical interventions, and longstanding challenges with staff, including turnover, training and workload.

Dr McInerney recognised that the foundations for conducting nurse-led trials now are well established. There are infrastructural supports to enable nurse-led trials, including the team in the HRB, PPI Ignite, clinical research facilities, the Irish Cancer Society support and other interdisciplinary collaboration and supports. In addition, nurses possess effective communication and patient education skills and are equipped with direct patient insight. Nurses understand the logistics and the pathways essential for trial design.

Regarding enablers of nurse-led cancer trials, Dr McInerney pointed to technological advancements, improved international collaborations, and established research priorities. She highlighted academic research from UCD that has shown nurses involved in conducting clinical trials have increased confidence and competence. She concluded by observing that “the energy that is currently around for conducting nurse-led trials is palpable, and we need to harness that.”



# Panel Discussion: The future for Non-drug trials



The next speaker was Katie Johnston, an oncology research dietitian, who shared details of the LIAM Mc trial, an Irish Cancer Society-funded trial and a UCC-sponsored trial, providing advice and support for men impacted by metastatic Genitourinary cancers. There are over 200,000 cancer survivors in Ireland, and research has shown that their needs, both medical and holistic, emotional and nutritional, are not being fulfilled.

The LIAM Mc trial is a 12-week multidisciplinary programme focusing on peer support and creating a safe environment for men. Participants undertake two physiotherapy sessions per week over the 12 weeks and receive fortnightly dietetic input and cancer-specific symptom management from an advanced nurse practitioner.

The programme also provides additional education sessions for community support, psycho-oncology, social work, pastoral care, occupational therapy, and community support, such as the Irish Cancer Society Daffodil nurses.

The study started recruitment in May last year, and 16 patients have been enrolled to date, with approximately six men per cohort. Ms Johnston explained that the primary outcome is feasibility, but the study is also concerned with quality of life, physiotherapy outcomes, body composition outcomes, and diet quality; “the patient is the central focus, and we are working around them.”

Ms Johnston spoke of how integral PPI has been to the trial, with patients involved from the conception of the study design. Patients give regular, honest feedback and have recently helped to improve the patient information leaflet, creating a new version that is more accessible and user-friendly.

Patient feedback from the first cohort led to significant changes to the programme, including moving the sessions out of the hospital and into a community space.

In discussing the results, Ms Johnston said that the programme improved participants' body composition, muscle mass, and strength and holistically improved their overall quality of life.

Quoting from a patient to illustrate the real-life impact, Ms Johnston shared, “I felt myself coming back. I found the old Frank that I had lost.” This feedback is vital to understanding what this 12-week programme does.

Reflecting on what the team have learned from delivering this complex lifestyle intervention, Ms Johnston focussed on the need for dedicated support and protected time for research, the importance of meaningful patient involvement and the critical need for funding to power research.

Next, Ms Emma Noone, Research Project Manager at Saint Luke's Radiation Oncology Network, discussed how advancements in radiotherapy will shape the future of trials, opportunities in homegrown investigator-initiated trials, and utilising collaboration to progress and keep momentum in a fast-changing oncology environment.

One trend Ms Noone predicts will continue to grow is hypofractionation. Previous studies have shown that hypofractionation is safe and effective, similar to standard radiation therapy. It can lead to improved treatment outcomes and potentially positive economic impacts while being a less invasive treatment for patients. AI will undoubtedly play a role in the future of radiotherapy.

Fundamentally, AI is a computer algorithm, and as radiation oncology and its treatment are interwoven with computing technologies, AI is one of the critical advances that will enable the clinical application and sophistication of adaptive radiotherapy. Future RT trials exploring the benefits of adaptive radiotherapy by improving treatment accuracy and sparing healthy tissues in tighter time constraints will reduce healthcare costs and improve patient outcomes.

# Panel Discussion: The future for Non-drug trials

“In the next 25 years, it's predicted that the typical cancer patient in Europe will be over 70 years of age. Therefore, the cancer patients we consider to be the elderly and more fragile will be the typical cancer patients of tomorrow,” Ms Noone continued. The cohort of older patients is currently underrepresented in RT trials. An increase in trials that include this demographic should be considered to meet the future needs of populations. In addition to delivering international collaborative and combined modality studies, radiation oncology is uniquely placed and experienced in delivering investigator-initiated trials.

There are many benefits to RT IITs as they focus on unmet medical and academic needs, provide an excellent opportunity for PPI, foster collaboration, and promote knowledge sharing. However, challenges include limitations of time, funding, and resources.

The final aspect Ms Noone discussed was collaboration. “Collaboration is and always will be important to future RT studies. Cancer Research and treatment are multifaceted and thus require a multifaceted approach.”

She hopes the RT community will develop and enhance existing relationships, foster new ones, and ultimately promote knowledge sharing and expertise exchange. The future of RT trials holds great promise for advancing cancer care treatment through integrating emerging technologies, assessing and addressing unanswered clinical questions through IITs, and developing collaborative research partnerships.

Ms Siobhan Gaynor opened by sharing with the audience the differences she observed between receiving her two cancer diagnoses. “What I witnessed as a primary breast cancer patient was an amazing service, mainly nurse-led, where I felt supported and listened to, and I was confident that the protocols were adhered to. What I recognised a year later [after being diagnosed with metastatic breast cancer] was that there are no standards, there are no guidelines. There are no statistics.”

Ms Gaynor explained that, with her background as a scientist, she wanted to help address this lack of data and understanding. Patients with metastatic breast cancer and other stage 4 cancers are now living longer and have needs that the clinical community must know how to meet.



Ms Gaynor recognised that a range of patient voices and a credible data set would be needed to effect change, inform guidelines, and shape the services required. With this in mind, she approached Prof Seamus O'Reilly with an idea for a survey to engage other patients about what was important to them and what changes were needed to the available support and services.

That was two years ago, and at the time of the Retreat, two posters on this research were due to be presented at ESMO Breast and two more at ASCO in Chicago.

“Timelines are important, and they are important to patients.” While a randomised controlled clinical trial can take up to ten years from concept to publication, this first-ever patient-led survey that Cancer Trials Ireland worked on took just two years.

This level of commitment and flexibility was critical to the project's success. In terms of outcomes, the survey showed that many of the assumptions clinicians have made about patients with metastatic disease are incorrect. The data collected from the patients surveyed revealed a high degree of commonalities in the self-expressed needs and that quality of life is often more important to patients than length of time.

Ms Gaynor concluded by asking the audience to remember that there are many different approaches to research and that it is critical to include as many voices as possible.

**“Please keep asking if there is a better, faster, or more interesting way to do things. Keep asking questions and keep being curious.”**

# Panel Discussion: The future for Non-drug trials



Next, Prof Leonie Young shared with the audience her experiences with translational research or biobanking, which she has been involved in for many years. At the RCSI Beaumont Cancer Centre, over 5,000 patients are participating in translational clinical trials within the hospital. This provides the hospital with an enormous resource from which to do research that is relevant to the patient.

These patients directly contribute to research by participating. For patients, this can be a method of taking charge of their disease and also hopefully providing information that may prevent future patients from having to go through the same cancer journey that they did.

RCSI Beaumont Cancer Centre is undergoing ISO accreditation, and while the process is expensive and arduous, it will positively affect the ability to share the material collected rigorously. It will also enable hospital staff to use the material collected to provide patients with feedback regarding their management, which may be necessary, for example, if rare mutations arise.

Prof Young continued by telling the audience about the audience about the 09-07 clinical trial with a particular focus on patients that end up advancing to have breast cancer brain metastasis. Almost 5000 patients have been recruited to date, creating the world's largest cohort of matched primary and brain metastatic tumours.

Many clinical trials  
have arisen directly  
from translational  
studies

The study team has also undertaken whole genome and bulk RNA sequencing and uncovered hugely actionable alterations. This is incredibly important for patients with metastatic disease who have not done well on their original therapeutic path.

In brain metastases, 30% of patients change their molecular subtype from primary to metastatic disease. Yet, clinically, most institutions will treat those patients based on what their primary tumour looks like. Unless evidence is found and presented, clinical practice will not change.

Giving a flavour of the national landscape for biobanking, Prof Young shared that it has been transformative to come together as a community to talk about biobanking and to have an iterative or indexing biobank which captures all the biobanking activity that's going on throughout the country.

With other centres nationally, including Galway, now also undertaking ISO accreditation, in the future there will be a collection of cancer biobanking material in Ireland that's all ISO accredited.

Prof Young emphasised that biobanking is real research that makes real-life changes; “this is not tissue that sits in a freezer, and then we do some genomics on it every so often and hopefully get a publication.”

Finally, in conclusion, Prof Young stressed that unless accreditation systems like the Mission for Cancer and the OEI appreciate clinical trials and put them in their metrics for clinical trial activity, they will not be valued by governments and, therefore, the situation will not improve.

# Panel Discussion: The future for Non-drug trials



Finally, in this session, the audience heard from Kate O'Connell, a research support officer at UCC and Cork University Hospital, who spoke about survivorship studies, specifically the LYSA study.

LYSA is an investigator-initiated trial, much based on the National Cancer Strategy and its recommendations for the survivorship cohort.

Recommendation 40 was that every patient get a treatment summary and care plan, recommendation 41 was a needs assessment, recommendation 42 was the development of patient pathways to be shared with other healthcare professionals and primary care, and recommendation 43 was that we had developed survivorship programmes in primary care and through our voluntary and charity sectors.

The study's main objective was to evaluate the feasibility of introducing a women's survivorship clinic incorporating symptom management through electronic patient-reported outcome collection into routine follow-up care in patients with early-stage hormone receptor-positive breast and gynaecological cancer post-primary curative therapy.

The study, which recruited 200 women, also had secondary objectives, including examining symptoms, exploring self-care agency, evaluating endocrine therapy adherence, examining the patient's condition, satisfaction with the service resource, the economic impact of the service, and the impact of a dietetic intervention.

Sharing learning points from the study, Ms O'Connell recalled the impact of the COVID-19 pandemic and the HSE cyber-attack. These events changed some of the approaches taken, including introducing virtual informed consent and clinic visits. Data management employed a hybrid trial master file. Serial electronic patient-reported outcomes were used, along with a colour-coded trigger list for clinical practice.

The PPI voice was very important throughout, with patient advocates involved from the first grant application and throughout the course of the trial.

Ms O'Connell praised the fact that a second site opened in Galway but noted that this caused additional complications regarding the different ethics processes. She reflected on the importance of 'Team Science' in this study, which involved nurses, a dietitian, two PIs, academic research dietitians, liaison nurses, gynae nurses, and other clinical experts.

Feasibility findings from the study were presented at ASCO, and the study team hopes that the data gathered will inform survivorship care in Ireland in the future.

The data from LYSA  
will inform  
survivorship care in  
Ireland.

# Panel Discussion: CTI in 2030 - What does the future look like, and how do we get there?

- Dr Anne Fortune, UCD & The Mater Hospital (Chair)
- Professor Donal Brennan, UCD Gynaecological Oncology Group
- Professor Ronan Cahill, UCD & The Mater Hospital
- Professor Sinead Brennan, Irish Research Radiation Oncology Group
- Ms Ashley Bazin, Team Leader, Tallaght University Hospital
- Dr Grainne O’Kane, Chair of CTI Gastrointestinal (GI) DSSG



We should aim to be a place where academic surgeons can flourish and recruit patients onto trials.

The day's final session was a panel discussion chaired by Dr Anne Fortune on the topic of 'CTI in 2030 – What does the future look like, and how do we get there?'

Introducing the session, Dr Fortune shared reflections from her colleagues at The Mater on what the future will look like. Some key phrases were 'sustainable, embedded, flexible, patient-based, hybrid models, networking and collaboration.'

Prof Donal Brennan started the discussion, sharing that "between 2016 and 2020, it's estimated that approximately 24.5 billion was spent on Cancer Research globally, but of that, the spend on surgical research was about 1.5% of the entire research expenditure in cancer, and the spend on radiation was approx. 2.5%. Between now and 2030 worldwide, 45 million people will require surgery for cancer across the world, and about half of those will need radiation. Little work has been done to understand how to deliver that cost-effectively, safer, and more patient-friendly."

For several reasons, surgeons have not been the most significant contributors to clinical trials. Clinical trials are considered more difficult in surgery, and more institutional input is required to understand how trials can fit into day-to-day workloads.

However, many great examples exist of why we need to do surgical trials. Looking to the future, Prof Brennan identified implementing new technologies safely and measurably as a big challenge. He reflected on the importance of retaining an innovative spirit in surgery to try new things and embedding the idea of doing so in a controlled fashion within a clinical trial environment.

In conclusion, Prof Brennan said, "That is where we need to be in 2030; we need to be a country that provides evidence-based surgical practice and a place where academic surgeons can flourish and recruit patients onto trials."

# Panel Discussion: CTI in 2030



Prof Cahill echoed the importance of new technologies, citing biomaterials, genomics, robotics, data analytics, and artificial intelligence as the advancements that will move things forward.

He reflected that these depend on networks, distributed expertise, and infrastructure instead of individuals, centres, and hospitals buying and using something. For Irish cancer care to lead, the HSE must lead in digitalising services.

He told the audience that in speaking with clinicians, academics, trainees, members of industry, and clinical colleagues, there is a general feeling that the connections within hospitals, between hospitals and between hospitals and other stakeholders are not as strong as they should be.

Regarding AI in operations, the issues are that the response times are very short from prompt to action, and the actions are often irreversible. In the short term, surgical videos may play a role in critical anatomy identification, instrument identification, or comparison of different parts of operations.

Initially, a few minor things may not seem enormously impactful, but nonetheless, some parts of the decision in the operation are outsourced. Within 5-10 years, we could see some semi-autonomous or component steps of operations being done, but this will require a different way of thinking about how things are set up and resourced.

Next, Prof Sinead Brennan spoke about radiation trials, stating that to meet the target set out in the National Cancer strategy of 6% of all patients going on clinical trials, there would need to be 600 patients a year recruited to RT trials. “That sounds like a lot and a far cry from where we are, but it can be done. There are pockets of excellence around the country.”

Speaking of IRROG, she shared that the organisation's mission is to ensure that every patient has equal access to a clinical trial no matter where they live and where they get their treatment, in addition to increasing the overall number of patients on RT clinical trials.

To meet these goals, clinical trials need to be considered a standard of care, and more oncologists must get involved in clinical trials. “There is a clinical trial in everybody and probably an IIT in everybody.”

Prof Brennan acknowledged that the first clinical trial can be challenging; it is hard work, but it becomes more manageable, and with the proper support and mentorship, the number of new PIs can increase.

Prof Brennan went on to praise the energy in the room around improving startup efficiency: “For every month that a trial delays opening, patients are missing out.” IITs answer important academic questions relevant to patients. They raise the standard of care in our hospitals, and a high-quality radiotherapy design plan can increase overall survival.

Increased HRB funding for clinical trials will enable more ‘homegrown’ IITs that meet the needs of Irish patients. Her final point was expanding patient trial access and rolling out trials nationally wherever possible.

**To make an impact nationally, we need more trials and more investigators.**

# Panel Discussion: CTI in 2030

Ashley Bazin highlighted some issues relevant to sites and staff on the ground, particularly clinical trial nurses. The recent steep increase in inclusion-exclusion criteria has created challenges in recruiting to trials. They will also lead to increased screen failures, which are much work for sites and devastating for patients. Consideration must be given to how those patients who fail screening are cared for and what structures or protocols are in place for their needs.

Another issue stemming from the increased inclusion and exclusion criteria is diversity. Much work has been put into ensuring that trial access is fair and equitable and that patients from diverse communities can be accrued to trials. Yet, protocols are becoming more and more restrictive.

Picking up on a theme much discussed during the day, Ms Bazin echoed calls for permanent positions for research staff. She noted, however, that there are other barriers to recruitment than permanent positions.

To attract staff, visibility must be increased within individual hospitals and nationally. One way to achieve this would be to introduce a requirement to spend in a clinical trials unit in nursing education. This would give nurses an insight into the work being done and provide an opportunity to encourage them and get them excited about clinical trials.

Career progression is another barrier.; “We need a promotional structure where our data managers and our nurses can see that there is room to move up the ladder and see this as a long-term choice”, said Ms Bazin.

The importance of funding for translational studies was again emphasised. Ms Bazin noted that for young PIs, translational studies are often the first introduction to creating a trial to a protocol and an opportunity to learn GCP and to get to know the trials team. This contributes to the future of research.

**We must consider  
how we support  
patients who fail  
screening.**



Dr Grainne O’Kane was the final member of the panel to give her thoughts. She began by stating that an ideal ambition for 2030 would be to have a clinical trial for every patient at every stage of their disease, stretching from early detection to survivorship. “Listening to everybody today, it feels like we already have many pieces of the jigsaw here in Ireland.”

There has been much discussion in the community about increasing efficiencies and ensuring that Ireland is an attractive place for Pharma to come and run drug trials. Still, there is a need to ensure that translational components are embedded in every part of trials. Genomics is now considered a standard of care but is still unavailable for many patients.

Dr O’Kane shared that she believes that Ireland should aim for more than the 6% target of patients on trials included in the National Cancer Strategy. Looking to other similar-sized countries, such as Denmark, they have more significant resources in place, such as national biobanks that the government partly funds.

More government support is needed in Ireland to provide patients with the expected level of care. It was noted that Ireland has a strong partnership with pharma, with many companies headquartered here that produce drugs. There should be an opportunity to leverage that partnership to bring therapeutic trials to this country.

Dr O’Kane praised the huge multidisciplinary team involved in trials, which includes oncologists, surgeons, radiation therapists, nurses, and others. As a community, we should seek more opportunities to collaborate nationally, particularly on neo-adjuvant drug trials. We should ensure that patients know what trials are available at all sites, “it is about breaking down barriers. There is no point in clinical trial units operating in silos.”

# Panel Discussion: CTI in 2030

In the Q&A that followed, Dr Fortune mentioned that speed is seen as an issue in Ireland and questioned what can be done and what is being done to address this. Dr O’Kane pointed to the work happening around GDPR and efficiencies as crucial activity in this regard.

Comparisons were drawn between COVID and cancer, as patients were brought onto trials very rapidly during the pandemic, within months of COVID being identified as a disease, which shows that it is possible to move quickly.

Prof Gerry Hanna noted that the key drivers for the fast progress seen in COVID were investing a lot of money and a lot of people and reducing permissions and lead times. The same drivers will be required to see comparable progress in cancer. “Funding for protected clinical academic time should be a core component of that strategy.”

Further remarking on COVID, Ms Clayton-Lea reflected that a critical reason that processes were expedited during COVID was the amount of public pressure on politicians to find a solution. This community has an opportunity to come together in a single voice and put pressure on the government now concerning cancer care, particularly cancer research.

Dr O’Connor noted that within Ireland, there is heterogeneity around trial startup times, in terms of types of cancer, and across institutions. What institutions do differently to achieve these short start-up times must be examined and learned from. Getting top-level support from CEOs and hospitals seems to be one common thread around successful initiatives.

Ms Mulroe echoed these comments, saying that the CEO of a hospital and the DPO often needs to be ‘bought in’ and share the desire to get trials moving quickly.

Prof Donal Brennan raised the issue of surgical centralisation, observing that “we have too much surgery going on for different cancers in different hospitals, and we need to think about surgical centralisation for a particular number of cancers, particularly ovarian and rectal cancer.”

The surgical centralisation that has already been implemented in GI has resulted in massive improvements. Another issue he raised was the medical-legal liability in the country and the challenges that it brings.





# CLOSING REMARKS: PROF SEAMUS O'REILLY



Professor Seamus O'Reilly shared the following thoughts in closing the Retreat for 2024: "I'd like to thank all of our speakers and panellists. We have plenty of food for thought for the next grant application, including the importance of nursing and allied health services and studies for our patients in our community."

He reflected that during the day, we discussed new treatments that are proceeding at pace in other jurisdictions, such as cellular therapies, which we are behind in Ireland. In contrast, we are progressing well in different areas, such as patient-led research.

The importance of the patient voice was again emphasised as Prof O'Reilly shared plans for a co-created survey on prostate cancer launching in the coming months. He referred to the aforementioned plans for a public survey around GDPR, including questions about biobanking and data protection, to determine what the public deems reasonable regarding GDPR for going on a trial or what is deemed sensible for a consent form for a biobanking study.

Sustainability in cancer clinical trials will also be critical looking into the future, "the SHAMROCK trial core activities have been input into a sustainability calculator for a paper that will come out later this year. Integrating these calculations routinely into what we do is essential for making cancer care more sustainable and in a measurable way.

Prof O'Reilly praised the "wonderful" session discussing the importance of lifestyle trials, which are increasingly important as we begin to think more holistically about cancer for Irish families.

In conclusion, Prof O'Reilly stated that the goal of Cancer Trials Ireland, concerning the current grant cycle and all future grant cycles, is to leverage as much as possible for patients and communities. "The great ideas shared today and the many voices we have heard will be integrated and synthesised and used to advocate for patients, cancer clinical trials, and our community."



“The great ideas shared today and the many voices we have heard will be integrated and synthesised and used to advocate for patients, cancer clinical trials, and our community.”



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

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