Irish Society of Medical Oncology

cancer trials ireland

Together, we're finding answers to cancer.

REPORT

NATIONAL TRAINING DAY 2025

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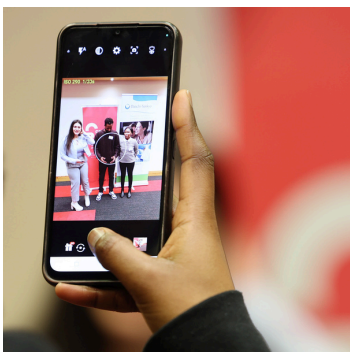

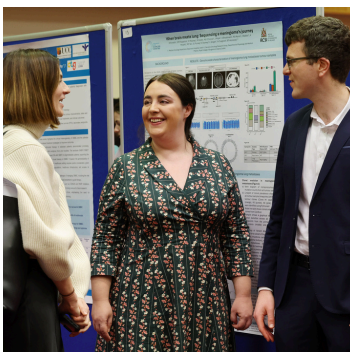

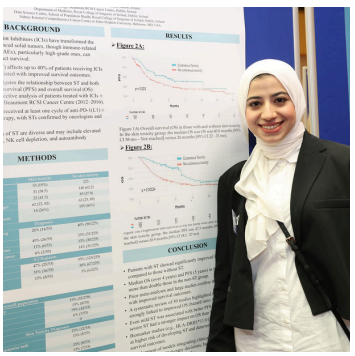

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KEY TAKEAWAYS & ACTION POINTS

Early involvement

- Trainees should ideally become involved in clinical research at an early stage in their careers but the demographics of the medical workforce are changing. As a result it is becoming more diverse, a hugely positive development.
- Mentorship is crucial to encouraging and empowering trainees to partake in clinical research. This would ideally be an organic relationship but a more structured approach also works well.
- Successful involvement in clinical research allows trainees to gather essential skills for use later in their career.
- A culture of clinical research inspires younger colleagues and ensures succession.

Funding

- Ireland needs new funding models if it is to compete globally in clinical trials research.
- The health service does not directly fund clinical research but the acknowledgement of clinical research within the Programme for Government is a positive step.
- Fellowships, bursaries and grants are available and should be maximised and new funding sources explored.

Training

- While fellowships that allow trainees to carry out clinical research abroad are critical for building international relationships and bringing expertise back to Ireland, more opportunities are opening up here for trainees keen to get involved in research.
- Fellowships that allow protected time for research are essential - the number of these must be increased.

Collaboration

- Collaboration whether it is between institutes, countries, research networks or between disciplines is crucial to improving the quality and output of clinical trials.
- Trainees must begin to grow their networks from an early stage by joining working groups, attending international meetings, and joining research networks.
- Nurses, radiation therapists and other allied health professional involvement in trials must be encouraged.
- Public and patient involvement (PPI) is now an essential part of clinical research from the earliest stages and while there are challenges, it ensures trials are designed that will recruit and retain the required numbers while producing relevant outputs for the patient population.

Benefits

- Trainees benefit from involvement in clinical research in a plethora of ways. From learning key laboratory skills to writing grant applications to building their network nationally and internationally, the gains are enormous. Many also spoke of how research involvement gives them time to reflect on their work outside of their busy clinical schedule.

INTRODUCTION

The Cancer Trials Ireland annual Training Day offers a unique opportunity for trainees to learn from leading experts, share their research, and connect with peers.

This year for its second iteration Cancer Trials Ireland joined forces with the Irish Society of Medical Oncology (ISMO) to host a joint Training Day 2025, which had almost 200 in-person attendees with many more viewing the day's proceedings online.

The opening session featured a welcome from Angela Clayton-Lea and Professor Michaela Higgins, setting the stage for insightful discussions and knowledge-sharing. This was followed by 20 oral presentations from trainee oncologists, showcasing cutting-edge research and advancements in oncology.

Ms Angela Clayton-Lea opened the meeting by noting that the number of patients on cancer trials in Irish centres continues to grow year on year - in 2023 there were 1,860 patients participating in a trial but figures for 2024 show a steep increase to more than 2,800. Merging with ISMO for the Training Day this year was an easy yes, she said. "Collaboration is at the heart of what we do in Cancer Trials Ireland."

"Today is a culmination of many years of trying to integrate trainees into what we do in Cancer Trials Ireland, exposing what we do to the training environment," said Professor Seamus O'Reilly.

ISMO President Professor Michaela Higgins noted the huge response to calls for abstracts from the NCHD community - with 57 abstracts submitted, a more competitive process had to be initiated that ultimately selected 20 doctors to deliver oral presentations while the remainder participated in the poster presentation.

Bursaries were awarded to the best in each category. For the poster presentations Ruth Kieran and Rachel Dillon were the winners, while for the oral presentations Ruth Hutch, Gavin Dowling, Clara Forrest, and Sean O'Moore Davis were recognised.

NCHD PRESENTATIONS

Cyclin dependent kinase 12 as a potential therapeutic target in HER2-positive breast cancer. *Gavin Dowling, Beaumont Hospital*

Clinical impact of anti-EGFR rechallenge in RAS/BRAF wild-type metastatic colorectal cancer. *Dermott McMorrough, Mater Misericordiae University Hospital*

Effect of COVID - 19 on incidence of De Novo and Relapsed Breast cancer - 10 years Review – Institution/Medical Oncologist experience. *Abdullah Mohammed, University Hospital Waterford*

Are routine steroids required to prevent significant nausea in patients receiving low-dose cisplatin? A retrospective chart review. *Liam Moran, University Hospital Galway*

Quantifying the Public-Private Reimbursement Gap: A Retrospective Analysis of 154 EMA-Approved Anti-Cancer Drugs in Ireland's Healthcare System. *Raisa Berzina, University Hospital Galway*

A prospective translational study, investigating the association of gut microbiome (GM) diversity with pathological complete response (pCR) after neoadjuvant treatment (NAT) in early-stage breast, rectal and esophageal cancer – A trial in progress. *Rachel Clarke, Beaumont Hospital*

Immunotherapy-mediated Sarcoid-Like Reactions in Solid Tumours: A Case Series. *Maggie O'Connor, Beaumont Hospital*

Acceleration in the rate of Practice-Changing Publications guiding Systemic Treatment of Advanced Cancer: A Review of Landmark Studies (1994–2023). *Divya Edappazhathil, University Hospital Galway*

Characterising the genomic landscape of anaplastic thyroid cancer: an integrated analysis. *Ruth Hutch, St James's Hospital*

A Retrospective Review of Peritoneal Portacaths for Malignant Ascites: A Potential Alternative? *Cormac O'Flaoinn, University Hospital Waterford*

Circulating cell-free DNA for colorectal cancer screening. *Finbarr Conroy, Mater Misericordiae University Hospital*

Radical chemoradiotherapy for cervical cancer: introduction of GCIG interlace into an Irish tertiary cancer centre. *Emma Pounder, University Hospital Limerick*

An evaluation of the utilisation of biosimilar monoclonal antibody drugs in Ireland and barriers to their usage. *Kate Coakley, Beaumont Hospital*

Impact of the addition of carboplatin and pembrolizumab to neoadjuvant chemotherapy (NACT) in triple negative breast cancer (TNBC): a large, retrospective, two-centre, real-world study. *Karolina Weiner-Gorzel, St Vincent's University Hospital*

NCHD PRESENTATIONS

Utilizing a targeted 50-gene NGS panel testing to identify actionable alterations and define the genomic landscape in patients with solid tumors. *Aonghus McCarthy, St James's Hospital*

Trial in progress: A multicentre single arm phase II trial of domvanalimab (anti-PD-1) and zimberelimab (anti-TIGIT) in patients with NSCLC with CNS metastases (PROTECT). *Orla Fitzpatrick, Beaumont Hospital*

Challenges around tissue testing for BRCA mutations in routine clinical practice for prostate cancer. *Trishhani Yogaretnam, Tallaght University Hospital*

'Is it my last Christmas?' Using real-world data as a prompt to reflect on goal-concordant advanced lung cancer care – a retrospective, longitudinal study. *Clara Forrest, Cork University Hospital*

Picture This! Using Visual Aids to Improve Communication between Oncologists and their Patients. *Shauna Moore-Davis, University Hospital Galway*

Falls in Cancer: Modifiable risk factors to improve cancer outcomes for elderly patients. *Christopher Cluxton, University Hospital Waterford*

SESSION ONE: INTEGRATING TRAINEES, RTS AND NURSES INTO RESEARCH

Chaired by Dr Michael McCarthy, this session explored how oncology trainees, radiation therapists, and nurses can play a greater role in clinical research, featuring insightful presentations from experts across the field.

Collaborative Opportunities - Professor Declan Devane, HRB TMRN

The HRB-Trials Methodology Research Network (HRB-TMRN) is a collaborative initiative between a number of Irish and international university partners and its mission is to strengthen how they plan, do and share the findings of trials in Ireland with a view to having an international impact. This will mean, Prof Devane explained, that the trials the network is involved in will be better in terms of how they are conducted, better planned and designed, and better reported and usable for decision-makers.

There are four core pillars of activity that underpin the work of TMRN, namely support, training and education, research and innovation and public and patient involvement and engagement. "There is evidence to demonstrate that the HRB TMRN has helped create a culture shift in understanding of trials methodology and how we advance knowledge and share the findings of randomised trials," Prof Devane said. Grant application support is offered, which is focused primarily on embedding primary trials methodology questions or work practices within Grant applications. The HRB TMRN has helped more than 100 applicants to date in this way. But there are various support levels to meet different needs, and critically they offer partnerships across a large number of international consortia, networks and initiatives.

The network can also facilitate introductions to working groups that specialise in specific areas relevant to trials methodology and there are opportunities for irish partners to become involved at all different levels.

Dr Michael McCarthy

Prof Declan Devane

"Joining a working group offers an opportunity to build on the achievements of the broader collective network while also opening up and exploring a new collaborative opportunities and avenues," Prof Devane explained.

In terms of research and innovation, members of HRB are leading or collaborating on a number of impactful primary trials methodology research projects. They led on the Priority I study, which is prioritising recruitment in randomised trials, which explored the top 10 questions about methodological uncertainties, and are currently leading the Priority II study, which is looking at the top 10 uncertainties about how to better retain trial participants.

While the core outcome seed funding call has recently concluded, there are opportunities with "SWAT" or study within a trial funding. This is a "brilliant vehicle" for embedding primary trials methodology within a trial and the studies are inherently cost effective as they are part of a trial.

Public engagement is a priority and HRB TMRN partners lead out work within other institutions on public involvement and engagement, Devane explained. This includes the START initiative, which asks primary school children to plan, design, and execute their own randomised controlled trial. Training and education is a core activity of the network, and they have run many training events across partner sites that have been attended by more than 30,000 stakeholders, while hundreds of hours of very high quality training has been recorded and is available on their website.

Conducting a PhD in Clinical Research: Lessons Learned - Dr David O'Reilly, Beaumont RCSI Cancer Centre

Clinical research fellow Dr David O'Reilly offered an insight into not only his ongoing research but the process and the pathway towards gaining a PhD in clinical research. His PhD is broadly focused on improving outcomes in non small cell lung cancer (NSCLC) using non-invasive diagnostics and novel biomarker discovery. The PLAN (PLAsma genomic testing in Patients with Advanced Non-Small Cell Lung Cancer) study spans the patient journey from the time of initial diagnosis to initial therapy and second-line therapy and is aiming to improve patient time to diagnosis as well as the accuracy of their diagnosis. Its primary objective is to establish the feasibility of liquid biopsy for genomic diagnosis and targeted therapy selection where there is a radiological suspicion of advanced lung cancer.
Results have already shown that the introduction of liquid biopsy resulted in a three week reduction in time to genomic report. "This time is so important for patients with advanced lung cancer," said Dr O'Reilly.

With his team, he is also working on improving the experience of patients at the time of receiving first-line therapy for advanced disease. The transitional study BRAND (Biomarkers of Response to Immunotherapy in Advanced Non-small cell lung cancer using Dynamic breath and blood analysis) builds on Prof Hennessy's work in studying exhaled breath concentrate (EBC) in lung cancer patients, which has demonstrated enhanced sensitivity compared with plasma for the detection of EGFR mutations. The central hypothesis of the study is that reductions in circulating tumour (ct)DNA measured 3-6 weeks post treatment commencement can be used to predict clinical benefit to treatment for patients with NSCLC receiving immunotherapy. Initial results suggest that EBC ctDNA at three weeks does indeed predict the benefit of pembrolizumab.

Dr David O'Reilly

Dr O'Reilly and colleagues are also working to define strategies to minimise toxicity of combinations in the second-line setting. "All of these contribute to the ultimate goal, which is to improve outcomes in NSCLC using non-invasive diagnostics and novel biomarker discovery."

Mentorship is an essential component of Dr O'Reilly's work, and he praised his three mentors in the Beaumont RCSI Cancer Centre, Prof Jarushka Naidoo, Prof Bryan Hennessy and Dr Sinead Toomey. Collaboration is key to successful research, and he noted he has gained the opportunity to collaborate with colleagues in biostatistics and molecular pathology, and benefited from the support of the Cancer Clinical Trials Unit and Cancer Trials Ireland. He has also developed important skills in clinical research such as study set-up and multi-site study management, laboratory work such as PCR and flow cytometry and genomics, and biostatistics such as meta analysis The process has allowed him gain experience in grant writing, which is "challenging and arduous" but will ultimately be "very valuable" throughout his career. Dr O'Reilly also noted that his research has also helped him truly understand the importance of PPI in research.

While the three branches of his research could have tangible impacts on the experiences and outcomes of lung cancer patients, Dr O'Reilly also spoke of the personal value he has gleaned from his research work. "It is an opportunity to innovate and exercise critical thinking, and also offers a bird's eye view of our healthcare system and the broader field," he said. "Often in clinical practice, we are so busy with the day to day so it's good to have an opportunity to reflect."

Integrating Student Radiation Therapists & Nurses in Research - Ms Roisin O'Maolalai, St Luke's Radiation Oncology Network

The role of radiation therapists (RTs) within radiation oncology research is finally beginning to expand, Ms O'Maolalai told the audience. While radiation tends to be one of the lesser known modalities in cancer care, some 50 per cent of cancer patients require radiation therapy at some point in their cancer treatment and 40 per cent of cancer cures are attributed to radiation therapy. Technological advances in radiation oncology now make it possible to treat sites that were previously deemed untreatable, allow individualised treatments, and deliver ablative doses of radiation therapy to disease sites where surgery would have been the only curative option

There are currently 753 CORU registered RTs in Ireland with 300 working in the public sector and currently it is the only four year degree in Ireland focused on cancer treatment. A radiation therapist is an expert oncology healthcare professional with clinical responsibility for precise administration of radiation therapy and also functions as the main point of contact with patients during their visits to radiotherapy. "They are highly trained and specialised in cancer care, detail oriented, and focused on improving cancer outcomes, meaning they are an excellent resource for cancer clinical trials." The goal now is to maximise this resource by raising the profile of clinical trials among the working profession and creating career progression within the research RT role.

One initiative that sought to introduce radiotherapy students to clinical trials saw a structured timetable devised for the student clinical trials unit rotation to maximise learning opportunities. A survey was designed to collect student feedback on their experience and it was found that 90 per cent of the students had never spent time in a clinical trials unit before, while 54 per cent of students did not know that RTs could work in clinical trials prior to their CTU rotation.

Ms Roisin O'Maolalai

100 per cent of the students reported that it was worthwhile for students to spend time in CTU during their clinical placements, said Ms O'Maolalai. "The survey results aided us in formalising time spent in CTU as a formal aspect of clinical placement."

The Irish Research Radiation Oncology Group (IRROG) is also working on raising the profile of CTU among qualified RTs via conferences and meetings, as well as social media output and this is bearing fruit, she added; during a time of extreme staff shortages, there were 10 applicants for the most recent CTU RT post at SLRON.

In terms of career progression the role of the Advanced Practice Radiation Therapist (APRT) has now been established following a review of the profession and a working group established to launch an APRT pilot programme. IRROG and CTI are working together to increase trials across all RT departments, Ms O'Maolalai said.

"We need specialised RTs in our clinical trials units and we also need all RTs to be research RTs: aware of all clinical trials ongoing in their department, involved in the development of new clinical trials, and implementing the findings of research to continue to improve cancer patient outcomes in Ireland."

Trainees' Research Experience - Dr Jill Nicholson, St Luke's Radiation Oncology Network

Dr Nicholson is currently the St Lukes Institute of Cancer Research Fellow, having completed the Radiation Oncology Specialist Training scheme in 2023. This radiation oncology training scheme is based at centres in Dublin, Cork and Galway. Formal research training on the scheme includes several days of problem-based learning, as well as a comprehensive course centred on educating trainees on the practice of evidence-based medicine.

The overwhelming themes that emerge in the medical literature pertaining to the involvement of trainees in research are early involvement, and also the issue of perceived barriers, such as time, funding, and mentors. Relating to the latter, Dr Nicholson echoed the sentiment, saying good mentorship programmes are crucial.

A survey of radiation oncology SpRs on their experience of clinical trials had many positive findings, such as that 100 per cent of respondents had had some exposure to clinical trials. While 82% had moderate experience assessing and reporting toxicity, just 45% had completed baseline data forms. And while 73 per cent feel supported by the trial team, 73 per cent highlighted barriers to research involvement such as being too busy with clinical work and the burden of added paperwork. Despite these, some 82 per cent want to engage in clinical trials in the future. Dr Nicholson echoed Ms O'Maolalai on the positive impact of IRROG, which has made more trials available to radiation oncology trainees.

Her own experience was that she did become involved in research early on in her career but had no time, funding or consistent mentorship. Now as a clinical research fellow awarded by St Luke's Institute of Cancer Research, she has access to "amazing support and facilities" as part of the trimodality fellowship and a 75/25 split between research and clinical work, respectively. She is also able to take on extra research-linked activities, such as being a trainee editor with RCR Clinical Oncology Jounral, partaking in Royal College of Radiologists question writing and an overseas observership.

Dr Jill Nicholson

She is now leading an investigator-initiated trial as part of the fellowship, which offers the opportunity to answer a clinical question. The Open Trial is a comparative randomised clinical trial evaluating the setup accuracy and patient experience of faceless radiotherapy masks versus conventional full-face masks for head and neck radiotherapy patients. While the primary endpoint is the setup accuracy, the secondary endpoints include the patient experience. "Our first question was are they safe but our second question was does that matter if patients aren't happy with them?" explained Dr Nicholson. She is involved in the statistical analysis, database, randomisation, design, monitoring, timelines, PPI, and trial registration, and she advised those trainees involved in research that many of these are "moving parts" that can be worked on in parallel to speed the process up.

Dr Nicholson's advice to her fellow trainees is that they should understand which trials they are registered on as there may be several they are not aware of. Networking is also critical. "It is so important to interact and engage with all the stakeholders that can play a role in clinical trials." She also noted the social aspect of being involved in research and opportunities to network and collaborate with clinicians and researchers in other institutes. For Nicholson, the rewards far outweigh the challenges. "There is lots to be gained and lots to learn."

Expanding RN-led Research - Ms Caitriona Duggan, University of Galway

As an advanced nurse practitioner (ANP) in oncology at Portiuncula Hospital and PhD candidate, Ms Duggan outlined how she became involved in clinical research. Although research is included in the ANP Practice standards and requirements as set out by NMBI, she explained that systematic reviews show that to date there have been very few interventional studies and systematic reviews where nurses are the principal investigators.

Ms Duggan's research career was kickstarted when she became the joint recipient of the Cancer Nurse Research Award from the Irish Cancer Society, alongside her supervisor, Dr. Peter Carr, from the University of Galway. With the success of this grant funding as well as organisational support from the Saolta hospital group and Portiuncula Hospital management, a pathway similar to a research fellowship was developed that would allow Ms Duggan to conduct a PhD on a part-time basis with protected time and maintaining her clinical privileges.

Nurses must begin by identifying the research question, such as clinical gaps or areas in cancer care that need more investigation. Securing funding can be the biggest challenge, but there are available funding sources, including grants and scholarships. For nurses, balancing their clinical duties with the demands of a PhD programme can be difficult. In keeping with one of the emerging themes of the day, Ms Duggan emphasised that collaborating with experienced researchers and mentors is "crucial" to success.

Her project is focused on the use of vascular access devices for the delivery of systemic anti-cancer therapy (SACT). While 75 per cent of SACT is delivered through the intravenous route, it is known from many studies that one in four peripheral intravenous catheters (PIVC) fail, while they can cause other complications such as phlebitis. "This is a huge cost to the health service but also a huge individual cost to the patient - we knew we could do better," stated Ms Duggans.

Ms Caitriona Duggan

The randomised controlled trial involved the use of ultrasound to improve first-time insertion success, compared to the traditional method of "touch and feel". The first step was evidence synthesis via a scoping review; Ms Duggan ultimately conducted the largest scoping review in this area, involving 240 papers across 32 countries and with 38 unique complications. This scoping review was published in Critical Review in Oncology/Haematology. This will be followed by a Cochrane systematic review, which is being carried out in conjunction with a large group of international and European collaborators and should be published later in 2025. The interventional portion of the study is entitled "Effectiveness of Ultrasound for Peripheral Intravenous Cannulation in Oncology Patients"; this is currently awaiting ethical approval and hope to begin recruiting imminently. Ms Duggan again emphasised the importance of mentorship and organisational support but also highlighted "personal motivation" as a critical success factor.

PANEL DISCUSSION

The morning session concluded with a panel discussion featuring all speakers and Prof Seamus O'Reilly. Prof O'Reilly asked whether peers are motivated by others' research success? Dr Nicholson is in the position of being part of a trimodality fellowship with medical oncology, surgery, and radiation oncology, and she explained that this allows for increased output. "We have been able to support some of the trainees to become involved in projects," she said. Duggan noted that in nursing it is seen as "aspirational or inspirational" to carry out a PhD but currently their career structure is capped at ANP, "the incentive to go down the route of the PhD isn't necessarily there".

O'Reilly noted there are increasing opportunities for trainees to be involved in investigator initiated trials and as the landscape changes there will be more people becoming involved in research. O'Maolaiai says with radiation therapists, it is evident there is increasing interest in research positions and advanced practice roles as part of research are now being offered. "This is really positive for radiation therapists looking to progress and provides an opportunity to encourage people to stay in Ireland and gain research skills here." Dr Nicholson agreed: "Now with more protected time, more funding and more mentorship available, people may choose to stay here instead."

The challenges and opportunities of incorporating PPI into research were also highlighted. Ms O'Maolalai said compensation for patient participants is needed to adequately reward them for their time but noted that it would also help encourage more patients to become involved and allow for diverse patient voices.

Ms Duggan stressed the importance of a clear plan for patients so that expectations are set; "this avoids conflict in the future". Prof O'Reilly said PPI is not simple or straightforward, and specific training is required in order to learn how to do it properly - the RCSI has a course in PPI, which helped him personally to gain a better understanding of how PPI works and should work in practice.

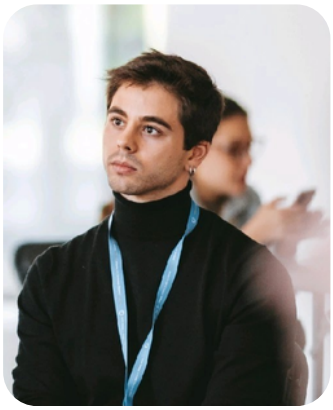
Commenting from the audience, Prof Roisin Connolly said there will be a balance needed - while exposure to skills and experience abroad will be necessary to enrich Ireland's research landscape, the growing number of opportunities here is to be welcomed. "Cancer is going to increase by 70 per cent in the lifetime of the young people in this room," said Prof O'Reilly. "We need more people to look after patients in our communities, so the more flexible the training programmes are and the more diverse the workforce the better that will be." The take home message was that structured, protected research time is needed and more protected posts like the Breakthrough Cancer, Irish Cancer Society and Friends of St Luke's posts are integrated into our healthcare delivery. "These are transformational as they can influence the careers of your colleagues and the people that come after you." The "importance of breaking down barriers" so that trials can be shared and opened in other centres across the country was also highlighted.

There is work happening at a national level on this. The National Clinical Trials Oversight Group has been established, which includes 30 different representatives. They have made interim recommendations and will do a workforce mapping exercise to look at research nurses networks through the country.

SESSION TWO: LEARNING FROM OURSELVES AND OTHERS

Chaired by Prof Seamus O'Reilly, this session focused on learning from a diverse lineup of local and international experts to enhance oncology research and training. Speakers shared insights on clinical trial design, social media engagement, patient referrals, and expanding academic research.

Prof Seamus O'Reilly



Mr Sergi Fayos Villalta

Simplifying Patient Referrals - Mr Sergi Fayos Villalta, Trialing

Mr Fayos Villalta is a member of the Trialing team, a group of oncologists who aimed to tackle one of the main challenges they were experiencing in their clinical practice, which was identifying suitable trials for their patients and referring them to the right centres. "As oncologists you all know how time consuming and frustrating it can be."

The solution they have developed is Trialing, a free platform that makes this entire process easier and faster by allowing oncologists to determine the most relevant trial for a patient almost instantaneously. The platform then allows the oncologist to easily contact the centre running the trials and receive a response within 24 hours. If there is no response, a member of Trialing's team follows up on the oncologist's behalf.

Each of the trials on the platform has been evaluated by Trialing's medical team and they have also created a key data summary for each one. Oncologists based in Ireland can search trials in Ireland but also those taking place across Europe. "We have gone from not even knowing which trials are even available for our patients to sharing the clinical data of my patient and contacting the most appropriate trial site within two minutes," explained Fayos Villalta. "It offers unprecedented efficiency and there is a dedicated group of clinicians available for support every step of the way."

It was announced that Cancer Trials Ireland now actively recommends Trialing as the primary platform for oncologists to search for clinical trials and make referrals and the platform is now fully functional in Ireland and ready to use. During his presentation, he demonstrated how to use the tool. "The value of the platform is its simplicity and ease of use."

Trialing website: https://trialing.org/

Social Media Advice for Trainees – Mr Eoghan Cooke, University College Cork/National Clinical Trials Office

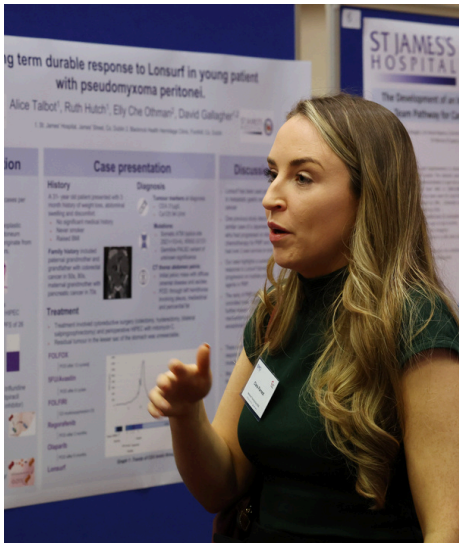
While social media can seem overwhelming, it can be a powerful tool for those involved in research, explained Mr Cooke. As a first step, he advised researchers to think about what they want to say and who they want to reach; "it is crucial to identify your audience".

LinkedIn is a fantastic resource for a professional audience, while for more patient-facing and public engagement platforms like Instagram and Threads have a significant reach. LinkedIn is best for more technical information, while Instagram lends itself to more visually appealing trial content.

The National Clinical Trials Office uses the Linkedin platform as a "storefront" for clinical trials in Ireland and has grown its reach significantly with consistent posting of quality content. It now has more than 2,500 followers on LinkedIn, from an original base of almost none, he pointed out.

Mr Eoghan Cooke

Originally a recruitment tool, Mr Cooke explained that it can help trial teams that are recruiting for team members by amplifying their message. He also advised researchers to use the articles feature, which drives engagement. A master file that can be easily modified means that teams can plan ahead, and reuse and recycle content. "You do not need to produce fresh content every week." He advised using faces wherever possible, to personalise the message. "Experiment to find out what works and use human faces where possible as this enhances engagement and makes it feel less corporate."



Developing and Encouraging Clinical Research in an Acute Hospital - Mr Alan Sharp, Designated Group CEO of the Bons Secours Hospital System

As a previous CEO of the Mater Hospital, Mr Sharp outlined his experience of working with the Clinical Trials Research Unit (CTRU) there. He noted that since 2019, the hospital has seen a doubling in the number of patients admitted for cancer. Research is a critical component of their treatment, he said; "we need research that delves into a space that nobody else has really looked at or is looking for a breakthrough that can translate back down onto the floor, where the patient will find that benefit very quickly."

While the Mater Hospital is involved in many phase III and phase IV studies, it has recently opened the door to participation in phase I early stage clinical trials, ensuring earliest possible access to groundbreaking therapies in oncology. The development of START, the early cancer phase trials unit, not only means patients can access these drugs on average eight years earlier, but it also creates a pipeline for the other phases of the research at the very earliest stage, Mr Sharp explained.

While people participate in trials for altruistic reasons, personal reasons and even financial reasons, in his opinion, the biggest barrier to clinical research is finance. In the five years he was CEO of the Mater Hospital, he spent approximately €2 billion on the prvery little from the HSE for research. "Without high quality clinical trials you won't have high quality care, it is absolutely essential for driving your health system forward." Clinical trials offer access to new treatments, additional supports and the potential to improve care for others, he noted, but it also provides hope for the patient, their family and their loved ones. "The literature always leaves out the word hope," he said. "When a patient goes on to a clinical trial, it provides them with a little bit of hope."

The success of clinical trials is built on networking and relationships and it is Mr Sharp's opinion that fellowship schemes are hugely important. "It allows you to create those networks and relationships and offer opportunities to learn. You don't just bring the knowledge back, you bring the relationship back."

Mr Alan Sharp

Building strong working relationships is a lifelong endeavour for doctors. Strong leadership is also essential. "You need leadership that sees beyond what the system is looking for and looks at what the system needs in the future."

Within the hospital environment, researchers need to be united in a single unit, fostering that culture of interdisciplinary collaboration. It is also crucial to create an innovative environment, one that is exploring assistive technologies and artificial intelligence. "This all feeds into a culture of innovation and research."

What is stopping Ireland from being able to compete on the world stage when it comes to research is ample investment, Mr Sharp believes. Every hospital, he said, should have a Research Board in order to drive research and ensure funding is ringfenced. "The more research you do the more opportunities you have."

The new consultant contract does mention research but he sees it as a "missed opportunity". Recruiting consultants for START has required an ad hoc approach, attempting to current contracts while maintaining indemnity for consultants and their access to patients. As START begins to deliver trials at scale, these mechanisms will need to become more sophisticated.

As he concluded, Mr Sharp noted that the research unit at the Mater Hospital was not funded by the Department of Health, it was the Department of Education. "You're using all of the infrastructure of healthcare but very little money comes that way. It all comes through the academic side."

Medsir Activity Overview and Potential Synergies - Ms. Federica Turrisi, MEDSIR

An international company that focuses on the design, development, and management of independent and collaborative research in oncology, MEDSIR was founded by a group of breast cancer specialists in 2012. Ms Turrisi explained that it helps connect pharmaceutical and biotech companies. It acts as a CRO in Spain but in other countries it subcontracts other CROs or operative networks.

MEDSIR has developed more than 60 studies during the past 13 years, involving more than 2,000 patients along 187 hospitals. While originally it focused on breast cancer trials, in recent years it has expanded to include trials in lung cancer and brain cancer, among others.

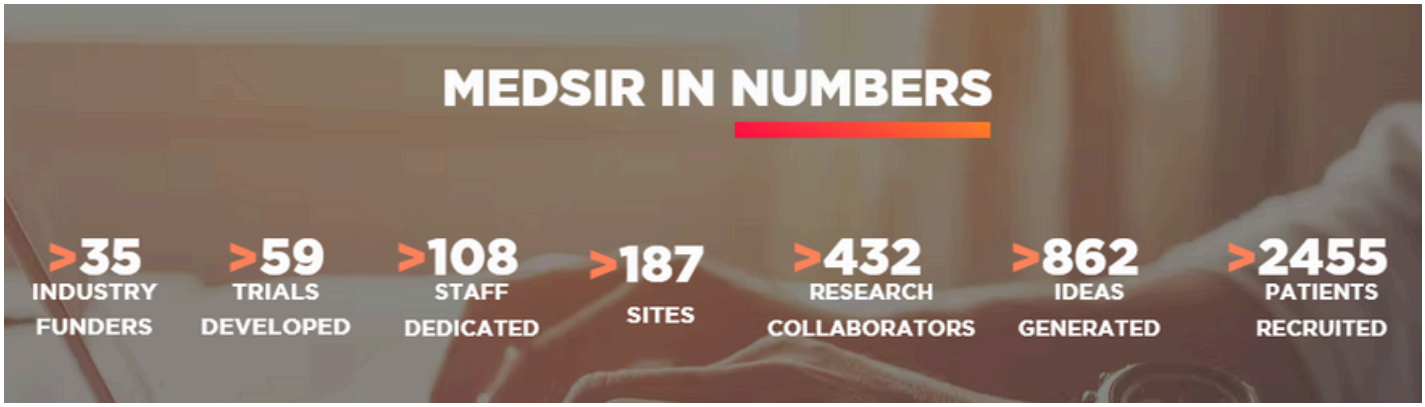
Its network includes more than 400 oncologists based all over the world. To date, it has secured more than €160 million for its trials. While it is a commercial entity, Ms Turrisi noted that the relationship between MEDSIR and the oncologist is not financial and the intellectual property related to the trial belongs solely to the oncologist. The trials cost slightly more to run, but this is a reflection of their quality, she added.

MEDSIR provides collaborative, consultative clinical trial support designed to drive a real impact beyond a single study. "As it was founded by clinicians with expertise in oncology, our company knows the challenges of studying cancer and the opportunities that come from supporting investigators."

Ms. Federica Turrisi

The organisation also offers research preceptorships, think tank meetings and brainstorming sessions.

Ms Turrisi outlined a number of studies that MEDSIR has been integrally involved in, such as Tuxedo-3, which evaluated the intra-/extracranial efficacy and safety of HER-DXd in pretreated metastatic breast cancer and non-small cell lung cancer with brain metastases. She also highlighted a number of potential Cancer Trials Ireland-MEDSIR synergies, such as the strategic evaluation, funding procurement and development of investigator-initiated trials. Their role, she explained, is helping to "strike the balance between the clinical need in your hospital and what the funders want".



Methodological Innovations In Myeloma Clinical Trials Research, An Early Phase Perspective - Dr Andrew Hall, University of Leeds

A biostatistician from Leeds Institute for Clinical Trials research who works on a number of investigator initiated and charity funded studies. Dr Hall outlined his role in providing statistical and logistical oversight from study inception all the way through to publication. He has worked mainly in multiple myeloma, a condition for which there is no cure, but there have been significant advances in treatments over the past few decades. Since the advent of targeted therapies for multiple myeloma at the turn of the millennium, risk stratification has become essential, and a frailty assessment dictates how they proceed with first line treatment. At diagnosis, Dr Hall explained, approximately 25 per cent of multiple patients can be identified, using cytogenetics, to have inferior survival (i.e. are high-risk). Additionally, standard-risk patients, with detectable disease (minimal residual disease (MRD)-positive) post autologus stem cell transplant (ASCT), fare worse compared with those who do not (MRD-negative).

The Leeds Clinical Trials Research Unit myeloma portfolio includes early and late phase haematology trials. Early phase studies are run through the UK Myeloma Research Alliance Concept and Access Research Programme (CARP), an initiative funded by Myeloma UK. As the methodological lead for the early phase portfolio, Dr Hall explained that he exercises "joined up thinking", as when designing early phase trials he is trying to feed into the late phase strategy. This methodological expertise is underpinned by infrastructure funding which includes capacity development, PPI and EDI. Its large late phase portfolio, funded by Cancer Research UK includes Myeloma XI, XIV and XV; with Myeloma XI until recently the biggest myeloma trial in the world.

The Phase I PROMMISE trial is the first platform clinical trial developed through CARP. A platform trial has the flexibility to add and drop study arms, by design Dr Hall explained.

Dr Andrew Hall

They used an adaptive Bayesian design to determine the recommended treatment dose with a toxicity rate between 20 and 34 per cent, and allocated patients based on observed toxicity. The model-assisted design gives pre specified decision criteria for dose escalation. This is an example of a "pragmatic" trial design, noted Dr Hall.

A further example of methodological innovation include an external comparator design in a setting where it was unethical to randomise high-risk patients to a treatment that simply would not work for them. "You can overcome these barriers by comparing their new data to their historical data in this setting." The phase II OPTIMUM MUK nine study used external control data from the Myeloma XI study. Patients were involved at the design stage, they used historical data to make strong estimates of what improvement in progression-free survival would be. "We could see that the proportion of patients alive at 18 months is greater than the external control arm with a really high degree of certainty. " The study, beyond its fantastic clinical results, recruited over a year ahead of schedule and this was due to the high unmet patient need.

Dr Hall noted that external control trial designs are not going to replace an RCT, which will remain the gold standard, but can significantly improve the quality of single arm trials designs which traditionally have had a pooper reputation due to inherent confounding. Prof O'Reilly agreed it is a scenario that will become more common over time, particularly in rarer cancer subtypes, as the study population becomes smaller and smaller.

Expanding Academic Research in Ireland -Professor Peter Doran, Director of University College Dublin Clinical Research Centre

"Sometimes it seems as if the system puts the academic environment, the university environment, and the health environment at loggerheads," Prof Doran said, noting that the original Sláintecare report does not even mention universities, "despite producing the doctors and nurses that work in the system". Everyone in health should be open to collaboration and in clinical trials this is even more important "if we want to do better trials", he said, noting fruitful collaborations with colleagues in fields as diverse as archaeology and mathematics.

The global clinical trials market is worth $65 billion and has more than three million employees across CRO, academic and hospital sites, meaning it is a significant contributor to economic activity. Clinical trials unequivocally improve patient care, enhance safety and effectiveness and drive innovation. Through rigorous scientific study, researchers uncover new insights that lead to better healthcare practices and outcomes and allows evaluation of relative effectiveness of different treatments or interventions. They also help a health system attract and retain the best staff. "The importance of clinical trials cannot be understated."

Globally, there are 450,000 trials registered of which oncology accounts for the largest proportion at 35 perr cent. Despite these "extraordinary numbers", however, biomedical and clinical research globally is at a time of great threat. For the last 40 years the vast majority of advancements came from US-funded research but this landscape has changed significantly over the last 15 years. China is now funding research at a greater scale than the US is, but also multiple research projects are being paused, thanks to the recent US presidential executive order cutting funding to the National Institutes of Health (NIH). Prof Doran has received emails for US-based research groups he is part of informing him that all work has stopped.

Prof Peter Doran

Yet this also means there is an opportunity for those involved in clinical research in Ireland, especially those wishing to run academic trials and investigator-led trials. These trials address unmet clinical needs, advance innovation, allow for capacity building, and enable investigator development. "In the absence of a focus on academic clinical trials, studies that address unmet needs would never be done."

Prof Doran said developing Ireland's investigator capacity is "an active process"; "it is no longer good enough to rely on people returning from the US." Clinical trials are difficult: they are expensive, time consuming, and it is difficult to recruit and retain patients. These challenges are even more acute with investigator initiated trials, but new approaches are emerging to address these challenges and accelerate drug development. These include innovative approaches to trial design, leveraging technology to enable trial conduct, and novel approaches to improving patient engagement.

Decentralised trials should become the norm, said Prof Doran, with access more of a priority.

"This would mean that Irish people, regardless of where they live, get access to trials as part of their routine care." The use of master protocols helps to streamline trial design, while platform trials allow for more agility and flexibility.

Digital tools and wearable technologies are increasingly being embedded in clinical trials, while artificial intelligence and machine learning is inescapable. Patient-centred trial design allows research teams to focus on designs that are sensible for the patient population, allowing for improved trial relevance and patient satisfaction, as well as higher enrollment and retention rates. He acknowledged there can be challenges: "It's about balancing patient preferences with scientific rigor and ensuring diverse representation."

The UCD Clinical Research Centre has been involved in a total of 490 studies, with 192 commenced since 2021 of which 64% were academic-led. He advised trainees that academics and universities care about the impact of their trials, such as the number of publications that result and the field weighted citation index. The CTU located within the CRC is a dedicated unit designed to drive clinical research growth within UCD. It is enabling the development of critical clinical trials and trials methodologies, and facilitates the design, implementation, management & analysis of investigator initiated trials. "The main aim is ensuring the integrity, compliance and scientific rigor of clinical research," said Prof Doran.

As we endeavour to build trial capacity within Ireland, the professor said it is essential to consider the importance of leadership. "We have to think about who will be the trial leaders and how can we support them?" Our finding models need work but we are developing capacity the whole time. With its thriving life sciences and tech sectors that create a unique research environment Ireland is well positioned to compete globally.

Prof Doran asked trainees what their contribution will be. "How are you going to make sure the ecosystem that has been painstakingly developed and is reasonably well positioned can grow and continue to deliver for patients and their families?" He advised them that their ability to develop multidisciplinary collaborations will be what distinguishes them from an academic perspective and he encouraged them to become involved from a policy perspective. "Get your voice heard - make sure that people know what you think is important."

Young Investigators and Cancer Trials Ireland, Prof Seamus O'Reilly & Prof Gerry Hanna, Clinical Lead & Vice-Cinical Lead, Cancer Trials Ireland

Succession in clinical research has to be re-imagined, Prof O'Reilly told the audience. Whereas previously it was a pipeline, with just one entry point, it has now been suggested that it is more of a "braided river", with people joining the field at different career stages. "Today things are different, people may have multiple careers, or may have had gaps for personal reasons." This means the workforce is much more diverse, which is overall a positive thing, he stated. "To harness that diversity we need to be flexible in what we do in terms of encouraging people at different stages in their career. There are times when people leave the research domain and rejoin it for different reasons but it is never too early to become involved in research."

One of the issues with practising cancer medicine is that clinicians are exposed to the "chronic emotional labour" of dealing with patients at most challenging times of their lives. Burnout in the oncology workforce is thus a problem - burnout rates are significantly higher than they were a decade ago and rates are higher in the younger workforce.

Clinical trials face other barriers. For Cancer Trials Ireland, the major problem is the average "time to first patient" - this is among the longest in Europe. Cancer Trials Ireland is actively working and strategising to reduce this time. Prof O'Reilly noted that the Board Strategy is focused on reducing operational friction within the organisation in order to speed the processing of information.

As expressed previously, more funding sources are required so work is ongoing to find new sources but also maximise current sources. "We are also increasing engagement with clinicians and listening to learn how to do things better." Ensuring succession and sustainability means focusing on young investigators, and many initiatives have been introduced as part of viewing this as a strategic priority.

Prof Gerry Hanna

These include the annual Cancer Trials Ireland National Training Day and the Cancer Trials Ireland National Cancer Retreat, and also strategic collaboration with ISMO. Inclusion and integration of young investigators in the DSSG, trials, publications, presentations, projects, webinars, and collaborator initiatives is ongoing. Meetings take place at ASCO and ESMO that include young investigators. A number of other Young Investigator initiatives have been proposed such as the appointment of a nursing/allied health professional lead, while efforts are being made to expand links with radiotherapy, haematology, nursing and allied health colleagues. A Young Investigator/Board Member Working Group is also set to be established.

Enhanced integration of radiation oncology into Cancer Trials Ireland is also being prioritised and the establishment of the All-Ireland Translational Radiation Oncology Network (ATRON) is "a tremendously exciting move", Prof O'Reilly said. The establishment of the National Clinical Trials Oversight Group is also a hugely positive move and Cancer Trials Ireland is a member.

Bureaucracy, Prof O'Reilly said, has a body count. "This is not an abstract thing for our patients." The reality is that patients who are delayed access to trials may die. Cancer Trials Ireland continues to advocate for all patients who may be eligible for a clinical trial.

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