DSSG Digest

Spring 2024

The DSSG Digest has the most up to date news and listing of cancer trials and studies underway in Ireland.

cancer trials ireland

Together, we're finding answers to cancer.

Supported by

Irish Cancer Society

HRB Health Research Board

Clinical Lead

Prof Seamus O'Reilly

Streamlining our processes and regulations around clinical trials is vital for keeping Ireland globally competitive. We're only as fast as our slowest part.

In taking up my role as Clinical Lead for Cancer Trials Ireland this January, I am excited for the future of cancer trials in Ireland. Conducting clinical trials in Ireland was and is a passion of mine – just as it is for all of the investigators and site staff whose default setting is to go the extra mile to get trials open and get options to patients. It is gratifying to see this passion arrayed and displayed in new ways, in this role, but equally we cannot continue to rely on passion to open trials in the years ahead.

To that end I will be working closely with the executive team and Board of Cancer Trials Ireland to reduce the 'time to first patient'. Our acting CEO has outlined the priorities for 2024, and I look forward to engaging with you at today's DSSG meetings, and at the upcoming Cancer Retreat as we look to secure the future of trials in Ireland more robustly.

Oncology is also at an exciting stage within Ireland, with many new agents in the pipeline. For example, there is a drug class called anti-body drug conjugates and there are 160 of these in development globally. Creating an environment in our hospitals where patients have access to this innovation is of great significance.

Cancer Trials Ireland has four themes for the next four years, the first of which is 'streamlining'. We need to be efficient in bringing trials into Ireland and remove as many barriers as possible. We are competing with other countries, so our processes and regulations - particularly around GDPR - must be streamlined. Much like other enterprises, you're only as good as your weakest link and you're only as fast as your slowest part.

The second theme is bringing more studies into Ireland. Getting patients access to the studies arising from the 160 drugs mentioned above is a key objective for our organisation. There are international meetings taking place all the time; we will continue to go to these meetings and interact with the relevant companies and with the international co-operative groups that are involved in trials on drugs like these. Our ongoing objective is to highlight Ireland's infrastructure and development, the intellectual capital here, and the patient population that would benefit.

The third theme is succession. In any organisation we need to nurture the next generation. We look at ways of nurturing the next generations so they can be involved in clinical trials. It is not just about doctors. Building an infrastructure where we can encourage, recruit, and retain nurses and data managers in our system is also hugely important. If you don't have a team, you can't build around it.

The final theme is sustainability. Healthcare itself is very climate-unfriendly, while fossil fuel pollution contributes to cancer. In France, they calculated that 3% of their breast cancer cases are due to fossil fuel pollution from cars. It's a worsening problem that we're all affected by.

Last year in 2022 we set up the national green cancer clinical trials initiative and we've established a green charter for cancer trials in Ireland. Our group also published a paper last year called 'Climate Toxicity'. It's the first time the term has been used in medical literature. You can read more about that on page 16.

I am honoured to represent you to the Clinical Executive Committee and Board of Cancer Trials Ireland, and I look forward to working closely with you in the weeks, months and years ahead.

cancer trials ireland

Together, we're finding answers to cancer.

Acting CEO

Angela Clayton-Lea

The National Training Day in January, and the subsequent Board Strategy Day have been instrumental in shaping CTI's priorities for 2024. First and foremost, I want to thank you, the members of CTI, for your engagement and support over the past few months. Your input is vital, and we will continue to seek that from you as the year unfolds. The next opportunity for you to do that will be on May 10th at the Cancer Retreat (see: page 17).

Turning then to our 2024 priorities, they are: -

- **GDPR**
- **Funding**
- **Operational efficiency / lean processes**
- **Clinician engagement**

The CTI Board approved these priorities in late February, and I am delighted to report that a selection of our Board members have taken a sponsor role with respect to each priority.

All of this work meanwhile will be underpinned by a concerted drive to communicate our value – to patients, government, decision-makers, stakeholders, media, international groups (collaborative & pharma), but most crucially with you, our members.

One significant factor causing delays to trials opening in Ireland – and industry even deciding to attempt to open trials in this country – is the ongoing GDPR-related issues. There is an urgent need for harmonisation of DPIA templates and interpretation of current GDPR legislation. A small sub-group will undertake a series of high-level actions in support of the community's need to streamline processes impacted by GDPR issues. Patients' views will be sought and presented to the Data Protection Commission as part of this exercise.

Our collective need to secure increased funding support is paramount. Maximising existing funding opportunities and securing new funding streams requires increased efficiency, collaboration, and greater engagement with EU funded projects. Learning from other groups e.g., ETOP, and lobbying for government support is essential. CTI will provide a voice for learnings from the current HRB grant cycle – this will be explored further as part of the CTI's 2 Retreat on May 10th .

We are actively looking at what we can do to support more Investigator Initiated Trials (IITs). These types of trials are an essential element of why CTI exists - we will be taking steps to drive enablers so that investigators can open more IITs in Ireland. In support of IIT funding, our Head of Research & Business Development, Dr Verena Murphy will now include a slide on funding calls in the DSSG's. An accompanying 'open calls' website page is in development – as is a step-by-step guide on how to develop an IIT, from concept to open stage.

With respect to operational efficiency and leaner processes, the metric that matters most is 'Time to First Patient'. The timeline for opening a new study is key in making Ireland attractive globally - concerted efforts will be made to reduce this timeline within CTI and without, working collaboratively to minimise external delays.

In terms of clinician engagement – which applies not only to doctors, but all clinical site staff – we are already exploring how best to establish a mentoring programme, with a discussion taking place at today's stakeholder meeting. With the help of members, we will begin to see what elements are appropriate for CTI to provide, and what can be achieved with the help of partners such as ISMO.

We have already helped to establish fortnightly troubleshooting site meetings - further actions and shared learnings from the National Training Day will be published in the coming days.

In closing, I want to thank you once again for your energy, efforts, and engagement with a view to improving the clinical oncology research landscape in Ireland, and thereby bringing more new drugs and treatments to Irish patients.

The Pat Smullen Fund for Pancreatic Cancer

As we reported in the last Digest, we are very excited about the new position in UCD, the Pat Smullen Chair in Pancreatic Cancer. We very hope to bring news of an appointment to this role in the coming month or two. Exciting times for pancreatic research in Ireland!

Meanwhile, the Pat Smullen Fund Committee is scheduled to meet in the coming weeks, where we will discuss studies funded by the Fund (see: updates below). You can also read more about how the horse racing community continue to support Cancer Trials Ireland and pancreatic cancer research in Fundraising News on page 22.

DP-IMRT Pancreas (CTRIAL-IE 17-12)

'A non-randomised Phase I/II study of dose-escalated hypofractionated Dose-Painted Intensity Modulated Radiotherapy (DP-IMRT) in resectable/ borderline resectable pancreatic adenocarcinoma'. The aim of this IIT is to improve outcomes in pancreatic ductal adenocarcinoma by delivering higher RT doses targeted directly at the centre of the tumour. The study opened in SLRON and SVUH in Jan-2024, and the CI is Dr Gerard McVey. This study is partly funded by HRB, Pat Smullen fund and Irish Cancer Society, and is the first Cancer Trials Ireland/ IRROG collaborative radiotherapy clinical research study in GI Oncology.

PaTcH (CTRIAL-IE 20-27)

Led by Dr Austin Duffy, PaTcH trial is open to accrual at MMUH and SVUH. 9 patients have been recruited to date. PaTcH is a single arm phase 2 clinical trial to explore primary and emerging resistance mechanisms in patients with metastatic refractory pancreatic cancer treated with trametinib and hydroxychloroquine.

An interim analysis was planned when the first 10 patients reached the primary analysis timepoint of twelve weeks. However, a decision was made to analyse the data earlier (when 7 patients accrued) and continue with patient accrual as sufficient patients were confirmed to be progression free having reached the 12-week timepoint before the required ten patients were accrued.

The interim analysis met the pre-specified rule for continuing accrual to 22 patients (i.e. at least 2 patients being progression-free at 12 weeks after start of treatment), as two patients (33.3%) had remained progression free at the 12 week timepoint out of six patients eligible for the primary analysis at database interim lock.

As the interim was performed early with 6 patients evaluable for the primary endpoint and met the objective of two progression free patients at 12 weeks, there is no statistical reason to halt enrolment after the 10th patient has been accrued and the study can enrol up to 22 evaluable patients in the second stage.

New DSSG Chair: Melanoma

Professor Fergal Kelleher trained in melanoma in the world-famous Peter Mac Callum Cancer Institute, Melbourne, Australia prior to taking up appointment in 2016 as a Consultant Medical Oncologist. In St James's Hospital he is the Medical Oncology lead for melanoma as well as treating other cutaneous malignancies. He is co-clinical lead for the Cancer Immunology Research Theme TSJCI.

Surgical study

MelMarTII (CTRIAL-IE 20-37)

Melanoma is fast becoming a growing concern for Ireland. Despite the country's reputation for overcast skies and a relatively cool climate, the number of melanoma cases is on the rise, with a projected increase by 207% in males and 140% in females by 2045. This alarming trend can be attributed to a combination of factors including a large population of fair-skinned people, environmental changes, and underestimating the dangers of excessive sun exposure.

Although Ireland only gets around half the amount of sunshine compared to Australia, many Irish people travel to sunnier destinations where exposure to intense UV radiation can significantly increase the risk of developing melanoma later in life.

Despite melanoma excision surgery being regularly performed in Ireland and Australia, each country has different guidelines for the operation. Irish surgeons typically use a 1-2cm margin, depending on the breslow depth of the melanoma excision margin for thicker cutaneous melanomas, while Australian surgeons operating on the same size melanoma commonly use a 1cm excision margin.

To help address the urgent need for an international consensus for the surgical treatment of stage II melanoma, St James's Hospital Dublin, The Mater Misericordiae University Hospital Dublin, Beaumont Hospital Dublin and Cork University Hospital will participate in the Australia-led Melanoma Margins Trial, known as 'MelMarT-II'. St James's Hospital in Dublin and the Mater Misericordiae University Hospital in Dublin will be activated in March 2024 .

Each Irish hospital aims to enrol 30 patients into the trial, which will study almost 3,000 patients across nine countries, including major coordinating trial centres in Australia, Europe, and North America.

A surgeon's decision to use either a 1 cm or 2 cm excision margin for stage II melanoma can impact a patient's quality of life & survival. A larger excision margin can lead to complex surgical reconstruction, poorer cosmetic appearance, post-operative complications, and impact on function. But if the excision margin is too small, the melanoma might return or spread.

Prof Shirley Potter (left)

Ms Marlese Dempsey (right)

Prof Jim Clover (left)

Dr Barry O'Sullivan (right)

The MelMarT-II trial, coordinated by Melanoma and Skin Cancer Trials, will determine whether a 1 cm or a 2 cm margin is best and provide certainty for melanoma patients and their doctors in deciding the most effective treatment.

Principal Investigator from the Mater Misericordiae University Hospital, Dublin, Professor Shirley Potter (top left), is leading the MelMarT-II trial's efforts in Ireland, along with Ms Marlese Dempsey (top right) at St James's Hospital, Prof Jim Clover (lower left) at Cork University Hospital and Dr Barry O Sullivan (lower right) at Beaumont Hospital Dublin.

Dr Shirley Potter stated: "We are delighted that Irish melanoma patients will be contributing to this fantastic global effort to improve outcomes for stage II melanoma patients. This trial addresses an important unanswered clinical question concerning the surgical management of melanoma. Substantial dedication from Cancer Trials Ireland and the Irish Cancer Society has been invested in the establishment of this surgical trial in Ireland, and we anticipate that it will yield improvements in the quality of life for our Irish melanoma patients."

Australian Co-Study Chair, Prof Michael Henderson from the Peter MacCallum Cancer Centre in Melbourne said, "This international collaborative effort will provide the high-quality evidence required to update clinical practice for stage II melanoma in Australia and world-wide."

Prof Marc Moncrieff, the trial's United Kingdom Co-Study Chair added, "With almost 2,000 patients recruited into the trial already, we are on track to meet our enrolment target by the end of 2024." Read more information about the MelMarT-II trial.

Gynae updates: Open studies

OVHIPEC-2 (CTRIAL 20-07)

Led by Prof. Donal Brennan, sponsored by The Netherlands Cancer Institute, this study is investigating primary cytoreductive surgery with or without hyperthermic intraperitoneal chemotherapy (HIPEC) for FIGO stage III epithelial ovarian cancer. This study is now open in Mater Misericordiae University Hospital. This study aims to recruit 538 patients globally to the trial. 10 Irish patients per year are expected to be recruited to this trial. Currently, we have an incredible 9 patients randomised already to this trial, which is due to end recruitment later this year.

22-05 HELP-ER

Led by Dr. Sharon O'Toole, HELP-ER is a translational study brought to Ireland through our links with ENGOT, in which blood samples and FFPE samples are collected from patients with First Relapsed Ovarian Cancer. This prospective study aims to Improve the AGO Score for resectability by adding HE4 serum concentration levels and CA125. This study is open in the Beacon hospital who have 2 patients enrolled in the study and 2 patients in screening.

22-08 XPORT

Led by Dr. Dearbhaile Collins, XPORT is a A Phase 3, Randomized, Placebo-Controlled, Double-Blind Trial of Selinexor in Maintenance Therapy After Systemic Therapy for Patients With p53 Wildtype, Advanced or Recurrent Endometrial Carcinoma. Brought to Ireland through ENGOT, this study is sponsored by Karyopharm Therapeutics and aims to evaluate efficacy and safety for maintenance administration of selinexor in patients with p53 wt advanced or recurrent EC. A total of 220 patients with p53 wt advanced or recurrent EC will be enrolled in this study, which is now open in Cork University Hospital & St. James's Hospital, and each site have 1 patient each in screening. The study will soon open in University Hospital Waterford, University Hospital Galway and the Beacon Hospital shortly. We look forward to welcoming our first patient on this important endometrial study.

Gynae Event update:

GCIG 1st Cervical Cancer Consensus Conference

GCIG, the Gynaecologic Cancer Intergroup hosted a call for member countries to put in an application to host the 1st Cervical Cancer Consensus Conference. This conference is to bring together delegates from each GCIG member group, to present, discuss, agree and later publish guidance on topics including outstanding clinical research questions and reference arm standards for clinical trials in cervix cancer.

Cancer Trials Ireland successfully won this bid, and the well anticipated conference will take place over 2 days in Dublin Castle on 14th and 15th October 2024 in line with the IGCS 2024 Annual Global Meeting, which will be held in Dublin, Ireland October 16 - 18, 2024. The second planning meeting was held in Barcelona on 5th and 6th of March, in which the outline for the conference was discussed with the committee. We look forward to continuing our planning for this important event.

Olivia McLoughlin (far left) and Lucy Murphy (far right) of Cancer Trials Ireland meet David Tan, GCGS & CCRN Chair (middle left), Alison Brand, GCIG Chair (centre), Michael Bookman, GCIG Chair-Elect at the GCIG Spring 2024 meeting on March 5-6, 2024 at the Vall d'Hebron Institute of Oncology (VHIO) in Barcelona ahead of the 1st Cervical Cancer Consensus Conference - Clinical Research to be held in Dublin on October 13-14, 2024 at Dublin Castle.

Gynae Studies in Development:

21-29 NRG GY019:

Led by Prof Karen Cadoo and sponsored by NRG in the US, this study is a Randomized Phase III, Two-Arm Trial of Chemotherapy with Letrozole Versus Letrozole alone in Patients with Stage II-IV, Primary Low-Grade Serous Carcinoma of the Ovary or Peritoneum. 450 participants are expected to be recruited globally by 2026, with 20 of those patients coming from St. James's Hospital and Cork University Hospital. This study aims to investigate which of the two treatment regimens is better for patients. CTI are working hard to open this trial, with sites open once a protocol amendment is approved.

22-18 GLORIOSA

Led by Dr. Michael McCarthy is A Randomized Phase 3 Trial Of Mirvetuximab (Mirv) + Bevacizumab (Bev) Maintenance In patients with Folate Receptor alpha high platinum-sensitive ovarian cancer. A total of 418 patients will be enrolled in this study, which will open in University Hospital Waterford, University Hospital Galway, Cork University Hospital, St. James's Hospital, Beaumont Hospital and Sligo University Hospital shortly.

22-19 Navtemadlin

Led by Dr. Dearbhaile Collins is a Randomized Phase 2/3 Study of Navtemadlin in Subjects with TP53 wildtype Advanced or Recurrent Endometrial Cancer Who responded after Chemotherapy. A total of 188 patients will be enrolled in this study, which will open for Part 2 of the study in University Hospital Waterford, University Hospital Galway, Cork University Hospital, St. James's Hospital and the Beacon Hospital shortly.

23-04 MK-2870-005 ENGOT-En23

Led by Dr. Dearbhaile Collins is A Phase 3, Randomized, Active-controlled, Open-label, Multicenter Study to Compare the Efficacy and Safety of MK-2870 Monotherapy Versus Treatment of Physician's Choice in Participants With Endometrial Cancer Who Have Received Prior Platinum-Based Chemotherapy and Immunotherapy. A total of 710 patients will be enrolled in this study, which will open in Cork University Hospital, St. James's Hospital and the Mater Hospital.

23-15 ReFrame_STRO-002

Led by Prof. Karen Cadoo, this is a Phase 2/3 Open-label Study Evaluating the Efficacy and Safety of Luveltamab Tazevibulin (STRO-002) versus Investigator's Choice of Chemotherapy in Women with Relapsed Platinum-resistant Epithelial Ovarian Cancer (including Fallopian Tube or Primary Peritoneal Cancers) Expressing Folate Receptor alpha (FOLR1). 600 patients are expected globally, with first patient in planned in May 2024. Sites selected in Ireland include Cork University Hospital, Galway University Hospital, Mater University Hospital and St. James's Hospital, in which an application has been made via CTIS, and will shortly include the addition of University Hospital Waterford site.

New DSSG Chair: *Gynae*

Extending a warm welcome to the new incoming Chair of the Gynae DSSG, Prof Karen Cadoo. Prof Cadoo is a Medical Oncologist and Cancer Geneticist at St. James's Hospital (SJH) and Clinical Associate Professor, Trinity College Dublin. She co-leads the inherited cancer genetics programme at SJH and the cancer prevention pillar of the Trinity St. James's Cancer Institute. Her research is centered on drug development, inherited genetics, the interplay with tumor biology, and the potential to target these therapeutically. She has served as member of NRG Oncology Ovarian Cancer Committee and is Cancer Trials Ireland representative to ENGOT.

Breast studies

CTRIAL 23-06 CAMBRIA-2

The CAMBRIA-2 study is an AstraZeneca sponsored international, multi-centre, phase III, open-label, randomised study to assess the efficacy and safety of Camizestrant (AZD9833, a next generation, oral selective estrogen receptor degrader +/- abemaciclib versus standard endocrine therapy (aromatase inhibitor or tamoxifen) + / - abemaciclib as an adjuvant treatment.

The CAMBRIA-2 study will be enrolling patients who have ER+/HER2- early breast cancer with intermediate-high or high risk of recurrence, who have completed definitive locoregional therapy and have no evidence of disease, and who meet the inclusion criteria for study participation. Patients will be designated as having intermediate-high or high risk of recurrence based on clinical and genomic features, including baseline tumour size, number of involved axillary lymph nodes, tumour grade, Ki67, and genomic signature assessment from the patient's medical records, if available. The main objective of this study is to measure the safety and demonstrate the superiority of camizestrant +/- abemaciclib as compared to standard endocrine therapy +/- abemaciclib by assessment of invasive breast cancer-free survival (IBCFS).

The global study accrual target is 5500 patients, with the aim to recruit 40 patients per year across all Irish sites. The overall study duration will be approximately 14 years, including the recruitment period of 3.5 years, starting from FPI in October 2023 in Canada, and the treatment period of 7 years.

The Chief Investigator in Ireland is Prof Seamus O'Reilly (Cork University Hospital). The study has received full approval under the new CTR and is planned to open in Ireland Q2 2024. The study will be open at 7 sites across Ireland, Cork University Hospital (Principal Investigator (PI): Prof Seamus O'Reilly), University Hospital Galway (PI: Prof Maccon Keane), University Hospital Waterford (PI: Dr Miriam O'Connor), Beaumont (PI: Prof Patrick Morris), Mater Private Hospital (PI: Prof Catherine Kelly), Mater Misericordiae University Hospital (PI: Dr Emily Harrold) and St Vincent's University Hospital (PI: Prof Micheala Higgins).

CTRIAL 23-03 TREAT ctDNA

The TREAT ctDNA study is an EORTC sponsored international, multi-centre, randomised, open-label, superiority, phase III trial of elacestrant (ORSERDU®, new selective estrogen receptor degrader (SERD) versus standard adjuvant endocrine therapy in patients with ER+/HER2- breast cancer and ctDNA relapse.

The main objective of this study is to evaluate whether elacestrant can delay occurrence of distant metastasis or death when compared to standard endocrine therapy in ER+/HER2- patients with ctDNA relapse. ctDNA is tumour derived fragmented DNA shed into a patient's bloodstream that is not associated with cells. ctDNA quantity can very among individuals and depends on the type of tumour, location, stage, tumour burden, and response to therapy. Therefore, ctDNA may be a useful biomarker after potentially curative treatment to identify individuals at high-risk of relapse, allowing for effective therapies to be introduced at time when disease burden is still minimal. Elacestrant, a new oral selective estrogen receptor degrader, has shown significant clinical benefits in patients with ER+/HER- advanced or metastatic breast cancer following progression on a CDK4/6-inhibitor and could be used at a time of ctDNA relapse to delay occurrence of distant metastasis.

The global study accrual target is 220 patients, with the aim to recruit a total of 12-15 patients across the Irish sites. The overall study duration will be approximately 8.7 years, including the recruitment period of 5.7 years and the treatment period of 2 years.

The Chief Investigator in Ireland in Prof Catherine Kelly (Mater Private Hospital). The study has received approval under the new CTR and is planned to open in Ireland Q2 2024. The study will open at 5 sites across Ireland, Beacon (Principal Investigator (PI): Dr Lisa Prior), St James's Hospital (PI: Dr Ciara O'Hanlon Brown), Mater Private Hospital (PI: Prof Catherine Kelly), Mater Misericordiae University Hospital (PI: Dr Geraldine O'Sullivan Coyne) and University Hospital Waterford (PI: Dr Miriam O'Connor).

Breast studies

SHAMROCK

'Single arm phase 2 trial of neoadjuvant trastuzumab deruxtecan (T-DXd) with response-directed definitive therapy in early stage HER2-positive breast cancer: a standard chemotherapy-sparing approach to curative-intent treatment – SHAMROCK study' has opened to accrual in October 2023 and already has eight patients enrolled from the study accrual target of 80 patients. SHAMROCK study is open to accrual at Beaumont Hospital, Cork University Hospital, St. James's Hospital and University Hospital Limerick. St. Vincent's University Hospital will open to accrual shortly.

In this trial, patients are getting trastuzumab deruxtecan intravenously every three weeks for up to six cycles. A mandatory repeat biopsy at Cycle 2 Day 14 will be performed for the RNA Disruption Index (RDI) score assessment to evaluate how cancer is responding to the study treatment and project how many cycles of study treatment patients should be getting to benefit from the treatment but to minimise exposure to the chemotherapy as much as possible to reduce side effects for the patients.

The primary study objective is to evaluate the efficacy of T-DXd in the neo-adjuvant treatment of HER2-positive breast cancer using pathological complete response (pCR) as the primary endpoint. In addition to safety assessments, measures of the efficacy of the study treatment will include event-free survival (EFS) and overall survival (OS) of patients treated with only T-DXd and trastuzumab. Several translational sub-studies will study the molecular evolution of tumours during treatment and aim to develop a biomarker panel that optimises the prediction of the pCR.

The study is led by Prof Bryan Hennessy, and Cancer Trials Ireland is the study sponsor. The Shamrock study is funded by a grant from Breast Cancer Ireland. AstraZeneca and Daiichi-Sankyo are the co-developers of trastuzumab deruxtecan, which they will supply for this study.

SASCIA

The SASCIA study has closed to recruitment and reached over it's target of 40 patients now randomised to the study, with a total of 46 patients randomised across all 6 sites. The SASCIA clinical research study (Phase III Postneoadjuvant Study Evaluating Sacituzumab Govitecan, an Antibody Drug Conjugate in Primary HER2-negative Breast Cancer Patients with High Relapse Risk After Standard Neoadjuvant Treatment) is designed to evaluate whether the administration of a drug called sacituzumab govitecan has an additional benefit compared to a standard treatment of physician's choice. We look forward to hearing about the results of the SASCIA study after completion of patient follow up.

New DSSG Chairs: Gastrointestinal

Professor Aisling Barry joins the GI DSSG as the Radiation Oncology Co Chair. Professor Barry is a consultant radiation oncologist at Cork University Hospital and the first Professor and Chair of Radiation Oncology at University College Cork.

Dr Darren Cowzer joins the GI DSSG as the Colorectal Co Chair. Dr Cowzer is a Consultant Medical Oncologist at Mater Misericordia University Hospital, who has recently returned to Ireland from Memorial Sloan Kettering Cancer Center, New York.

Lymph & Haem studies

Dr Janusz Krawczyk

CPD-DARA (CTRIAL 19-17)

Sponsored by Cancer Trials Ireland and with Dr Janusz Krawczyk as Chief Investigator, the CPD-DARA trial is a phase Ib trial that will assess the addition of daratumumab (subcutaneous) [DARA] to chemotherapy regimen of cyclophosphamide, pomalidomide and dexamethasone (CPD) to increase the activity of this regimen in patients with relapsed/ refractory multiple myeloma. The study is receiving funding from Janssen, BMS and Friends of Cancer Trials Ireland. This trial is a national study that is open in three BCNI sites (University Hospital Galway, Beaumont Hospital and Cork University Hospital).

Recruitment commenced in December 2021 and the last patient was enrolled in June 2023. The study met its primary objective in April 2022 when the Maximum Tolerated Dose (MTD) and recommended phase II dose (RP2D) of CPD in combination with DARA was established. Recruitment is now closed and a total of 16 patients of a target of 20 were recruited to the study. The study is in follow up and 3 patients (all at the Galway site) remain on study treatment. The last patient last visit is expected in Q3 2026. Although the main endpoint of this trial is safety, efficacy measures will also be evaluated in patients treated with this regimen. To date the study is progressing well and there have been no dose limiting toxicities reported.

The first analysis was completed in Q1 2024 and an abstract has been prepared with the preliminary results which have been submitted for the European Hematology Association Conference which will take place in Madrid in June 2024.

HOVON150 (CTRIAL-IE 19-18)

The HO150 trial is a phase 3 multicentre, double-blind, randomised, placebo-controlled trial for patients with newly diagnosed acute myeloid leukaemia (AML) or myelodysplastic syndromes with excess blasts-2 with an IDH1 or IDH2 mutation eligible for intensive chemotherapy. The primary outcome measure of the trial is event-free survival (EFS). The HO150 trial plans to enrol approximately 968 patients globally. Six patients have been enrolled at Irish sites, to date. Four Irish sites are participating in the HO150 trial: St James's Hospital (Principal Investigator (PI): Dr Catherine Flynn), Beaumont Hospital (PI: Dr Philip Murphy), Cork University Hospital (PI: Dr Vitaliy Mykytiv), University Hospital Galway (PI: Dr Janusz Krawczyk).

The duration of patients' treatment will be up to 2.5 years; patients will be followed-up until 10 years after registration on the trial. The trial is sponsored by HOVON. In Ireland, Cancer Trials Ireland are supporting HOVON with coordination of the trial, including assisting with the transition to the Clinical Trial Regulation.

The HO150 IDH2 cohort met its accrual target in April 2023. The IDH1 cohort is expected to remain open to accrual until Q3 2024.

MBC Patient-Led Research Project (CTRIAL-IE 23-05)

Congratulations to Siobhan Gaynor (pic below) who spearheaded the roll-out of CTI's first patient-led research project. The study surveyed more than 250 people in Ireland with MBC and two poster abstracts have been accepted for ESMO 2024. Two further submissions have been made to ASCO 2024.

Siobhan Gaynor

Patient Consultants Committee, Breast DSSG

Lung Study

NeoCOAST-2 (CTRIAL 22-23)

NeoCOAST-2 is a Phase II study assessing the efficacy and safety of neoadjuvant and adjuvant treatment in patients

NeoCOAST-2 is a Phase II study assessing the efficacy and safety of neoadjuvant and adjuvant treatment in patients with resectable, early stage (Stage II to IIIB) non-small cell lung cancer. It is an open-label, multi-arm, multicentre, randomised study. Up to now, eligible participants have been randomised to one of the following treatment regimens.

Arm 1: Oleclumab + durvalumab + platinum doublet chemotherapy as neoadjuvant treatment and Oleclumab + durvalumab as adjuvant treatment.

Arm 2: Monalizumab + durvalumab + platinum doublet chemotherapy as neoadjuvant treatment and Monalizumab + durvalumab as adjuvant treatment.

Arm 3: Volrustomig (MEDI5752) + platinum doublet chemotherapy as neoadjuvant treatment and Volrustomig (MEDI5752) as adjuvant treatment.

Arm 4: Dato-DXd + durvalumab + single agent platinum chemotherapy as neoadjuvant treatment and durvalumab as adjuvant treatment.

Arm 5: AZD0171 + durvalumab + platinum doublet chemotherapy as neoadjuvant treatment and AZD0171 + durvalumab as adjuvant treatment.

Arms 1, 2, 4 & 5 have now closed and a protocol amendment has been submitted to open two new arms based on the current Arm 3.

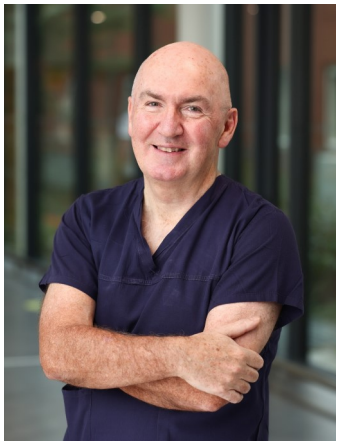
Primary outcome measures are the number of participants with pathological complete response and the number of participants experiencing adverse events and serious adverse events.

Secondary outcome measures include event free survival, disease free survival, surgical resection, major pathological response, objective response rate, overall survival, serum concentration of study interventions (durvalumab/oleclumab/monalizumab/volrustomig), anti-study drug antibodies, baseline PD-L1 expression and changes in ctDNA.

This is a global study sponsored by AstraZeneca with 92 sites open across North America, Europe and Asia. The study is lead in Ireland by Prof Jarushka Naidoo and is open at four sites - Beaumont Hospital (Prof Jarushka Naidoo), University Hospital Galway (Dr Silvie Blazkova), Mater Misericordiae University Hospital (Dr Deirdre Kelly) and St. James's Hospital (Dr Sinead Cuffe).

The study has enrolled 223 patients out of a global target of 350 with 3 of these in Ireland. Recruitment is currently on hold in Ireland as we await approval of the protocol amendment to open two new treatment arms.

GI Study



Prof John Reynolds

Dr Grainne O'Kane

NEEDS (CTRIAL-IE 20-36)

The NEEDS study is now open to recruitment in St. James's Hospital, with our first patient in screening for this important trial with Prof. John Reynolds, as Chief Investigator, and Dr. Grainne O'Kane, and will have the Radiotherapy complete in St. Luke's Hospital St. James's Campus with Dr. Moya Cunningham. The NEEDS study hopes to recruit 12 pts per year, with a total of 20 patients recruited in Ireland to this important trial. NEEDS is a Neoadjuvant trial, investigating locally advanced squamous cell carcinoma (SCC) of the oesophagus. The aim of the study is to compare outcomes after neoadjuvant chemoradiotherapy with subsequent esophagectomy to definitive chemoradiotherapy with surveillance and salvage esophagectomy as needed in patients with resectable locally advanced squamous cell carcinoma (SCC) of the esophagus, with the aim to provide generalizeable guidance for future clinical practice.

Radiotherapy updates: Open studies

Open Studies, including two new Investigator-initiated RT trials (see Pat Smullen Fund update for CTRIAL-IE 17-12 update, page 4) and three new collaborative group studies:

PACE NODES (CTRIAL-IE 23-01):

The aim is to determine whether 5 fraction prostate and pelvic node SBRT has superior biochemical/ clinical-failure free rate than 5 fraction prostate SBRT, in patients with high risk localised prostate cancer. The study is open in SLRON and Bons UPMC as of Jan-2024, and is due to open in MWROC at UHL. Dr Paul Kelly (Bons UPMC in Cork) is the Irish National Lead Investigator (NLI). The study is coordinated internationally by Institute of Cancer Research, UK.

E2RADIatE (CTRIAL-IE 21-28)

OligoCare/Re-Care Cohorts: The aim is to collect real-world data on cancer patients treated with radiotherapy, to support radiotherapy research and to provide evidence of the role of radiation oncology in a multidisciplinary approach. This study is open in SLRON and Beacon as of Feb-2024, and is due to open in UHG. Prof Frances Duane (SLRON) is the Irish National Lead Investigator (NLI). The study is coordinated internationally by EORTC.

EXPERT BIG (CTRIAL-IE 19-03):

The aim is to determine if omission of RT is not inferior to RT in terms of local recurrence-free interval after breast conserving surgery in patients with stage I, luminal A early breast cancer who are planned to receive adjuvant endocrine therapy. The study is open in SLRON and UHG as of Mar-2024, and is pending in CUH and Mater Private Hospital MWROC at UHL . Prof Sinead Brennan (SLRON) is the Irish NLI. The study is coordinated internationally by BIG and BCT.

Spine SABR (CTRIAL-IE 20-03)

'Dose-escalated SABR (stereotactic ablative radiotherapy) for Solid Tumour Spine Metastases'. The aim of this Investigator-initiated trial (IIT) is to determine the maximum RT dose that can be delivered safely to spinal metastases, without increasing the amount of treatment-induced side effects. This study is open in SLRON (Prof Clare Faul / CI) and Beacon (Dr Siobhra O'Sullivan), with the first patient enrolled at SLRON in Feb 2024, and will open at other Irish sites later in 2024. This study has Irish Cancer Society funding and is the first Cancer Trials Ireland/ IRROG radiotherapy clinical research study in CNS oncology, and the first Cancer Trials Ireland IIT to have an electronic CRF (RAVE).

PRESERVE (CTRIAL-IE 20-04)

'Preservation of Swallowing in Resected Oral Cavity Squamous Cell Carcinoma: Examining Radiation Volume Effects (PRESERVE): A Randomized Trial'. The purpose of this study is to compare the usual treatment area of radiation to a reduced treatment area to see if radiation to a smaller area on the neck is associated with acceptable rates of regional recurrence and will improve quality of life. The study is open in SLRON (30 patients), CUH, UHG (1 patient). Prof Sinéad Brennan (SLRON) is the Irish NLI, and Dr David Palma of Lawson Health Research Institute (Canada) is the sponsor. SLRON has the highest accrual of all international sites. The study is due to close September 2024.




Team members from SLRON (left to right): Bahareh Khosravi, Dr Brian O'Neill, Emma Noone, Dr Orla McArdle

SABR COMET-3 (CTRIAL-IE 19-21)

'Phase III Randomized Controlled Trial and Economic Evaluation of Stereotactic Ablative Radiotherapy for Comprehensive Treatment of Oligometastatic (1-3 metastases) cancer'. This 'basket' study assesses the impact of SABR plus standard of care treatment, compared to standard of care treatment only, on overall survival, oncologic outcomes, and quality of life in patients with one controlled primary tumour and 1-3 metastatic lesions. The study is coordinated internationally by BC Cancer, Canada. In Ireland the study is open in SLRON (NLI for Cancer Trials Ireland sites: Prof John Armstrong), Bons UPMC, and Beacon Hospital. The study is due to close summer 2024.

SOURCE Lung (CTRIAL-IE 18-33)

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

Recently closed to accrual:

CompARE (CTRIAL-IE 17-14)

'Phase III randomised controlled trial Comparing Alternative Regimens for escalating treatment of intermediate and high-risk oropharyngeal cancer'. The main objectives of this study are to examine the outcomes of alternative treatments aiming to improve overall survival time in intermediate and high-risk oropharyngeal cancer and to compare Quality of Life, toxicity outcomes and swallowing function of these alternative treatments. The study was open in SLRON/SJH (21 patients) and UHG (3 patients), and closed to accrual in January 2024. Prof Sinéad Brennan (SLRON) is the Irish NLI, and University of Birmingham is the sponsor.

Pending Radiotherapy Studies:

NRG HN009 (CTRIAL-IE 22-04): The aim is to determine whether RT with low-dose cisplatin weekly is superior, in terms of acute toxicity and overall survival, to RT with high-dose cisplatin every 3 weeks for patients with locoregionally advanced squamous cell carcinoma of the head and neck.

TAORMINA (CTRIAL-IE 22-16): The aim is to assess the efficacy and safety of SABR and systemic therapy (investigational arm) compared with systemic therapy alone (standard treatment) in patients with oligometastatic breast cancer. In addition, the study aims to evaluate potential biomarkers of response and early progression by use of tumour tissue and blood.

EUROPA (CTRIAL-IE 21-27): The aim is to compare exclusive endocrine therapy and exclusive RT in patients aged ≥70 with low-risk early breast cancer.

NRG GU012 SAMURAI (CTRIAL-IE 22-17): The aim is to determine whether the addition of SABR to the primary tumour in combination with standard of care immunotherapy improves outcomes compared to immunotherapy alone in Renal Cell Carcinoma (RCC) patients.

RAVINA (CTRIAL-IE 21-28): The aim is to assess the benefit of adding xevinapant to RT in terms of duration of locoregional event-free survival (LREFS) in older patients with LA-HNSCC.

Additional studies in development include **SIMPLIFY SABR COMET**, which aims to determine if single fraction SABR is non-inferior to multiple fraction SABR, with respect to Healthcare Provider (HCP)-reported grade 3-5 adverse events related to treatment.

Database lock:

TRI-LARC (CTRIAL-IE 12-38)

This is an IIT which enrolled 94 patients at the three SLRON centres between 2014 and 2020. Prof Brian O'Neill is the CI. The study aimed to compare the incidence of acute grade ≥2 gastrointestinal toxicity for patients undergoing 3DRT versus IMRT for locally advanced rectal cancer. The database was locked in Jan-2024, and two study publications are planned.

Academic Publications from Cancer Trials Ireland Investigators

Breast

CTRIAL-IE 12-43: TRIO 022/ PALOMA-2
Rugo, H. S., S. Im, A. A. Joy, Y. Shparyk, J. M. Walshe, B. Sleckman, S. Loi, K. P. Theall, S. Kim, X. Huang, E. Bananis, R. Mahtani, R. S. Finn, V. Diéras (2024) "**The effects of adding palbociclib to endocrine therapy to treat advanced breast cancer: a plain language summary of a study using the PALOMA-2 and PALOMA-3 trial results**" Future Oncol 20(1):5-16 PMID: 37916267

Slamon, D. J., V. Diéras, H. S. Rugo, N. Harbeck, S. Im, K. A. Gelmon, O. N. Lipatov, J. M. Walshe, M. Martin, M. Chavez-MacGregor, E. Bananis, E. Gauthier, D. R. Lu, S. Kim, R. S. Finn (2024) "Overall Survival With Palbociclib Plus Letrozole in Advanced Breast Cancer" J Clin Oncol JCO2300137 PMID: 38252901 DOI: 10.1200/JCO.23.00137 (Online ahead of Print)

CTRIAL-IE 22-01: SHAMROCK
Dowling, G. P., S. Toomey, P. Bredin, I. Parker, E. Mulroe, J. Marron, O. McLoughlin, A. Teiserskiene, C. Power, A. M. O'Shea, M. Greally, P. G. Morris, D. Duke, A. K. Hill, B. T. Hennessy (2024) "**Neoadjuvant trastuzumab deruxtecan (T-DXd) with response-directed definitive therapy in early stage HER2-positive breast cancer: a phase II study protocol (SHAMROCK study)**" BMC Cancer 24(1):91. PMID: 38233810 DOI: 10.1186/s12885-024-11851-4

Gastrointestinal

Power, R. F., D. E. Doherty, I. Parker, D. J. Gallagher, M. A. Lowery, K. A. Cadoo (2024) "**Modifiable Risk Factors and Risk of Colorectal and Endometrial Cancers in Lynch Syndrome: A Systematic Review and Meta-Analysis**" JCO Precis Oncol 8:e2300196 PMID: 38207227

CTRIAL-IE (ICORG) 10-14: Neo-AEGIS
Reynolds, J. V., V. Donachie, J. Marron, A. Shevlin, Neo-AEGIS Investigators and Trial Group (2024) "**Management of locally advanced adenocarcinoma of the oesophagus and oesophagogastric junction: the Neo-AEGIS trial - Authors' reply**" Lancet Gastroenterol Hepatol 9(2):104-105 PMID: 38215774

Genitourinary

CTRIAL-IE 17-30: IRONMAN
Chen, N., C. B. McGrath, C. I. Ericsson, J. B. Vaselkiv, E. M. Rencsok, K. H. Stopsack, H. E. Guard, K. A. Autio, D. E. Rathkopf, D. Enting, R. L. Bitting, J. Mateo, C. W. Githiaka, K. N. Chi, H. H. Cheng, I. D. Davis, S. G. Anderson, S. M. Badal, A. Bjartell, K. M. Russnes, E. I. Heath, M. M. Pomerantz, J. C. Henegan, T. Hyslop, E. Esteban, A. Omlin, R. McDermott, A. P. Fay, A. A. Popoola, C. Ragin, J. Nowak, T. Gerke, P. W. Kantoff, D. J. George, K. L. Penney, L. A. Mucci (2024) "**Marital status, living arrangement, and survival among individuals with advanced prostate cancer in the International Registry for Men with Advanced Prostate Cancer**" Cancer Epidemiol Biomarkers Prev DOI: 10.1158/1055-9965.EPI-23-1207 PMID: 38189661 (Online ahead of Print)

Gynaecology

CTRIAL-IE 16-04: PRIMA - ENGOT-ov26 / GOG-3012 (Online ahead of Print)
Mirza, M. R., A. González-Martín, W. S. Graybill, D. M. O'Malley, L. Gaba, O. S. Yap, E. M. Guerra, P. G. Rose, J. Baurain, S. A. Ghamande, H. Denys, E. Prendergast, C. Pisano, P. Follana, K. Baumann, P. M. Calvert, J. Korach, Y. Li, I. A. Malinowska, D. Gupta, B. J. Monk (2024) "**A plain language summary of publication of the efficacy and safety of individualized niraparib dosing based on baseline body weight and platelet count in the PRIMA/ENGOT-OV26/GOG-3012 trial**" Future Oncol DOI: 10.2217/fon-2023-0755 PMID: 38251916

CTRIAL-IE 20-06: Soraya
Matulonis, U. A., D. Lorusso, A. Oaknin, S. Pignata, A. Dean, H. Denys, N. Colombo, T. V. Gorp, J. A. Konner, M. R. Marin, P. Harter, C. G. Murphy, J. Wang, E. Noble, B. Esteves, M. Method, R. L. Coleman (2023) "**Efficacy and Safety of Mirvetuximab Soravtansine in Patients With Platinum-Resistant Ovarian Cancer With High Folate Receptor Alpha Expression: Results From the SORAYA Study**" J Clin Oncol 41(13):2436-2445 PMID: 36716407

CTRIAL-IE 14-02: SHAPE trial
Plante, M., J. S. Kwon, S. Ferguson, V. Samouëlian, G. Ferron, A. Maulard, C. Kroon, W. Van Driel, J. Tidy, K. Williamson, S. Mahner, S. Kommoss, F. Goffin, K. Tamussino, B. Eyjilfsdottir, J. Kim, N. Gleeson, L. Brotto, D. Tu, L. E. Shepherd, et al., for the CX.5 SHAPE investigators (2024) "**Simple versus Radical Hysterectomy in Women with Low-Risk Cervical Cancer**" N Engl J Med 390:819-829 DOI: 10.1056/NEJMoa2308900

CTRIAL-IE 14-02: SHAPE trial (Article)
M. Plante (2024) "**A simple hysterectomy is considered a safe option for low-risk early-stage cervical cancer patients and improves quality of life" Canadian Cancer Trial Group"**

ICORG 10-12: ANZGOG-0701 Symptom Benefit Study
Roncolato, F., M. T. King, R. L. O'Connell, Y. C. Lee, F. Joly, F. Hilpert, A. Lanceley, Y. Yoshida, J. Bryce, P. Donnellan, A. Oza, E. Avall-Lundqvist, J. S. Berek, J. A. Ledermann, D. Berton, J. Sehouli, M. Kaminsky, M. R. Stockler, M. Friedlander (2023) "**Hidden in plain sight - Survival consequences of baseline symptom burden in women with recurrent ovarian cancer**" Gynecol Oncol 185:128-137 PMID: 38412736 (Online ahead of Print)

Patient Consultants Committee: Update

Our Patient Consultants Committee (PCC) now has members in seven DSSGs, with 20 members in total. The committee is chaired by Patrick Kivlehan (L&H DSSG) with recently appointed Deputy Chair Clodagh Flynn (Breast DSSG).

Following the PCC Strategy Day in November 2023, the committee produced a report on 'Trial Roadblocks for Patients' that was considered at the CTI Board Strategy Day. The main findings of this report covered Public & Patient perceptions / awareness of trials; contact and communications with cancer patients; the trials process as a participant (relating to documentation, co-ordinating care); and capacity and interest in conducting trials within the system.

At the January CTI National Training Day, our committee member Sarah McGrath (Breast DSSG) spoke about the patient perspective on trials, in conversation with Prof Ray McDermott. Sarah was very keen to demystify the process around trials – and emphasise that trials are not a last or final option. Some trials, like the one she partook in (Add Aspirin) are not onerous and could be potentially useful in the future of cancer research and care.

The first PCC meeting of 2024 was held in February and hosted a discussion on patient views on GDPR, consent and data, as it is a priority item for CTI. This GDPR session was attended by CTI Board member, Paul Keane. The committee also reviewed the roles of the PCC in CTI and held a workshop on patient-led research ideas. It was an excellent day, the majority of the PCC were able to attend in person with the balance online, and we took the opportunity to welcome new members and engage with a number of CTI staff from different departments.

In February, PCC members attended the joint international conference IACR/EACR/AACR held in Dublin. There, PCC members engaged with researchers about the importance of Public and Patient Involvement (PPI), attended talks and developed the first IACR/EACR PPI Award for Posters. For people who had not been to a cancer research conference before it was a window into the research oncology community. PPI involvement in this conference was a new avenue for the European Association for Cancer Research (EACR) where PPI is not as advanced as it is in Ireland, and the Irish PPI representatives were very well received by all.

PPI Co-ordinator

Sarah McLoughlin

Left to right: Siobhan Freeney (PCC, Breast DSSG), Clodagh Flynn, Vice-Chair (PCC, Breast DSSG), Robbie Connell, Bridget Carr & Krista Costello (both PCC & Gynae DSSG), Acting CEO of CTI, Angela Clayton-Lea, Sarah McLoughlin, PPI Co-ordinator at CTI.

Left to right: Bridget Carr, Krista Costello & Rita McInerney (all Gynae DSSG), Miriam Staunton (Melanoma DSSG), Tanya Knott (MTB), Peter Kelly & Patrick Kivlehan (both L&H DSSG), Clodagh Flynn & Siobhan Gaynor (both Breast DSSG), Jed Van De Poll (L&H DSSG)

Greening Cancer Clinical Trials

Our group published a paper last year called 'Climate Toxicity' which is the impact of climate change on cancer care and the impact of cancer on climate change. It's the first time the term has been used in medical literature.

Climate change is very bad for cancer and it disrupts cancer care. Fossil fuel pollution also contributes to cancer. In France, they calculated that 3% of their breast cancer cases are due to fossil fuel pollution from cars. To put that in context, 7% of breast cancer in Ireland is due to alcohol. It's a problem that's getting worse. We're all affected by it, 40% of our citizens were affected by global warming last year either through flooding or extreme weather events. We want to build sustainability into clinical trials and also awareness of it.

But when we look at the carbon footprint of clinical trials themselves, it is half the carbon footprint of Denmark, which is a country of 5 million people. Indeed, healthcare itself is very climate-unfriendly. If you take for instance the carbon footprint of health care in the United States, it is the same as the entire nation of the United Kingdom. The carbon footprint of the NHS, the UK health system, is the same as the nation of Croatia.

In ireland, if someone has a robotic hysterectomy today in Cork, the carbon footprint of that is someone driving in a car from Madrid to Moscow. If someone has a tonsillectomy in Cork and that generates 15 kilograms of waste, to incinerate that is 5,000 litres of water as the carbon footprint of nine families for a day. That's just one operation.

So, in 2022 we set up the national green cancer clinical trials initiative and we've established a green charter for cancer trials in Ireland. As the Clinical Lead of Cancer Trials Ireland, the Board of charged me to integrate a green charter into what we do. That ranges from if we have a meeting, we look at what type of sandwiches we order. A vegetarian sandwich's carbon footprint is half of a carnivore sandwich. It also extends into things like pensions and financial planning.

Our group published a paper last year called 'Climate Toxicity' which is the impact of climate change on cancer care and the impact of cancer on climate change. It's the first time the term has been used in medical literature. Our ambition is to look at other groups and green clinical trial groups globally and to integrate with them, work, and collaborate with them to be a sustainable clinical trial group.

The decisions that need to be made about healthcare, about climate change, are political in addition to individual. But if the medical community is silent about this, it's very hard for the politicians to be vocal. We need to speak up. Both in terms of the impact of climate change on our patients, in terms of cancer care but also in terms of being more active and more responsible in healthcare. I think that sometimes people feel that healthcare is so important, that the same standard shouldn't apply to it as everything else. But I think that's a missed opportunity, especially since it contributes so much.

I spoke about climate change five or six times last year and what people are really taken aback by, is the impact of healthcare on climate change and how damaging our practice is to climate change. The second aspect is how enthusiastic the younger generation is and how engaged they are. I think that's very reassuring and I think we all need to be involved here. We all have a stake here.

NATIONAL GREEN CANCER CLINICAL TRIALS INITIATIVE
cancer trials ireland

Cancer Retreat: May 10th 2024

Cancer Trials Ireland is pleased to announce the date for the 2024 Cancer Retreat – Friday May 10th. This year's theme is "Securing Our Futures". The agenda is being finalised, and while many of the individual contributors are currently being confirmed we can at this point outline the shape of the event.

Session 1: Plenary

In the plenary session, the event will address learnings from the National Training Day, and the outcomes from the 2024 CTI Board Strategy Day, including the priorities agreed (see: CEO address, p3). One of our confirmed speakers will be Ms Averil Power, CEO of the Irish Cancer Society, who kindly took an active role in our Strategy Day earlier this year. We aim to also feature a presentation on a recent submission for PEACEPLUS funding (All-Island initiative).

Session 2: Workshop - Learnings from the HRB grant

Preparations are already beginning for the next HRB Grant cycle, so we wanted to provide an opportunity for members to share their experiences and learnings from the current cycle. CRFs, CRCs and sites will receive a simple template feedback tool in advance of the Retreat. These findings will form the basis of discussion on the day – the aim is to start a collaborative dialogue to inform our approach to the grant.

Session 3: Panel Discussion - The future of non-drug trials

After the break, there will be a series of short presentations (5 mins approx.) on Nurse-led research, lifestyle studies, RT Trials, Biobanking , PPI, survivorship and more, all followed by a panel discussion, taking us up to our final session: -

Session 4: Panel Discussion - CTI in 2030

'What will the future look like, and how will we get there?'. That will be the theme for opening presentations on: the future of surgical studies, AI in trials, Nursing career development, RT, and medical oncology. The purpose of this session is to discuss some of the opportunities and challenges envisaged in the next 5-6 years, to ensure that CTI (as your research network) is positioned to secure all our futures.

We hope that you have already marked the date in your calendar, and we encourage you to attend the event (in RCSI, Dublin) if at all possible. The Retreat is run for the benefit of all CTI members and your participation is essential.

Below: Guests, speakers & participants from the 2023 Cancer Retreat

Cancer Trials Ireland studies open to accrual (as of Jan 31st 2024)

Purple = Industry studies - Green = Cancer Trials Ireland in-house studies - Orange = Collaborative Group studies - Adopted IIT - Adopted Collab study

DSSG	General Group	Cancer Trials Ireland No:	Study Name:	Total Accrual (to 31-Jan-2024)	TUH	Beacon	BH	BonS	BonS/ UPMC	CUH	UHG
Breast	Trans	09-07	Breast Cancer Proteomics and Molecular Heterogeneity	4828			3009			1075	
Breast	Clinical	20-24	SASCIA (closed to accrual 31-Jan- 2024)	46			8			5	
Breast	Imaging	21-02	EA1183 FEATURE (closed to accrual 22-Dec-2023)	2						2	
Breast	Clinical	21-15	DESTINY-Breast05 (closed to accrual 12-Feb-2024)	11						1	
Breast	Clinical	21-31	MK 7339 002 / KEYNOTE-B49 (closed to accrual 22-Feb-2024)	3							
Breast	Clinical	21-32	Novartis EPIK-B5	1			Open				
Breast	Clinical	22-01	SHAMROCK	2			2			Open	
Breast	Trans	22-21	Exosomes in TNBC	19							
Breast	Obser-vational	24-21	UCARE	44							44
Breast	Imaging	24-22	Wavelia	51							51
CNS	Radio	20-03	Spine SABR	0		Open			ISU		
GI	Radio	17-12	DP-IMRT Pancreas	0							
GI	Clinical	24-17	MK 3475-587/ Keynote-587	6	6						
GI	Clinical	20-27	PaTcH	9							
GI	Clinical	24-16	Cardia	0							
GI	Clinical	20-36	NEEDs	0							
GI	Clinical	18-44	Astellas 8951-CL-5201 (accrual closed since last DSSG)	5				0			
GI	Clinical	21-07	DESTINY DS8201-A-U306	4	Open		Open			Open	
GI	Clinical	23-17	FORTITUDE-101	0							
GI	Clinical	21-35	HERIZON-GEA-01 (ZWI-ZW25-301) Zymeworks (accrual closed since last DSSG)	4							
GI	Clinical	23-25	Mountaineer-03	0			Open	Open			
GU	Radio	23-01	PACE NODES	0					Open		
GU	Clinical	20-16	MK3475-905 (bladder) (study on hold)	3	2						
GU	Clinical	21-20	MK3475- 365	3	3						
GU	Clinical	21-37	MK6482-022	17	5		2			2	
GU	Clinical	21-38	IMvigor011 B042843	1	Open					1	
GU	Clinical	20-32	PEACE 6: VULNERABLE	2	2						
GU	Trans	17-30	IRONMAN	106	46	9					
GU	Trans	22-10	Pivotal Study BP-007 (accrual closed since last DSSG)	6							
GU	Clincial	22-11	SABRE	16					16		
GU	Registry	23-09	SLECT	78	78						
GU	Inven-tional Pro-gramme	23-18	LIAM Mc	16						16	
Gynae	Clinical	20-07	OVIHIPEC 2	9							
Gynae	Clinical	22-03	ENGOT ov65 (accrual closed since last DSSG)	3						Closed	
Gynae	Clinical	21-03	ENGOT cx11 (accrual closed since last DSSG)	3						3	
Gynae	Clinical	19-02	ENGOT cx12 (accrual closed since last DSSG)	0							
Gynae	Clinical	22-02	ENGOT en15 (accrual closed since last DSSG)	6				1			
Gynae	Clinical	18-35	ENGOT cx8 (accrual closed since last DSSG)	0				Closed		Closed	
Gynae	Trans	22-05	ENGOT ov47 HELPER	2		2					
Gynae	Clinical	22-08	ENGOT en-20 SIENDO Part 2 XPORT	0		TBI				0	TBI
Lymph &	Clinical	19-34	Isa-RVD	31			3				TBI
Lymph &	Clinical	19-18	Hovon 150	6			Open			1	2
Lymph &	Clinical	21-22	MK1026-003	0			Open				
Lymph &	Clinical	21-43	LOXO-BTK 20020	3			1				
Lymph &	Clinical	21-47	Dream M14	0			0			ISU	

Cancer Trials Ireland studies open to accrual (as of Jan 31st 2024)

Key: Site open to accrual | Site to be initiated | Site in Set -up | Site initiated but not active (Pending)

LUH	Mater	MWROC at UHL	MRH	MUH	OLLHD	OLCHC	UHL	SLRON	SJH	SUH	SVUH	UHW	Whit	International Sites
							385		Closed		Open	359		
							4		12		14	3		
	4						Open		4		2			
									Open		3			
									Open		1			
							Open		Open		TBI			
	11										8			
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	Open											Open		
		ISU						Open						
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	Open						ISU				Open	ISU		
										15	36			
								6						
	9													
									3					
									Closed					
									Closed			Closed		
									5					
	Closed								Closed			Closed		
									0			TBI		
	12						10		1			5		TBI
									3					
							ISU							
									2					

Cancer Trials Ireland studies open to accrual (as of Jan 31st 2024)

Purple = Industry studies - Green = Cancer Trials Ireland in-house studies - Orange = Collaborative Group studies - Adopted IIT - Adopted Collab study

DSSG	General Group	Cancer Trials Ireland No:	Study Name:	Total Accrual (to 31-Jan-2024)	TUH	Beacon	BH	BonS	BonS/ UPMC	CUH
Lymph & Haem	Clinical	23-19	CARTITUDE-5	0						
Lymph & Haem	Clinical	23-12	MajesTEC-4	0						
Head & Neck	Clinical + Radio	17-14	CompARE (accrual closed since last DSSG)	24						
Head & Neck	Clinical	21-41	VERSATILE-002 (PDS0101-HNC-201)	1						
Head & Neck, and Melanoma	Clinical	20-08	Keynote 630 (MK-3475-630)	2						
Head & Neck	Radio	20-04	PRESERVE	31						Open
Head & Neck	Radio	23-24	OPEN	19						
Lung	Radio	18-33	SOURCE Lung	29		2				
Lung	Clinical	20-21	AcceleRET-Lung / BO42864	2						
Lung	Clinical	21-13	KRYSTAL-12 (accrual closed since last DSSG)	7	1		3			
Lung	Clinical	22-07	KRYSTAL-7 (on-hold)	1			1			
Lung	Trans	23-11	BRAND	48			25			
Lung	Clinical	22-23	NeoCOAST-2	0			Open			
Lung	Clinical	23-12	LATIFY	2			2			Open
Lung	Trans	22-15	PLAN	58		1	19			
Lung	Clinical	22-09	ADEPPT	1			1			ISU
Melanoma	Clinical	18-50	R2910-ONC-1788	4						2
Melanoma	Clinical	20-37	MelMarT-II	0						
Melanoma	Clinical	22-25	R3767 ONC 2055	0			0			0
Melanoma	Clinical	22-26	R3767 ONC 2011	3						
Melanoma	Clinical	22-28	KEYVIBE-010	0			0			
Basket	Radio	19-21	SABR COMET-3	11		0			7	
Basket	Clinical	19-27	MK7339-002/LYNK-002	5	Closed			3		
Basket	Radio	21-28	E2RADIatE	0		Open				
Basket	Clinical	22-22	Immuno Fertility	5			5			
Basket	Observation-al	24-18	POST	131						
Basket	Trans	24-19	TAGNEY	11				11		
Basket	Observation-al	24-27	CRL Lymphoedema Trial	95				95		
Basket	Survivorship	24-31	Sleepio SAC	21						
Basket	Clinical	24-11	ANTHOS ANT 007 - Aster	2						2
Basket	Clinical	24-23	Gut Microbiome	15			15			
Paeds	Trans	16-34	LLR Leukaemia Cell bank	0						
Paeds	Registry	16-37	EWOG-MDS-2006	10						
Paeds	Clinical	16-41	LINES (accrual closed since last DSSG)	4						
Paeds	Trans	16-42	Renal IMPORT	56						
Paeds	Trans	16-43	Tumour Banking Study	143						
Paeds	Trans	16-46	EWOG-SAA 2010	24						
Paeds	Trans	16-49	NB SCI Study	3						
Paeds	Clinical	16-53	Interfant 06	6						
Paeds	Clinical	16-81	SIOP Ependymoma II	11						
Paeds	Clinical	16-82	MyeChild (accrual closed since last DSSG)	28						
Paeds	Clinical	18-16	ITCC 059	2						
Paeds	Clinical	18-17	PHITT	7						
Paeds	Clinical	18-18	LCH IV	5						
Paeds	Trans	18-19	MAPPYACTS	0						
Paeds	Trans	18-24	ITCC 054 (accrual closed since last DSSG)	0						
Paeds	Clinical	18-36	LOXO-TRK-15003 (accrual closed since last DSSG)	3						
Paeds	Clinical	19-31	DIPG Registry	0						
Paeds	Registry	20-29	LOGGIC CORE	4						
Paeds	Registry	23-26	EBMT	40						

Cancer Trials Ireland studies open to accrual (as of Jan 31st 2024)

Key: Site open to accrual | Site to be initiated | Site in Set -up | Site initiated but not active (Pending)

UHG	LUH	Mater	MWROC at UHL	MRH	MUH	OLLHD	OLCHC	UHL	SLRON	SJH	SUH	SVUH	UHW
Open													
3									21	See SLRON tab			
										1			
									Screening only	2			
1									30				
									19				
									27				
										2			
Open								Open		3		Open	
										23			
Open		Open								TBI			
								Open				Open	
								1		37			
ISU								ISU		TBI			ISU
1												1	
										Open			
0												0	
												3	
										0			
									4				
		Closed										2	
TBI									Open				
												131	
		19										2	
							on hold						
							10						
							4						
							56						
							143						
							24						
							3						
							6						
							11						
							28						
							2						
							7						
							5						
							0						
							0						
							3						
							0						
							4						
							40						

Fundraising News

Friends of Cancer Trials Ireland

It is once more time to express our deep thanks and gratitude to the organising committee and patrons of the Friends of Cancer Trials Ireland. Last November's gala event raised a staggering €100,092 for Cancer Trials Ireland, and the Friends have agreed to run the event again in 2024. Particular thanks to the organising committee members, namely: Deirdre McDermott, Rita Lovett, Katherina Sheahan, Kim Fitzgerald, Grace McDermott, Liz Coughlan, Fiona Collins, Julie Liston, Mairead O'Brien and Paula Murphy.

Thanks to the Friends of Cancer Trials Ireland organising committee

Templeogue Tennis Club

Towards the end of 2023, the Ladies Committee of the Templeogue Tennis Club raised €6,817.50 for Cancer Trials Ireland. This is the second year in a row that Cancer Trials Ireland is lucky enough to be the beneficiary of the Club's generosity and consideration, and we want to thank Felicity McCarthy and her fellow club members for their excellent efforts.

Nestle Staff Charity

Andy Creevy, whose wife took part in the LOXO trial several years back, continues to be a consistent supporter of Cancer Trials Ireland. A few years ago, Andy inspired his colleagues in Nestle to pick CTI as it's charity of choice, and in the past few months alone, staff have raised over €12,000, most recently via the Runamuck adventure race. Nestle's staff will continue to support us in 2024, with a sponsored hill walk this Spring, and with Andy himself taking part in the Liffey Descent on May 11th. Other events are planned for later in 2024 as well.

Individual donations

Just as Cancer Trials Ireland is lucky enough to benefit from large fundraisers like the Friends of Cancer Trials Ireland, the Property Picnic, and the Pat Smullen Race Day, we are also fortunate to be in consideration for dozens of individuals who donate to us with smaller amounts that all add up to a significant amount. So, thank you to the Ballyfoyle Agricultural Show, Nicola Miley, the several individuals who chose us as their recipient of choice for the Dublin Marathon last October, Caterine Duggan, Jack Harrison, Rod Nowlan, Anne Birrane, Andrew McGrath, Tina Redmond, Yvonne McCarthy, Emilio Cirillo, Dermot Drew, Martin O'Sullivan and Frank Van Der Beek.

Upcoming fundraisers

In 2024, Cancer Trials Ireland will benefit from at least two more significant fundraisers – the Pat Smullen Race Day on Aug 31st, and the Property Picnic on May 16th. This year's Property Picnic is being spearheaded by Colliers, while the Pat Smullen Race Day will seek to expand on the excellent Charity Race it ran for the first time in 2023. (Include pics) Both events are repeat fundraisers, and already the Property Picnic has amassed more than €72,000.

cancer trials ireland

Together, we're finding answers to cancer.