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DSSG Digest

Spring 2023

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

All-Island Collaboration

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Clinical Lead:

Prof Ray McDermott

2023 looks like being a good year for Cancer Trials Ireland. There are no less than 20 trials in development, of which six are IMP – and of which three of these six are Investigator Led Trials. You'll find further details of them (SHAMROCK, PATCH, ADEPTT) within the pages of this Digest. There are a further seven RT & RT/IMP trials in development too, two of which are ILTs as well – Dose Painting IMRT for pancreas cancer, and Spine SABR for CNS. Sticking with the category of ILTs, I also want to highlight two translational studies, CADY (breast) and FEED (pancreas). The HRB grant that we all operate under no longer funds translational research, and yet we know how vital it is – and we see this reflected in our investigators finding a way to fund and execute it.

Meanwhile, and in addition to the studies mentioned above, the last Scientific Management Group (SMG) meeting approved a further two RT trials and three gynae IMP studies, with another five IMP and one last RT still in the discussion phase.

All of this works continues to demonstrate the ambition of investigators and the wider clinical oncology research community in Ireland, whether other green shoots are starting to show through as well. The HSE NCCP has appointed 11 medical oncologists in the past two years, and we will soon provide the NCCP with evidence to support appointments and structural changes for nurses, radiation therapists, pharmacists, data managers and other support staff. This will arise from a survey of site staff being developed by Cancer Trials Ireland and collaborators such as Dr Laia Raigal in Cork.

We have already seen positive developments with NREC, and today (March 31st 2023) we will hear about HSE plans to appoint six positions to address data protection issues. These developments – the appointments, surveys, NREC developments, and now GDPR developments – are a direct result of the Cancer Trials Ireland network speaking with a unified voice to provide our political decision-makers with the evidence they need to make beneficial changes to the oncology research environment today. I am not suggesting that these problems are solved, by any means, but the high visibility of cancer in Ireland, and its projected rise in incidence in the coming decades ensure that we are an important stakeholder in shaping how that care is delivered.

We will continue to advocate on the issues that profoundly impact trials in Ireland, including protected time, because we can see that our efforts bear fruit.

In the meantime I invite you to peruse this Digest, and sample the breadth of what Cancer Trials Ireland is currently doing – from trial management, to the Molecular Tumour Board, to advocating, to events like the Cancer Retreat, and initiatives like Greening Trials, the Patients Consultants Committee, to welcoming home the next generation of our clinical leaders. I am delighted to welcome Grainne O'Kane as the new Chair of the GI DSSG – just as I want to thank Prof Austin Duffy for his years of service on the role. Finally, I want to recognise the significant contribution of our retiring Group Statistician, Imelda Parker. Imelda has been working with Cancer Trials Ireland since the (early) ICORG days, and she has been instrumental to the milestones we have achieved over the past two decades and more.

Eibhlin Mulroe & Enda Kenny, IRROG conference

Top left: Eibhlin Mulroe & Meg Mooney, Assoc Director CTEP, NCI

Top Middle: Dr Satish Gopal, Director of NCI Centre for Global Health (centre) with AICRI, HRB, InterTrade Ireland delegation

Top right: Dr James Gulley, Dr Mairead O'Driscoll (HRB), Dr Daire Bracken, Eibhlin Mulroe, Kieran Briscoe

Eibhlin Mulroe with Mary Harney & Danny McCoy, CEO of IBEC

Eibhlín Mulroe
CEO

Delivering a compelling All-Island cancer trial proposition

For the week of St Patrick's Day, I was fortunate to be a part of a delegation that travelled to Washington DC to promote an All-Island approach to cancer trials and research with an incredibly support and influential group of people and institutions in America, including the National Cancer Institute, the US-Ireland Research Partnership, the US State Department, the National Institute of Health, and those ambassadors and members of Congress who welcomed our delegation and our message of All-Island and transatlantic collaboration.

I want to thank the other members of the All Island Cancer Research Institute (AICRI) delegation team, including Prof Liam Gallagher of AICRI, Prof Mark Lawler of Queens University Belfast and Ciaran Briscoe, North East Cancer Research & Education Trust.) The AICRI were delighted to be joined by Dr Mairead O'Driscoll from HRB, Prof Philip Nolan, CEO, SFI, Margaret Hearty, CEO, and Richard Kennedy, Chair of InterTrade Ireland.

Day 1: One of the highlights of the trip was organised by QUB in the NCI, Bethesda where we celebrated 25 years of the Good Friday Agreement, and All-Island co-operation. Mairead O'Driscoll spoke, as did Liam Gallagher, Mark Lawler and myself, and the audience included NCI Director Satish Gopal for Global Health. Together we emphasised the importance of all-island collaboration, and our track record of working with NCI to run trials and research together, and to train nurses and investigators. The meeting also included our outgoing GI DSSG Chair, Austin Duffy, and soon-to-return Irish investigator, Geraldine O'Sullivan Coyne who previously worked at NCI and talked about the valuable learning from that experience in the context of leading ILTs. QUB have 9 PhD's currently working in NCI and they presented to the audience on their basic and translational research. ,

That afternoon I had the fantastic opportunity to take a tour of the NCI trials facility on the Bethesda NCI campus. This is a whole hospital dedicated to running cancer clinical trials from bench to bedside. I was mindful of the many Irish patients including Vicky Phelan who travelled there to avail of the innovative clinical trials offering novel treatments. Prof Duffy earlier that day had talked about his wish to provide some of those phase 1 trials to the Irish population in Dublin and his ambition to set up a phase 1 unit here.

Day 2: I had the opportunity to present at the US-Ireland Research Partnership, which included members of the US State Department. Mark Lawler outlined the history of our collaboration, Liam Gallagher presented our 'ask' as a delegation while I presented the argument for investing in cancer trials, and cancer research in Ireland, emphasising the economic benefits of this investment.

That evening I was invited to attend the IBEC dinner which was celebrating Peace and Prosperity on the Island. The week before I had spoken at an IBEC event in Dublin which acknowledged the impact of the Good Friday Agreement on our very first HRB grant over 20 years ago.

Day 3: Our delegation met with staff at the office of Congressman Neale of Massachusetts (we also met Congressman Higgins of New York's team on Thursday) where we restated the case for investment and collaboration. After that we attended the Science Foundation Ireland's St Patrick's Day medal ceremony, which goes to Irish Diaspora researchers.

That evening we met a wider cross-section of the Irish-American philanthropic community at the Ireland Fund Dinner including Senator Joe Kennedy, the Irish Ambassador to Washington, the US Ambassador to Irelandand our own Taoiseach Leo Varadkar.

Day 4: Thanks to Mark Lawler and QUB, we were invited to a breakfast event hosted by the (State Department's) Northern Ireland Bureau which provided us the opportunity to speak to Jane Brady, the head of the civil service in NI alongside all the main political leaders. Later that morning I attended an event marking 25 years of women working in Northern Ireland. This was an incredible event, hosted by Hilary Clinton, where I got to speak to our own Mary Robinson about our green cancer trials initiative. That evening we attended an event in the Irish Ambassador's residence on the eve of St Patricks Day, and the following morning Liam Gallagher and Kieran Briscoe, took the train to NYC to meet An Tanaiste Micheal Martin and actually march in the St Patrick's Day parade (my hat goes off to them). Staying in Washington afforded me the opportunity to meet Meg Mooney, Associate Director of the Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis (DCTD), at the National Cancer Institute (NCI), which manages drug use on trials in America. She represents a critical group within NCI if we are to enact NCI trials on the island of Ireland in the future.

Prior to the trip to America, there was much else besides happening in the all-island space. On Feb 24th an AICRI delegation (including myself and Prof Maeve Lowery) presented to the Oireachtas Committee for the Implementation of the Good Friday Agreement. That gave us the opportunity to highlight a proposal to the PEACE PLUS fund. A few days later I took part in an IBEC event for Peace + Prosperity.

Congressman Neale, Eibhlin Mulroe, An Taoiseach, Leo Varadkar & Porf Liam Gallaher, UCD

Mary Robinson & Eibhlin Mulroe

Breast: SHAMROCK (CTRIAL-IE 22-01)

Prof Bryan Hennessy

Led by Prof Bryan Hennessy, sponsored by Cancer Trials Ireland, 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' is adaptive multicentre trial to investigate how effective neoadjuvant treatment with trastuzumab deruxtecan is for patients with early stage or locally advanced HER2 positive breast cancer.

In this trial an in-vitro diagnostic test will be used to help identify patients who are excellent responders to the neoadjuvant treatment with trastuzumab deruxtecan (T-DXd) and potentially to discontinue neoadjuvant treatment earlier if a pathological complete response (pCR) is predicted.

RNA Disruption Assay (RDA™) is a molecular test based on the analysis of RNA disruption, a qualitative and quantitative alteration of the ribosomal ribonucleic acid (rRNA) of tumour cells that correlates with chemotherapy response in primary breast cancer. RDA was developed to evaluate the extent of RNA disruption during treatment, as assessed by a proprietary algorithm and expressed by an RNA Disruption Index (RDI). It stratifies patients' response into 3 response zones: non-response (zone 1), partial-response (zone 2) and response (zone 3). Recent additional clinical studies have indicated that lack of pCR and clinical progression is preferentially associated with absent or minimal RNA disruption measured as early as 20 days following the first cycle of neoadjuvant chemotherapy.

Neoadjuvant therapy is an increasingly common mode of chemotherapy in clinical practice. There is some evidence that identifying non-responders early in neoadjuvant treatment and offering alternative agents (response-guided or adaptive therapy) increased pCR rates and/or survival while minimising morbidity.

Study team expects that RDI measured after 2 cycles of drug treatment (35 +/- 4 days) of starting T-DXd treatment will allow an accurate RDA assessment for all patients, including patients who are slow responders. The study will investigate its performance as a predictive marker of pathological complete response (pCR) and disease-free survival. Those patients with a high chance of pathological complete response (pCR) based on the RDI score will undergo a breast imaging after four cycles of T-DXd. If they also have imaging complete response (iCR) at that point they will proceed to surgery after four cycles of T-DXd. Other patients who have a high chance of pCR based on the RDI score but iCR is not attained after four cycles or who have a low/intermediate chance of pCR based on the RDI score will receive six cycles of T-DXd.

The RNA Disruption Assay is an in-vitro diagnostic test and in line with the IVDR Regulation 2017/746, a performance study for this IVD is required to be approved in Ireland prior to commencement of a clinical trial in which this IVD is being used for a medical purpose. In this case this RDA is being used to make medical management decisions for trial subjects and thus a performance study is required. The Shamrock study has already received NREC Clinical Trials approval and HPRA Clinical Trials approval with a condition that an interventional clinical performance study for the assay will get authorisation in Ireland. Currently submission documents are being prepared and will be submitted for approval to HPRA Medical Devices and NREC Medical Devices in near future.

The study is funded by grant from Breast Cancer Ireland. AstraZeneca and Daiichi-Sankyo are the co-developers of trastuzumab deruxtecan (T-DXd) and they will supply it for this study.

SHAMROCK study It will be open to recruitment at four sites initially (Beaumont Hospital, St. Vincent's University Hospital, Cork University Hospital, and University Hospital Limerick) with potentially more sites opening in the future.

Lymph & Haem: 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. Cancer Trials Ireland and Blood Cancer Network Ireland (BCNI) worked closely on development of this trial. The study is receiving funding from Janssen and BMS. This trial is a national study that will run in three BCNI sites (University Hospital Galway, Beaumont Hospital and Cork University Hospital).

The study sites were initiated from March to November 2021 and recruitment commenced in December 2021. The first stage in the study was to establish the Maximum Tolerated Dose (MTD) and recommended phase II dose (RP2D) of CPD in combination with DARA. The MTD was established at Dose Level 1 on April 29th 2022. Patients have been continued to be recruited to the study at the RP2D. A total of 20 patients will be recruited to the study in total. T

To date 14 patients have been enrolled in total across the 3 study sites. Recruitment is expected to continue until the start of Q3 2023. The last patient last visit is expected in Q2 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.

Breast studies open to accrual:

SASCIA (CTRIAL-IE 20-24)

The SASCIA study is making great strides with twenty six patients now randomised to the study, which is eleven more since the last reporting – twelve in St Vincent's Hospital, seven in Beaumont Hospital, three in St. James's Hosipital, two in Cork University Hospital, and one each in University Hospital Limerick and University Hospital Waterford. Four patients are currently in screening for this study. It is pleasing to see widespread geographic engagement with the study, which aims to recruit 40 patients in total. 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.

Roche GO42784/ TRIO 045 (lidERA Breast Cancer) (CTRIAL-IE 21-04)

Led by Prof. Janice Walshe in Ireland, this is a study sponsored by Roche which is investigating the efficacy and safety of adjuvant giredestrant compared with endocrine therapy of physician's choice in patients with medium- and high-risk Stage I-III histologically confirmed estrogen receptor (ER)-positive and human epidermal growth factor receptor 2 (HER2)-negative early breast cancer. This study is now open in seven Irish hospitals. This study aims to recruit 4100 patients globally to the trial. In Ireland currently 33 patients have been recruited to this study, which is due to end recruitment in January 2024.

ZEST/ GSK 213831 (CTRIAL-IE 21-16)

Led by Prof. Patrick Morris in Ireland, this is a study sponsored by GSK which is looking to assess the efficacy and safety of Niraparib in patients with either tumor mutation in the BRCA gene HER2- breast cancer (independent of hormone receptor [HR] status, including HR positive [+] and TNBC) or tumor BRCA wild type TNBC with molecular disease based on the presence of circulating tumor Deoxyribonucleic acid (ctDNA) following surgery or completion of adjuvant therapy. Patients who have completed definitive therapy at any time in the past are eligible for ctDNA monitoring and potential enrollment onto the trial. This study is now open in Beaumont Hospital and St. James's Hospital, Dublin. This study aims to recruit 800 patients globally to the trial. In Ireland currently 15 patients have been pre-screened for this study and 2 patients demonstrated a positive ctDNA result but both were screen failures. Study is due to end recruitment in December 2025.

EPIK-B5 (CTRIAL-IE 21-32)

Led by Prof. Janice Walshe, this is a study sponsored by Novartis and is aiming to obtain more comprehensive data on the efficacy and safety of alpelisib (BYL719) in combination with fulvestrant compared with placebo plus fulvestrant in men or postmenopausal women with HR-positive, HER2-negative advanced breast cancer with a PIK3CA mutation who progressed or relapsed on or after treatment with an AI plus a CDK4/6 inhibitor. This study is now open in St. Vincent's University Hospital, Beaumont Hospital and St. James's Hospital, Dublin. This study aims to recruit 234 patients globally to the trial. 4 patients per centre are expected to be recruited to this study, which is due to end recruitment October 2023.

KEYNOTE-B49 (CTRIAL-IE 21-31)

Led by Prof. John Crown, this is a study sponsored by Novartis and is aiming to assess the safety and efficacy of pembrolizumab plus the investigator's choice of chemotherapy compared to placebo plus the investigator's choice of chemotherapy in the treatment of chemotherapy-candidate hormone receptor-positive, human epidermal growth factor receptor 2-negative (HR+/HER2-) locally recurrent inoperable or metastatic breast cancer. This study is now open in St. Vincent's University Hospital and St. James's Hospital, Dublin. This study aims to recruit 800 patients globally to the trial. 4 patients per centre are expected to be recruited to this study, which is due to end recruitment February 2024. The first Irish patient was randomised to this study recently in St. Vincent's University Hospital.

DESTINY-Breast05 (CTRIAL-IE 21-15)

Led by Prof. Janice Walshe, this is a study sponsored by Daiichi Sankyo and is investigating the efficacy and safety of trastuzumab deruxtecan (T-DXd) compared with trastuzumab emtansine (T-DM1) in high-risk patients with residual invasive HER2-positive breast cancer following neoadjuvant therapy. This study is now open in St. Vincent's University Hospital, Cork University Hospital, University Hospital Limerick, Mater Misericordiae University Hospital and St. James's Hospital. This study aims to recruit 1600 patients globally to the trial. In Ireland currently 5 patients have been randomised on this study, which is due to end recruitment June 2024.

DESTINY-Breast12 (CTRIAL-IE 21-05)

Led by Prof. Roisin Connolly, this is a study sponsored by AstraZeneca and is investigating the efficacy and safety of Trastuzumab deruxtecan (T-DXd) in patients with or without brain metastasis, with previously treated advanced/ metastatic HER2-positive breast cancer whose disease has progressed on prior anti-HER2-based regimens and who received no more than 2 lines/regimens of therapy in the metastatic setting (excluding tucatinib). This study is now open in St. Vincent's University Hospital, Cork University Hospital and Mater Misericordiae University Hospital. This study aims to recruit 500 patients globally to the trial. In Ireland currently 21 patients have been randomised on this study, which is due to end recruitment March 2023.

Gynae news:

ENGOT-en15/ KEYNOTE-C93-00 (CTRIAL:22-02)

Led by Prof. Karen Cadoo, this is a study sponsored by MSD which is investigating Pembrolizumab versus Platinum Doublet Chemotherapy in Participants With Mismatch Repair Deficient (dMMR) Advanced or Recurrent Endometrial Carcinoma in the First-line Setting. This studyis now open in Bon Secours Cork and St. James's Hospital, Dublin. This study aims to recruit 350 patients globally to the trial. 3 patients per centre are expected to be recruited to this study, which is due to end recruitment Summer 2023. Our first patient was recruited to this study recently in Bon Secours.

ENGOT-ov65 / KEYNOTE-B96 (CTRIAL 22-06)

Led by Dr. Dearbhaile Collins, this is another study sponsored by MSD investigating Pembrolizumab/Placebo Plus Paclitaxel With or Without Bevacizumab for Platinum-resistant Recurrent Ovarian Cancer. This study opened recently in St. James's Hospital, with it's final site at Cork University Hospital opening shortly. This study aims to recruit 616 patients globally to the trial. 8 Irish patients are expected to be recruited to this trial, which is due to end recruitment in May 2023. We currently have 1 patient randomised. Referrals are encouraged for this important trial.

OVHIPEC-2 (CTRIAL 20-07)

Led by Dr. 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 4 patients randomised already to this trial, which is due to end recruitment in 2024.

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. The CTI are working hard to get this study open, with HPRA approvals recently received and are now awaiting NREC approvals before they open the Irish sites.

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 will be open in XX.

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 will open in University Hospital Waterford, University Hospital Galway, Cork University Hospital, St. James's Hospital and the Beacon Hospital.

Other studies In early stages include 22-18 Gloriosa (Immunogen), 22-19 Navtemadlin (Kartos) and 22-20 RAINBO Blue / TAPER, which is a study sponsored by CCTG. More on these studies will be provided in the next DSSG Digest.

Lymph & Haem: HO150 (CTRIAL 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).

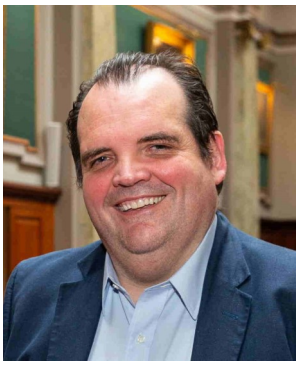
The duration of patients' treatment will be up to 2.5 years; patients will be followed-up until 10 years after registration on the trial.

The trial is sponsored by HOVON. In Ireland, Cancer Trials Ireland are supporting HOVON with coordination of the trial.

The HO150 trial is expected to meet its accrual target for the IDH2 cohort in Q2 2023, at which point recruitment will be closed. The IDH1 cohort is expected to remain open to accrual until Q1 2024.

Prostate: DASL HiCaP *(CTRIAL-IE 19-32)*

CI Prof Ray McDermott - 68 Participants Randomised in Ireland & the UK



The DASL-HiCaP study has now recruited over 900 patients globally and is on target to complete recruitment by the end of June this year. This includes a significant contribution of 68 participants to date randomised across Ireland and the UK.

Prof. Ray McDermott is the Chief Investigator in Ireland, along with Dr. Paul Kelly, Co-Chief Investigator. The study opened in Ireland in Summer 2021 and has recruited 27 participants at 8 sites: Cork University Hospital, Bons/UPMC Cork, St. Luke's Rathgar, Mater Misericordiae University Hospital, Mater Private Hospital, Tallaght University Hospital, The Beacon Private Hospital and Galway University Hospital. SLRON at St. James's Hospital also opened to recruitment early this year and the team are actively screening patients for the study.

Dr. Simon Hughes is the Chief Investigator in the UK where 41 patients have been randomised with 10 open sites: Guy's Hospital, Royal Marsden Hospital, Aberdeen Royal Infirmary, Beatson WOSCC, Nottingham City Hospital, Kent & Canterbury Hospital, Western General Hospital in Edinburgh and Royal United Hospital Bath. These were joined in January by Belfast City Hospital and Charing Cross Hospital.

DASL-HiCaP is a randomised phase 3 study, which aims to demonstrate that the addition of a new oral hormonal therapy, darolutamide, to the standard radiation therapy and testosterone suppression improves the outcomes of men with localised high-risk prostate cancer. Prostate cancer remains the most common cancer in men across Ireland and the UK, and the leading cause of cancer-related mortality for men in developed countries.

Definitive radiation therapy (RT), plus androgen deprivation therapy (ADT) with a luteinising hormone releasing hormone analogue (LHRHA) for at least one year, is standard of care for men with very high risk localised prostate cancer, or with very high risk features and persistent PSA after radical prostatectomy. However, incurable distant metastases develop within 5 years in approximately 15% of people with very high risk features despite this treatment.

Darolutamide is a novel antagonist of the androgen receptor (AR) with favourable tolerability due to negligible penetration of the blood-brain barrier.

DASL-HiCaP is a study designed to see if adding Darolutamide to standard treatment decreases the risk of metastasis, as well as improving quality of life and potentially decreasing the risk of prostate cancer death.

The participants in this study will take Darolutamide orally twice daily for 96 weeks or placebo twice daily for 96 weeks. They will also be treated with an LHRHA for 96 weeks, plus RT starting at approximately week 8-24 from randomisation.

DASL-HiCaP is a global collaborative investigator-initiated trial led by ANZUP (The Australian and New Zealand Urogenital and Prostate Cancer Trials Group) and sponsored by the University of Sydney NHMRC Cancer Trials Centre, in collaboration with Cancer Trials Ireland, Canadian Cancer Trials Group, Memorial Sloan Kettering Cancer Center and The Prostate Cancer Clinical Trials Consortium. Cancer Trials Ireland is the European Sponsor and regional coordinating centre. The University of Sydney NHMRC Clinical Trials Centre provides central study coordination. Bayer is providing drug and financial support.

L&H: Isa-RVD *(CTRIAL-IE 19-34)*

The CTRIAL-IE 19-34 Isa-RVD study is a Cancer Trials Ireland sponsored phase II, multi-centre, single-arm, open label study to evaluate the efficacy and safety of the combination regimen Isatuximab, Lenalidomide, Bortezomib, and Dexamethasone in patients with Newly Diagnosed Multiple Myeloma. The Chief Investigator is Prof Peter O'Gorman (Mater Hospital).

The study opened to recruitment in March 2022; to date, 20 patients have been recruited. The recruitment period will last 18 months (closing September 2023) and a maximum of 43 patients will be enrolled in the study.

The Isa-RVD study is enrolling patients who are newly diagnosed with multiple myeloma (no previous treatment for multiple myeloma) and who meet the entry criteria for study participation. The main objective of the study is to evaluate the stringent Complete Response (sCR) rate by the end of two cycles of induction treatment, defined as the proportion of patients who have achieved sCR, according to International Myeloma Working Group (IMWG).

The Isa-RVD study is open in the following sites in Ireland: Mater Misericordiae University Hospital (Principal Investigator (PI): Prof Peter O'Gorman), Mater Private Hospital (PI: Prof Peter O'Gorman), St James's Hospital (PI: Dr Patrick Hayden), Beaumont Hospital (PI: Prof Siobhan Glavey), University Hospital Waterford (PI: Dr Senthil Kumar), and University Hospital Limerick (PI: Prof Ruth Clifford).

University Hospital Galway (PI: Dr Janusz Krawczyk) is expected to open to recruitment in Q2 2023. This study will also be opened at a site in Denmark, also expected to open in Q2 2023.

Radiotherapy updates:

OPEN STUDIES:

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 (SLH and BC) and CUH, and is expected to open in UHG soon. Prof Sinéad Brennan (SLRON) is the Irish National Lead Investigator (NLI), and Dr David Palma of Lawson Health Research Institute (Canada) is the sponsor.

SOURCE Lung (CTRIAL-IE 18-33)

'Stereotactic Ablative Radiation Therapy Of UltRaCEntral LUNG tumours' (CTRIAL-IE 18-33) 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).

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 is open in SLRON, SJH and UHG. Prof Sinéad Brennan (SLRON) is the Irish NLI, and University of Birmingham is the sponsor.

SABR COMET-3 (CTRIAL19-2 1)

(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 currently open in SLRON (NLI for Cancer Trials Ireland sites: Prof John Armstrong), Bons Secours Radiotherapy Cork in Partnership with UPMC Hillman Cancer Centre and Beacon Hospital.

Pending Studies in Radiotherapy:

Two new Irish Investigator-led RT trials are also in development currently with the Irish Research Radiation Oncology Group (IRROG), and are planned to open in 2023:

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' (CI: Dr Gerard McVey), and **Spine SABR** (CTRIAL-IE 20-03) 'Dose-escalated SABR for Solid Tumour Spine Metastases' (CI: Prof Clare Faul).

Cooperative group Studies set-up:

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.

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.

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 stereotactic ablative radiotherapy (SABR) to the primary tumor in combination with immunotherapy improves outcomes compared to immunotherapy alone in Renal Cell Carcinoma (RCC) patients.

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.

Head & Neck DSSG

2022 was a record year for the head and neck group at Cancer Trials Ireland with 18 patients recruited to international clinical trials, including CTRIAL-IE 17-14 CompARE (2); CTRIAL-IE 19-39 MK3475-689 (6); CTRIAL-IE 20-04 PRESERVE (9) and CTRIAL-IE 20-08 MK3475-630: (1). These trials have been open at St Luke's Radiation Oncology Network and St James Hospital. With the establishment of the Health Research Board (HRB) funded Irish Research Radiation Oncology Group (IRROG) these trials will open at more radiotherapy sites across the country, increasing the opportunity for patients with head and neck cancer in Ireland to participate in practice changing international clinical trials which ultimately results in better patient outcomes.

IRROG, led by Prof Sinead Brennan, aims to improve the national radiotherapy research infrastructure, to enhance national collaboration and co-operation, to streamline research procedures and processes, therefore, increasing access to clinical trials for radiotherapy patients regardless of where they receive their treatment across Ireland.

Prof Sinead Brennan

Dysphagia is a common long-term toxicity of radiotherapy treatment which has a significant impact on QOL for patients. Many trials are focusing on reducing side effects such as dysphagia and feeding tube dependence. We previously participated in the practice changing DARS trial (CTRIAL-IE 16-23) which showed the benefit of using dysphagia optimised intensity modulated radiotherapy (DO-IMRT) to reduce RT dose to the dysphagia/aspiration related structures (DARS) including pharyngeal constrictor musculature, improved swallowing function compared to standard IMRT (S-IMRT) for patients treated with radical radiotherapy. Of those treated with DO-IMRT, 81% reported high normalcy of diet and 92% said they felt comfortable eating in public, compared with just under 73% and 85% of those treated with standard IMRT respectively. Many of these patients had HPV positive oropharyngeal cancer which has an excellent prognosis and therefore quality of life and survivorship is increasingly important in this group. The PRESERVE trial (Preservation of Swallowing in Resected Oral Cavity Squamous Cell Carcinoma: examining radiation volume effects; is an academic trial from the Lawson Health Research Institute in Canada aiming to reduce dysphagia in patients receiving post-operative radiotherapy. Patients with at least one pathologically negative neck are randomised to +/- exclusion of the pN0 hemi-neck from the radiotherapy volume. PRESERVE is currently open at SLRON (12 patients have been recruited to date) and Cork University Hospital. Galway University Hospital will also open later this year.

The prognosis for early stage HPV positive patients treated with chemoradiotherapy is excellent but for advanced stage HPV disease, especially in those with a significant smoking history, and for patients with HPV negative oropharyngeal cancer, trials are investigating methods of treatment intensification to improve survival outcomes. The CompARE trial is a Phase III randomised controlled trial Comparing Alternative Regimens for Escalating treatment of intermediate and high-risk oropharyngeal cancer. Patients are randomised to standard of care cisplatin with Radiotherapy +/- durvalumab immunotherapy. The Compare trial is an academic CRUK Trial and is open at SLRON and St James Hospital and Galway University Hospital.

The Keynote 689 is a phase 3 randomised open label study which evaluates Pembrolizumab as neoadjuvant therapy and in combination with standard of care as adjuvant therapy for stage III-IVA resectable locoregionally advanced head and neck squamous cell carcinoma (LA-HNSCC). It is open at St James Hospital and St Luke's Radiation Oncology Network and to date 7 patients have been recruited. It is the first quadruple modality study in Ireland involving immunotherapy, surgery and chemoradiotherapy. In Keynote 689 patients are randomised to +/- neoadjuvant pembrolizumab followed by standard of care surgery, postoperative radiotherapy and chemotherapy.

The NRG Head Neck 009 trial is due to open in 2023 at SLRON SLH, SLRON SJH and Galway University Hospital. This is a randomized phase II/III trial of radiation with high-dose cisplatin (100 mg/m2) every three weeks versus radiation with low-dose weekly cisplatin (40 mg/m2) for patients with loco-regionally advanced squamous cell carcinoma of the head and neck. This is a large academic trial which seeks to finally address the long standing query of whether high dose cisplatin or low dose cisplatin should be standard of care. Whilst the majority of clinical trials stipulate high dose cisplatin concomitant with radiotherapy, in the community many centres routinely use low dose weekly cisplatin due to the increased ototoxicity, emesis and bone marrow suppression associated with high dose cisplatin.

The majority of head and neck cancer trials are academic international trials sponsored by Cancer Trials Ireland. Tremendous effort is required by the team at CTI as well as local sites to navigate the regulatory and legal processes to open these academic trials here in Ireland and offer Irish patients the opportunity to participate in practice changing trials and novel methods of treating head and neck cancer. IRROG is working together with CTI on start-up efficiency to open these trials more quickly and through IRROG these trials will be opened nationally to ensure that all patients in Ireland can access high quality academic radiotherapy trials at a radiotherapy centre close to them.

IRROG: Inaugural conference

Gavin Lawler

The Irish Research Radiation Oncology Group (IRROG) held their inaugural conference on 20th January 2023 in Trinity College Dublin. The conference was specifically designed as a hybrid event with the support of a HRB Conference and Event Scheme Grant. This allowed flexible attendance of both clinical personnel, researchers and patients attracting over 250 attendees in-person and 70+ online throughout the day.

Mr. Enda Kenny, former Taoiseach of Ireland opened the conference highlighting the importance of quality cancer care and equity of access for the population. He acknowledged clinical trials are key to progressing and improving cancer outcomes for patients.

The 5 conference sessions started by focusing on IRROG with presentations on their foundation, first year's operations and work packages which included updates on their existing portfolio and plans regarding investigator initiated studies, combined modality trials and international collaborations.

Session 2 focused on national research stakeholders and assisting trials group to achieve the 6% target accruals in the National Cancer Strategy. It detailed an overview of the funding mechanisms and supports available from the HRB, Cancer Trials Ireland's role as a sponsor and how they can support ILTs, and the HRB-TMRN's methodology supports and seed funding opportunities. The session ended with an engaging panel discussion around supporting and promoting radiotherapy clinical trials. Key areas discussed included infrastructure resources, personnel and protected time for clinicians/allied health professionals. The consensus supported collaboration and engagement between groups, to promote efficiencies and reduce research/resource wastage. The Irish Cancer Society also highlighted the different grants they have available to support protected time and infrastructures.

The third session focused on a key area of importance for IRROG, Public/Patient Involvement (PPI), and started with a presentation from the Irish Cancer Society on why PPI is central to ensuring impactful research and the funding supports they have available to support PPI. PPI contributors should, where possible, be adequately compensated for their work. IRROG's experience developing and starting our own PPI group was shared. It highlighted the importance of ensuring sufficient resources and time are invested to develop PPI appropriately. PPI should not be viewed as a tick box and requires dedicated support mechanisms to operate sufficiently. IRROG would like to thank their PPI members for their willingness to participate and continued enthusiasm to impact and shape radiotherapy clinical trials.

A highlight of the session focused on how our trials may inadvertently exclude patients in reference to gender, race, sexual orientation etc. A number of useful resources to develop strategies to ensure trial design and recruitment strategies are more diverse and inclusive were shared. The final talk emphasised the power of PPI engagement with a presentation from Dr. Kristin Higgins and Ms. Montessa Lee, a stage IV lung cancer survivor who advocated to publicise and raise awareness of a small-cell lung cancer trial amongst the targeted population. A previous study, for a similar population took 11 years to recruit to, however with the involvement of Ms. Lee/PPI the trial reached the target accrual in 3 years.

Left to right: Gavin Lawler, Marc Nolan, Enda Kenny, Prof Sinead Brennan, Eibhlin Mulroe, Olivia McLoughlin, Aoife Shannon, Eithne Nicol

Session 4 Career Development and Mentoring began with an engaging Dragon's Den style pitch which highlighted the important role of radiation therapists and international advanced practice, querying why Ireland lags behind and has not implemented advanced practice programmes. This is a critical national issue at present as retention of experienced professionals within the profession continues to be a challenge.

An introduction to Studies Within A Trial (SWAT), how they're conducted and by what means they're integrated into larger trials was presented. SWATs are a useful methodology technique to improve study design and outcomes. IRROG's first SWAT developed by Róisín O'Maolalaí with the assistance of the HRB-TMRN will review the implications of using paper versus electronic questionnaires for patient reported outcomes. Patients will be split 50:50 into each group, at the time of enrolling into the larger main study (Spine SABR - which is evaluating radiotherapy dose escalation technique for spinal metastases) for the SWAT component allowing additional research and outcomes to be developed from the one study population, in an efficient and effective use of research and patient resources. The role physicists play in investigator initiated trials was also shared emphasising the importance of quality assurance and trial planning review when designing and implementing IITs to ensure consistent delivery.

The session ended with the presentation of the first IRROG Medal. The competition highlighted the work trials units are doing across the country and applicants were invited to submit a quality improvement project which streamlined or resulted in efficiencies within trials units. It was judged by Dr. Michelle Leech, Trinity College Dublin, Dr. Sandra Galvin, HRB-TMRN and Dr. Claire Kilty, Irish Cancer Society. The inaugural winner was Ms. Karen Molan, Research Radiation Therapist, Cork University Hospital for her project "A Clinical Trial Patient Care Pathway Development For Approval of Radiotherapy Planning Quality Assurance (RTQA) by an external body".

The final session focused on keynote addresses from international field experts from Ireland, the UK and Canada who shared experiences on the pitfalls and effective methods to streamline protocol development, trial conduct operations.

Overall, the conference offered the first opportunity for a dedicated national gathering of the radiotherapy research community and research infrastructure stakeholders. The feedback has been extremely positive. IRROG would like to thank all of the sponsors, chairs, presenters, participants, PPI members, patients and attendees for their participation and support on the day.

Gastrointestinal:

PaTcH (CTRIAL-IE 20-27)

The PaTcH study will open to accrual March 2023. The study will be opened at two sites, Mater hospital and St Vincent's University Hospital. The Mater hospital has been initiated and will open to accrual this month. St Vincent's University Hospital will be initiated the first week of April. The PaTcH trial is funded by the Pat Smullen Pancreatic Cancer Fund and will recruit 22 patients with metastatic pancreatic cancer who have previously progressed on at least one line of systemic therapy. 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.

NEEDS (CTRIAL-IE 20-36)

The NEEDS study will be opening early 2023, with both HPRA approvals and NREC approvals now received. The team at CTI are now preparing to Initiate this study, which will be opened in St. James's Hospital, with Prof. John Reynolds, as Chief Investigator, and Dr. Grainne O'Kane (pictured right), 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 neoadju[1]vant 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.

NeoAegis CTRIAL 10-14 Study Database Lock and Publications

The NeoAegis study had database lock in Nov 2022. In this phase III trial, 377 patients with cT2-3 N0-3 M0 Adenocarcinoma of the oEsophagus and oesophagoGastric junction were randomly assigned to multimodal CROSS regimen or peri-operative chemotherapy at 24 sites across Ireland, UK, Denmark, France and Sweden. The primary outcome was overall survival. The study was led by Professor John Reynolds, St James Hospital, and sponsored by Cancer Trials Ireland. The trial was funded by the Health Research Board Ireland, Irish Cancer Society, Oesophageal Cancer Fund Ireland and Cancer Research UK.

In 2021, Professor John Reynolds presented the preliminary results at ASCO 2021. Most recently Professor Maeve Lowery presented the primary outcome analysis at ASCO GI 2023. This randomised control trial reveals no evidence that peri-operative chemotherapy is unacceptably inferior to multimodal therapy in the primary outcome of overall survival, notwithstanding greater proxy markers of local tumor response in the CROSS arm. Oncologic and operative outcomes were consistent with optimum modern benchmarks. These data strongly suggest non-inferiority and support equipoise in clinical decision making in modern practice.

The Neo Aegis trial team are currently working on the publication of the final manuscript. Close out activities have commenced at the central office, HRB-CRFG and trial sites.

We would like to thank our collaborators in HRB – CRF Galway for all their hard work on the data management and statistics deliveries on the study.A special thanks to all the sites and patients who participated in the study.

L&H: HO156 (CTRIAL-IE 19-16)

The HO156 trial is a phase 3 multicentre, open-label, trial for patients with newly diagnosed acute myeloid leukaemia (AML) or myelodysplastic syndromes with excess blasts-2 with FLT3 mutations eligible for intensive chemotherapy. The primary outcome measure of the trial is event-free survival (EFS).

The HO156 trial plans to enrol approximately 777 patients globally. 11 patients have been enrolled at Irish sites, to date. Eight Irish sites are participating in the HO156 trial: University Hospital Galway Principal Investigator (PI): Dr Janusz Krawczyk, St James's Hospital (PI: Dr Eibhlin Conneally), Beaumont Hospital (PI: Dr John Quinn), Cork University Hospital (PI: Dr Vitaliy Mykytiv), Mater Misericordiae University Hospital (PI: Dr Michael Fay), University Hospital Limerick (PI: Dr Hilary O'Leary), Tallaght University Hospital (PI: Dr Ronan Desmond), St Vincent's University Hospital (PI: Dr Liam Smyth).

The duration of patients' treatment will be up to 18 months; 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. The HO156 trial is expected to meet its accrual target in Q2 2023, at which point recruitment will be closed.

Pending study in Lymph & Haem

PETReA: "A Phase 3 evaluation of PET-guided, Response-Adapted therapy in patients with previously untreated, high tumour burden follicular lymphoma".

PETReA is an investigator-led clinical trial that is being run by the University of Liverpool and is planned to open in Ireland in 2023. The trial aims to assess a new response-adapted therapy for patients with follicular lymphoma. Patient will receive initial treatment with rituximab or obinutuzumab plus chemotherapy. Patients' response to initial treatment is then assessed by CT and PET scans. Based on the results of these scans, patients will either receive further treatment with or without the immunomodulatory agent lenalidomide or no further treatment. The trial will assess whether treatment outcomes for patients with follicular lymphoma can be improved by adding lenalidomide to treatment with rituximab or obinutuzumab. PETReA is planned to open in five hospitals in Ireland. The lead hospital is University Hospital Limerick and Dr Hilary O'Leary is the Chief Investigator.

Lung Portfolio: The PLAN Study

PLAsma genomic testing in Patients with Advanced Non-Small Cell Lung Cancer

This is a multi-centre, non-interventional study which will investigate the use of plasma genotyping for initial genomic testing in newly diagnosed advanced NSCLC. The study aims to evaluate the feasibility of a plasma-based circulating tumour DNA mutation testing pathway using NGS and initiated at the Rapid Access Lung Cancer Clinic (RALCC) for patients with suspected NSCLC in Ireland. This proof of principle initiative aims to establish a robust patient pathway for systematic somatic mutation testing in patients with NSCLC in Ireland using plasma-based testing. Plasma will be tested for circulating tumour DNA mutations using a validated NGS-based assay, at one of two testing laboratories in Ireland. Proving feasibility through a clinical trial in Ireland is crucial to inform successful applications for authorisation of liquid biopsy to the National Clinical Cancer Programme and to inform clinical trials that aim to identify novel therapies for Irish patients. The investigators believe an upfront plasma-based pathway would lower median turnaround time in the Irish context.

In this study, patients will have a plasma genotyping assay completed at institutional Rapid Access Lung Cancer Clinics (RALCC), alongside standard tissue-based biopsy and genotyping. Patients will be enrolled at the time of radiological suspicion of diagnosis of advanced NSCLC.

Prof Jarushka Naidoo

For the purpose of this study, liquid biopsy (ctDNA) assays are in development at the Cancer Molecular Diagnostics lab at St. James' Hospital & RCSI Molecular Laboratory at Beaumont Hospital. Results will be communicated to clinicians. The expected turnaround time from the time of blood draw to genotyping result will be 7 days. The study is due to open in Q2 of 2023 at Beaumont Hospital, St. James' Hospital & University Hospital Limerick. The Principal Investigator for this study is Prof Jarushka Naidoo & Dr Brendan Doyle. Dr David O Reilly is opening this study as part of a PhD programme. Clinical investigators involved in this include Dr Grzegorz Korpanty (University Hospital Limerick), Dr Parthiban Nadarajan (St. James' Hospital) & Dr Sinead Cuffe (St. James' Hospital). The molecular pathology leads in this study are Prof Stephen Finn (St. James' Hospital) & Dr Brendan Doyle (Beaumont Hospital).

Patient Consultants Committee update:

Since the appointment of Sarah McLoughlin as Cancer Trials Ireland's PPI Co-ordinator, the activity of the Patient Consultant's Committee has ramped up significantly. This began with a strategy day to discuss priorities and strategy for the coming three years. That strategy has since been developed into a draft document which has generated the following priorities for the coming year:

- Strengthen PCC activities – particularly around DSSG meetings and Patient review of documents
- Focus on recruiting new PCC members
- Support & advance the MBC patient-led research project

In reverse order, and thanks to the assistance of the breast DSSG, Prof Seamus O'Reilly, the team in CTI, and the truly tireless efforts of Siobhan Gaynor, this metastatic breast cancer proposal was brought to the breast DSSG last week where it was approved. The next step is to obtain ethical approval. It's an exciting time for this study as this model will be used to develop future patient-led research in other disease areas.

The Breast DSSG also saw the pilot introduction of a 'Patient Impact Slide', a practice originally started in the Gynae DSSG. The Patient Impact component aims to assess new Investigator-Led Trial proposals from a patient perspective. International research shows that properly structured Public & Patient Involvement leads to increased study accrual and even funding. As PPI is now a clear deliverable for grant funding, the PCC looks forward to adding value to trial design and outcomes in the future through mechanisms such as the Patient Impact slide. Already we are seeing an uptick in studies requesting that patients review documents and this is work that the Patient Consultants Committee is experienced in. To enable this, investigators and project teams will need to start factoring patient time into their budgets and planning in future.

On the recruitment front, the Breast DSSG welcomed a new patient member this year. Moira Hanbidge joined the PCC earlier this year. Cancer Trials Ireland continues to search for new PCC members with a target of achieving two PCC members per DSSG in the years to come. As part of this year's Just Ask campaign, Cancer Trials Ireland will reach out directly to patients and those affected by cancer and cancer trials through a social media campaign. This will drive demand for training and on-boarding to support new PCC members, and Sarah has been exploring the literature and networks of PPI in Ireland in response.

Meanwhile, the PCC are connecting with their Northern Irish counterparts, the Northern Ireland Cancer Research Consumer Forum (NI-CRCF), so expect further news on that in the coming months. Finally, CTI is keenly looking forward to the PPI Session in this year's Cancer Retreat, which will feature Grainne O'Kane and others. Grainne's experience of PPI in Canada will further build the case for PPI by providing investigators with concrete examples of how the practice augments clinical trials.

Lung Portfolio: *Updates on open & upcoming trials. We have an expanding portfolio of trials available for lung cancer patients in Ireland.*

First line treatment of Non-Small Cell Lung Cancer

KRYSTAL-7 *(CTRIAL-IE 2-207)*

This is a Phase 2 Trial of Adagrasib (MRTX849) with Pembrolizumab in Patients with Advanced NSCLC with KRAS G12C Mutation. This is currently recruiting patients at Beaumont Hospital and will also open in University Hospital Limerick, St James's Hospital and University Hospital Galway.

AcceleRET-Lung */ BO42864 (CTRIAL IE: 20-21)*

This is a trial of Pralsetinib Vs SOC platinum-based chemotherapy for first line RET fusion-positive, metastatic NSCLC. Open at St James's Hospital with two patients enrolled.

CA224-104 ***RELATIVITY*** *(CTRIAL IE: 21-12)*

This a trial of Relatlimab + Nivolumab + chemotherapy Vs. Nivolumab + chemotherapy as first line treatment for stage IV or recurrent NSCLC and is open at Beaumont Hospital & St. Vincent's University Hospital. Three patients have been enrolled in Ireland and we are currently awaiting NREC Approval to open part 2 of the study.

Second line treatment of Non-Small Cell Lung Cancer

KRYSTAL-12 *(CTRIAL IE: 21-13)*

This is A randomized phase III study of MRTX849 vs. Docetaxel in patients with previously treated non-small cell lung cancer with KRAS G12C mutation. This study is recruiting at Beaumont Hospital, Tallaght University Hospital, St. James's Hospital and University Hospital Limerick, and will also open at St. Vincent's University Hospital. Four patients have been randomised with more currently in screening.

M14-239 *(CTRIAL IE: 18-49)*

Recruitment to the M14-239 (CTRIAL IE: 18-49) study of Study of Telisotuzumab Vedotin (ABBV-399) in participants with previously treated c-Met+ NSCLC has been extended until April this year.

Treatment of Extensive Stage Small Cell Lung Cancer

MK-7684A-008 (CTRIAL-IE 22-06)

This is a study of MK-7684A in combination with Etoposide and Platinum followed by MK-7684A vs Atezolizumab in combination with Etoposide and Platinum followed by Atezolizumab for the first-line treatment of participants with extensive stage SCLC. It is the first clinical trial available for this group of patients in Ireland for many years. Beaumont Hospital has entered one participant and has another in screening, St. James's Hospital will open to recruitment soon.

Observational

IMMUNO FERTILITY *(CTRIAL IE: 22-22)*

This is a prospective observational study investigating the impact of immune checkpoint inhibitors for cancer on fertility in males and females of childbearing age. It is open at Beaumont Hospital in collaboration with the Merrion Fertility Clinic.

Upcoming Studies:

NeoCOAST-2 *(CTRIAL IE: 22-23)*

This phase II open-label, randomised study of Neoadjuvant and Adjuvant treatment in patients with resectable, early-stage (II to IIIA) NSCLC is awaiting NREC approval and will open at Beaumont Hospital, The Mater, University Hospital Galway and St James's Hospital.

ADEPPT *(CTRIAL IE: 22-09)*

Another study awaiting approval, this is a single-arm phase II trial of Adagrasib in elderly (≥70 years) patients or with poor performance status and KRAS G12C-mutant NSCLC. It is due to open at Beaumont Hospital, St James's Hospital, University Hospital Limerick, University Hospital Galway, Cork University Hospital and University Hospital Waterford.

PLAN *(CTRIAL IE: 22-15)*

This is a study of plasma genomic testing in patients with advanced NSCLC. It is due to open in Q2 of 2023 at Beaumont Hospital, St. James' Hospital & University Hospital Limerick. (Also see separate article on this study).

Lymph & Haem: CLL17 (CTRIAL 20-22)

The CLL17 trial is a phase 3 multicentre, randomized, prospective, open-label trial for patients with previously untreated chronic lymphocytic leukaemia (CLL). The primary objective of the trial is to compare the efficacy of continuous Ibrutinib monotherapy with fixed duration Venetoclax plus Obinutuzumab and fixed-duration Venetoclax plus Ibrutinib by measuring progression-free survival (PFS) in patients with previously untreated CLL.

The CLL17 trial enrolled 909 patients in 180 sites across Europe. Ireland had an initial target accrual of 40 patients and, after only 18 months of recruitment, exceeded that target with a total of 86 patients randomised. Globally, St James's hospital was the joint highest recruiting site with a total of 19 patients randomised. Ireland was the fourth highest recruiting country, with a fraction of the number of recruiting sites of the three highest recruiting countries.

Eight Irish sites are participating in the CLL17 trial: Beaumont Hospital (Principal Investigator (PI): Prof Patrick Thornton), Cork University Hospital (PI: Dr Derville O'Shea), St James's Hospital (PI: Prof Elizabeth Vandenberghe), University Hospital Waterford (PI: Prof Ezzat Elhassadi), Mater Misericordiae University Hospital (PI: Dr Anne Fortune), University Hospital Limerick (PI: Prof Ruth Clifford), University Hospital Galway (PI: Dr Amjad Hayat), and St Vincent's University Hospital (PI: Dr Liam Smyth).

The duration of patients' treatment will depend on their randomly assigned treatment group. Patients will undergo staging assessments at fixed timepoints throughout the study to measure their response assessment and will be followed up until end of trial, with last patient last visit expected in Q3 2027.

The trial is sponsored by the University of Cologne and conducted by the German CLL Study Group (GCLLSG) in collaboration with several global cooperative groups, including Cancer Trials Ireland. In Ireland, Cancer Trials Ireland are supporting GCLLSG with coordination of the trial.

CLL17 closed to recruitment in November 2022.

Irish Molecular Tumour Board

The MTB continues to go from strength to strength. In January we succeeded in our efforts to have MTB meetings CPD -accredited. The CPD points are awarded by the Royal College of Physicians Ireland. This is great recognition of the high educational value of the meetings and the important role they have to play in precision oncology in Ireland.

In early March Cancer Trials Ireland hosted a very well attended webinar about NGS testing, which will shortly be uploaded to our Vimeo page, and then made available through the Cancer Trials Ireland website. Lastly, and also in March, core members of the MTB team, including it's Clinical Lead, Dearbhaile Collins, Tanya Knott (patient advocate, MTB steering committee member), and Claire Bermingham from Cancer Trials Ireland, we guests on the Cancer Trials Ireland podcast, hosted by Eibhlin Mulroe. This podcast will be released in the coming months as part of a three-part series.

The MTB continues to meet regularly on the last Tuesday of every month from 4-5pm. For further information on the MTB click here.

More info: webpage, / Claire.Bermingham@cancertrials.ie.

How it works

MTBs are meetings for expert review of complex tumour genomic findings; discussion of their clinical and therapeutic significance.The treating clinicians use a patient case template to share anonymized patient information prior to the MTB sessions. Anonymized patient information is shared in a structured way so that experts can prepare the patient case and clinicians can have an informed discussion during a MTB session.

Who is on the expert panel?

- Dr Terri McVeigh - a consultant clinical geneticist in the Royal Marsden NHS Foundation Trust, specializing in cancer genetics
- Dr Rodrigo Dienstmann - Principal Investigator of the Oncology Data Science Group of the Vall d'Hebron Institute of Oncology (VHIO) in Barcelona, Spain
- Dr. Stephen Finn - an Associate Professor, Consultant Pathologist and Principal Investigator at The University of Dublin, Trinity College and at St. James's Hospital Dublin
- Prof Marie-Dominique Galibert - Deputy Director of the Institute of Genetics and Development of Rennes (IGDR) and the Head of the Gene Expression and Oncogenesis Research Team – Labellisée Fondation ARC

Cancer Retreat 2023: News

This year's Cancer Retreat (May 19th, 2023) will focus on streamlining the processes around cancer trials, which builds on stakeholder meeting around data protection taking place at the Spring DSSG. Since January, a committee of CTI staff, doctors and researchers has developed a survey for site staff that covers staffing, training and the obstacles that challenge the timely initiation and operation of trials in Ireland today.

The results of that survey will be presented at the Cancer Retreat, where they will be discussed by a panel that includes team leaders from sites, the HRB, and Dr Laia Raigal who is co-ordinating the survey. Other panellists to be confirmed. This discursive session will follow a series of plenary speakers including myself and CTI's CEO, Eibhlin Mulroe as well as a keynote speaker as yet to be announced.

Following these two sessions we will welcome three investigators to present on their individual Investigator-Led Trials, which include, SHAMROCK (a breast study), ISA-RVD with Prof Peter O'Gorman, and a Dr Stuart McIntosh on a surgical ILT in Belfast. This ILT's session will be followed by a session about Public & Patient Involvement featuring Grainne O'Kane, the new GI DSSG Chair. Grainne's time in Toronto has given her hands-on experience of public and patient involvement in trials and research in Canada, where the practice is more firmly embedded, and understood. This remains a key component for contemporary grant funding and it's an under-developed aspect of the clinical oncology research in Ireland.

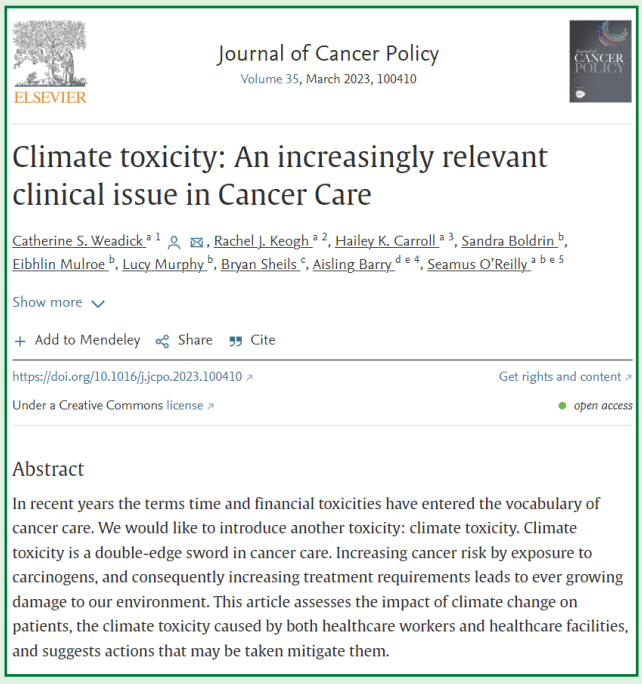
After the Retreat ends, Cancer Trials Ireland will again host a webinar aimed at the general public, offering them an opportunity to log onto our web page and view a live discussion about trials, from the perspective of a patient (one of our Patient Consultants Committee), with support and technical expertise provided by myself and a member of the Irish Cancer Society.

Registration for the Retreat opens imminently, and I look forward to sharing further announcements in the coming weeks. See you in May 19th in the Royal College of Surgeons!

Agenda at a glance (9am - 1pm)

- Session 1: Plenary speakers
- Session 2: Streamlining cancer trials
- Session 3: Investigator Led Trials
- Session 4: Public & Patient Involvement
- Retreat Ends
- Public Webinar (2pm)

Greening Cancer Trials: Prof Seamus O'Reilly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Journal of Cancer Policy

Volume 35, March 2023, 100410

Climate toxicity: An increasingly relevant clinical issue in Cancer Care

Catherine S. Weadick [a 1], Rachel J. Keogh [a 2], Hailey K. Carroll [a 3], Sandra Boldrin [b], Eibhlin Mulroe [b], Lucy Murphy [b], Bryan Sheils [c], Aisling Barry [d e 4], Seamus O'Reilly [a b e 5]

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Abstract

In recent years the terms time and financial toxicities have entered the vocabulary of cancer care. We would like to introduce another toxicity: climate toxicity. Climate toxicity is a double-edge sword in cancer care. Increasing cancer risk by exposure to carcinogens, and consequently increasing treatment requirements leads to ever growing damage to our environment. This article assesses the impact of climate change on patients, the climate toxicity caused by both healthcare workers and healthcare facilities, and suggests actions that may be taken mitigate them.

I am pleased to report a publication in this space which is a timely boost for the Green Trials Initiative. The paper pictured (click to read in full) was published in the Journal of Cancer Policy in March. It assesses the impact of climate change on patients, the climate toxicity caused by both healthcare workers and healthcare facilities, and suggests actions that may be taken mitigate them.

In other news in this space, we hope to trial an upcoming Investigator Led Trial as a 'proof of concept' for future Green trials, by reviewing the study and seeing where the carbon touching points are, including during activation and monitoring. If you are interested in joining the Green Trials Initiative, email: Sandra.boldrin@cancertrials.ie or lucy.murphy@cancertrials.ie.

EORTC: *MOU signed with Cancer Trials Ireland*

In June 2022, EORTC and Cancer Trials Ireland (CTI) started discussions on the potential opening of the Irish network to a closer collaboration with EORTC. As Cancer Trials Ireland is the all-Ireland hub for cancer trials and the leading cancer research organization for Ireland, it has many similarities to EORTC, and so a closer collaboration between both organizations seems a logical next step.

Cancer Trials Ireland's DSSG, disease-specific sub-groups, match the structure of EORTC. Since June 2022 connections have been made in 4 major disciplines: Breast, Head & Neck, Brain and Lung, being the groups covering the largest incidence of cancer in Ireland.

Together with Cancer Trials Ireland, IRROG (Irish Research Radiation Oncology Group) also sought a collaboration with EORTC. The IRROG network covers the radiation oncology sites in Ireland and focuses on setting strategies in radiation oncology, as does the EORTC Radiation Oncology Scientific Council (ROSC). IRROG is supported by Cancer Trials Ireland for the set-up and coordination of its research portfolio.

EORTC and Cancer Trials Ireland have this week signed a memorandum of understanding that will cover the intention for keeping the mutual networks informed on planned, ongoing research that could benefit from a larger contribution. All members of Cancer Trials Ireland can become members of EORTC, allowing for direct communication. Going forward the Irish network will have a direct connection with the EORTC for new projects and research opportunities.

EORTC establishes its scientific strategy through the Scientific Chairs Council (SCC) formed by the leadership of its Groups and Task Forces. A specific Council dedicated to radiation oncology – the Radiation Oncology Scientific Council (ROSC), integral to the SCC – supports the development of the scientific strategy with the specificities of this discipline. The SCC is therefore a unique place to meet for all disciplines across tumour types and address together major shared oncological challenges. The SCC establishes the scientific strategy and prioritisation process of the Organisation. Integral to existing clinical research infrastructures and solutions developed by EORTC Headquarters, the scientific strategy focuses of oncological questions where EORTC brings an additional substantial value to the international scientific and patient communities. The EORTC scientific strategy is updated as science evolves and on a 3 to 5 years structural basis.

As an independent, non-governmental, non-profit cancer research Organisation established under the laws of Belgium, EORTC's mission is to coordinate and conduct international translational and clinical research to improve the standard of cancer treatment for patients.

AGITG's Late Stage Colorectal Cancer Idea Generation Workshop

Australian Gastro-Intestinal Trials Group (AGITG) have invited Cancer Trials Ireland GI Investigators to participate in their upcoming annual AGITG Idea Generation Workshop which will be held on Friday 19 May 2023, 9AM-12PM Australian Eastern Standard Time (AEST). This year, the focus of the workshop is on developing clinical trials that address gaps in late-stage colorectal cancer knowledge and research.

Ideas can be submitted via the submission portal. Closing date for submission is Thursday 6 April 9am AEST.

The workshop is a fantastic opportunity for multidisciplinary international collaboration and professional development. If you are interested in contributing to the development of ideas selected for presentation by attending the workshop, please contact the GI Operations Lead: anna.shevlin@cancertrials.ie

THE Cancer Trials Ireland PODCAST

Second series coming soon!

New Chair:

Gastrointestinal DSSG

We are delighted to announce that Dr Grainne O'Kane (SJH/TCD) has agreed to take over as chair of the GI DSSG. Grainne returned to Ireland from Canada last year, see her 'Returning Investigator' presentation here.

She replaces the multitalented Prof Austin Duffy, whose research and writing will benefit the new Phase 1 unit being opened in the Mater Hospital. We wish him very well with this project and thank him for his years of service to the GI DSSG.

Team Leader News:

Ashley Bazin wins award

Huge congratulations to Ashley Bazin of TUH, winner of the Irish Cancer Society Support Staff of the Year award, at the Cancer Society's Research awards in February. Since first coming into the role in 2006 she has seen the team grow from three to eight staff, with Ashley performing multiple important functions including as a research nurse, team leader, manager and mentor to others.

Cancer Trials Ireland wishes to thank every member of support staff in Ireland - the RNs, pharmacists, radiation therapists, data & research managers who all go the extra to get, and keep, trials open in Ireland.

Imelda Parker: Thank you!

We say goodbye to Imelda Parker, our Group Statistician who is retiring at the end of March. Imelda joined us back in 2010 and over the last 12 years has had an immense contribution to the success of Cancer Trials Ireland.

Imelda has supported Chief Investigators across the country in the design, analysis and reporting of Cancer Trials Ireland studies; she has completed numerous interim and final analyses, represented Cancer Trials Ireland in Data and Safety Monitoring Boards, Trial Steering Committees and is an author on over 30 CTI publications, including two of the latest publications in this Digest (overleaf).

Her ability to explain statistical considerations to all of us non-statisticians over the years has been very much appreciated! As a key member of the Operations and Biometrics team her great team spirit, sense of humour and passion for the work in Cancer Trials Ireland will be very much missed.

On behalf of the Cancer Trials Ireland members and staff, we thank her for all she has done, and we wish her well in her retirement.

Group Statistician Vicky Donachie (below) joins the organisation with over 20 years of experience including 4 years in research working on Investigator Initiated Trials and 19 years in the pharmaceutical industry on Phase I-IV Clinical Trials. Vicky is based in the UK and will work with us on a part time basis. Currently she is busy working through all our SOPs and getting up to speed with all CTRIAL studies. Welcome to the team Vicky!

Academic Publications from Cancer Trials Ireland Investigators

Gynaecological

Recommendation Paper - not study related

Vergote, I., A. Gonzalez-Martin, D. Lorusso, C. Gourley, M. R. Mirza, J. Kurtz, A. Okamoto, K. Moore, F. Kridelka, I. McNeish, A. Reuss, B. Votan, A. du Bois, S. Mahner, I. Ray-Coquard, E. C. Kohn, J. S. Berek, D. S. P Tan, N. Colombo, R. Zang, N. Concin, D. O'Donnell, A. Rauh-Hain, C. S. Herrington, C. Marth, A. Poveda, K. Fujiwara, G. C. E Stuart, A. M. Oza, M. A. Bookman, participants of the 6th Gynecologic Cancer InterGroup (GCIG) Ovarian Cancer Consensus Conference on Clinical Research (2022) "**Clinical research in ovarian cancer: consensus recommendations from the Gynecologic Cancer InterGroup**." Lancet Oncol e374-e384. PMID: 35901833

Genitourinary

CTRIAL-IE 20-20: TRITON-3
Fizazi, K., J. M. Piulats, M. N. Reaume, P. Ostler, R. McDermott, J. R. Gingerich, E. Pintus, S. S. Sridhar, R. M. Bambury, U. Emmenegger, H. Lindberg, D. Morris, F. Nolè, J. Staffurth, C. Redfern, M. I. Sáez, W. Abida, G. Daugaard, A. Heidenreich, L. Kriege, B. Sautois, A. Loehr, D. Despain, C. A. Heyes, S. P. Watkins, S. Chowdhury, C. J. Ryan, A. H. Bryce; TRITON3 Investigators (2023)" **Rucaparib or Physician's Choice in Metastatic Prostate Cancer**" N Engl J Med 388(8):719-732. PMID: 36795891

CTRIAL-IE (ICORG) 07-11: SCC Retreat
Wallace, N. D., M. T. Dunne, O. McArdle, C. Small, I. Parker, A. M. Shannon, A. Clayton-Lea, M. Parker, C. D. Collins, J. G. Armstrong, C. Gillham, J. Coffey, D. Fitzpatrick, O. Salib, M. Moriarty, M. R. Stevenson, A. Alvarez-Iglesias, M. McCague, P. G. Thirion "**Efficacy and toxicity of primary re-irradiation for malignant spinal cord compression based on radiobiological modelling: a phase II clinical trial**" (2023) Br J Cancer 128(4):576-585. PMID: 36482188

Lung

CTRIAL-IE 15-39: D5160C00022/ ASTRIS
Cheema, P., B. C. Cho, H. Freitas, M. Provencio, Y. M. Chen, S. Kim, Y. Wu, A. Passaro, C. Martin, M. Tiseo, G. Chan, K. Park, B. Solomon, O. Burghuber, J. Laskin, Z. Wang, S. Y. Lee, Y. Hu, J. Vansteenkiste, H. Zhang, E. Hanrahan, T. Geldart, R. Taylor, L. Servidio, J. Li, F. Marinis "**A real-world study of second or later-line osimertinib in patients with EGFR T790M-positive NSCLC: the final ASTRIS data"** (2023) Future Oncol 10.2217/fon-2022-0919. PMID: 36656302

Breast

CTRIAL-IE 10-11: Circulating miRNAs
Davey, M. G., A. McGuire, M. C. Casey, R. M. Waldron, M. Paganga, E. Holian, J. Newell, H. M. Heneghan, A. M. McDermott, M. M. Keane, A. J. Lowery, N. Miller, M. J. Kerin "**Evaluating the Role of Circulating MicroRNAs in Predicting Long-Term Survival Outcomes in Breast Cancer: A Prospective, Multicenter Clinical Trial"** (2023) J Am Coll Surg 236(2):317-327. PMID: 36648259

ICORG 11-23: APHINITY / BIG 4-11
Azambuja, E., E. Agostinetto, M. Procter, D. Eiger, N. Pondé, S. Guillaume, D. Parlier, M. Lambertini, A. Desmet, C. Caballero, C. Aguila, G. Jerusalem, J. M. Walshe, E. Frank, J. Bines, S. Loibl, M. Piccart-Gebhart, M. S. Ewer, S. Dent, C. Plummer, T. Suter, APHINITY Steering Committee and Investigators "**Cardiac safety of dual anti-HER2 blockade with pertuzumab plus trastuzumab in early HER2-positive breast cancer in the APHINITY trial**" (2023) ESMO Open 10.1016/j.esmoop.2022.100772. PMID: 36681013

CTRIAL-IE 15-16: FLIPPER

Tibau, A., M. T. Martínez, M. Ramos, L. De La Cruz-Merino, A. Santaballa, M. O'Connor, N. Martínez-Jañez, F. Moreno, I. Fernández, J. A. Virizuela , J. Alarcón, J. de La Haba-Rodríguez, P. Sánchez-Rovira, C. R. Albacar, C. B. Muiño, C. Kelly, M. Casas, S. Bezares, L. Rosell, J. Albanell "**Quality of life with palbociclib plus fulvestrant versus placebo plus fulvestrant in postmenopausal women with endocrine-sensitive hormone receptor-positive and HER2-negative advanced breast cancer: patient-reported outcomes from the FLIPPER trial**" (2023) Ther Adv Med Oncol 15:17588359221148921. PMID: 36743520

Other

O'Reilly, S., H. K. Carroll, D. Murray, L. Burke, T. McCarthy, R. O'Connor , C. Kilty, S. Lynch, J. Feighan, M. Cloherty, P. Fitzpatrick, K. Falvey, V. Murphy, M. J. O'Leary, S. Gregg, L. Young, E. McAuliffe, J. Hegarty, A. Gavin, M. Lawler, P. Kavanagh, S. Spillane, T. McWade, M. Heffron, K. Ryan, P. Kelly, A. Murphy, M. Corrigan, H. P. Redmond, P. Redmond, P. Walsh, P. Tierney, M. Zhang, K. Bennett, M. Mullooly (2023) "**Impact of the COVID-19 pandemic on cancer care in Ireland - Perspectives from a COVID-19 and Cancer Working Group**" J Cancer Policy 36:100414. PMID: 36841473

Weadick, C. S., R. J. Keogh, H. K. Carroll, S. Boldrin, E. Mulroe, L. Murphy, B. Sheils, A. Barry, S. O'Reilly (2023) "**Climate toxicity: An increasingly relevant clinical issue in Cancer Care"** J Cancer Policy 35:100410. PMID: 36773799

****

Abstracts: Oral and Poster Presentations

Gastrointestinal

CTRIAL-IE (ICORG) 10-14: Neo-AEGIS
Reynolds, J. V., S. R. Preston, B. O'Neill, M. A. Lowery, L. Baeksgaard, T. Crosby, M. Cunningham, S. Cuffe, G. O. Griffiths, R. Roy, S. Falk, G. Hanna, F. R. Bartlett, I. Parker, A. Alvarez-Iglesias, M. Nilsson, G. Piessen, S. Risum, N. Ravi, R. S. McDermott (2023) "**Neo-AEGIS (Neoadjuvant Trial in Adenocarcinoma of the Esophagus and Esophago-Gastric Junction International Study): Final primary outcome analysis**" ASCO-2023-Neo-AEGIS . (41.4_suppl.295) 10.1200/JCO.2023.41.4_suppl.295

Genitourinary

CTRIAL-IE 20-20: TRITON-3
Fizazi, K., J. M. Piulats, M. N. Reaume, P. Ostler, R. McDermott, J. R. Gingerich, E. Pintus, S. S. Sridhar, R. M. Bambury, U. Emmenegger, H. Lindberg, D. Morris, TRITON3 Investigators "**Rucaparib or Physician's Choice in Metastatic Prostate Cancer**" N Engl J Med-2023-Metastatic Prostate Cancer (388:719-732) 10.1056/NEJMoa2214676

Select double-page View for full tables

Cancer Trials Ireland studies open to accrual (as of March 2022)

Purple = Industry studies Green = Cancer Trials Ireland in-house studies Orange = Collaborative Group studies

DSSG	General Group	Cancer Trials Ireland	Study Name:	Total Accrual	TUH	Beacon	BH	BonS	BonS/ UPMC	CUH	UHG
Breast	Trans	09-07	Breast Cancer Proteomics and Molecular Heterogeneity	4406			2630			1032	
Breast	Clinical	17-15	IMpassion030/ ALEXANDRA (on hold)	17			13				
Breast	Clinical	20-24	SASCIA	26			7			2	
Breast	Clinical	21-04	GO42784/ TRIO 045/ lidERA Breast Cancer	48			7	8		1	20
Breast	Clinical	21-05	DESTINY-Breast12	21						1	
Breast	Clinical	21-15	DESTINY-Breast05	5						Open	
Breast	Clinical	21-16	ZEST/ GSK 213831	0			Open				
Breast	Clinical	21-31	KEYNOTE-B49	0							
Breast	Clinical	21-32	Novartis EPIK-B5	0			Open				
GI	Clinical	11-32	Lithium	2						2	
GI	Clinical	20-27	PaTcH	0							
GI	Clinical	18-43	MK7902-002/E7080-G000-311/ LEAP-002	1							
GI	Clinical	18-44	Astellas 8951-CL-5201	4				1			
GI	Clinical	21-07	DESTINY DS8201-A-U306	0	Open		Open			TBI	
GI	Clinical	21-34	LEAP-015 (MK-7902-015)	4	TBI		2			TBI	
GI	Clinical	21-06	Krystal-10		Open		Open				
GI	Clinical	21-35	HERIZON-GEA-01 (ZWI-ZW25-301) Zymeworks	1							
GU	Clinical	16-21	PEACE III (closed to accrual 03-Mar-2023)	17	4					8	
GU	Clinical	19-32	DASL HiCaP	26	2	1			6	1	Open
GU	Clinical	20-16	MK3475-905 (bladder) (study on hold)	3	0						
GU	Clinical	21-17	MK 6482- 011	9	9						
GU	Clinical	21-20	MK3475- 365	3	3						
GU	Clinical	21-18	MK 6482- 012	2	2		Open				
GU	Clinical	21-37	MK6482-022	5	3		1				
GU	Clinical	21-38	IMvigor011 B042843	0	Open					Open	
GU	Clinical	20-32	PEACE 6: VULNERABLE	0							
GU	Trans	17-30	IRONMAN	86	37	6					
GU	Trans	22-10	Pivotal Study BP-007	6							
GU	Observational	22-10	Pivotal Study BP-007 part II								
Gynae	Clinical	20-07	OVIHIPEC 2	0							
Gynae	Clinical	22-03	ENGOT ov65	0						To open	
Gynae	Clinical	22-02	ENGOT en15	1				1			
Gynae	Trans	22-05	ENGOT ov47 HELPER	0		Open				To open	To open
H & L	Clinical	19-17	CPD-DARA	14			4			3	7
H & L	Clinical	19-34	Isa-RVD	20			2				TBI
H & L	Clinical	18-15	Paradigme	7							1
H & L	Trans	20-33	Irish & ASH COVID Registry	102	Open		2	4		9	6
H & L	Clinical	20-35	MOR208C310	2			2				TBI
H & L	Trans	21-24	COVID Vaccine	75							
H & L	Clinical	19-18	Hovon 150	6			Open			1	2
H & L	Clinical	19-16	Hovon 156	11	Open		Open			3	Open
H & L	Clinical	21-11	BGB-3111-306	12						1	4
H & L	Clinical	21-08	GMI-1271-301	6							6
H & L	Clinical	21-09	EFC15992/ITHACA	0			Open				
H & L	Clinical	21-10	CC220-MM-002 "EXCALIBER"	0			ISU			ISU	ISU

Open Studies | Studies To Be Initiated (TBI) | Studies in Set-Up (ISU) | Studies initiated but not active

LUH	Mater	MRH	MUH	OLLHD	OLCHC	UHL	SLRON	SJH	SUH	SVUH	UHW	Whit	International Sites
						385		closed		Open	359		
	4					closed							
	TBI					1		3		12	1		
						2		TBI		9	1		
	8									12			
	3					Open		1		1			
								Open					
								TBI		Open			
								TBI		Open			
								Open					
	To be activated									TBI			
										1			
								Open		3			
								Open					
								2					
	TBI									1			
								1					
							Open			5			
	10						6	Open					TBI
	0												
										1			
										Open			
									12	31			
							6						
	Open												
								Open					
								Open					
	To open	To open						To open					
	5					7		1			3		
	4							2					
Open	10	Open	8	Open		25		1	2	28	7		
						Open		Open		TBI			
						75							
								3					
	5					1		2		TBI			
	Open					1		2			3		
	Open							Open					
								ISU					

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DSSG	General Group	Cancer Trials Ireland No:	Study Name:	Total Accrual	TUH	Beacon	BH	BonS	BonS/ UPMC	CUH	UHG
H & L	Clinical	21-22	MK1026-003	0			ISU				
H & L	Clinical	21-21	ME-401-004/The COASTAL Study	0							
H & L	Clinical	21-43	LOXO-BTK 20020								
H & L	Clinical	21-47	Dream M14								
Head & Neck	Clinical + Radio	17-14	CompARE	2							Open
Head & Neck	Clinical + Radio	19-39	Keynote 689 (MK-3475-689)	7							
Head & Neck	Clinical	21-41	VERSATILE-002 (PDS0101-HNC-201)	0							
Head & Neck & Mela-noma	Clinical	20-08	Keynote 630 (MK-3475-630)	1							
Head & Neck	Radio	20-04	PRESERVE	13						Open	ISU
Lung	Radio	18-33	SOURCE Lung	20		1					
Lung	Clinical	18-49	AbbVie M14-239	0						Closed	
Lung	Clinical	19-25	BMS CA209-73L	2							
Lung	Clinical	20-21	BLU-667-2303/ BO42864	2							
Lung	Clinical	21-12	CA224-104	3			3				
Lung	Clinical	21-13	KRSYTAL-12	5	1		3				
Lung	Clinical	*22-06	MK7684A-008 / KEYVIBE 008	2			2				
Lung	Clinical	*22-07	Krystal-007	1			1				
Lung	Clinical	22-22	Immuno Fertility	3			3				
Mela-noma	Clinical	18-50	R2910-ONC-1788	4						0	
Mela-noma	Clinical	22-25	R3767 ONC 2055	0			0			0	0
Mela-noma	Clinical	22-26	R3767 ONC 2011	2							
Mela-noma	Clinical	22-29	ION-013/KN-D18	0							
Basket	Clinical	15-42	LOXO-101	5							
Basket	Clinical	19-27	MK7339-002/LYNK-002	5	Closed			3			
Basket	Clinical	16-19	Add-Aspirin (closed to accrual 31-Jan-2023)	204	16		5	16		52	3
Basket	Clinical	18-29	CUPISCO - MX39795								
Basket	Radio	19-21	SABR COMET-3	7		0			4		
Paeds	Trans	16-34	LLR Leukaemia Cell bank	103							
Paeds		16-37	EWOG-MDS-2006	10							
Paeds	Clinical	16-41	LINES	4							
Paeds	Trans	16-42	IMPORT	40							
Paeds	Trans	16-43	Tumour Banking Study	227							
Paeds	Registry	16-44	EU-Rhabdoid Registry	8							
Paeds	Trans	16-46	EWOG-SAA 2010	24							
Paeds	Clinical	16-53	Interfant 06	6							
Paeds	clinical	18-17	PHITT	4							
Paeds	clinical	16-81	SIOP Ependymoma II	8							
Paeds	clinical	18-18	LCH IV	3							
Paeds	Clinical	18-36	LOXO-TRK-15003	3							
Paeds	clinical	16-82	myechild	18							
Paeds	Trans	19-04	Monty Biomarker study	3							
Paeds	Trans	19-05	NBL LK Study	6							
Paeds	Trans	16-49	NB SCI Study	3							
Paeds	Trans	16-35	EBMT	509							
Paeds	Clinical	18-16	ITCC 059	2							
Paeds	Trans	18-24	ITCC 054	0							
Paeds	Trans	UNK	OLIE	0							

Open Studies | Studies To Be Initiated (TBI) | Studies in Set-Up (ISU) | Studies initiated but not active

LUH	Mater	MRH	MUH	OLLHD	OLCHC	UHL	SLRON	SJH	SUH	SVUH	UHW	Whit	International Sites
						ISU							
ISU								ISU					
							2	See SLRON tab					
							Screening only	7					
								0					
							Screening only	1					
							12						
							19						
	Open					Open		Closed		Open			
								Closed		Closed			
								2					
										Open			
						Open		1		Open			
										0			
										0			
										2			
	0												
										5			
	Closed									2			
	18					21	20		24	14	15		
										2	1		
							3						
					103								
					10								
					4								
					40								
					227								
					8								
					24								
					6								
					4								
					8								
					3								
					3								
					18								
					3								
					6								
					3								
					509								
					2								
					0								
					0								

Fundraising News

Friends of Cancer Trials Ireland

November 2022 brought us the very welcome return of the Friends of Cancer Trials Ireland gala lunch, which raised an incredible €141,000 for cancer trials. The event is superbly and generously organised by a voluntary committee, most of who are pictured below. The event featured a speeches, comedy, and an interview with the clinical leaders of Cancer Trials Ireland, Professors Ray McDermott and Seamus O'Reilly. They were joined on stage by George O'Reilly a patient from Tallaght University Hospital who was able to share his experience of being on a trial with the audience.

Members of the Friends of Cancer Trials Ireland

Dr Claire Kilty, Irish Cancer Society & Prof Ray McDermott, Cancer Trials Ireland

There was also a video interview with Dr Karen Caidoo on the NRG -GY019 study, which will bring a new option for people with a rare form of ovarian cancer.

Pictured above: Deirdre McDermott, Rita Lovett, Katherina Sheahan, Kim Fitzgerald, Grace McDermott, Liz Coughlan, Fiona Collins, Julie Liston, Mairead O'Brien Absent: Paul Murphy

Dunnes Stores HQ / Kay Butler

We are indebted to the colleagues of Kay Butler, in Dunnes Stores HQ, who raised almost €14,000 in memory of her earlier this year. That money is being divided between Cancer Trials Ireland, and the Irish Hospice Association, (€6,700 each approx.) both of whom the family credited with bringing comfort and care to a mother of three and dear partner to her husband, Cormac.

Ballymacads / Cathryn Gibney

Cancer Trials Ireland is extremely grateful to the family, friends and riding partners of Cathryn Gibney, who recently hosted a Ballymacad trekking event and charity auction in her memory. We want to thank this group, and particularly Liz Brogan, lifelong friend and riding companion of Cathryn's, for helping to raise a staggering €26,650. Among many other things, Cathryn was a committee member and secretary of the Ballymacads, and she continued to ride even during her illness.

Above: Pauline Gibney, George Aubrey, Liz Brogan, Prof Ray McDermott, and Hazel Aubrey - Ballymacads raised €26,650 in memory of Cathryn Gibney, daughter of Pauline, husband of George, mother to Hazel (right) and (not pictured) Alice and Sophie.

TCD Horse Racing Society

The Horse Racing Society in TCD ran a Cheltenham Fundraising event during race week which raised €7,640 for pancreatic research. It was a wonderful quiz event held in the Horseshow House, and we want to thank the society, and Hannah Smullen, and congratulate them on an excellent event.

Edmondstown Golf Club

A big thank you to Joyce Duffy and her friends on the committee of the Edmondstown Golf Club, whose Captain's Charity event and raffle raised €7,313 for Cancer Trials Ireland, when it ran last Autumn. We are indebted to the Edmondstown golfers, which include our own Board member, Rory Montgomery.

Other donations

- **Aisling Gannon & Brian McKeon – a further €1,000 (on top of €2,920 donated last October)**
- **Thank you to the family & friends of the late Virginia Duffy for raising €700**
- **Barberstown Castle / Cheltenham preview night - €575**

cancer trials ireland

Together, we're finding answers to cancer.