



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



# DSSG Digest

## Winter 2023

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



**Prof. Ray McDermott Passes Torch to Prof. Seamus O'Reilly as Clinical Lead at Cancer Trials Ireland**

Looking back on the past six months at Cancer Trials Ireland, I am heartened to see the initiation of some great, investigator-led trials across the portfolio. We all know how critical investigator-led trials are to advancing cancer research in Ireland by posing those vital academic questions. There is a real sense that we are coming out of the roadblocks and challenges we experienced during the pandemic and into a very active period for this type of trial, which is great to see. In the past few months, sites have opened for, and the first patients have been accrued to, the SHAMROCK trial, led by Prof. Bryan Hennessy, and the ADEPPT trial, led by Prof. Jarushka Naidoo. You can read more about both later in this edition of the Digest.

More positive developments for the future may transpire due to the many valuable conversations we had with international collaborators at the ESMO Congress in October. The event provides excellent networking opportunities for oncologists and other stakeholders from all around the world. Through those conversations, we were able to offer our support to international collaborative groups wishing to bring their trials to Europe, with CTI being in a unique position to do this. Opening innovative, high-quality trials at Irish sites directly supports our mission to be globally recognised for collaboration in clinical research and will ultimately deliver improved outcomes for Irish patients.

Speaking of international partnerships, I am delighted that the Board of Cancer Trials Ireland has agreed to support the annual award of one fellowship programme at Memorial Sloan Kettering, New York. This is a fantastic opportunity to forge partnerships with our respected colleagues across the pond and deliver expert training opportunities to our doctors.



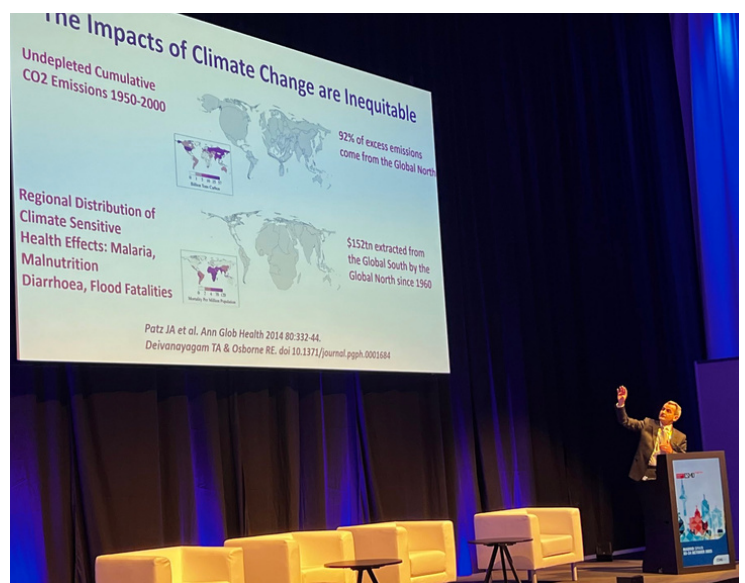
Productive meetings at ESMO – above.

## Clinical Lead: Prof. Ray McDermott



I was pleased to be again involved in the Cancer Retreat held in May at RCSI. This year's Cancer Retreat focussed on streamlining the processes around cancer trials, building on a previous stakeholder meeting around data protection held at the Spring DSSG. Working closely with CTI staff, doctors, and researchers this year, we have identified several obstacles that challenge the timely initiation and operation of trials in Ireland today. I will continue to push for Cancer Trials Ireland to work towards addressing these obstacles where possible, including advocating for a harmonised approach to GDPR in clinical trials in publicly funded hospitals.

There remains one last piece of news for me to share before signing off: I will, as many of you know, be imminently stepping down as Cancer Trials Ireland Clinical Lead to be replaced by my colleague Prof. Seamus O'Reilly. I will still be closely involved on the clinical side, remaining as Vice Clinical Lead for one year. I wish to extend my very best wishes to Seamus, and I wish him every success in the role of Clinical Lead, which he will begin in January 2024.



Prof. Seamus O' Reilly presenting at ESMO. Wishing Seamus well as he takes over as Clinical Lead from January.



## Welcome to the Winter DSSG Digest for 2023!

As we approach the end of the year, it is important to take some time to reflect on what has been achieved and to prepare for the challenges of the New Year ahead.

### ESMO 2023

One of my personal highlights since the last DSSG Digest was our successful trip to the ESMO Congress 2023 in Madrid, where we had the opportunity to meet with colleagues, existing and potential partners, and collaborators from across the globe and have meaningful, in-person discussions about new trials and opportunities for Irish patients. At the conference poster session, we presented a poster drafted by me and co-authored with colleagues from within CTI and around the world, on the challenges of sponsoring NCI and non-EU-sponsored trials in the EU. Keep an eye out for the paper to follow.

Also at ESMO, our Vice-Clinical Lead Prof. Seamus O'Reilly presented a fantastic session on 'Climate Toxicity in Cancer Care' – a call to action for us all to continue to work towards a greener global healthcare community.

### Welcome to our New COO

Closer to home, Cancer Trials Ireland has welcomed a new Chief Operating Officer, Angela Clayton-Lea. Angela has 20 years of experience in healthcare, having worked clinically as a Research Radiation Therapist before moving to Operations Management. Angela will provide overall direction, leadership, and expertise in our operations, helping us to ensure that our strategy is achieved. Angela has already started looking for ways that we can increase the efficiency of processes related to the set-up of trials, including streamlining the feasibility stage. Welcome, Angela – it's great to have you on board!



Above and right – presenting our poster and meeting partners at ESMO.



Left, Welcoming new COO, Angela Clayton-Lea.

## CEO: Eibhlín Mulroe



### Patients Consultant Committee

I am delighted to see our Patients Consultants Committee membership grow significantly this year. They now total 17 members, and we are so grateful to them for lending their wisdom, time, and passion to the cause of patient advocacy and involvement in cancer trials. The PCC were a strong focus of our Cancer Retreat back in May, with Patient Consultants Committee chair Patrick Kivlehan and member Siobhan Gaynor taking the stage, along with our patient involvement co-ordinator Dr. Sarah McLoughlin. Last month many of them came together here at RSCI for their Strategy Day, where they discussed issues including processes, timelines, and communications.

### The Pat Smullen Chair in Pancreatic Cancer

Thanks to the continued and incredible support of Pat Smullen's family and friends and the wider horse racing community, we launched the Pat Smullen Chair in Pancreatic Cancer in July of this year at University College Dublin. This new position will anchor expertise in pancreatic research in Ireland with the ambition of creating a global centre of excellence for treating and researching this form of cancer, which has one of the poorest outcomes. This role is another way Pat's legacy lives on and brings incredible benefits to patients with pancreatic cancer in Ireland.

As we look to 2024, we will continue striving to bring cancer trials to Ireland, to benefit Irish patients and their families. We are keen to initiate more investigator-led academic trials, and we look forward to working with our members to ask even more important research questions.



## GCIG 1st Cervical Cancer Consensus Conference - Clinical Research

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

Cancer Trials Ireland was successful in its bid to host this important conference. It will take place over two days in Dublin Castle on the 14th and 15th of October 2024 in line with the International Gynaecological Society 2024 Annual Global Meeting, which will be held in Dublin, Ireland, on October 16 - 18, 2024. Many people and organisations, including the Minister for Health and the Irish Cancer Society, supported Cancer Trials Ireland to host this conference. We would like to thank them and those who helped with the application. The first planning meeting was held in Chicago at the GCIG Spring Meeting.



The GCIG Spring Meeting in Chicago.

## GYNAE STUDIES IN DEVELOPMENT:

### CTRIAL-IE 21-29 NRG GY019

Led by Prof. Karen Cadoo sponsored by NRG Oncology in the US and Cancer Trials Ireland in Ireland, this study is a Randomised 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, including patients from St. James's Hospital and Cork University Hospital. This study aims to investigate which of the two treatment regimens is better for patients. CTI are working hard to open this trial, with sites open by the end of 2023.

### CTRIAL-IE 23-15 ReFrame\_STRO-002

Led by Prof. Conleth Murphy, this is a Phase II/III Open-label Study Evaluating the Efficacy and Safety of Luveltamab Tazevibulin (STRO-002) versus Investigator's Choice of Chemotherapy in Women with Relapsed Platinum-resistant Epithelial Ovarian Cancer (including Fallopian Tube or Primary Peritoneal Cancers) Expressing Folate Receptor alpha (FOLR1). 600 patients will be enrolled globally, with first patient in planned in May 2024. Sites selected in Ireland include Bon Secours Cork, Cork University Hospital, Galway University Hospital, Mater Misericordiae University Hospital and St. James's Hospital.

### CTRIAL-IE 22-18 GLORIOSA

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

### CTRIAL-IE 22-08 XPORT

Led by Dr. Dearbhaile Collins, XPORT is a Phase III, Randomised, Placebo-Controlled, Double-Blind Trial of Selinexor in Maintenance Therapy After Systemic Therapy for Patients With p53 Wildtype (wt), Advanced or Recurrent Endometrial Carcinoma (EC). 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 shortly.

### CTRIAL-IE 23-04 MK-2870-005 ENGOT-En23

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

### CTRIAL-IE 22-19 Navtemadlin

Led by Dr. Dearbhaile Collins, this is a Randomised Phase II/III Study of Navtemadlin in subjects with TP53wt Advanced or Recurrent Endometrial Cancer who responded after Chemotherapy. A total of 188 patients will be enrolled in this study. Part 2 will open at University Hospital Waterford, University Hospital Galway, Cork University Hospital, St. James's Hospital and the Beacon Hospital shortly.



## OPEN GYNAE STUDIES:

### ENGOT-en15/ KEYNOTE-C93-00 (CTRIAL-IE 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 study, open in Bon Secours Cork and St. James's Hospital, Dublin and which have to date enrolled one patient and 5 patients respectively, is expected to close in December 2023, with 350 patients enrolled globally.

### CTRIAL-IE 22-05 HELP-ER

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

### OVHIPEC-2 (CTRIAL-IE 20-07)

Led by Dr. Donal Brennan, and 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, including 10 Irish patients per year. To date, an incredible five patients have been randomised already to this trial, which is due to end recruitment in 2024.

## OTHER STUDIES IN EARLY STAGES:

Other studies in the early stage of set-up include CTRIAL-IE 22-20 RAINBO Blue / TAPER, which is a study sponsored by CCTG, and CTRIAL-IE 22-12 IMGNo420, a study sponsored by Immunogen. More information on these studies will be provided in the next DSSG Digest.

## Lung Portfolio:

### CTRIAL-IE 22-09 ADEPPT

This study is led by Chief Investigator and overall ETOP-IBCSG Trial Chair Prof. Jarushka Naidoo. The trial is sponsored by ETOP IBCSG Partners Foundation with Cancer Trials Ireland co-ordinating the study in Ireland.

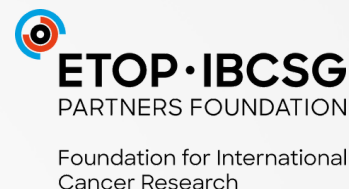
The aim of the study is to assess the clinical efficacy of adagrasib treatment in patients with KRASG12C-mutant NSCLC, in patients who are elderly ( $\geq 70$  years) or those with poor performance status (ECOG PS=2).

The trial focuses on providing access and information on novel therapies, in populations commonly excluded from clinical trials. Elderly patients with NSCLC and PS2 are often excluded from clinical trials but constitute  $>40\%$  of the population with lung cancer. Currently, there are no approved targeted therapy for patients with KRAS G12C-mutant NSCLC available in Ireland.

The primary endpoint for this study is Objective Response Rate (ORR) per RECIST v1.1 assessed at 12 weeks. Secondary endpoints include Durable clinical benefit, Time to progression, progression free survival, overall survival, safety, and patient related outcomes.



Prof. Jarushka  
Naidoo



Exploratory endpoints include blood and tissue-based biomarkers (circulating genomic, immunologic parameters). Tumour tissue from the primary tumour will be collected for molecular genetic profiling. Plasma samples and whole blood samples (for DNA and RNA extraction) will also be collected.

Participating countries include Ireland, Spain, Italy, France, the United Kingdom and Belgium with 68 patients as the global recruitment target- recruitment is competitive for this study.

Beaumont Hospital (PI: Prof Jarushka Naidoo) was initiated on the 9th November. Other Irish sites include St James's Hospital (PI: Dr. Sinead Cuffe), Cork University Hospital (PI: Dr. Dearbhaile Collins), University Hospital Waterford (PI: Dr Paula Calvert) and University Hospital Limerick (PI: Dr Grzegorz Korpany).

## Prostate: CTRIAL-IE 19-32 DASL HiCaP – Accrual Complete!

The DASL-HiCaP study reached its global recruitment target of 1100 participants this summer. This includes a fantastic contribution of 95 participants randomised across Ireland and the UK.

This is a tremendous achievement, particularly considering all the difficulties that COVID put in front of us and would not have been possible without all the hard work of our sites. We want to extend our sincerest thanks to the study staff at all our sites, your contributions are very much appreciated.

The study will continue for some time yet, with the majority of patients still on treatment, and some now entering the follow up phase. We look forward to continuing to work with you all to deliver this important study.

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 recruited 36 participants at 9 sites: Bons/UPMC, Cork, Mater Misericordiae University Hospital, Mater Private Hospital, Galway University Hospital, St. Luke's Radiation Oncology Network (SLRON) at Rathgar and St. James's Hospital, Tallaght University Hospital, Cork University Hospital and The Beacon Private Hospital.

Dr. Simon Hughes is the Chief Investigator in the UK where 59 patients were randomised across 9 sites: Royal Marsden Hospital, Kent & Canterbury Hospital, Aberdeen Royal Infirmary, Guy's Hospital, Charing Cross Hospital, Royal United Hospital Bath, Belfast City Hospital, Beatson WOSCC and Western General Hospital in Edinburgh.

DASL-HiCaP is a randomised phase III 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 take Darolutamide orally twice daily for 96 weeks or placebo twice daily for 96 weeks and are also 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.



## NEW CO-CHAIR: BREAST DSSG

We are pleased to inform you that Prof. Frances Duane (SLH/SJH) has accepted the position of Co-Chair of the Breast DSSG. Fran has been actively leading breast cancer radiation oncology research in Ireland, and we are confident that she will be a great success in her new role.

She succeeds Prof. Roisin Connolly, who recently stepped down as Co-Chair. Roisin brought tremendous enthusiasm and energy to the position and worked towards strengthening international links for clinical trials. Her expertise and attention to detail in DSSG processes will be greatly missed, and we wish her all the best in her continuing role as a strong voice for breast cancer research in Ireland.

*Thanks to Prof. Roisin Connolly*



## Breast: CTRIAL-IE SASCIA (CTRIAL-IE 20-24)

The SASCIA study has reached its target of 40 patients now randomised to the study in Ireland, and the Irish target has been increased to a maximum of 50 patients, with recruitment aiming to close at the end of the year. To date, twelve patients have been enrolled at St Vincent's Hospital, eight each at Beaumont Hospital and St. James's Hospital, five at Cork University Hospital, and three each at University Hospital Limerick and University Hospital Waterford. Four patients are currently in screening for this study. The SASCIA clinical research study (Phase III Post neoadjuvant 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.

After the recruitment period, patients will continue on treatment until their cycles are complete. Patients will then continue a follow-up period until a primary endpoint is reached, meaning until recurrence occurs or end of trial, whichever comes first. Patients expect to be followed up for about five years, and then can register for long-term follow-up.

## Breast: SHAMROCK Study (CTRIAL-IE 22-01)

Funded by Breast Cancer Ireland, sponsored by Cancer Trials Ireland and with Prof. Bryan Hennessy as Chief Investigator.

'Single arm phase II 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 Phase II open-label, single-arm, 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, patients will get T-DXd 5.4mg/kg intravenously every three weeks for up to six cycles. A mandatory biopsy after two doses of T-DXd will be performed for the RNA Disruption Index (RDI) score assessment. Patients with a high chance of pathological complete response (pCR) based on the RDI score will undergo repeat breast imaging after four cycles of T-DXd. If they also have imaging complete response (iCR) at that point, patients 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 undergo repeat breast imaging after six cycles of T-DXd. Patients with iCR after six cycles of T-DXd, regardless of RDI score, will proceed to surgery.

Patients who have a low/intermediate chance of pCR based on the RDI score and residual disease on imaging after six cycles of T-DXd will undergo either further systemic therapy or proceed to surgery (at the discretion of their treating physician). After surgery study patients will be followed up at six-monthly intervals for up to three years from registration.

The primary study objective is to evaluate the efficacy of T-DXd in the neo-adjuvant treatment of HER2-positive breast cancer using pathological complete response (pCR) as the primary endpoint.



*The SHAMROCK Study  
is funded by Breast  
Cancer Ireland.*



*Prof. Bryan Hennessy*

In addition to safety assessments, measures of the efficacy of the study treatment will include event-free survival (EFS) and overall survival (OS) of patients treated with only T-DXd and trastuzumab.

A number of translational sub-studies will study the molecular evolution of tumours during treatment and aim to develop a biomarker panel that optimises the prediction of the pCR. One of the study's secondary objectives is to determine the sensitivity and specificity for predicting pCR of RDI and imaging and tomosynthesis biopsy alone and in combination.

Study accrual target is 80 patients with HER2-positive stage 2-3 breast cancer.

The study will be sponsored by Cancer Trials Ireland and funded by a grant from Breast Cancer Ireland. AstraZeneca and Daiichi-Sankyo are the co-developers of trastuzumab deruxtecan (T-DXd) and are supplying the drug for this study.

SHAMROCK study opened to recruitment at Beaumont Hospital in October, and they already have one patient in the study. Four other sites (St. Vincent's University Hospital, Cork University Hospital, St. James's Hospital and University Hospital Limerick) will open to accrual in the near future.

## GI STUDIES

### CTRIAL-IE 20-36 NEEDS

The NEEDS study will be opening before Christmas 2023, with both HPRA approvals and NREC approvals now received. The team at CTI is 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, with Radiotherapy completed in St. Luke's Hospital St. James's Campus with Dr. Moya Cunningham. It is hoped to enrol 20 patients in Ireland to this important trial which is open globally and sponsored by the Karolinska University in Stockholm, Sweden. NEEDS is a Neoadjuvant trial, investigating locally advanced squamous cell carcinoma (SCC) of the oesophagus. The aim of the study is to compare outcomes after neoadjuvant chemoradiotherapy with subsequent esophagectomy to definitive chemoradiotherapy with surveillance and salvage oesophagectomy as needed in patients with resectable locally advanced squamous cell carcinoma (SCC) of the oesophagus, with the aim to provide generalisable guidance for future clinical practice.

### DP-IMRT Pancreas (CTRIAL-IE 17-12) to open at SLRON and SVUH

**Study Title:** A non-randomised Phase I/II study of dose-escalated hypofractionated Dose-Painted Intensity Modulated Radiotherapy (DP-IMRT) in resectable/ borderline resectable pancreatic adenocarcinoma.

The DP-IMRT Pancreas study aims to evaluate if a hypo-fractionated dose-escalated radiotherapy regime can improve the outcomes in patients with resectable or borderline resectable pancreatic adenocarcinoma. The primary objective is to establish the maximum tolerated dose of radiotherapy (RT) to the pancreas and to assess the rate of patient withdrawal from trial treatment due to acute  $\geq$  Grade 3 AEs (Adverse events) graded per National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE). Approximately 67 patients will be enrolled in order to have a maximum of 61 evaluable patients (including Phase I and Phase II). Only patients who have had the 4-week post-RT assessment will be evaluated.

It is hypothesised that the dose-escalated RT regime in this study, with advanced treatment delivery techniques, will enable increased dose delivery to the target, which will potentially result in an increased number of patients achieving a microscopically margin-negative resection (R0) and increase the number of patients who would be eligible for resection. We anticipate that tumour control will increase with increasing dose, and the normal tissue toxicity will determine the level of increase that is achievable. QoL and toxicity assessments are part of the trial. This study is among the first Investigator-led trials (ILTs) developed through a collaboration between Cancer Trials Ireland and the Irish Research Radiation Oncology Group (IRROG). An allocation of Irish Cancer Society (ICS) funding will go to sites, and a portion of the Pat Smullen Pancreatic Cancer Fund will go towards data management of the study, which will be performed by St Luke's Radiation Oncology Network (SLRON).

Dr. Gerard McVey is the Chief Investigator, and the National Institute for Cellular Biotechnology (NICB) at DCU is the translational collaborator on this study. The site initiation visit at SLRON and SVUH was conducted in August 2023, and sites will be activated in Q1 2024. The study will open in SLRON and SVUH initially before being rolled out at other sites.

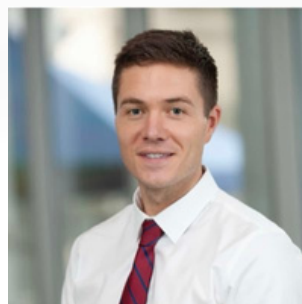
For more information, please visit [Study Details | Dose-Painted Intensity Modulated Radiotherapy Pancreas \(DP-IMRT Pancreas\) | ClinicalTrials.gov](#)



Dr Gerard McVey is the Chief Investigator, and NICB (DCU) is the translational collaborator on this study

## NEW GASTROINTESTINAL DSSG CO-CHAIR

Dr. Darren Cowzer, Consultant Medical Oncologist, Mater Misericordia University Hospital, joined the Gastrointestinal DSSG in September 2023 as Co-Chair looking after the colorectal sub-division.



Welcome Dr. Darren Cowzer



## HEAD AND NECK UPDATES

Cancer Trials Ireland Head & Neck (H&N) oncology studies recruited very well over the first three quarters of 2023, with 32 patients enrolled. The accrual numbers to H&N studies are trending upwards in recent years: 8 patients were enrolled in 2021 and 24 patients in 2022 which represents a 200% year-on-year increase in accruals in 2022. Since the establishment of the Irish Research Radiation Oncology Group (IRROG) in January 2022, we have seen an increase in H&N radiotherapy trials opening across the country.

## HEAD AND NECK TRIALS

### CompARE (CTRIAL-IE 17-14)

'Phase III randomised controlled trial Comparing Alternative Regimens for escalating treatment of intermediate and high-risk oropharyngeal cancer'. University Hospital Galway under Principal Investigator (PI) Dr. Joseph Martin has recently enrolled their first two participants on the study.

The purpose of CompARE is 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. Patients are randomised to immuno-chemoradiotherapy vs standard of care chemoradiotherapy.

The study is also open in St Luke's Radiation Oncology Network (SLRON) and St. James Hospital (SJH) under PI and Irish National Lead Investigator (NLI) Prof. Sinead Brennan and co-PI Dr. Cliona Grant. Combined, the sites have enrolled 15 participants over the last 15 months.

### DARS (CTRIAL-IE 16-23)

A phase III randomised multicentre study of dysphagia optimised intensity modulated radiotherapy (DO-IMRT) versus standard intensity modulated radiotherapy (S-IMRT) in head and neck cancer

The results of this study were published in The Lancet Oncology in July 2023, and are practice-changing. They suggest that dysphagia-optimised (DO) intensity modulated radiotherapy (IMRT) improves patient-reported swallowing function compared with standard IMRT, and that DO-IMRT should be considered a new standard of care for patients receiving radiotherapy for pharyngeal cancers. The study enrolled two patients at SLRON under PI Prof. Sinead Brennan.

### PRESERVE (CTRIAL-IE 20-04)

'Preservation of Swallowing in Resected Oral Cavity Squamous Cell Carcinoma: Examining Radiation Volume Effects (PRESERVE): A Randomised Trial'.

This study has been recruiting very well in SLRON under PI and NLI Prof. Sinead Brennan. To date, 31 patients have been registered at SLRON – over 42% of the international accrual of 73 patients, making SLRON the highest recruiter internationally.

The PRESERVE study is investigating whether we can omit radiotherapy to the neck in a pathologically node negative neck post neck dissection, with the potential advantage of reducing radiotherapy side effects for patients with oral cavity cancer.

The study is also open at Cork University Hospital and University Hospital Galway.



**PRESERVE STUDY PI and NLI Prof. Sinead Brennan**

## **CANCER TRIALS IRELAND / IRROG: SPINE SABR (CTRIAL-IE 20-03) STUDY OPENED IN NOVEMBER 2023**

The Spine SABR (CTRIAL-IE 20-03) study has been designed to determine the maximum tolerated dose of stereotactic radiotherapy to the spine, delivered in two fractions with a simultaneous integrated boost technique for patients with oligometastatic or oligoprogressive spine disease.

Cancer Trials Ireland activated the study in SLRON (PI: Prof. Clare Faul) on 21st November and plans to initiate Beacon Hospital (PI: Dr Siobhra O'Sullivan) over the coming weeks, with Bon Secours Radiotherapy Centre in partnership with the UPMC Hillman Cancer Centre (Cork), Mater Private and other IRROG sites joining in 2024. This is the first Cancer Trials Ireland/IRROG radiotherapy Investigator Led Trial (ILT) to have an electronic CRF and RAVE database managed by Cancer Trials Ireland. Participating sites will receive funding from the Irish Cancer Society.

The MRI pictured (to the right) shows a metastatic tumour (yellow arrow) in a patient's spine. Spine metastases occur in approximately 30-40% of patients with metastatic disease, and the incidence is increasing. Spine stereotactic ablative radiotherapy (SABR) is an advanced and complex technique, which allows the precise delivery of very high doses of radiotherapy to the tumour within the vertebral bone, while sparing the spinal cord and nearby organs. Some studies suggest that high dose single fraction SABR (24 Gy) results in optimum local control, however this comes at the expense of increased normal tissue toxicity, and is an independent risk factor for post-SABR vertebral compression fracture (VCF).

To date, there is no consensus as to the optimal dose fractionation regime for spine SABR in the oligo-metastatic population. In practice, choosing between single fraction or fractionated (2, 3 or 5) spine SABR tends to vary depending on the institution in which a patient is treated, and on clinician's preference.



This Phase I/II multi-centre non-randomised CTRIAL-IE 20-03 study of dose-escalation is proposed to determine the maximum tolerated dose (MTD) of 2 fraction spine SABR delivered using a simultaneous integrated boost (SIB) technique, based on the hypothesis that this will provide excellent local control while keeping VCF rates low. The higher dose will be prescribed to the visible tumour, with the lower (prophylactic) dose prescribed to adjacent bone at risk of sub-clinical spread. There will be two parallel treatment arms (high versus low baseline risk of post-SABR VCF), and three dose levels of sequential escalation within each arm.

The maximum dose level of 32 Gy in two fractions was chosen as this is modelled to be biologically equivalent to 24 Gy in one fraction. The MTD from Phase I in each arm will then be used in a Phase II cohort expansion for efficacy and toxicity assessment. Up to 168 patients will be enrolled.

This study will support the efficient expansion of SABR to all Irish cancer patients, and the results will inform national and international SABR guidelines.



## LYMPH & HAEM UPDATES

### 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, 28 patients have been recruited. The recruitment period will close in July 2024, and a maximum of 52 patients will be enrolled in the study.



*Prof. Peter O’Gorman :  
Isa-RVD 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 Very Good Partial Response or better rate by the end of two cycles of induction treatment, defined as the proportion of patients who have achieved VGPR or better, according to International Myeloma Working Group (IMWG).

The Isa-RVD study is open in the following sites in Ireland: Mater Misericordiae University Hospital (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).

Two further sites are also expected to open: University Hospital Galway (PI: Dr Janusz Krawczyk) and Aarhus, Denmark.

### CLL17 (CTRIAL-IE 20-22)

The CLL17 trial is a phase III multicentre, randomised, 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 (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 time points throughout the study to measure their response assessment. They will be followed up until the end of the trial, with the last patient 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 is supporting GCLLSG with the coordination of the trial. CLL17 closed to recruitment in November 2022.

## Irish Molecular Tumour Board (MTB)



*Dr. Dearbhaile Collins*

The MTB continues to grow and evolve under the guidance of clinical lead Dr Dearbhaile Collins. The MTB has expanded into haematological malignancies and hosted its inaugural Haematology-Oncology MTB back in June. This MTB provides a forum for haematologists across the whole country to bring complex genomic results for discussion with a panel highly experienced in the interpretation of genomics in haematological malignancies. Prof. Ruth Clifford leads the meetings which will continue to run in 2024.

Education remains a vital component of the MTB program, and in October, CTI hosted a second successful educational webinar on the theme of NGS testing in oncology.

The solid tumour MTB continues to meet on the last Tuesday of every month from 4-5 pm. Haematology-Oncology MTBs take place on the third Wednesday every two months from February 2024 at 5-6 pm.

## How it works?

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

## Who is on the MTB expert panel?

### Solid Tumour

- 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

### Haematology-oncology

- Terri McVeigh (see opposite)
- Dr Mark Catherwood, PhD. Consultant Clinical Scientist, Belfast City Hospital. Head of Cancer Molecular Diagnostics, Regional Molecular Diagnostics Service, Belfast Health and Social Care Trust. Honorary lecturer at Queen's University Belfast and Ulster University.
- Dr Richard Dillon, MD. Consultant Haematologist, Guy's Hospital, London. Clinical senior lecturer in Cancer Genetics, Department of Medical & Molecular Genetics, School of Basic & Medical Biosciences, King's College London.
- Dr Lesley Ann Sutton, PhD Principal clinical scientist, Cancer Molecular Diagnostics Clinical senior lecturer, Trinity Translational Medicine Institute

## MTB fundraising

The MTB team would like to give the fantastic SJK Foundation cycling team a huge thank you for their outstanding fundraising efforts. In September, a team of 6 women cycled from Paris to Nice and raised an impressive €70,000 in aid of the SJK Ralston project, a study for Irish Carcinoma of Unknown Primary (CUP) patients that will be run through the MTB.

For further information on the MTB, visit <https://www.cancertrials.ie/molecular-tumor-board/> or email MTB@cancertrials.ie.





## *The Pat Smullen Chair in Pancreatic Cancer established at University College Dublin*

It was with much delight that earlier this year Cancer Trials Ireland was able to announce the creation of the Pat Smullen Chair in Pancreatic Cancer at University College Dublin (UCD). The new position will anchor expertise in pancreatic research in Ireland with the ambition of creating a global centre of excellence for treatment and research of this form of cancer which has one of the poorest outcomes.

The position will receive €900,000 (€180,000 per annum) in funding over five years from Cancer Trials Ireland's Pat Smullen Pancreatic Cancer Fund with matching funding for the role from the HSE National Cancer Control Programme (NCCP). UCD will then take over Cancer Trials Ireland funding contribution to continue the partnership with the HSE NCCP.

The new Chair will share their time between their clinical work as a treating physician at St Vincent's University Hospital – the national surgical centre for pancreatic cancer – and their research work at UCD School of Medicine. At UCD, they will work to identify, attract, open and monitor new pancreatic cancer trials for patients in Ireland.

It is thanks to Pat's family and friends, the unswerving support of the horse racing community, and many others whose lives have been affected by pancreatic cancer, that the Pat Smullen Chair in Pancreatic Cancer has been made possible.



The Smullen family: (l-r) Ger Smullen, Paddy Smullen, Áine Smullen, Mary Smullen, Frances Crowley, and Sarah and Hannah Smullen at the launch of the Pat Smullen Chair in Pancreatic Cancer at UCD.

## *New Paper published on The Cancer Legacy of the Good Friday Agreement*



Cancer Trials Ireland has co-authored a paper on The Cancer Legacy of the Good Friday Agreement with colleagues from Northern Ireland, Ireland, the UK and the U.S., led by Queen's University Belfast. The research highlights the health and economic impact of the Good Friday Agreement on cancer across the island of Ireland in the last 25 years and was published in the *Journal of Cancer Policy*, the number one cancer policy journal globally.

The study highlights the impact of the Ireland - Northern Ireland - U.S. National Cancer Institute Cancer Consortium, the brainchild of former Queen's Professor and Vice Chancellor Patrick Johnston. The Consortium is a unique partnership, established in 1999, between the governments of Ireland, Northern Ireland and the U.S. as a direct result of the Good Friday Agreement. The study shows how the Consortium acted as a catalyst, enhancing cancer research quantity and quality between researchers in Northern Ireland and Ireland and with premier institutions in the U.S.

The study highlighted a 550% increase in the quality of joint cancer research on the island, an economic dividend of that enhanced research leading to a rise in university spin-out activity and an improvement in cancer outcomes on the island of Ireland.

## Cancer Retreat 2023

Cancer Trials Ireland once again hosted Ireland's flagship Cancer Retreat as part of its annual celebration of the International Clinical Trials Day 'Just Ask' campaign.

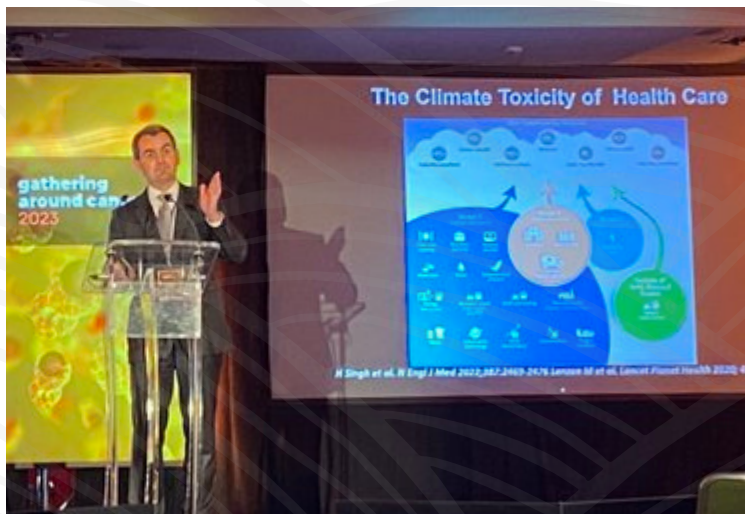
This half-day hybrid event was attended by members of Cancer Trials Ireland and stakeholders in clinical oncology research from Ireland and around the world. The event was held both in person at RSCI in Dublin and remotely via MS Teams.

The 2023 Cancer Retreat focused on streamlining the processes around cancer trials, with two lively and insightful panel discussions featuring researchers, trial unit managers, clinical leads and research nurses, facilitated by Eibhlín Mulroe, CEO of Cancer Trials Ireland.

Public and patient involvement was another key strand to the day, with attendees hearing from Patient Consultants Committee chair Patrick Kivlehan and member Siobhan Gaynor, along with our patient involvement co-ordinator Dr. Sarah McLoughlin.



## Prof Seamus O'Reilly addresses the Gathering Around Cancer on Climate Change & Cancer



The Gathering Around Cancer meeting serves as an annual update on the latest trends and treatments in medical oncology. This year, it was held in Dublin on the 16th and 17th of November. Cancer Trials Ireland Vice-Clinical Lead Professor Seamus O'Reilly gave a presentation on Climate Change and cancer, highlighting the impact of climate toxicity on cancer care and the disparity and inequality in those impacted by climate change.

The presentation was a popular session in the day's agenda, with many attendees taking to social media to praise the engaging content. Prof O'Reilly is the founder of the National Green Cancer Clinical Trials Initiative.

## Cancer Trials Ireland Podcast

Our podcast series is going from strength to strength, with a further four episodes in season two covering topics including the difficulty of diagnosing and treating Pancreatic Cancer, the Molecular Tumour Board and what NCI-MATCH has taught us about genomics and the future of cancer treatment.

All episodes are available to listen to now via Spotify, Apple Podcasts and Acast – or wherever you get your podcasts.



[www.cancertrials.ie/resources/podcast](http://www.cancertrials.ie/resources/podcast)



## *PPI: Patient Consultants Committee Update*

Since the last DSSG Digest, there has been a significant growth in the Patient Consultant Committee (PCC) membership, which now has 17 members.

Many group members met at RCSI in November for an in-person strategy day. Led by Chair Patrick Kivlehan and supported by Cancer Trials Ireland PPI Coordinator Sarah McLoughlin, the group discussed challenges and roadblocks that cancer patients face in accessing clinical trials, as well as potential actions and solutions.

The group have more meetings and activities planned for 2024.

Members of the Patients Consultants Committee at their November 2023 Strategy Day



## *Bridget Carr presented with 2023 Laura Brennan Award*

Cancer Trials Ireland PCC member and tireless patient advocate Bridget Carr, has been announced as the 2023 recipient of the Irish Society of Gynaecological Oncology Laura Brennan Award.

The award is presented on an annual basis by the ISGO to a patient, organisation or member of the public as a recognition of outstanding achievement in the areas of gynaecological oncology patient advocacy and or patient and public involvement (PPI) in research.

The award was presented at the annual meeting in Belfast on Dec 1st. Congratulations Bridget!

## *Martin Sweeney interviewed on Answers for Cancer*

The Answers for Cancer podcast, hosted by oncology nurses Anne-Marie Fay and Michelle Matthews, aims to help answer questions cancer patients might have about their diagnosis and treatment. They have interviewed an array of different medical practitioners who work with cancer patients to discuss various topics such as fertility, new treatments, fatigue, and mental health.

In their most recent episode, released in October, Martin Sweeney, a great supporter of Prostate Cancer patients and a member of our PCC, speaks about some of the side effects experienced from prostate cancer treatment and how talking about these personal and intimate issues can be central to people's treatment outcomes.





## Academic Publications from Cancer Trials Ireland Investigators

### Breast

#### CTRIAL-IE 16-20: POSITIVE

Partridge, A. H., S. M. Niman, M. Ruggeri, F. A. Peccatori, H. A. Azim Jr, M. Colleoni, C. Saura, C. Shimizu, A. B. Sætersdal, J. R. Kroep, A. Mailliez, E. Warner, V. F. Borges, F. Amant, A. Gombos, A. Kataoka, C. Rousset-Jablonski, S. Borstnar, J. Takei, J. E. Lee, J. M. Walshe, M. Ruiz-Borrego, H. Moore, C. Saunders, V. Bjelic-Radisic, S. Susnjak, F. Cardoso, K. L. Smith, T. Ferreira, K. Ribi, K. Ruddy, R. Kammeler, S. El-Abed, G. Viale, M. Piccart, L. A. Korde, A. Goldhirsch, R. D. Gelber, O. Pagani, International Breast Cancer Study Group; POSITIVE Trial Collaborators (2023) "Interrupting Endocrine Therapy to Attempt Pregnancy after Breast Cancer" *N Engl J Med* 388(18):1645-1656. PMID: 37133584

#### CTRIAL-IE 15-49: NeoTRIP

Wang, X. Q., E. Danenberg, C. Huang, D. Egle, M. Callari, B. Bermejo, M. Dugo, C. Zamagni, M. Thill, A. Anton, S. Zambelli, S. Russo, E. M. Ciruelos, R. Greil, B. Györfy, V. Semiglazov, M. Colleoni, C. M. Kelly, G. Mariani, L. Del Mastro, O. Biasi, R. S. Seitz, P. Valagussa, G. Viale, L. Gianni, G. Bianchini, H. R. Ali (2023) "Spatial predictors of immunotherapy response in triple-negative breast cancer" *Nature* 621(7980):868-876 PMID: 37674077

#### CTRIAL-IE (ICORG): 10-11 Circulating miRNAs

Davey, M. G., R. Abbas, E. P. Kerin, M. C. Casey, A. McGuire, R. M. Waldron, H. M. Heneghan, J. Newell, A. M. McDermott, M. M. Keane, A. J. Lowery, N. Miller, M. J. Kerin (2023) "Circulating microRNAs can predict chemotherapy-induced toxicities in patients being treated for primary breast cancer" *Breast Cancer Res Treat* 202(1):73-81 PMID: 37540289

#### CTRIAL-IE (ICORG): 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

#### CTRIAL-IE (ICORG): 06-32 NSABP B42

Mamounas, E. P., H. Bandos, P. Rastogi, B. C. Lembersky, J. Jeong, C. E. Geyer, L. Fehrenbacher, S. K. Chia, A. M. Brufsky, J. M. Walshe, G. S. Soori, S. R. Dakhil, J. L. Wade, E. C. McCarron, S. M. Swain, N. Wolmark (2023) "Ten-year Update: NRG Oncology/NSABP B-42 Randomized Trial: Extended Letrozole Therapy in Early-stage Breast Cancer" *J Natl Cancer Inst* 115:djado78 PMID: 37184928

#### CTRIAL-IE 15-16: FLIPPER

Tibau, A., M. T. Martínez, M. Ramos, L. D. Cruz-Merino, A. Santaballa, M. O'Connor, N. Martínez-Jañez, F. Moreno, I. Fernández, J. A. Virizuela, J. Alarcón, J. de Haba-Rodríguez, P. Sánchez-Rovira, C. R. Albacar, C. B. Muiño, C. Kelly, M. Casas, S. Bezares, L. Rosell, J. Albanell (2023) "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" *Ther Adv Med Oncol* 15:17588359221148921 PMID: 36743520

#### CTRIAL-IE: 10-05 TCHL

Gaynor, N., A. Blanco, S. F. Madden, B. Moran, J. M. Fletcher, D. Kaukonen, J. S. Ramírez, A. J. Eustace, M. S. McDermott, A. Canonici, S. Toomey, A. Teiserskiene, B. T. Hennessy, N. O'Donovan, J. Crown, D. M. Collins (2023) "Alterations in immune cell phenotype and cytotoxic capacity in HER2+ breast cancer patients receiving HER2-targeted neo-adjuvant therapy" *Br J Cancer* 129(6):1022-1031 PMID: 37507543

#### CTRIAL-IE (ICORG): 11-23: APHINITY / BIG 4-11

Azambuja, E de., E. Agostinetti, 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 (2023) "Cardiac safety of dual anti-HER2 blockade with pertuzumab plus trastuzumab in early HER2-positive breast cancer in the APHINITY trial" *ESMO Open* 8(1):100772 PMID: 36681013

#### CTRIAL-IE: 15-17 PALLAS

Pfeiler, G., D. Hlauschek, E. L. Mayer, C. Deutschmann, S. Kacarovsky-Strobl, M. Martin, J. L. Meisel, N. Zdenkowski, S. Loibl, M. Balic, H. Park, A. Prat, C. Isaacs, E. Bajetta, J. M. Balko, M. Bellet-Ezquerria, J. Bliss, H. Burstein, F. Cardoso, H. Fohler, T. Foukakis, K. A. Gelmon, M. Goetz, T. C. Haddad, H. Iwata, J. Jassem, S. Lee, B. Linderholm, M. Los, E. P. Mamounas, K. D. Miller, P. G. Morris, E. Munzone, E. N. Gal-Yam, A. Ring, L. Shepherd, C. Singer, C. Thomssen, L. Tseng, P. Valagussa, E. P. Winer, A. C. Wolff, G. Zoppoli, J. Machacek-Link, C. Schurmans, X. Huang, E. Gauthier, C. Fesl, A. C. Dueck, A. DeMichele, M. Gnani, PALLAS Groups and Investigators (2023) "Impact of BMI in Patients With Early Hormone Receptor-Positive Breast Cancer Receiving Endocrine Therapy With or Without Palbociclib in the PALLAS Trial" *J Clin Onco* JCO2300126 PMID: 37556775

## Academic Publications from Cancer Trials Ireland Investigators

### Gastrointestinal

#### Not study specific:

Punt, C. J. A., V. Heinemann, T. Maughan, C. Cremolini, E. Van. Cutsem, R. McDermott, G. Bodoky, T. André, P. Osterlund, A. J. Teske, P. Pfeiffer (2023) "Fluoropyrimidine-induced hand-foot syndrome and cardiotoxicity: recommendations for the use of the oral fluoropyrimidine S-1 in metastatic colorectal cancer" *ESMO Open* 8(2):101199 PMID: 37018874

#### 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, I. Parker, S. L. Risumlund, R. Roy, S. Falk, G. B. Hanna, F. R. Bartlett, A. Alvarez-Iglesias, M. P. Achiam, M. Nilsson, G. Piessen, N. Ravi, D. O'Toole, C. Johnston, R. S. McDermott, R. C. Turkington, S. Wahed, S. Sothi, H. Ford, M. S. Wadley, D. Power, Neo-AEGIS Investigators and Trial Group (2023) "Trimodality therapy versus perioperative chemotherapy in the management of locally advanced adenocarcinoma of the oesophagus and oesophagogastric junction (Neo-AEGIS): an open-label, randomised, phase 3 trial" *Lancet Gastroenterol Hepatol* 8(11):1015-1027 PMID: 37734399

#### 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." *Journal of Clinical Oncology* Volume 41, Issue 4\_suppl

### Genitourinary

#### CTRIAL-IE 15-46: PACE-B

Van As, N., A. Tree, J. Patel, P. Ostler, H. Van Der Voet, D.A. Loblaw, W. Chu, D. Ford, S. Tolan, S. Jain, J.G. Armstrong, P. Camilleri, K. Kancharla, J. Frew, A. Chan, O. Naismith, G. Manning, S. Brown, C. Griffin, E. Hall (2023) "5-Year Outcomes from PACE B: An International Phase III Randomized Controlled Trial Comparing Stereotactic Body Radiotherapy (SBRT) vs. Conventionally Fractionated or Moderately Hypo Fractionated External Beam Radiotherapy for Localized Prostate Cancer" *International Journal of Radiation Oncology, Biology, Physics* VOLUME 117, ISSUE 4, E2-E3

#### CTRIAL-IE (ICORG) 08-17: IMRT Prostate

Nicholson, J., B. D. O'Neill, P. Thirion, M. Cunningham, G. McVey, J. Coffey, A. M. Mihai, P. J. Kelly, N. Elbeltagi, M. Dunne, E. Noone, I. Parker, A. M. Shannon, M. McCague, A. Alvarez-Iglesias, H. Kelly, R. O'Donovan, D. Hajdaraj, G. Lawler, J. G. Armstrong (2023) "A Prospective Phase II Dose Escalation Study Using IMRT for High Risk NoMo Prostate Cancer" *International Journal of Radiation Oncology, Biology, Physics* VOLUME 117, ISSUE 2, SUPPLEMENT , E422

#### CTRIAL-IE 14-06: ENZAMET

Sweeney, C. J., A. J. Martin, M. R. Stockler, S. Begbie, L. Cheung, K. N. Chi, S. Chowdhury, M. Frydenberg, L. G. Horvath, A. M. Joshua, N. J. Lawrence, G. Marx, J. McCaffrey, R. McDermott, M. McJannett, S. A. North, F. Parnis, W. Parulekar, D. W. Pook, M. N. Reaume, S. K. Sandhu, A. Tan, T. H. Tan, A. Thomson, F. Vera-Badillo, S. G. Williams, D. Winter, S. Yip, A. Y. Zhang, R. R. Zielinski, I. D. Davis, ENZAMET trial investigators and Australian and New Zealand Urogenital and Prostate Cancer Trials Group (2023) "Testosterone suppression plus enzalutamide versus testosterone suppression plus standard antiandrogen therapy for metastatic hormone-sensitive prostate cancer (ENZAMET): an international, open-label, randomised, phase 3 trial" *Lancet Oncol* 24(4):323-334. PMID: 36990608

#### CTRIAL-IE 16-70: BMS CA209-274 / CheckMate 274

Bajorin, D. F., J. A. Witjes, J. E. Gschwend, M. Schenker, B. P. Valderrama, Y. Tomita, A. Bamias, T. Lebre, S. F. Shariat, S. Park, D. Ye, M. Agerbaek, D. Enting, R. McDermott, P. Gajate, A. Peer, M. I. Milowsky, A. Nosov, J. N. Antonio Jr, K. Tupikowski, L. Toms, B. S. Fischer, A. Qureshi, S. Collette, K. Unsal-Kacmaz, E. Broughton, D. Zardavas, H. B. Koon, M. D. Galsky (2023) "Treatment of muscle-invasive urothelial cancer with nivolumab (CheckMate 274 study): a plain language summary" *Future Oncol* 19(6):413-426 PMID: 36919916

#### CTRIAL-IE 15-21: The ExPeCT Trial

Sheill, G., L. Brady, B. Hayes, A. Baird, E. Guinan, R. Vishwakarma, C. Brophy, T. Vlajnic, O. Casey, V. Murphy, J. Greene, E. Allott, J. Hussey, F. Cahill, M. Van. Hemelrijck, N. Peat, L. Mucci, M. Cunningham, L. Grogan, T. Lynch, R. P. Manecksha, J. McCaffrey, D. O'Donnell, O. Sheils, J. O'Leary, S. Rudman, R. McDermott, S. Finn (2023) "ExPeCT: a randomised trial examining the impact of exercise on quality of life in men with metastatic prostate cancer" *Support Care Cancer* 31(5):292 PMID: 37086362

## Academic Publications from Cancer Trials Ireland Investigators

### Genitourinary cont.

#### CTRIAL-IE 20-19: KEYLYNK - 010

Antonarakis, E. S., S. H. Park, J. C. Goh, S. J. Shin, J. L. Lee, N. Mehra, R. McDermott, N. Sala-Gonzalez, P. C. Fong, R. Greil, M. Retz, J. P. Sade, P. Yanez, Y. Huang, S. D. Begbie, R. A. Gafanov, M. D. Santis, E. Rosenbaum, M. P. Kolinsky, F. Rey, K. Chiu, G. Roubaud, G. Kramer, M. Sumitomo, F. Massari, H. Suzuki, P. Qiu, J. Zhang, J. Kim, C. H. Poehlein, E. Y. Yu (2023) "Pembrolizumab Plus Olaparib for Patients With Previously Treated and Biomarker-Unselected Metastatic Castration-Resistant Prostate Cancer: The Randomized, Open-Label, Phase III KEYLYNK-010 Trial" *J Clin Oncol* 41(22):3839-3850 PMID: 37290035

#### CTRIAL-IE 13-23: Neo-adjuvant abiraterone prostate study

Murphy, G., I. Parker, M. Sheehan, P. J. Kelly, C. Small, P. G. Thirion (2023) "Single-arm phase 2 clinical trial evaluating neoadjuvant abiraterone and gonadotrophin-releasing hormone agonist in high-risk localised prostate carcinoma: CTRIAL-IE (ICORG) 13-23" *Journal of Clinical Oncology* Volume 41, Issue 6\_suppl

### Gynaecology

#### CTRIAL-IE 18-35: ENGOT cx8/GCT1015-05

Vergote, I., E. V. Nieuwenhuysen, R. E. O'Cearbhaill, A. Westermann, D. Lorusso, S. Ghamande, D. C. Collins, S. Banerjee, C. A. Mathews, C. Gennigens, D. Cibula, K. S. Tewari, K. Madsen, F. Köse, A. L. Jackson, I. A. Boere, G. Scambia, L. M. Randall, A. Sadozye, J. Baurain, E. Gort, M. Zikán, H. G. Denys, N. Ottevanger, F. Forget, C. M. Andreassen, L. Eaton, M. J. Chisamore, L. Vi. Nicacio, I. Soumaoro, B. J. Monk (2023) "Tisotumab Vedotin in Combination With Carboplatin, Pembrolizumab, or Bevacizumab in Recurrent or Metastatic Cervical Cancer: Results From the innovaTV 205/GOG-3024/ENGOT-cx8 Study" *J Clin Oncol* JCO2300720 PMID: 37651655

#### CTRIAL-IE: 16-04 PRIMA

Mirza, M. R., A. González-Martín, W. S. Graybill, D. M. O'Malley, L. Gaba, O. W. S. Yap, E. M. Guerra, P. G. Rose, J. Baurain, S. A. Ghamande, H. Denys, E. Prendergast, C. Pisano, P. Follana, K. Baumann, P. M. Calvert, J. Korach, Y. Li, I. A. Malinowska, D. Gupta, B. J. Monk (2023) "Prospective evaluation of the tolerability and efficacy of niraparib dosing based on baseline body weight and platelet count: Results from the PRIMA/ENGOT-OV26/GOG-3012 trial" *Cancer* 129(12):1846-1855 PMID: 37060236

#### CTRIAL-IE (ICORG) 09-06: Endometrial IMRT

Nugent, K., D. Browne, M. Dunne, L. O'Sullivan, A. M. Shannon, D. Sharma, S. Bradshaw, O. McArdle, O. Salib, N. Lavan, C. Gillham (2023) "Acute Gastrointestinal and Genitourinary Toxicity Results from a Prospective Randomized Phase II Trial Evaluating Adjuvant Pelvic Radiotherapy Using Either IMRT or 3-Dimensional Planning for Endometrial Cancer" *International Journal of Radiation Oncology, Biology, Physics* VOLUME 117, ISSUE 2, SUPPLEMENT, E702

#### CTRIAL-IE (ICORG) 09-06: Endometrial IMRT

Nugent, K., D. Browne, M. Dunne, L. O'Sullivan, A. M. Shannon, D. Sharma, S. Bradshaw, O. McArdle, O. Salib, N. Lavan, C. Gillham (2023) "Prospective randomised phase II trial evaluating adjuvant pelvic radiotherapy using either IMRT or 3-Dimensional planning for endometrial cancer" *Acta Oncol* 62(8):907-914 PMID: 37493622

### 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. Chang, 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. de Marinis (2023) "A real-world study of second or later-line osimertinib in patients with EGFR T790M-positive NSCLC: the final ASTRIS data" *Future Oncol* 19(1):61-75 PMID: 36656302

#### Editorial (not study specific)

Keogh, R. J., M. P. Barr, A. Keogh, D. McMahon, A. Baird, S. Cotter, D. Breen, G. J. Fitzmaurice, D. Fitzpatrick, C. O'Brien, S. P. Finn, J. Naidoo (2023) "Lung Cancer in the Republic of Ireland" *J Thorac Oncol* 18(7):851-857 PMID: 37348994

#### Book Chapter

O'Reilly, D., A. Botticella, S. Barry, S. Cotter, J. S. Donington, C. Le Pechoux, J. Naidoo (2023) "Treatment Decisions for Resectable Non-Small-Cell Lung Cancer: Balancing Less With More?" *Am Soc Clin Oncol Educ Book* 43:e389950 PMID: 37220324



## Academic Publications from Cancer Trials Ireland Investigators

### Lymph & Heam

#### CTRIAL-IE 16-60: CLL1

Fürstenau, M., Y. J. Thus, S. Robrecht, C. H. M. Mellink, A. Kevie-Kersemaekers, J. Dubois, J. Tresckow, M. Patz, M. Gregor, P. Thornton, P. B. Staber, T. Tadmor, M. Levin, C. da Cunha-Bang, C. Schneider, C. B. Poulsen, T. Illmer, B. Schöttker, A. Janssens, I. Christiansen, T. Nösslinger, M. Baumann, H. Hebart, T. Gaska, J. C. Regelink, E. C. Dompeling, V. Lindström, G. Juliusson, A. Widmer, J. Goede, N. Goldschmidt, F. Simon, N. De Silva, A. Fink, K. Fischer, C. Wendtner, M. Ritge, M. Brüggemann, E. Tausch, M. Spaargaren, E. Eldering, S. Stilgenbauer, C. U. Niemann, M. Hallek, B. Eichhorst, K. Kreuzer, A. P. Kater (2023) **"High karyotypic complexity is an independent prognostic factor in patients with CLL treated with venetoclax combinations"** *Blood* 142(5):446-459 PMID: 37172204

### Other

Harvey, H., H. Carroll, V. Murphy, J. Ballot, M. O'Grady, D. O'Hare, G. Lawler, E. Bennett, M. Connolly, E. Noone, M. G. Kelly, A. Bazin, A. Daly, E. Mulroe, R. McDermott, S. O'Reilly (2023) **"The Impact of a National Cyberattack Affecting Clinical Trials: The Cancer Trials Ireland Experience"** *JCO Clin Cancer Inform* 7:e2200149 PMID: 37053539

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

Kumar, S., L. Shen, D. S. Hong, R. McDermott, V. L. Keedy, M. Casanova, G. D. Demetri, A. Dowlati, S. G. Melcón, U. N. Lassen, S. Leyvraz, T. Liu, V. Moreno, J. Patel, T. Patil, A. B. Mallick, N. Sousa, M. Tahara, D. S. Ziegler, R. Norenberg, P. Arvis, N. Brega, A. Drilon, D. S W. Tan (2023) **"Larotrectinib efficacy and safety in adult patients with tropomyosin receptor kinase fusion sarcomas"** *Cancer* 129(23):3772-3782 PMID: 37769113

# Cancer Trials Ireland studies open to accrual (as of October 2023)

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

DSSG	General Group	CTI No.	Study Name:	Total Accrual	TUH	Beacon	BH	BonS	BonS/UPMC	CUH	UHG
Breast	Trans	09-07	<a href="#">Breast Cancer Proteomics and Molecular Heterogeneity</a>	4735			2916			1075	
Breast	Clinical	20-24	<a href="#">SASCIA</a>	40			8			5	
Breast	Clinical	21-04	lidERA Breast Cancer (accrual closed)	63			11	8		3	25
Breast	Clinical	21-15	<a href="#">DESTINY-Breast05</a>	9						1	
Breast	Clinical	21-31	<a href="#">KEYNOTE-B49</a>	2							
Breast	Clinical	21-32	<a href="#">Novartis EPIK-B5</a>	1			Open				
Breast	Clinical	22-01	<a href="#">SHAMROCK</a>	0			Open			TBI	
GI	Clinical	20-27	<a href="#">PaTcH</a>	5							
GI	Clinical	18-44	<a href="#">Astellas 8951-CL-5201</a>	4				1			
GI	Clinical	21-07	<a href="#">DESTINY DS8201-A-U306</a>	2	Open		Open			TBI	
GI	Clinical	21-06	<a href="#">Krystal-10</a>	2	Open		Open				
GI	Clinical	23-17	<a href="#">FORTITUDE-101</a>	0							
GI	Clinical	21-35	<a href="#">HERIZON-GEA-01 (ZWI-ZW25-301) Zymeworks</a>	2							
GU	Clinical	19-32	<a href="#">DASL HiCaP (Accrual closed)</a>	36	2	1			8	2	3
GU	Clinical	20-16	<a href="#">MK3475-905 (bladder) (study on hold)</a>	3	0						
GU	Clinical	21-17	<a href="#">MK 6482- 011 (Accrual closed)</a>	17	17						
GU	Clinical	21-20	<a href="#">MK3475- 365</a>	3	3						
GU	Clinical	21-18	<a href="#">MK 6482- 012 (Accrual closed)</a>	5	4		1				
GU	Clinical	21-37	<a href="#">MK6482-022</a>	18	5		2			2	
GU	Clinical	21-38	<a href="#">IMvigor011 B042843</a>	0	Open					Open	
GU	Clinical	20-32	<a href="#">PEACE 6: VULNERABLE</a>	0	Open						
GU	Trans	17-30	<a href="#">IRONMAN</a>	103	46	8					
GU	Trans	22-10	Pivotal Study BP-007	6							
GU	Observational	22-10	Pivotal Study BP-007 part II	0							
GU	Clinical	22-11	<a href="#">SABRE</a>	6					6		
GU	Registry	23-09	<a href="#">SLECT</a>	50	50						
GU	Inventional	23-18	<a href="#">LIAM Mc</a>	5						5	
Gynae	Clinical	20-07	<a href="#">OVIHIPEC 2</a>	4							
Gynae	Clinical	22-03	<a href="#">ENGOT ov65</a>	0						To open	
Gynae	Clinical	21-03	<a href="#">ENGOT cx11</a>	3						3	
Gynae	Clinical	19-02	<a href="#">ENGOT cx12</a>	0							
Gynae	Clinical	22-02	<a href="#">ENGOT en15</a>	1				1			
Gynae	Clinical	18-35	<a href="#">ENGOT cx8</a>							Closed	
Gynae	Trans	22-05	<a href="#">ENGOT ov47 HELPER</a>	0		Open				To open	To open
H & L	Clinical	19-17	<a href="#">CPD-DARA (Accrual closed)</a>	16			6			3	7
H & L	Clinical	19-34	<a href="#">Isa-RVD</a>	29			3				TBI
H & L	Trans	20-33	<a href="#">Irish &amp; ASH COVID Registry</a>	102	Open		2	4		9	6
H & L	Trans	21-24	<a href="#">COVID Vaccine</a>	75							
H & L	Clinical	19-18	<a href="#">Hovon 150</a>	6			Open			1	2
H & L	Clinical	19-16	<a href="#">Hovon 156 (Accrual closed)</a>	11	Open		Open			3	Open
H & L	Clinical	21-22	<a href="#">MK1026-003</a>	0			ISU				
H & L	Clinical	21-43	<a href="#">LOXO-BTK 20020</a>	3			1				
H & L	Clinical	21-47	<a href="#">Dream M14</a>	2			0			ISU	

## Open Studies

### Sites To Be Initiated (TBI)

## Sites in Set-Up (ISU)

### Sites initiated but not active

[illegible]



# Cancer Trials Ireland studies open to accrual (as of October 2023)

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

DSSG	General Group	CTI No.	Study Name:	Total Accrual	TUH	Beacon	BH	BonS	BonS/UPMC	CUH	UHG
Head & Neck	Clinical + Radio	17-14	<a href="#">CompARE</a>	17							2
Head & Neck	Clinical + Radio	19-39	<a href="#">Keynote 689 (MK-3475-689)</a>	9							
Head & Neck	Clinical	21-41	<a href="#">VERSATILE-002 (PDS0101-HNC-201)</a>	1							
Head & Neck & Melanoma	Clinical	20-08	<a href="#">Keynote 630 (MK-3475-630)</a>	1							
Head & Neck	Radio	20-04	<a href="#">PRESERVE</a>	22						Open	ISU
Lung	Radio	18-33	<a href="#">SOURCE Lung</a>	25		2					
Lung	Clinical	18-49	<a href="#">AbbVie M14-239 (accrual closed)</a>	1						Closed	
Lung	Clinical	20-21	<a href="#">AcceleRET-Lung/_BO42864</a>	2							
Lung	Clinical	21-12	<a href="#">CA224-104 (accrual closed)</a>	3			3				
Lung	Clinical	21-13	<a href="#">KRYSTAL-12</a>	7	1		3				Open
Lung	Clinical	22-07	<a href="#">KRYSTAL-7 (on-hold)</a>	1			1				
Lung	Trans	23-11	<a href="#">BRAND</a>	34			19				
Lung	Clinical	22-23	<a href="#">NeoCOAST-2</a>	0			Open				
Lung	Clinical	23-12	<a href="#">LATIFY</a>	0			Open				
Lung	Trans	22-15	<a href="#">PLAN</a>	14			4				
Melanoma	Clinical	18-50	<a href="#">R2910-ONC-1788</a>	4						2	1
Melanoma	Clinical	20-11	<a href="#">R3767 ONC 1613 (accrual closed)</a>	8							
Melanoma	Clinical	22-25	<a href="#">R3767 ONC 2055</a>	0			0			0	0
Melanoma	Clinical	22-26	<a href="#">R3767 ONC 2011</a>	3							
Melanoma	Clinical	22-29	<a href="#">ION-013/KN-D18 (accrual closed)</a>	0							
Basket	Clinical	15-42	<a href="#">LOXO-101</a>	5							
Basket	Clinical	18-29	<a href="#">CUPISCO - MX39795</a>								
Basket	Radio	19-21	<a href="#">SABR COMET-3</a>	10		0			6		
Basket	Clinical	19-27	<a href="#">MK7339-002/LYNK-002</a>	5	Closed			3			
Basket	Clinical	22-22	<a href="#">Immuno Fertility</a>	3			3				
Paeds	Trans	16-34	<a href="#">LLR Leukaemia Cell bank</a>	0							
Paeds		16-37	<a href="#">EWOG-MDS-2006</a>	10							
Paeds	Clinical	16-41	<a href="#">LINES (accrual closed)</a>	0							
Paeds	Trans	16-42	<a href="#">Renal IMPORT</a>	56							
Paeds	Trans	16-43	<a href="#">Tumour Banking Study</a>	146							
Paeds	Trans	16-46	<a href="#">EWOG-SAA 2010</a>	24							
Paeds	Trans	16-49	<a href="#">NB SCI Study</a>	3							
Paeds	Clinical	16-53	<a href="#">Interfant Q6 (accrual closed)</a>	6							
Paeds	Clinical	16-81	<a href="#">SIOP Ependymoma II</a>	11							
Paeds	Clinical	16-82	<a href="#">MyeChild</a>	28							
Paeds	Clinical	18-16	<a href="#">ITCC 059</a>	2							
Paeds	Clinical	18-17	<a href="#">PHITT</a>	7							
Paeds	Clinical	18-18	<a href="#">LCH IV</a>	5							
Paeds	Trans	18-19	<a href="#">MAPPYACTS (accrual closed)</a>	0							
Paeds	Trans	18-24	<a href="#">ITCC 054</a>	0							
Paeds	Clinical	18-36	<a href="#">LOXO-TRK-15003 (accrual closed)</a>	3							
Paeds	Registry	20-29	<a href="#">LOGGIC CORE</a>	4							
H & L	Clinical	23-13	<a href="#">Affirm-AL</a>	0			2				
H & L	Clinical	23-19	<a href="#">CARTITUDE-5</a>	0							
H & L	Clinical	23-12	<a href="#">MajesTEC-4</a>	0							Open
H & L	Clinical	22-14	<a href="#">TAK-573-1501</a>	0						ISU	ISU

## Open Studies

### Sites To Be Initiated (TBI)

## Sites in Set-Up (ISU)

### Sites initiated but not active

[illegible]

## Fundraising News

### Friends of Cancer Trials Ireland

The annual Friends of Cancer Trials Ireland gala lunch returned in November 2023. The lunch was once again organised by the fabulous voluntary committee (most of whom are pictured to the right), and the MC was Evelyn Cusack from RTE. The attendees were fortunate to hear from Booker Prize-winning Irish author Paul Lynch, who shared his personal story of how participating in a cancer trial changed his life, and spoke about the importance of trials for patients in Ireland. This year's event, as every year, raised vital and much appreciated funds which will support bringing academic trials to Ireland.

Pictured right: Members of the Friends of Cancer Trials Ireland.



### Pat Smullen Champions Race and Coast to Curragh

Continuing the fantastic relationship between the horse racing community and Cancer Trials Ireland, the Curragh hosted the Pat Smullen Race Day in aid of Cancer Trials Ireland on Saturday, August 27th. This unique event included the second outing of the Coast to Curragh cycle, which started at Laytown Racecourse, taking in seven racecourses and two stud farms in total, finishing at the winning line at the Curragh during the race meeting.

The special race day also included a special charity lunch and auction with some fabulous prizes. The total donated from this year's event was an incredible €230,000. That brings the overall donation to almost €600,000 in 3 years. This money will make a big difference. Cancer Trials Ireland is incredibly grateful for the support of Pat Smullen's family and the whole horse racing community.



Photos from the Pat Smullen Race Day and the Coast to Curragh cycle in aid of Cancer Trials Ireland on Saturday August 27th.

Cheque presentation of €230,000 to Cancer Trials Ireland



## Fundraising News



Lucy Connolly, Rod Nowlan and Lily the dog, of Bannion; Eibhlin Mulroe, CEO Cancer Trials Ireland

### *Bannion Property & Friends – the Property Picnic*

In May of this year Bannion once again organised the fabulous 'Property Picnic', a fundraising event inspired by the memory of their dear friend and colleague Louise Creevy (nee Doherty). We were delighted to receive a cheque for €130,279 from this year's event in aid of Cancer Trials Ireland. This brings the total raised at the event in the last two years to over €300,000.

On behalf of the Board, staff and members of Cancer Trials Ireland we want to thank the 'Property Picnic' team, the wider property industry and especially all at Bannion for bringing this event to life. We are already looking forward to the 2024 event which will be hosted by Colliers, who have taken up the mantle from Bannion.

### *The Nancys run the Mini-Marathon*

Cancer Trials Ireland is grateful for the support of 'the Nancys', an inspirational group of women with one person who connected them all, Nancy Ward.

Nancy, American by birth, made Ireland her home nearly 17 years ago, and during that time, she gave many the gift of her wonderful friendship. Earlier this year, a group of Nancy's friends got together to tackle the Women's Mini Marathon in Dublin in her memory in June 2023. The group came out in force and, within a short time, raised a fantastic figure of €7,000 for Cancer Trials Ireland.

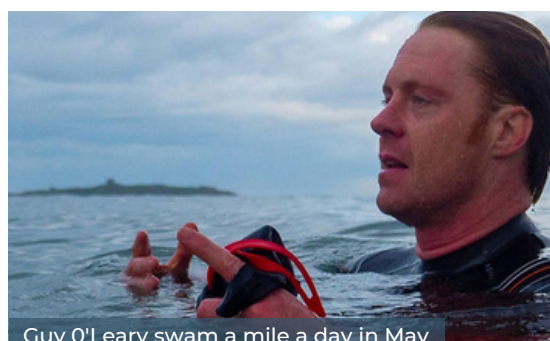
Nancy's friends wanted to support bringing clinical trials to Ireland, as they believed if Nancy thought she could be part of something that would lead to early detection, diagnosis or cure, she would be so happy, mainly to avoid other families going through what hers did. Thank you, 'The Nancys'!

### *Ballyfoyle Agricultural Show*

The Ballyfoyle Agricultural Show, in Kilkenny made a very much appreciated €1,000 donation to Cancer Trials Ireland as part of the proceeds from their charity show held in June this year.



Members of The Nancys with Verena Murphy of Cancer Trials Ireland



Guy O'Leary swam a mile a day in May

### *Swimming a Mile a Day in May*

Dublin-based sailor Guy O'Leary swam a mile each day during the month of May in aid of cancer research. Guy, a cancer survivor, has been fundraising since 2019 when he swam a mile each day in May in various locations, whether in pools, inland waters or the sea. Since then, his efforts have raised enough money to fund 8 years of PhD cancer research. We are delighted that this year Guy has donated €4,615 to the work of Cancer Trials Ireland from his fundraising.



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