



# Winter 2022

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



# DSSG Digest



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

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We are happy to report that accruals are once more on the rise after years of pandemic or ransomware disruptions. As accruals for the first nine months of 2022 will show (they will be published in the coming days), we are ahead of where we were in 2021 and 2020 – as is to be expected to a return to relative normality. We are still far short of where we would like to be, whether in relation to the macro targets of the Cancer Strategy, or our own goals, unit by unit, but there are causes for some celebration, so let's start there.

First congratulations to Jarushka Naidoo and the lung DSSG. At the height of the pandemic, lung accruals were at 0 – but this year alone three new lung studies have opened in Ireland, with patients accruing to Krystal 7, Krystal 12 and MK-7684A-008. You'll find more details about these studies on page 9, and PIs Dr Naidoo and Dr Cuffe would welcome any and all referrals, should you encounter suitable patients in clinic.

There are also exciting developments in the Breast DSSG, with the predicted arrival of the SHAMROCK study, led by Prof Bryan Hennessy. You'll find the details of this Investigator-Led Trial on page 5, it is scheduled to open in Q1 of 2023 (tbc) and is currently going through ethics & regs. In GI meanwhile, the PATCH study, led by Prof Austin Duffy, and funded by the Pat Smullen Fund, will provide new options for pancreatic patients, perhaps covering those affected by the closure to recruitment of the Paricalcitol trial this year. Another ILT, this time in Gynae (NRG-GY019) will open next year, led by Dr Karen Cadoo.

Opening ILTs is one of the core missions of Cancer Trials Ireland and you, its members. We very much encourage you to develop research ideas and to bring them forward. Yes, funding for these studies will always be a challenge, even with HRB and Irish Cancer Society support, but Cancer Trials Ireland has considerable experience with protocol development, ethics & regs management, PPI and more so we would encourage all investigators and research nurses with an interest in research to engage with head office. Typically, proposals can take up to a year to properly develop, and Cancer Trials Ireland has the capacity to open 2-3 new ILTs each year. The time to start on your proposal is now.

## **Clinical Leadership message:**



**Prof Ray McDermott**    **Prof Seamus O'Reilly**

We cannot pretend the challenges of bureaucracy and structured funding don't still exist, and these heavily impact your ability to conduct research, but in the case of the National Research Ethics (NREC) Office, things are running much more smoothly. While only recently established, the Office is now running to deadline, and has expanded its resource to review clinical trials. This success is in part due to the efforts you and your teams put in supporting advocacy efforts led by CTI in 2020 (a petition on research ethics) and in 2021, with NREC involvement in the Cancer Retreat. CTI has continued to provide NREC with a platform to reach the oncology research community. The news on NREC is also positive from an industry standpoint, which is another priority for PIs and CIs, namely getting more industry studies into Ireland, and continuing to make the case for Ireland as a strong trials location.

As ever, one of the keys to that argument is the unified voice that we, as a national network of investigators and researchers, can present, so today we will close by commending your ongoing commitment and engagement, whether through your trials, post-ASCO catch-ups with ISMO, the Cancer Retreat, and of course the DSSG meetings themselves. Thank you all for your efforts and support.

## **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 plans to enrol approximately 897 patients in 180 sites across Europe. Ireland had an initial target accrual of 40 patients and, after only 18 months of opening to recruitment, has exceeded that recruitment target with a total of 86 patients randomised. Globally, St James's hospital is the joint highest recruiting site with a total of 19 patients randomised. Ireland is 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.

The CLL17 trial is expected to meet its accrual target in Q4 2022, at which point recruitment will be closed.



Welcome to the Winter 2022 DSSG Digest!

The general central office in Cancer Trials Ireland has moved to its brand new home in RCSI, on 121 St Stephen's Green, Dublin 2. We are delighted to be situated in a newly refurbished office space with our colleagues in RCSI, and we continue to explore the ways in which our partnership can benefit each other. That includes education initiatives, establishing a network of surgical trials in and outside oncology, and maximising the achievements of both organisations in cancer research. We are fortunate to have Prof Leonie Young as one of our DSSG Chairs, and also nominated to be a representative of RCSI on the Cancer Trials Ireland Board.

In terms of the latest updates from Cancer Trials Ireland, I will structure them around the five strategic objectives our Board and team identified in response to the requirements of HRB grant funding. The first of these is:

### **Maximising our contribution to the National Cancer Strategy**

As Prof McDermott & O'Reilly outline in their Clinical Leadership message, trials and accruals are once more on the right track. Our clinical leaders, and myself, continue to meet with the Chairs and Co-Chairs of the DSSGs to set achievable targets that will deliver on the HRB grant funding requirements. This work with the DSSG Chairs, is being matched by a review of procedures and processes within Cancer Trials Ireland with a view to streamlining and maximising trial operation capacity. This work is also highly relevant to our second strategic objective:

### **Optimal, stable and scalable talent to serve growth**

Since the Spring DSSGs, GCO was able to have its first full-compliment staff meeting (a staff strategy day) in June, in RCSI. In addition to highlighting the predictable challenges facing our clinical and other teams operating trial, it uncovered a very encouraging degree of passion running through the whole team, and a desire to do as much as possible to get trials open. The opportunity to do good, meaningful work on Investigator-Led Trials is a material driver for staff – and for the people who apply for positions in the organisation. Our June staff meeting was followed by a strategy day for line managers in the organisation that took place in late October, and throughout the year I have met one-to-one with staff members at every level of the organisation, and will continue to do so in 2023.

### **Position clinical research as an integral part of cancer care through thought leadership, advocacy, and influence**

I am happy to report that we will continue to host the Cancer Retreat in 2023 (likely on Friday 19th May, TBC) with the leadership and assistance of Prof Seamus O'Reilly. This year's meeting was well attended and well received, and it was great to celebrate our success stories – like CLL17, and the PACE studies in RT, just as we continue to highlight the long-standing challenges facing cancer trials in Ireland. We will continue to highlight and advocate on issues like data protection, protected time even as we acknowledge that there are no easy solutions, though as the Clinical Leadership message notes, there is at least some progress with NREC to applaud. I would encourage any / all members with a platform for reaching policy and decision makers to make their platforms available to Dr Ana Terres in HSE Research. Dr Terres has laid out a model for research governance, but we know well the challenges of funding, and we will only see changes here if we can collectively bring pressure to bear.

Also in the advocacy space, I'm pleased to report that Cancer Trials Ireland has appointed a Public & Patient Involvement (PPI) Co-ordinator – Sarah McLoughlin. This is another key area

**CEO:**

***Eibhlín Mulroe***



for investigators and other members going forward, that features both carrot and stick. The carrot is that the evidence exists to support PPI – as the Canadian Cancer Trials Group, and HRB's Anne Cody have shown, PPI benefits accruals, and funding. On top of this, HRB grant funding demands it. And so, this morning our Stakeholder Session focuses on PPI as it did in Autumn 2021, and for session of both the 2021 and 2022 Cancer Retreats. You can read about the intentions of the PPI Co-ordinator, guided by our Patient Consultants Committee, on page 10.

### **Deliver a compelling "All-Island" cancer trial proposition**

This is our fourth strategic objective and here too I am pleased to report tangible progress. Through the Cancer Consortium Ireland, Northern Ireland, and the National Cancer Institute in America are working together with Department of Health following the MOU signed by MOUs in March 2021. Through connections made we have been able to go open four CTI non-IMP trials on the island of Ireland. I'm personally involved in this work, through my Chairing the Consortium's Cancer Research & Trials Group, whose membership includes representatives of all Consortium members, including NCI and both Departments of Health. These non-IMP trials aim to bring scientific value in their own right, and also start to pave the way for the introduction of IMP trials from NCI. That remains a considerable challenge at this point, and it is for this reason – and on the advice of CTI's external advisory board – that we are seeking to establish a model for opening all-island studies by picking the lower hanging fruit of non-IMP trials to begin with.

Elsewhere, I continue to sit on the steering group of AICRI, we met the US Ambassador over the summer and I attended the recent event in the Herbert Park Hotel on Sept 28th.

### **Financially sustainable and funded for growth**

Beyond the multi-annual funding provided by HRB, I can now confirm that an MOU with the Irish Cancer Society is in its final stages that will see multi-annual funding for Cancer Trials Ireland to the tune of €1m annually over 3 years. This is a strong endorsement of the cancer trials community in Ireland, and the value we provide to patients in Ireland.

That view is reflected too by the philanthropic donations we have received this year, which near €500k. You can read about recent donations on page 11.

These donations – and the confidence shown by ICS – are a result of the experiences of patients, and their families and carers. CTI has no fundraising team, and does no proactive fundraising. We don't advertise, and the space for fundraising in cancer is very competitive. Nevertheless we continue to be the beneficiaries of incredible unsolicited generosity. Everything we receive is a result of someone contacting us, invariably due to the gratitude they feel for themselves or for a loved one who has experienced the cancer trials service throughout the country.

## **Gynae news:**

**Gynaecologic oncology trials are forging ahead in leaps and bounds this year, with 5 studies currently open for recruitment, and multiple more in development.**

### **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 study opened recently in Bon Secours Cork, with it's final site at St. James's Hospital opening shortly. 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.

### **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 2023.

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

Led by Dr. Donal Breannan, 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 was recently opened in the 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, which is due to end recruitment in December 2024.

### **ENGOT-cx8 / InnovaTV 205 (CTRIAL 18-35)**

Led by Dr. Dearbhaile Collins, sponsored by Seagen, this study is investigating tisotumab vedotin monotherapy and in combination with bevacizumab, pembrolizumab, or carboplatin in subjects with recurrent or stage IVB cervical cancer. This study has been open to recruit to several different arms; but is currently open to include the drug regimens (pembrolizumab, bevacizumab, carboplatin, and Tisotumab vedotin), and will be triplet or quadruplet combination based on bevacizumab eligibility. This study is currently recruiting patients in Cork University Hospital, St James's Hospital, University Hospital Galway, University Hospital Waterford, and Mater Misericordiae University Hospital. They are currently looking for 30 patients on the current Arm, in which 3 patients are already recruited. The recruitment is expected to close before Christmas of this year.

### **KEYNOTE-A18 / ENGOT-cx11 (CTRIAL 21-03)**

Led by Dr. Dearbhaile Collins, sponsored by MSD, this study is comparing the use of Chemoradiotherapy with or without Pembrolizumab for the treatment of High-risk Locally Advanced Cervical Cancer. This study is open to recruit in Cork University Hospital and St James's Hospital. This study aims to recruit 980 patients globally to the trial. 4 Irish patients are expected to be recruited to this trial, which is due to close before Christmas of this year.

## **Gynae Studies in Development:**

Cancer Trials Ireland are working on trials with NRG Oncology and ENGOT and hope to have over 5 new studies in 2023 for Irish gynaecologic oncology patients. These trials will be both using Investigational Medicinal Products and also translational studies. More information on these trials will be provided in the next DSSG digest.

## **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. 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 sample size of the study is based on the need to establish the maximum tolerated dose (MTD) and the recommended phase

II dose (RP2D) of CPD in combination with DARA. Patients were accrued in cohorts of 3 patients according to a standard 3+3 algorithm, with dose de-escalation and determination of MTD based on the occurrence of dose limiting toxicities (DLT), using the usual threshold probability of 33%. The MTD was established at Dose Level 1 on April 29th. The final dose level (Dose Level 1) will be expanded to include 18 patients into this study overall (expansion cohort).

To date 12 patients have been enrolled in total across the 3 study sites. Recruitment is expected to continue until the start of Q2 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: SHAMROCK (CTRIAL-IE 22-01)**

### **Sponsored by Cancer Trials Ireland and with Prof Bryan Hennessy (right) as Chief Investigator**

'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 Phase 2 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 repeat biopsy at Cycle 2 Day 14 (+/- 4 days) of starting T-DXd will be performed for the RNA Disruption Index (RDI) score assessment. As a safety measure patients will undergo clinical examination before each cycle of T-DXd to enable early identification of on-treatment locoregional progression. In the absence of early progression, those 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. Patients who have a high chance of pCR based on the RDI score will proceed to surgery after four cycles of T-DXd if they also have imaging complete response (iCR) at that point. 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. 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 molecular evolution of tumours during treatment and aim to develop a biomarker panel that optimises prediction of the pCR. One of study secondary objectives is to determine the sensitivity and specificity for prediction of 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 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 five sites initially (Beaumont Hospital, St. Vincent's University Hospital, Cork University Hospital, University Hospital Galway, and University Hospital Limerick) with potentially more sites opening in the future.

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

The SASCIA study is making great strides since the last DSSG Digest, which reported NREC and HPRA approval. To date, fifteen patients have been randomised to the study, which is twelve more since the last reporting – nine in St Vincent's Hospital, two in Cork University Hospital, and one each in University Hospital Limerick, University Hospital Waterford and Beaumont. A further six patients are in screening, two each in St. Vincent's Hospital, Beaumont Hospital and St. James's Hospital. 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.

## **Radiotherapy team at ASTRO**



**TRI-LARC (12-38): The acute toxicity and quality of life results were presented at an oral session by Dr Brian O'Neill SLRON (Study CI) and Dr Rebecca Geary at the recent Annual ASTRO 2022 meeting in San Antonio (25-Oct-2022). Pictured above: Dr Brian O'Leary & Aoife Shannon (Cancer Trials Ireland)**



## **Radiotherapy updates:**

*In addition to the normal updates on open/pending RT studies, this issue includes an article about IRROG from its manager, Mr Gavin Lawler*

### **OPEN STUDIES:**

#### **SOURCE Lung (CTRIAL-IE 18-33)**

'Stereotactic Ablative Radiation Therapy Of UltraCentral LUNG tumours' (CTRIAL-IE 18-33) is an Investigator-led 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).

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

'Preservation of Swallowing in Resected Oral Cavity Squamous Cell Carcinoma: Examining Radiation Volume Effects (PRESERVE): A Randomized Trial' is a Canadian Cooperative group study. 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 and CUH, and is in set-up in UHG. Prof Sinéad Brennan (SLRON) is the Irish National Lead Investigator, and Dr David Palma of Lawson Health Research Institute is the international sponsor.

### **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' (CIs: Prof Clare Faul and Dr Siobhra O'Sullivan).

#### **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 and SJH, and is in set-up in UHG. The target overall accrual is 785 patients. Prof Sinéad Brennan (SLRON) is the Irish National Lead Investigator, and University of Birmingham is the study sponsor.

#### **SABR COMET-3 (CTRIAL19-21)**

'Phase III Randomized Controlled Trial and Economic Evaluation of Stereotactic Ablative Radiotherapy for Comprehensive Treatment of Oligometastatic (1-3 metastases) cancer'. This international cooperative group '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. The overall international accrual target is 330 patients. In Ireland the study is currently open in SLRON (National Lead Investigator for Cancer Trials Ireland sites: Prof John Armstrong), Bons Secours Radiotherapy Cork in Partnership with UPMC Hillman Cancer Centre and Beacon Hospital.

### **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.

**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.

**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.

**TAILOR RT (MA.39) (CTRIAL-IE 21-01):** Aim to compare the breast cancer recurrence-free interval between patients with low risk breast cancer that received regional RT or not.

## IRROG: What you need to know

The Irish Research Radiation Oncology Group (IRROG) was established in January 2022, uniting all public radiotherapy departments and private collaborators across Ireland. We are funded via successful application by Prof. Sinead Brennan (IRROG Clinical Lead and Director of Research at St. Luke’s Radiation Oncology Network, Dublin) to the Health Research Board Cancer Trials Group scheme.

IRROG’s main aim is to improve access to radiotherapy clinical trials across Ireland and develop national radiotherapy research infrastructure. IRROG will enhance national collaboration and co-operation, to streamline research procedures & processes. IRROG encompasses and represents all radiotherapy clinical trial research personnel nationally.

The current research system is not fit-for-purpose and this is a monumental opportunity to improve the radiotherapy and national research infrastructure within Ireland to achieve better quality trials, including Irish investigator initiated studies and further improve our international collaborative research portfolio for patients.

Patients in Ireland are not receiving the level of access and participation they could/should be. Technological constraints limited participation of sites across Ireland and often restricted trials to Dublin centres, however this will soon be overcome with the current upgrade programmes to existing facilities nationally ensuring access to stereotactic ablative radiotherapy (SABR) and other techniques across the country.

IRROG intends to reduce points of delay working with national stakeholders such as CTI, improve accruals and trial access nationally in an effort to improve patient outcomes. We hope a study can open across the public/private network so patients have access in their local radiotherapy departments, in an effort to improve their quality of life and reduce the burden of travelling for accessing services.

IRROG is in our infancy, however we are already integrating throughout the national platform, increasing our visibility and impact for patients and also with international collaborators.

Our work packages, including paediatrics are:



**Prof Sinead Brennan**



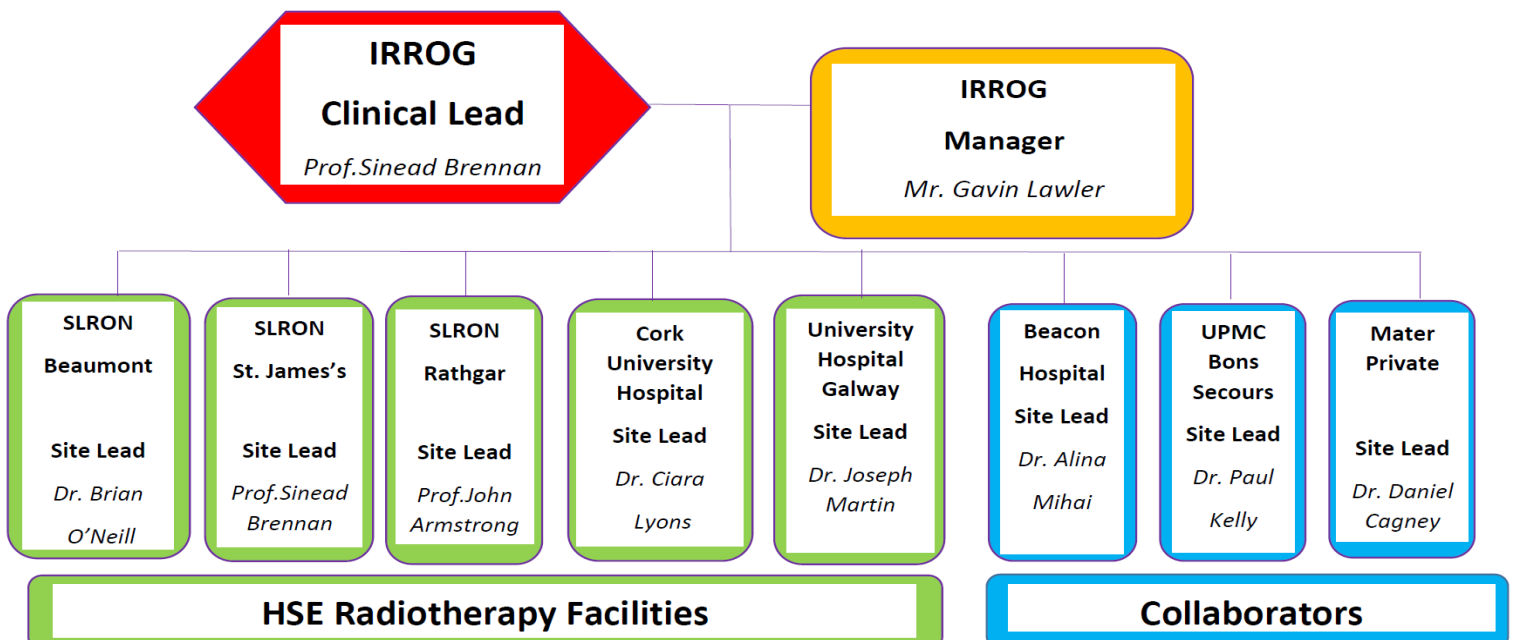
**Mr Gavin Lawler**

- WP1: Establishing IRROG + infrastructure, Communication Strategy
- WP2: Irish Academic Investigator Initiated Radiotherapy Trials
- WP3: International Advanced Radiotherapy Trials
- WP4: Combined Modality Trials RT+IMP

We are also in the process of establishing a Patient/Public Involvement (PPI) group who will be assisting to develop our logo initially as part of our PPI strategy and then be integrated throughout our group. The patient voice and representation is imperative to everything we do and can only improve our processes.

IRROG sites have an already established, individual success and history of participation in international clinical trials such as ADD-Aspirin, PACE, Enzarad, DasI-HiCAP and NRG GU005. Unified we are eager to improve our national collaboration with other groups and international collaboration and participation on studies worldwide.

We will be hosting our inaugural IRROG Conference on 20th January 2023. The conference will include a diverse range of national and international speakers with keynote addresses and sessions regarding radiotherapy clinical trials, national research stakeholders, PPI, mentoring and career development plus IRROG’s first year achievements. For more details on IRROG/our conference follow @IRROGTrialson twitter or email IRROG@slh.ie



## **Prostate: CTRIAL-IE 19-32 DASL HiCaP – 21 Irish accruals**

The DASL-HiCaP study continues to accrue well globally with over 700 patients recruited to the trial across more than 60 sites in Ireland, the UK, Australia, New Zealand, Canada and the US. The study reached 50% recruitment in May this year and is on target to complete recruitment by mid-2023.

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 21 participants at 7 sites: Cork University Hospital, Bons/UPMC Cork, St. Luke's Rathgar, Mater Misericordiae University Hospital, Mater Private Hospital, Tallaght University Hospital and The Beacon Private Hospital. It is also due to open at St. Vincent's University Hospital, Galway University Hospital and St. Luke's at St. James's Hospital before the end of 2022.

Dr. Simon Hughes is the Chief Investigator in the UK where 21 patients have been randomised with 8 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. Work is ongoing to open the study at 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



**Dr Paul Kelly, Co Chief Investigator, Ireland**

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.

## **Lymph & Haem: 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, 10 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 later in Q4 2022. This study will also be opened at a site in Denmark.



## Lung Portfolio: Three new studies open in Ireland 2022



**Prof Jarushka Naidoo, Chair, Lung DSSG, Cancer Trials Ireland**

### **KRYSTAL-7 (CTRIAL-IE 22-07)**

Led in Ireland by Dr. Jarushka Naidoo, this trial opened at Beaumont Hospital in October and will also be opening at Cork University Hospital, St. James's Hospital, University Hospital Limerick and University Hospital Galway.

KRYSTAL-7, conducted by Mirati Therapeutics, is a Phase 2 Trial of Adagrasib (MRTX849) with Pembrolizumab in Patients With Advanced Non-Small-Cell Lung Cancer (NSCLC) with KRAS G12C Mutation. KRAS G12C gene mutations occur in approximately 14% of non-small cell lung cancer adenocarcinomas.

The KRYSTAL-7 Study is evaluating whether the combination of investigational study drug (MRTX849), given in combination with an immunotherapy medicine pembrolizumab, as a potential first-line treatment, will benefit patients with this subset of cancer.

Potential participants must meet the following criteria to be eligible to participate in this study:

- Confirmed diagnosis of NSCLC
- Advanced, unresectable or metastatic NSCLC
- Tumour must have tested positive for the KRAS G12C mutation
- Life expectancy beyond three months
- ECOG of 0 or 1

Target of 4+ patients in Ireland. Referrals welcome.

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

Led in Ireland by Dr. Sinead Cuffe, MK-7684A-008 is the first clinical trial for patients with newly diagnosed extensive stage Small Cell Lung Cancer (SCLC) available to patients in Ireland for many years. This study is currently open in Beaumont Hospital and is also due to open at St. James's Hospital and Cork University Hospital.

SCLC is an aggressive neuroendocrine malignancy of the lung, and accounts for approximately 13% to 17% of all lung cancer cases.

MK-7684A-008, conducted by MSD, is a Phase 3, Randomized, Double-Blind 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 Small Cell Lung Cancer.

Potential participants must meet the following criteria to be eligible to participate in this study:

- Newly diagnosed extensive-stage SCLC
- ECOG of 0 or 1
- No active brain metastases requiring treatment
- No autoimmune or neurologic paraneoplastic syndromes
- No pneumonitis or interstitial lung disease

Target of 6+ patients from Irish sites, referrals welcome.

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

Led in Ireland by Dr. Jarushka Naidoo, this trial is open at Beaumont Hospital, Tallaght, St. James's Hospital & Galway University Hospital. It is expected to open at St Vincent's Hospital, Cork University Hospital and University Hospital Limerick soon.

KRYSTAL-12, conducted by Mirati Therapeutics, is a Phase 3 Trial of MRTX849 vs. Docetaxel in patients with previously treated non-small cell lung cancer with KRAS G12C mutation. KRAS G12C gene mutations occur in approximately 14% of non-small cell lung cancer adenocarcinomas.

The KRYSTAL-12 Study is evaluating the efficacy of the investigational agent MRTX849 (adagrasib) versus docetaxel in patients who have been previously treated for metastatic NSCLC with a KRAS G12C mutation

Potential participants must meet the following criteria to be eligible to participate in this study:

- Histologically or cytologically confirmed diagnosis of NSCLC
- Candidacy to receive treatment with docetaxel.
- Tumour must have tested positive for the KRAS G12C mutation
- Evidence of RECIST 1.1 defined disease progression on docetaxel per BICR
- ECOG of 0 -2

Target of 9 patients in Ireland. Referrals welcome.

## ***Gastrointestinal upcoming: NEEDS (CTRIAL-IE 20-36)***

The NEEDS study will be opening early 2023, with HPRA approvals now received and NREC approvals due in soon. This study 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 neoadjuvant chemoradiotherapy with subsequent esophagectomy to definitive chemoradiotherapy with surveillance and salvage esophagectomy as needed in patients with resectable locally advanced squamous cell carcinoma (SCC) of the esophagus, with the aim to provide generalizable guidance for future clinical practice.



***Dr Grainne O'Kane, St James's Hospital***

## ***Patient Consultants Committee update: New PPI Co-ordinator appointed to Cancer Trials Ireland***



***Sarah McLoughlin***

***Siobhan Gaynor***

Welcome to Sarah McLoughlin, our recently appointed Public & Patient Involvement (PPI) Co-ordinator. Sarah comes with a wealth of experience both in PPI and in health research, where she has previously worked in the UCD Con-

way Institute, and elsewhere. In terms of patient experience, Sarah is a cancer survivor who took part in a cancer clinical trial herself. With this experience, and her training in PPI and patient advocacy through the Irish Platform for Patient Organisations, Science & Industry (IPPOSI), she has developed a strong network in cancer and other patient advocacy.

As the CTI co-ordinator, she will enact the vision of the Patient Consultants Committee. That vision is under discussion at the Winter 2022 DSSG Stakeholders Session, where Sarah and PCC member Siobhan Gaynor will discuss:

- Recruiting new members to the PCC (the ambition is two patients per DSSG)
- Describe patient experiences of DSSG meetings to date, and with supporting the development of cancer trials more widely
- An update on the patient-led metastatic breast cancer research project from Siobhan Gaynor.

This session will be available on the Cancer Trials Ireland website. If you would like to contact Sarah about anything PPI-related, email: [sarah.mcloughlin@cancertrials.ie](mailto:sarah.mcloughlin@cancertrials.ie)

## ***Recently closed in Radiotherapy***

**NRG GU005 (CTRIAL-IE 18-02)** is an international cooperative group study which examines how well stereotactic body radiation therapy (SBRT) works compared to intensity-modulated radiation therapy (IMRT) in treating patients with localised intermediate risk prostate cancer. The study closed to recruitment in June with almost 700 patients enrolled. The study was open in the Beacon Hospital since 2019 under the Irish National Lead Investigator Dr Alina Mihai. Beacon was the joint 3rd highest recruiting centre of 136 international sites. Cancer Trials Ireland is the Irish sponsor, and NRG Oncology is the international sponsor.

**PACE C (CTRIAL-IE 15-46)** is a cohort of the PACE trial comparing conventional radiotherapy (RT) vs SBRT for intermediate/high risk prostate cancer patients who are non-

surgical candidates or who decline surgery. PACE is a phase III randomised controlled study comprising three parallel randomisations (PACE-A, PACE-B, and PACE-C) with a common experimental arm (SBRT). The PACE C study enrolled 22 patients at three sites in Ireland; Beacon Hospital, Bons Secours Radiotherapy Cork in Partnership with UPMC Hillman Cancer Centre, and SLRON at Beaumont Hospital. The Bons/UPMC (Dr Paul Kelly) was the highest Irish recruiter with 13 patients enrolled. Approximately 1200 patients were enrolled in total, and the study closed to recruitment in Ireland in May 2022. PACE is a collaborative group study sponsored (globally) by The Royal Marsden NHS Foundation Trust and coordinated by the Cancer Research UK-funded Clinical Trials and Statistics Unit at The Institute of Cancer Research, London. Prof John Armstrong is the Irish National Lead Investigator. The PACE B late toxicity results were published in the Lancet Oncology in October, and Prof John Armstrong (Study CI) was listed as an author.



**In 2019, Pat Smullen and the horse racing community raised €2.6m for pancreatic cancer trials and research. One of the outcomes of this was that Cancer Trials Ireland became associated with pancreatic cancer in the minds of people in Ireland – more on that below. Another is the establishment of the Pat Smullen Pancreatic Cancer Fund, to maximise these and other funds in pursuit of new options for patients with pancreatic cancer.**

Since being founded, the Pat Smullen Pancreatic Cancer Fund has successfully funded two IMP trials, one RT trial, and one nutritional study. In contrast to 2019, when no studies were open in pancreatic cancer, soon there will be three, with a fourth having closed after recruiting 15 patients in 2021/22. In addition, the Fund also supported the purchase of a Next Generation Sequencing Machine in SVUH, in 2020. This was in line with the Fund's stated objectives, which are to:

- Build lasting infrastructure in Ireland to aid with the diagnosis and treatment of pancreatic cancer.
- Fund research to improve the diagnosis, knowledge and treatment of pancreatic cancer in Ireland.

You can follow the latest news and developments of the Pat Smullen Pancreatic Cancer Fund on a dedicated web page on the Cancer Trials Ireland website: <https://www.cancertrials.ie/pat-smullen/>

## PaTcH (CTRIAL 20-27)

**Title:** Pilot study to explore primary and emerging resistance mechanisms in patients with metastatic refractory pancreatic cancer treated with trametinib and hydroxychloroquine

**Update:** PaTcH is a trial aiming to recruit 22 patients with advanced stage pancreatic cancer that have failed treatment. The hope is this trial may give participating patients a few more months of life. Set up of the trial is ongoing and it is planned that recruitment will start early in 2023.

## FEED (CTRIAL 20-26)

**Title:** Exploring the impact of a multi-modal nutritional intervention in patients undergoing chemotherapy for pancreatic cancer

**Update:** The FEED study aims to investigate the effectiveness of a multi-modal nutrition-led intervention, with and without resistance training, delivered concurrently to neoadjuvant

## The Pat Smullen Pancreatic Cancer Fund: Study updates

chemotherapy for patients with pancreatic cancer. This study will open in St Vincent's University Hospital (SVUH) and aims to recruit 70 patients. The funding for this study comes from the Pat Smullen Fund. The protocol is in development and this study is expected to open SVUH in 2023. Professor Ray McDermott and Dr Oonagh Griffin are the CIs.

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

**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

**Update:** 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 study protocol is in development between IRROG and Cancer Trials Ireland, with an additional translational sub-study currently being incorporated. An allocation of funding from the Pat Smullen Fund will go towards data management of the study, which will be performed by SLRON.

Dr Gerard McVey is the CI; the study will open in SLRON and SVUH initially before being rolled out at other sites.

## Paricalcitol (CTRIAL 19-33)

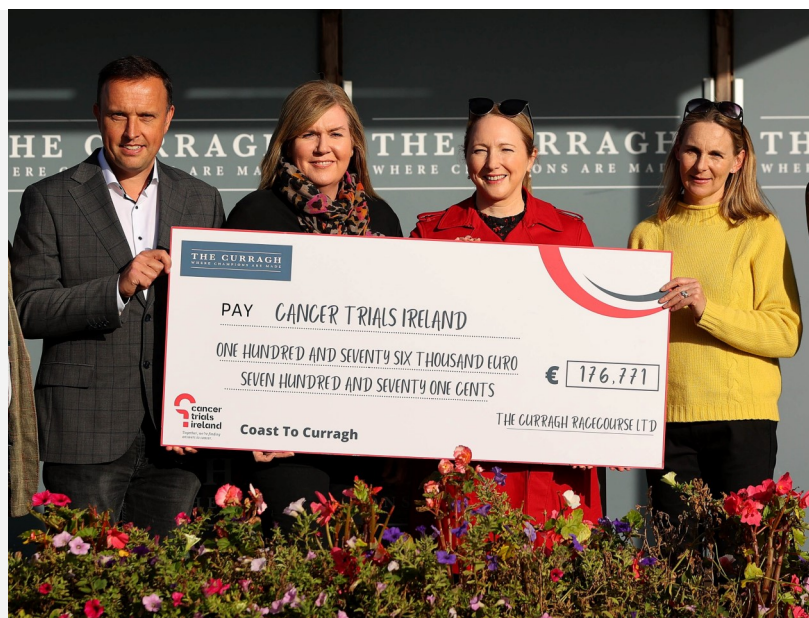
**Title:** Phase II, Open Label Clinical Trial of Paricalcitol in Combination With Gemcitabine/ Nab-Paclitaxel Therapy in Advanced Pancreatic Cancer

**Update:** The last patient on the Paricalcitol trial has completed follow-up. Data cleaning is now underway to allow the database to be locked for analysis. Imaging analysis and some translational assays are underway. A manuscript of the results will be published once these analyses are complete.

## Fundraising: pancreatic cancer

While the 2019 Longines Champions Weekend was critical for the Fund, the family and friends of Pat Smullen have continued to lend their support to pancreatic cancer. This includes the Coast to Curragh cycle, which raised €185,000 in 2021, for pancreatic cancer trials. This money is overseen by the Olive Lynch Fund, named for the mother of Gavin Lynch, another active member of the horse racing community. In 2022, the Coast to Curragh cycle teamed up with The Curragh, and Frances Crowley (Pat Smullen's wife) to roll out the inaugural Pat Smullen Race Day in late August 2022. This raised a further €176,771 for pancreatic trials.

**Pictured: (L-R) Gavin Lynch (Coast to Curragh), Barbara White (Horse Racing Ireland), Eibhlín Mulroe (Cancer Trials Ireland), and Frances Crowley, wife of the departed Pat Smullen.**





## Academic Publications from Cancer Trials Ireland Investigators

### Breast

Cancer Trials Ireland Study Number: short name. 06-31: TAILORx Study

Albain, K. S., R. J. Gray, D. F. Makower, A. Faghih, D. F. Hayes, C. E. Geyer, E. C. Dees, M. P. Goetz, J. A. Olson, T. Lively, S. S. Badve, T. J. Saphner, L. I. Wagner, T. J. Whelan, M. J. Ellis, W. C. Wood, M. M. Keane, H. L. Gomez, P. S. Reddy, T. F. Goggins, I. A. Mayer, A. M. Brufsky, D. L. Toppmeyer, V. G. Kaklamani, J. L. Berenberg, J. Abrams, G. W. Sledge & J. A. Sparano (2021). "Race, Ethnicity, and Clinical Outcomes in Hormone Receptor-Positive, HER2-Negative, Node-Negative Breast Cancer in the Randomized TAILORx Trial." *J Natl Cancer Inst* 113(4): 390-399.

Cancer Trials Ireland Study Number: short name. 10-05: TCHL

Eustace, A. J., S. F. Madden, J. Fay, D. M. Collins, E. W. Kay, K. M. Sheehan, S. Furney, B. Moran, A. Fagan, P. G. Morris, A. Teiserskiene, A. D. Hill, L. Grogan, J. M. Walshe, O. Breathnach, C. Power, D. Duke, K. Egan, W. M. Gallagher, N. O'Donovan, J. Crown, S. Toomey & B. T. Hennessy (2021). "The role of infiltrating lymphocytes in the neo-adjuvant treatment of women with HER2-positive breast cancer." *Breast Cancer Res Treat* 187(3): 635-645.

Cancer Trials Ireland Study Number: short name. 11-24: NSABP B47

Ganz, P. A., R. S. Cecchini, L. Fehrenbacher, C. E. Geyer, P. Rastogi, J. P. Crown, M. P. Thirlwell, D. M. Ellison, J. F. Boileau, P. J. Flynn, J. H. Jeong, E. P. Mamounas & N. Wolmark (2021). "NRG Oncology/NSABP B-47 menstrual history study: impact of adjuvant chemotherapy with and without trastuzumab." *NPJ Breast Cancer* 7(1): 55.

Cancer Trials Ireland Study Number: short name. 12-43: TRIO 022/ PALOMA-2

Gelmon, K., J. M. Walshe, R. Mahtani, A. A. Joy, M. Karuturi, P. Neven, D. R. Lu, S. Kim, P. Schnell, E. Bananis & L. Schwartzberg (2021) "Efficacy and safety of palbociclib in patients with estrogen receptor-positive/human epidermal growth factor receptor 2-negative advanced breast cancer with preexisting conditions: A post hoc analysis of PALOMA-2" *Breast* 59: 321-326

Cancer Trials Ireland Study Number: short name. 11-03: SOLE

Guerini-Rocco, E., K. P. Gray, C. Fumagalli, M. R. Reforgiato, I. Leone, P. Rafaniello Raviele, E. Munzone, R. Kammler, P. Neven, E. Hitre, G. Jerusalem, E. Simoncini, A. Gombos, I. Deleu, P. Karlsson, S. Aebi, J. Chirgwin, V. Di Lauro, A. Thompson, M. P. Graas, M. Barber, C. Fontaine, S. Loibl, J. Gavilá, K. Kuroi, B. Müller, S. O'Reilly, A. Di Leo, A. Goldhirsch, G. Viale, M. Barberis, M. M. Regan & M. Colleoni (2021). "Genomic Aberrations and Late Recurrence in Postmenopausal Women with Hormone Receptor-positive Early Breast Cancer: Results from the SOLE Trial." *Clin Cancer Res* 27(2): 504-512.

Cancer Trials Ireland Study Number: short name. 11-03: SOLE

Jerusalem, G., S. Farah, A. Courtois, J. Chirgwin, S. Aebi, P. Karlsson, P. Neven, E. Hitre, M. P. Graas, E. Simoncini, E. Abdi, C. Kamby, A. Thompson, S. Loibl, J. Gavilá, K. Kuroi, C. Marth, B. Müller, S. O'Reilly, A. Gombos, T. Ruhstaller, H. J. Burstein, M. Rabaglio, B. Ruepp, K. Ribí, G. Viale, R. D. Gelber, A. S. Coates, S. Loi, A. Goldhirsch, M. M. Regan, M. Colleoni & SOLE Investigators (2021) "Continuous versus intermittent extended adjuvant letrozole for breast cancer: final results of randomized phase III SOLE (Study of Letrozole Extension) and SOLE Estrogen Substudy." *Ann Oncol* 32 (10): 1256-1266.

Cancer Trials Ireland Study Number: short name. 15-02: PanTHER

Keegan, N. M., S. J. Furney, J. M. Walshe, G. Gullo, M. J. Kennedy, D. Smith, J. McCaffrey, C. M. Kelly, K. Egan, J. Kerr, M. Given, P. O'Donovan, A. Hernando, A. Teiserskiene, I. Parker, E. Kay, A. Farrelly, A. Carr, G. Calzaferri, R. McDermott, M. M. Keane, L. Grogan, O. Breathnach, P. G. Morris, S. Toomey & B. T. Hennessy (2021). "Phase Ib Trial of Copanlisib, A Phosphoinositide-3 Kinase (PI3K) Inhibitor, with Trastuzumab in Advanced Pre-Treated HER2-Positive Breast Cancer "PanTHER"" *Cancers (Basel)* 13(6): 1225.

Cancer Trials Ireland Study Number: short name. 14-11: PENELOPE-B

Loibl, S., F. Marmé, M. Martin, M. Untch, H. Bonnefoi, S. B. Kim, H. Bear, N. McCarthy, M. Melé Olivé, K. Gelmon, J. García-Sáenz, C. M. Kelly, T. Reimer, M. Toi, H. S. Rugo, C. Denkert, M. Gnant, A. Makris, M. Koehler, C. Huang-Bartelett, M. J. Lechuga Frean, M. Colleoni, G. Werutsky, S. Seiler, N. Burchardi, V. Nekljudova & G. von Minckwitz (2021). "Palbociclib for Residual High-Risk Invasive HR-Positive and HER2-Negative Early Breast Cancer-The Penelope-B Trial." *J Clin Oncol* 39(14): 1518-1530.

Cancer Trials Ireland Study Number: short name. 12-30: TailorX Tissue Bank

Lynch, S. M., N. M. Russell, S. Barron, C. A. Wang, T. Loughman, P. Dynoodt, B. Fender, C. Lopez-Ruiz, A. O'Grady, K. M. Sheehan, J. Fay, V. Amberger-Murphy, A. Saha, R. Klinger, C. A. Gonzalez, N. Al-Attar, A. Rahman, D. O'Leary, F. T. Lanigan, A. P. Bracken, J. Crown, C. M. Kelly, D. P. O'Connor & W. M. Gallagher (2021). "Prognostic value of the 6-gene OncoMasTR test in hormone receptor-positive HER2-negative early-stage breast cancer: Comparative analysis with standard clinicopathological factors." *Eur J Cancer* 152: 78-89.

Cancer Trials Ireland Study Number: short name. 15-17: PALLAS

Mayer, E. L., A. C. Dueck, M. Martin, G. Rubovszky, H. J. Burstein, M. Bellet-Ezquerria, K. D. Miller, N. Zdenkowski, E. P. Winer, G. Pfeiler, M. Goetz, M. Ruiz-Borrego, D. Anderson, Z. Nowecki, S. Loibl, S. Moulder, A. Ring, F. Fitzal, T. Traina, A. Chan, H. S. Rugo, J. Lemieux, F. Henao, A. Lyss, S. Antolin Novoa, A. C. Wolff, M. Vetter, D. Egle, P. G. Morris, E. P. Mamounas, M. J. Gil-Gil, A. Prat, H. Fohler, O. Metzger Filho, M. Schwarz, C. DuFrane, D. Fumagalli, K. P. Theall, D. R. Lu, C. H. Bartlett, M. Koehler, C. Fesl, A. DeMichele & M. Gnant (2021) "Palbociclib with adjuvant endocrine therapy in early breast cancer (PALLAS): interim analysis of a multicentre, open-label, randomised, phase 3 study." *Lancet Oncol* 22(2): 212-222.

Cancer Trials Ireland Study Number: short name. 16-20: IBCSG 48-14 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. R. Borrego, H. C. Moore, C. Saunders, F. Cardoso, S. Susnjár, V. Bjelic-Radisic, K. L. Smith, M. Piccart, L. A. Korde, A. Goldhirsch, R. D. Gelber & O. Pagani (2021) "Who are the women who enrolled in the POSITIVE trial: A global study to support young hormone receptor positive breast cancer survivors desiring pregnancy" *Breast* 59: 327-338.

### Genitourinary

Cancer Trials Ireland Study Number: short name. 16-70: BMS CA209-274/ CheckMate 274

Bajorin, D. F., J. A. Witjes, J. E. Gschwend, M. Schenker, B. P. Valderrama, Y. Tomita, A. Bamas, T. Lebret, S. F. Shariat, S. H. 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 "Adjuvant Nivolumab versus Placebo in Muscle-Invasive Urothelial Carcinoma." *N Engl J Med* 384(22): 2102-2114.

Cancer Trials Ireland Study Number: short name. 15-21: The ExPeCT Trial

Hayes, B., L. Brady, G. Sheill, A. M. Baird, E. Guinan, B. Stanfill, J. Dunne, D. Holden, T. Vljajnic, O. Casey, V. Murphy, J. Greene, E. H. Allott, J. Hussey, F. Cahill, M. Van Hemelrijck, N. Peat, L. A. Mucci, M. Cunningham, L. Grogan, T. Lynch, R. P. Manecksha, J. McCaffrey, D. O'Donnell, O. Sheils, J. J. O'Leary, S. Rudman, R. McDermott & S. Finn (2021) "Circulating Tumour Cell Numbers Correlate with Platelet Count and Circulating Lymphocyte Subsets in Men with Advanced Prostate Cancer: Data from the ExPeCT Clinical Trial (CTRIAL-IE 15-21)." *Cancers (Basel)* 13(18): 4690.

Cancer Trials Ireland Study Number: short name. 08-17: IMRT Prostate

Howe, O., L. White, D. Cullen, G. O'Brien, L. Shields, J. Bryant, E. Noone, S. Bradshaw, M. Finn, M. Dunne, A. M. Shannon, J. Armstrong, B. McClean, A. Meade, C. Badie & F. M. Lyng (2021) "A 4-Gene Signature of CDKN1, FDXR, SESN1 and PCNA Radiation Biomarkers for Prediction of Patient Radiosensitivity." *Int J Mol Sci.* 22(19): 10607.

Cancer Trials Ireland Study Number: short name. 13-21: Radium-223 & Enzalutamide mCRPC study

McDermott, R. S., J. Greene, J. McCaffrey, I. Parker, S. Helanova, A. M. Baird, A. Teiserskiene, M. Lim, H. Matthews, O. Deignan, J. Feeney, P. G. Thirion, S. P. Finn & P. J. Kelly (2021) "Radium-223 in combination with enzalutamide in metastatic castration-resistant prostate cancer: a multi-centre, phase II open-label study." *Ther Adv Med Oncol* 13: 17588359211042691.

Cancer Trials Ireland Study Number: short name. 11-05: GSK VEG113387 adjuvant pazopanib RCC study

Motzer, R. J., P. Russo, N. Haas, C. Doehn, F. Donskov, M. Gross-Goupil, S. Varlamov, E. Kopyltsov, J. L. Lee, H. Y. Lim, B. Melichar, M. Zemanova, B. Rini, T. K. Choueiri, L. Wood, M. N. Reaume, A. Stenzl, S. Chowdhury, R. McDermott, A. Michael, M. Izquierdo, P. Aimone, H. Zhang, C. N. Sternberg & PROTECT study investigators (2021) "Adjuvant Pazopanib Versus Placebo After Nephrectomy in Patients With Localized or Locally Advanced Renal Cell Carcinoma: Final Overall Survival Analysis of the Phase 3 PROTECT Trial." *Eur Urol* 79(3): 334-338

Cancer Trials Ireland Study Number: short name. 14-04: iPROSPECT study

Silva, R., B. Moran, A. M. Baird, C. J. O'Rourke, S. P. Finn, R. McDermott, W. Watson, W. M. Gallagher, D. J. Brennan & A. S. Perry (2021) "Longitudinal analysis of individual cfDNA methylome patterns in metastatic prostate cancer." *Clin Epigenetics* 13(1): 168.

Cancer Trials Ireland Study Number: short name. 14-06: ENZAMET

Sweeney, C. J., A. J. Martin, M. R. Stockler, S. Begbie, K. N. Chi, S. Chowdhury, X. Coskinas, M. Frydenberg, W. E. Hague, L. G. Horvath, A. M. Joshua, N. J. Lawrence, G. M. 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, E. Tu, F. Vera-Badillo, S. G. Williams, S. Yip, A. Y. Zhang, R. R. Zielinski & I. D. Davis (2021) "Overall Survival of Men with Metachronous Metastatic Hormone-sensitive Prostate Cancer Treated with Enzalutamide and Androgen Deprivation Therapy." *Eur Urol* 80(3): 275-279.

Cancer Trials Ireland Study Number: short name 15-46 PACE B Tree C. A, P. Ostler, H. van der Voet, W. Chu, A. Loblaw, D. Ford, S. Tolan, S. Jain, A. Martin, J. Staffurth, J. Armstrong, P. Camilleri, K. Kancherla, J. Frew, A. Chan, I. S. Dayes, A. Duffton, D. H. Brand, D. Henderson, K. Morrison, S. Brown, J. Pugh, S. Burnett, M. Mahmud, V. Hinder, O. Naismith, E. Hall, As. N. Van, PACE Trial Investigators (2022) "Intensity-modulated radiotherapy versus stereotactic body radiotherapy for prostate cancer (PACE-B): 2-year toxicity results from an open-label, randomised, phase 3, non-inferiority trial." *Lancet Oncol* 1308-1320.

## Gynaecological

Cancer Trials Ireland Study Number: short name. 16-68: FORWARD 1

Moore, K. N., A. M. Oza, N. Colombo, A. Oaknin, G. Scambia, D. Lorusso, G. E. Konecny, S. Banerjee, C. G. Murphy, J. L. Tanyi, H. Hirte, J. A. Konner, P. C. Lim, M. Prasad-Hayes, B. J. Monk, P. Pautier, J. Wang, A. Berkenblit, I. Vergot & M. J. Birrer (2021) "Phase III, randomized trial of mirvetuximab soravtansine versus chemotherapy in patients with platinum-resistant ovarian cancer: primary analysis of FORWARD I." *Ann Oncol* 32(6): 757-765.

Cancer Trials Ireland Study Number: short name. 11-29: ICON8/8B

Morgan, R. D., I. A. McNeish, A. D. Cook, E. C. James, R. Lord, G. Dark, R. M. Glasspool, J. Krell, C. Parkinson, C. J. Poole, M. Hall, D. Gallardo-Rincón, M. Lockley, S. Essapen, J. Summers, A. Anand, A. Zachariah, S. Williams, R. Jones, K. Scatchard, A. Walther, J. W. Kim, S. Sundar, G. C. Jayson, J. A. Ledermann & A. R. Clump (2021). "Objective responses to first-line neoadjuvant carboplatin-paclitaxel regimens for ovarian, fallopian tube, or primary peritoneal carcinoma (ICON8): post-hoc exploratory analysis of a randomised, phase 3 trial." *Lancet Oncol* 22(2): 277-288.

Cancer Trials Ireland Study Number: short name. 18-27: PORTEC 4a

Wortman, B. G., E. Astreinidou, M. S. Laman, E. M. van der Steen-Banasik, L. C. H. W. Lutgens, H. Westerveld, F. Koppe, A. Slot, H. A. van den Berg, M. E. Nowee, S. Bijmolt, T. C. Stam, A. G. Zwanenburg, J. W. M. Mens, I. M. Jürgenliemk-Schulz, A. Snyers, C. M. Gillham, N. Weidner, S. Kommos, K. Vandecasteele, V. Tomancova, C. L. Creutzberg, R. A. Nout & P. S. Group (2021). "Brachytherapy quality assurance in the PORTEC-4a trial for molecular-integrated risk profile guided adjuvant treatment of endometrial cancer." *Radiother Oncol* 155: 160-166.

## Lung

Cancer Trials Ireland Study Number: Short Name. 12-53: ETOP SPLENDOR

Peters, S., S. Danson, D. Ejedepang, U. Dafni, B. Hasan, H. S. Radcliffe, F. Bustin, J. Crequit, L. Coate, M. Guillot, V. Surmont, D. Rauch, J. Rudski, D. O'Mahony, I. B. Aranda, A. Scherz, Z. Tsourti, H. Roschitzki-Voser, A. Pochesci, G. Demonty, R. A. Stahel & M. O'Brien (2021) "Combined, patient-level, analysis of two randomised trials evaluating the addition of denosumab to standard first-line chemotherapy in advanced NSCLC - The ETOP/EORTC SPLENDOR and AMGEN-249 trials." *Lung Cancer* 161: 76-85.

Cancer Trials Ireland Study Number: short name. 14-13: MK3475-024/ KEYNOTE-024

Reck, M., D. Rodríguez-Abreu, A. G. Robinson R. Hui, T. Csósz, A. Fülöp, M. Gottfried, N. Peled, A. Tafreshi, S. Cuffe, M. O'Brien, S. Rao, K. Hotta, T. A. Leal, J. W. Riess, E. Jensen, B. Zhao, M. C. Pietanza & J. R. Brahmer (2021) "Five-Year Outcomes With Pembrolizumab Versus Chemotherapy for Metastatic Non-Small-Cell Lung Cancer With PD-L1 Tumor Proportion Score  $\geq 50$ " *J Clin Oncol* 39(21): 2339-2349.

## Irish Molecular Tumour Board

The Cancer Trials Ireland national MTB programme is a forum for oncologists to discuss the implications of their patient's cancer genomic findings.

Cancer Trials Ireland aims to embed the MTB programme into healthcare for Irish cancer patients. By fostering collaboration on cancer treatment decisions among Irish doctors, with support of national and international experts, the MTB is driving the transition towards precision oncology and personalised healthcare. The Irish MTB is led by Dr Dearbhaile Collins (picture).

Cancer Trials Ireland plans to develop the MTB as a valuable educational resource by creating an online platform to include training material on key concepts and educational cases. The development of a registry for patient data will provide beneficial reference material for oncologists. The ultimate goal is to connect the Irish MTB with other international MTBs and contribute to an international collection of cancer NGS data, their interpretation and any available treatment option.

The Irish MTB program was originally co-designed with Roche, and with local Irish doctors in 2019, and a pilot MTB programme was initiated in November 2020. As the national leading cancer trials organisation in the country, Cancer Trials Ireland got involved in the programme in 2021 and took over the operations of the Irish MTB in July 2022.

### How it works

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. Key questions are submitted to the experts to allow for



**Dr Dearbhaile Collins, Cork University Hospital**

proper preparation prior to the 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

### How can I find out more?

Visit our [dedicated webpage](#), or email [Claire.Bermingham@cancertrials.ie](mailto:Claire.Bermingham@cancertrials.ie).

## Greening Cancer Trials: Prof Seamus O'Reilly

At the Cancer Retreat in May, I announced a National Green Cancer Clinical Trials initiative. Global warming has become the major concern affecting us and many organisations have established green initiatives to mitigate it. Our colleagues in the laboratories are leading in this area and our Universities have Green Campus programs.

I proposed the establishment of a national initiative with representatives from all of the clinical trial units - consensus would be established on areas where progress could be made - initially in the workplace - computers, printers, travel, email etiquette, electricity use and then in patient interactions reducing travel burden through protocol development.

I am pleased to report progress. In late September, a group of trial site representatives met virtually to discuss an electronic Investigator site file in place in Beaumont Hospital and also to discuss other ways that the cancer trials community can reduce its carbon footprint and become a national and international leader in greening clinical trials.

Among the matters discussed was a simple awareness of the Initiative, and of our collective efforts, and small stickers (pictured right) speak to that purpose and provide some visibility in our working environment. These stickers will



shortly be distributed to all trial sites around the country, and the group will meet again later this month, on Monday 28th November (virtual).

If you would like to join this meeting, email [Sandra.Boldrin@CancerTrials.ie](mailto:Sandra.Boldrin@CancerTrials.ie) or [Lucy.Murphy@cancertrials.ie](mailto:Lucy.Murphy@cancertrials.ie).

I am acutely conscious that many of you are under pressure with staffing levels and the never ending stress of life in the Irish health service. I hope you feel, as we do, that the climate question is one that still demands our attention, even under the pressures we daily face.



# Cancer Trials Ireland studies open to accrual (as of Sept 30th, 2022)

Purple = Industry studies

Green = Cancer Trials Ireland in-house studies

Orange = Collaborative Group studies

Select double-page view for full tables

DSSG	General Group	Cancer Trials Ireland No:	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	17			13				
Breast	Clinical	18-05	KEYNOTE-756 (closed to accrual Aug 2022)	7				3			
Breast	Surgical	20-13	LigaSure	84			84				
Breast	Clinical	20-24	SASCIA	15			2			2	
Breast	Clinical	21-04	GO42784/ TRIO 045/ lidERA Breast Cancer	33			5	7		Open	11
Breast	Clinical	21-05	DESTINY-Breast12	14						Open	
Breast	Clinical	21-15	DESTINY-Breast05	4						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	3						2	
GI	Clinical	19-07	MK3475-937 (KEYNOTE-937)	1	Closed to accrual						
GI	Clinical	18-08	BMS CA209-8HW	2							
GI	Clinical	19-33	Paricalcitol (closed to accrual Nov-2021)	14	Closed to accrual		4			3	
GI	Clinical	18-44	Astellas 8951-CL-5201	2				Open			
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	18-10	FIDES-01 (ARQ 087-301)	0							
GI	Clinical	21-06	Krystal-10	1	Open		Open				
GU	Clinical	11-34	TIGER (closed to recruitment 26-Oct-2022)	3							
GU	Radio	15-46	PACE C (closed to recruitment 31-May-2022)	22		6			13		
GU	Clinical	16-21	PEACE III	17	4					8	
GU	Clinical	19-32	DASL HiCaP	19	Initiated but not active	1			4	1	
GU	Clinical	20-15	MK3475-866 (closed to recruitment 27-Jul-2022)	14	9					5	
GU	Clinical	21-17	MK 6482- 011	7	7						
GU	Clinical	21-20	MK3475- 365	3	3						
GU	Clinical	21-18	MK 6482- 012	0							
GU	Clinical	21-37	MK6482-022	1	Open		Open				
GU	Clinical	21-38	IMvigor011 B042843	0	Open					Open	
GU	Clinical	21-39	BMS CA209-67T	4	4						
GU	Clinical	20-32	PEACE 6: VULNERABLE	0							
GU	Trans	17-30	IRONMAN	86	37	6					
GU	Trans	22-10	Pivotal Study BP-007	2							
GU	Radio	18-02	NRG GU005 (closed to recruitment Jun 2022)	23		23					
Gynae	Trans	18-01	tBRCA Study (Closed to accrual Nov 2020)	200				15		22	
Gynae	Clinical	19-20	ENGOT-en9 / MK-7902-001/ LEAP-001 (closed to accrual)	3						Open	
Gynae	Clinical	20-06	Soraya (closed to accrual)	5			1	2		Open	
Gynae	Clinical	18-35	ENGOT CX8 (arm H open to accrual)	9						5	
Gynae	Clinical	20-07	OVIHIPEC 2	0							
Gynae	Clinical	22-03	ENGOT ov65	0						To open	
Gynae	Clinical	21-03	ENGOT cx11	3						3	
Gynae	Clinical	22-02	ENGOT en15	0				Open			
Gynae	Trans	22-05	ENGOT ov47 HELPER	0		Open				To open	To open
H & L	Clinical	19-17	CPD-DARA	12			4			3	5
H & L	Clinical	19-34	Isa-RVD	11			1				TBI
H & L	Clinical	18-15	Paradigme	7							1
H & L	Clinical	19-40	FEDR-MF-002 (FREEDOM2)	7						2	
H & L	Clinical	18-47	MO40598	4							
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	5			Open			1	1
H & L	Clinical	19-16	Hovon 156	8	Open		Open			3	Open
H & L	Clinical	20-22	CLL17	86			13			10	7

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							
								4					
	TBI					1		Open		9	1		
						2				7	1		
	6									8			
	3					Open		Open		1			
								Open					
								TBI		Open			
								TBI		Open			
						1							
						Open		2		Open			
						2				1	4		
								Open		2			
								2					
								Closed to accrual					
	TBI									1			
								3					
							3						
						Open				5			
	9						5			TBI			TBI
											Closed		
	0												
										1			
										Open			
									12	31			
							2						
	66					27		50			20		
								3					
	1							Open			1		
	2										2		
	Open												
								Open					
								Open					
	To open	To open						To open					
								To open					
	5					2		1			2		
	4							2					
	2							3					
								4					
Open	10	Open	8	Open		25		1	2	28	7		
						Open		Open		TBI			
						75							
								3					
	3					1		1		TBI			
	8					16		19		1	12		

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Select double-page  
View for full tables

DSSG	General Group	Cancer Trials Ireland No:	Study Name:	Total Accrual	TUH	Beacon	BH	BonS	BonS/UPMC	CUH	UHG
H & L	Clinical	21-11	BGB-3111-306	11						1	4
H & L	Clinical	20-34	INDEPENDENCE ACE-536-MF-002	4						Open	
H & L	Clinical	21-08	GMI-1271-301	6							6
H & L	Clinical	21-09	EFC15992/ITHACA	0			TBI				
H & L	Clinical	19-41	MOSAICC	0							
H & L	Clinical	21-10	CC220-MM-002 "EXCALIBER"	0			ISU			ISU	ISU
H & L	Clinical	21-22	MK1026-003	0			ISU				
H & L	Clinical	21-21	ME-401-004/The COASTAL Study	0							
Head & Neck	Clinical + Radio	17-14	CompARE	2						ISU	ISU
Head & Neck	Clinical + Radio	19-39	Keynote 689 (MK-3475-689)	6							
Head & Neck & Melano-ma	Clinical	20-08	Keynote 630 (MK-3475-630)	1							
Head & Neck	Radio	20-04	PRESERVE	2						Open	ISU
Lung	Clinical	17-37	MK3475-671	3						1	
Lung	Radio	18-33	SOURCE Lung	16		0					
Lung	Clinical	18-49	AbbVie M14-239	0						Open	
Lung	Clinical	19-25	BMS CA209-73L	2							
Lung	Clinical	19-26	BMS CA209-77T	0	0						
Lung	Trans	20-02	TERAVOLT	9							
Lung	Clinical	20-21	BLU-667-2303/ BO42864	2							
Lung	Clinical	21-12	CA224-104	?			Open				
Lung	Clinical	21-13	KRSYTAL-12	0			0				
Lung	Clinical	21-25	CANOPY-A	0			Open				
Lung	Clinical	21-26	ZEAL-1L	0						Open	
Melano-ma	Clinical	18-50	R2910-ONC-1788	0						0	
Melano-ma	Clinical	18-51	BMS CA045-001	0						0	0
Melano-ma	Clinical	20-11	R3767 ONC 1613	8							
Basket	Clinical	15-42	LOXO-101	5							
Basket	Clinical	19-27	MK7339-002/LYNK-002	5	Open			3			
Basket	Clinical	16-19	Add-Aspirin	194	15		5	15		50	3
Basket	Clinical	18-29	CUPISCO - MX39795								
Basket	Radio	19-21	SABR COMET-3	6		0			4	ISU	
Basket	Clinical	19-22	PUMA-NER (SUMMIT) (closed to accrual)	5						Open	
Paeds	Trans	16-34	LLR Leukaemia Cell bank	103							
Paeds		16-37	EWOG-MDS-2006	10							
Paeds	Clinical	16-39	LTJ Study *closed to recruitment 08-Jan-2020	8							
Paeds	Clinical	16-40	NBL BEACON * closed to recruitment 10-Feb-2021	8							
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	16-52	EURO EWING 2012 *closed to recruitment 13-Mar-2020	4							
Paeds	Clinical	16-53	Interfant 06	6							
Paeds	Clinical	18-19	MAPPYACTS *closed to recruitment 06-Jul-2020	29							
Paeds	clinical	18-17	PHITT	4							
Paeds	clinical	16-81	SIOP Ependymoma II	8							
Paeds	clinical	18-18	ICH IV	3							
Paeds	Clinical	18-36	LOXO-TRK-15003	3							
Paeds	clinical	16-82	myechild	18							
Paeds	Trans	16-51	MESTRAT study *closed to recruitment 01-May-19	1							
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	Trans	18-16	ITCC 059	2							
Paeds	Trans	18-24	ITCC 054	0							
Paeds	Trans	18-23	Bi Afatinib *closed to recruitment 05-Aug-2020	0							
Paeds	Trans	UNK	OLIE	0							





## Fundraising News

### Bannon Property & Friends – the Property Picnic

Not long after the Spring DSSG, Cancer Trials Ireland took a call from Bannon Property, where colleagues of the late Louise Creevy, inquired about doing a fundraiser. A remarkable nine weeks later, they held a live music event for 6,000+ people on top of which they raised a staggering €170,087 for cancer clinical trials. On behalf of the Board, staff and members of Cancer Trials Ireland we want to thank the 'Property Picnic' (a consortium of property and related companies brought together by Bannon Property) for their incredible efforts – and their preliminary (at this point) plans to run the event again in 2023. (Pic: right)



### Friends of Cancer Trials Ireland

This winter sees a very welcome return for the Friends of Cancer Trials Ireland gala lunch, which takes place in mid-November. Focusing on gynae and ovarian cancers, the Friends gather together a network of colleagues, friends, and family affected by cancer to raise money for this less prevalent but no less deadly form of the disease. This year's event will feature a video interview with the Irish PI for an investigator-led trial due to open in Q1 2023 (NRG-GY019). Cancer Trials Ireland wishes to thank the organising committee of this group, namely (pic left):

Julie Liston, Mairead O'Brien (Honorary Treasurer), Deirdre McDermott, Rita Lovett, Grace McDermott (Chair), Fiona Collins, Kim Fitzgerald, Liz Coughlan. **Not pictured:** Paula Murphy, Katherina Sheahan.

### Other fundraising news

While the pars above focus on larger fundraisers run on our behalf, Cancer Trials Ireland continues to benefit, unsolicited, from medium sized and smaller donations that come from the people, and family and friends of patients participating in cancer trials. Since March 2022, these include:

- Bequeathment / Monaghan - €30,000
- Aisling Gannon & Brian McKeon - €2,920
- Jim Giles / Cyclist from Nestlé - €1,200
- Templeogue Tennis club - €2,084
- Nestlé staff donation - €1,632.40
- David Kelly - €820
- Orla Naughton - €40

At the time of publication, fundraisers were underway, but incomplete, with:

- Dunnes Stores Headquarters staff
- Rathfarnham Tidy Towns
- Edmondstown Golf Course



Above: Fiona Craig, Eibhlín Mulroe, Frances Crowley @ The Curragh Pat Smullen Race Day

Below: Eibhlín Mulroe & Gavin Lynch (founder, Coast to Curragh)







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