DSSG Digest

Spring 2022

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

cancer trials ireland

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The key question for investigators, sites, and HRB grant groups (formerly clusters) is how performance gets measured in the coming months and years. The HRB will require unambiguous answers - on patients recruited, trial diversity, the diversity of patients on trials, answering unmet need, and publishing research results in the most prestigious journals possible.

But when it comes to metrics, one size does not fit all. not every investigator specialises in the more common forms of cancer, and not every site is situated in a large urban centre. So how do we proceed?

That is a question I will provide a fuller answer to in the near future. Myself and Prof Seamus O'Reilly, Vice-Clinical Lead for Cancer Trials Ireland, are meeting with the DSSG chairs one-to-one in order to figure out metrics that work for each DSSG. Obviously any commonalities that can apply will be shared, but where we need bespoke methods or metrics, we will identify, agree and track them.

We have to achieve these objectives while recognising that our pool of investigators is small, and fuelled by little more than passion in many cases. We are seeing an increasing number of returning investigators availing of contracts with hospitals and universities that protect time for research, but we are no closer to seeing research become a part of HSE contracts. As ever, that will be a focus for Cancer Trials Ireland in the coming years.

But if there is one priority we must keep in mind, above all others, it remains accruals. This is the life blood of our community, and success begets success, attracting more domestic and international investment. Last December, the DSSG chairs identified accruals as the key focus for the Cancer Retreat in May 2022. You can read more about the wider Cancer Retreat in Prof O'Reilly's piece on page nine, but I will take this opportunity to outline exactly what we will be doing to focus on accruals ahead of then.

Clinical Lead: *Professor Ray McDermott*



In the coming weeks we will begin a prioritisation exercise with investigators, and team leaders that looks at all the factors influencing six key headings for patient recruitment for trials. They are: Protocols & Patient Populations; Metrics; Staffing & capacity at sites; Sites / Groups – balancing industry trials & ILTs; Funding ILTs; Referrals

Under each heading we'll be seeking your feedback on what the key factors are, before weighting their importance. This exercise will assist the creation of 3-4 cross-cutting discussion points that will be discussed with investigators and team leaders in late April.

The outputs of this work will be presented at the Cancer Retreat, and will, I hope generate opportunities and ideas that improve the paramount measure of our success: how many people are on trials, and is that number growing? Successfully recruiting and treating more patients on trials is the foundation for achieving our other objectives of increased funding, protected time, more and better treatment options and trials, and international collaborations. It all stems from accruals. I look forward to your involvement in this process over the coming four weeks.

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) have been working 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). Beaumont Hospital was initiated on 11-Mar-2021. University Hospital Galway was initiated on 22-Sep2021 and Cork University Hospital was initiated on 02-Nov-2021. The first patient was enrolled at Beaumont Hospital on 08-Dec-2021 and there was subsequently one patient recruited at Galway University Hospital, two patients recruited at Cork University Hospital, and one more at Beaumont this week. Recruitment will continue for 12 months (until December 2022). The last patient last visit is expected in Q4 2025.

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 will be 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%. A decision will be made once the third patient completes cycle one at dose level 1 whether the maximum tolerated dose has been reached or whether the dose needs to be de-escalated. The final dose level will be expanded to include 18 patients into this study overall (expansion cohort).

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.



CEO: Eibhlín Mulroe

Welcome to the Spring DSSG Digest for 2022!

2022 marked the start of a new funding model for the cancer trials community in Ireland, thanks to a restructured grant funding model from the HRB.

This new period has informed a great deal of the work we are all focused on, within the general central office for Cancer Trials Ireland, and also out at the trial sites – the academically aligned groups. We are all mindful of our grant commitments and the need to meet HRB requirements in the years, so putting in place the metrics and mechanisms that will deliver these outputs is front and centre in our thinking.

Prof Ray McDermott addresses the specifics of this work as it relates to the DSSG's in the Clinical Lead address on the opposite page, so I want to take this opportunity to outline the intentions of Cancer Trials Ireland for the coming 4-5 years as the grant holders for the Cancer Trials Network.

Earlier this year, and led by our new Chair Deirdre Somers, the Board and leadership team of Cancer Trials Ireland took part in a day-long strategy meeting. The goal was to capture a vision for the next five years that complements the commitments we made in our HRB grant application. In broadest terms, our strategy for the period is to keep delivering an improved contribution towards delivery of the cancer strategy, position research as a fundamental part of cancer care, deliver a compelling All-Island cancer trials proposition, and all while solidifying our capacity to sponsor and operate trials.

Right now we are working with our teams and departments – clinical operations, biometrics, quality, pharmacovigilance, HR, communications and finance to map these strategic objectives onto a concrete, deliverable plan that meets annual and multiannual targets.

The question of capacity is one that has arisen recently, with some investigators seeking clarity on what the GCO capacity is, and how philanthropic funds are allocated to Investigator-Led Trials. The question is a complex one, that depends on funding, the life-stage of new or open trials, the complexity of the trials themselves, and the changing availability of human resources in GCO, and at site. Nevertheless, I am confident in saying that Cancer Trials Ireland has the capacity to open at least one Investigator-Led Trial every year, along with 4-5 collaborative groups trials. Some of which we might sponsor. The HRB grant is conditional on support for Investigator Led Trials, so we encourage investigators work with colleagues and mentors to develop research ideas, and protocols.

As we all know too well, developing good research questions and well designed, peer-reviewed protocols is not a quick process, typically taking a year or more. The time to start working on your proposals is right now. Trials are of course inherently risky – and trial design is a risk factor within that sphere. That is why, thanks to the input of the DSSG chairs in December 2021, we are focusing the upcoming Cancer Retreat in May 2022 on accruals, and the factors influencing them. You can read more about the Cancer Retreat – and your role informing it – on page nine.



Standing with Ukraine: The Board of Cancer Trials Ireland helped draft this statement earlier this month, and since then a Ukrainian member of staff is helping the Irish Cancer Society in his spare time to contact oncologists in Ukraine, liaise with Ukrainians in Ireland, and do some translation work. Like so many others around the world we have been stirred by the dedication, determination and poise of Sergii and his fellow Ukrainians at this extremely difficult time for their country.

Cancer Trials Ireland completes move to RCSI, St Stephen's Green

One of the significant benefits of partnering with RCSI to win the HRB Cancer Network Grant has been the move to RCSI campus on St Stephen's Green. We very much look forward to developing our relationship with RCSI and exploring the synergies we can share.

Our new address is:

Ardilaun House, 4th Floor Block B, 111 St. Stephen's Green, Dublin 2, D02 VN51



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

Prof Ray McDermott, Chief Investigator Ireland, Dr Paul Kelly, Co Chief Investigator Ireland and Dr Simon Hughes, Chief Investigator UK. The DASL HiCaP trial initiated its first site in Ireland in Q2 2021 with the first patient randomized on study in early Q3 2021.

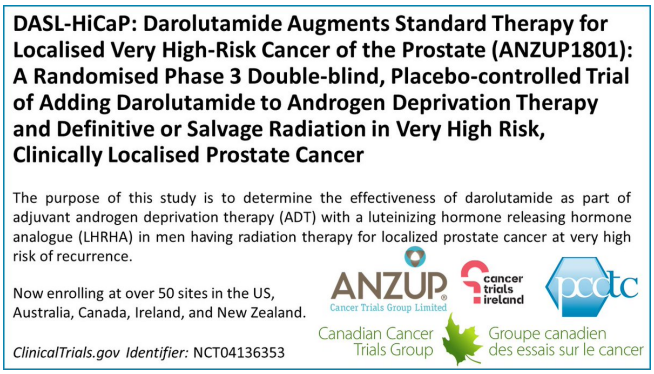
The trial is now open and recruiting at 6 sites in Ireland (Bons UPMC in Cork, Mater Misericordiae University Hospital, the Mater Private Hospital, Cork University Hospital and St. Luke's Hospital). TUH, Beacon to be activated during next weeks. CUH is activated. It is also planned to open in an additional one site (SVUH) in Ireland.

Two additional potential sites will be opened in Ireland: University Hospital Galway (UHG) & St. Luke's Network at St. James's Hospital (SLRON@SJH). As of the 10th of March 2022, eight patients have been recruited on trial in Ireland.

Current situation in UK: 4 sites activated; Guys; Aberdeen; Beatson; Royal Marsden. Sites: Kent, Nottingham and Bath SIVs towards the end of March. Edinburgh awaiting TROG credentialing and SIV to be scheduled. As of the 10th of March 20222, patients enrolled; 1 in Guy's and 1 in Aberdeen with another 1 in screening This trial is a multisite, international investigator-initiated study led by ANZUP in collaboration with the University of Sydney NHMRC - CTC with Cancer Trials Ireland acting as regional coordinating centre and EU Sponsor.

DASL is a randomised phase 3 double-blind, placebo-controlled trial of adding darolutamide to androgen deprivation therapy and definitive or salvage radiation in very high risk, clinically localised prostate cancer. The patient population are men aged 18 years or older with either very high-risk localised prostate cancer, or very high-risk features, e.g. persistent high level PSA or rise within one year following radical prostatectomy, and who are suitable for RT.

Participants are stratified into three categories as follows; previous radical prostatectomy, planned use of adjuvant docetaxel and clinical or pathological pelvic nodal involvement. The target enrolment for Ireland and the UK is 200 participants, he overall global target is 1100. As of the 10th of March 2022 the trial was open in 58 sites across Australia, New Zealand, the US, Canada and Ireland (including satellite sites) and had recruited 414 participants globally.



Colorectal: *Lithium Study (CTRIAL-IE 11-32)*

Sponsored by Cancer Trials Ireland and with Dr Janusz Krawczyk as Chief Investigator.

'A Phase Ib, Dose Escalation Study of Lithium when added to standard chemotherapy of Oxaliplatin and Capecitabine in Patients with Advanced Oesophago-Gastric or Colorectal cancer' is an open-label, dose-escalation trial to determine the dose of lithium that can be safely combined with standard treatment oxaliplatin and capecitabine chemotherapy.

The study is currently open to recruitment at two sites (Cork University Hospital and St James Hospital, Dublin) with two patients having initiated study treatment.

Patients are currently being allocated to Cohort 1, in which doses of lithium are selected to achieve serum lithium concentrations in the target range of 0.4 to 0.6 mmol/L. Between three and six patients will be enrolled onto each cohort using a modified Fibonacci 3+3 sequence. Future cohorts will aim for serum lithium concentrations of 0.6 to 0.8 mmol/L, followed by 0.8 to 1.0 mm/L until a maximum tolerated dose (MTD) is ascertained. As many as 18 patients may be enrolled into this study over an 18-month period.

The study concept was developed in a collaboration between researchers at University College Cork (UCC) and Cork University Hospital (CUH) who have found that adding lithium to chemotherapy regimens blocks cancer cells' ability to repair the internal damage normally inflicted by the treatment. It is hoped that this makes chemotherapy more effective and reduces risk of the cancer returning again. Lithium has been shown to interfere with the regulation of autophagy[1], which is a process that mediates the degradation and recycling of cellular components. Cancer cells use autophagy to repair cellular damage and adapt to adverse metabolic conditions.

Safety data from the study will be reviewed by a Phase I Committee at meetings convened at appropriate intervals prior to authorising any dose escalation or expansion of a cohort.

In addition to safety assessments, measures of the efficacy of the chemotherapy will include progression-free survival (PFS), objective response rate (ORR) and overall survival (OS). Study participants will receive up to six three-weekly treatment cycles, after which they will be followed-up at three -monthly intervals.

A translational sub-study will also investigate changes to biomarkers associated with autophagy and apoptosis (cell death).

The study is sponsored by Cancer Trials Ireland and funded by grants from Breakthrough Cancer Research and the Irish Cancer Society (ICS) .

Reference

1. Research leading to this trial is published in an open access journal

Trial Enrolment Information available on our website here.

Thank you: *Jonathan Westrup*

Jonathan Westrup served as Chair of the Cancer Trials Ireland for seven years, during which time he shepherded the organisation through a range of challenges, and substantial changes, from a rebranding of the organisation's name, the addition of a biometrics division, and the continued growth of an organisation that employs more than 55 people.

His tenure as Board chairperson came to an end last November, when he was replaced by Deidre Somers. On behalf of the staff and Board of Cancer Trials Ireland, thank you, Jonathan, for your years of commitment and dedication.



Jonathan Westrup, former Chairperson



Deirdre Somers, current chairperson

Lymph & Haem: *CLL17 exceeds Irish recruitment targets*

The highly anticipated CLL17 (CTRIAL-IE 20-22) trial has exceeded recruitment targets in Ireland, and continues to recruit Irish patients.

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 trial will also include a comparison of drug-related toxicities, discontinuations and quality of life parameters and will help physicians identify the best currently available individual treatment options for their patients.

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 trial plans to enrol approximately 897 patients in 180 sites across Austria, Belgium, Denmark, Finland, Germany, Ireland, Israel, Italy, Netherlands, Norway, Spain, Sweden, Switzerland.

The trial involves three treatment groups:

- Ibrutinib monotherapy: I arm
- Venetoclax plus Obinutuzumab: VG arm
- Venetoclax plus Ibrutinib: VI arm

Eligible patients are randomly assigned to treatment groups through a 1:1:1 randomisation process with stratification according to del(17p)/ TP53 (TP53 mutation and/or 17p deletion, neither TP53 mutation nor 17p Deletion), IGHV mutation status and fitness (CIRS > 6 points and/or GFR <70 ml/ min, with a CIRS ≤ 6 points and GFR ≥ 70 ml/ min)

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.

In Ireland, eight sites are participating in the CLL17 trial: Beaumont Hospital, Cork University Hospital, St James's Hospital, University Hospital Waterford, Mater Misericordiae University Hospital, University Hospital Limerick, University Hospital Galway, and St Vincent's University Hospital.

Ireland's target accrual was 40 patients and, after only 11 months of opening to recruitment, we have exceeded our recruitment target with a total of 54 patients randomised. Globally, St James's hospital is the joint highest recruiting site with a total of 14 patients randomised while Beaumont Hospital is joint fifth highest recruiting site with a total of 9 patients randomised.

The CLL17 trial is expected to continue recruiting Irish patients until late 2023.

Lymph & Haem: *Isa-RVD (CTRIAL-IE 19-34) begins initiating sites*

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 Professor Peter O'Gorman (Mater Hospital).

The main objective of this 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).

This study will run in the following sites in Ireland: Mater Misericordiae University Hospital, Mater Private Hospital, St James's Hospital, Beaumont Hospital, University Hospital

Waterford, and University Hospital Galway. Site initiations have begun, and sites are expected to begin recruiting patients later in March 2022. This study will also be opened at a site in Denmark.

Recruitment will be for 18 months and a maximum of 43 patients will be enrolled in the study.

St Vincent's University Hospital team members



Fausta Barazaite



Susan Cairney



Deirdre McDonnell



Jo Ballot



Naoise Kelly

Radiotherapy updates: Open

NRG GU005 (CTRIAL-IE 18-02)

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 has been open in the Beacon Hospital since 2019 under the Irish National Lead Investigator Dr Alina Mihai, and is due to close shortly. Beacon is currently the 3rd highest recruiting centre of over 100 international sites. NRG Oncology is the international sponsor.

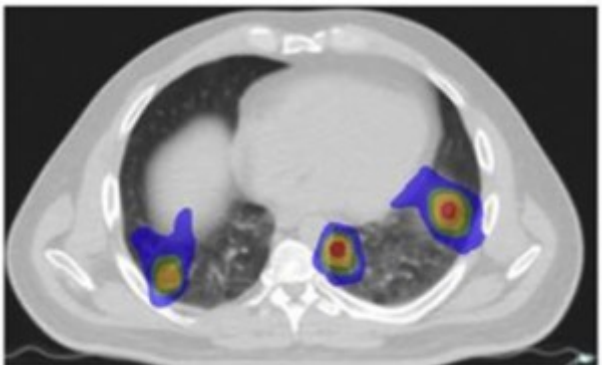
PACE-C (CTRIAL-IE 15-46)

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 study is open at three sites in Ireland; Beacon Hospital, Bons Secours Radiotherapy Cork in Partnership with UPMC Hillman Cancer Centre, and SLRON at Beaumont Hospital. The target global accrual is 1182 patients and the study is due to close to recruitment in mid-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.

In development:

Two new Irish Investigator-led trials are also in development currently, and are planned to open later in 2022:

DP-IMRT Pancreas (CTRIAL-IE 17-12) 'A non-randomised Phase I/II study of dose-escalated hypofractionated Dose-Painted Intensity Modulated Radiotherapy (DP-IMRT) in resectable/borderline resectable pancreatic adenocarcinoma' (CI: Dr Gerard McVey), and Spine SABR (CTRIAL-IE 20-03) 'Dose-escalated SABR for Solid Tumour Spine Metastases' (CI: Prof Clare Faul).



Axial slice of a radiation plan for stereotactic radiation therapy treatment of lung metastases.

SABR COMET 3 (CTRIAL-IE 19-21)

SABR COMET-3 (CTRIAL-IE 19-21) 'Phase III Randomized Controlled Trial and Economic Evaluation of Stereotactic Ablative Radiotherapy for Comprehensive Treatment of Oligometastatic (1-3 metastases) cancer'. This 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 297 patients. In Ireland the study is currently open at 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.

SOURCE Lung (CTRIAL-IE 18-33)

SOURCE Lung – 'Stereotactic Ablative Radiation Therapy Of UltRaCEntral LUNG tumours' (CTRIAL-IE 18-33) is an Irish 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).

Radiotherapy updates: *Pending*

PRESERVE (CTRIAL-IE 20-04)

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 has ethics approval to open at SLRON and CUH. Dr Sinéad Brennan (SLRON) is the Irish National Lead Investigator, and Dr David Palma of Lawson Health Research Institute is the international sponsor. On 22nd March, PRESERVE was activated at SLRON and is now open to recruitment.

CompARE (CTRIAL-IE 17-14)

CompARE (CTRIAL-IE 17-14) 'Phase III randomised controlled trial Comparing Alternative Regimens for escalating treatment of intermediate and high-risk oropharyngeal cancer' is a study sponsored by the University of Birmingham, UK. 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 planned to open at SLRON and SJH shortly, and at CUH and UHG thereafter. The target overall accrual is 695 patients. Dr Sinéad Brennan (SLRON) is the Irish National Lead Investigator.

Radiotherapy updates: *Closed*

ROAM (CTRIAL-IE 15-41)

ROAM (CTRIAL-IE 15-41) 'Radiation versus Observation following surgical resection of Atypical Meningioma: a randomised controlled trial (The ROAM trial)' is a UK Cooperative group study in follow up at SLRON Beaumont. Patients enrolled on the study were randomised to radiotherapy or active monitoring to determine whether early adjuvant fractionated radiotherapy reduces the risk of tumour recurrence or death due to any cause compared to active monitoring in newly diagnosed atypical meningioma. The study closed to accrual early in May 2021; 157 patients were enrolled globally on the Study, with 3 Irish patients being enrolled at SLRON Beaumont. Dr David Fitzpatrick (SLRON) is the Irish National Lead Investigator, and the Walton Centre NHS Foundation Trust is the international sponsor.

PORTEC-4a (CTRIAL-IE 18-27)

PORTEC-4a (CTRIAL-IE 18-27) 'Randomised Phase III Trial of molecular profile-based versus standard recommendations for adjuvant radiotherapy for women with early-stage endometrial cancer'. The primary objective of this international cooperative group study is to establish and compare the rates of vaginal relapse in patients with high-intermediate risk endometrial carcinoma treated after surgery with molecular risk profile-based recommendations (experimental arm) for no additional treatment (observation), vaginal brachytherapy or external beam radiotherapy, or with vaginal brachytherapy (standard arm). The study closed to accrual on 24-Dec-2021. It had been open at St Luke's Radiation Oncology Network (SLRON), Dublin, under the Irish National Leaf Investigator Dr Charles Gillham. Pathology and molecular profiling were carried out by the Pathology Lab at St James' Hospital (Prof Stephen Finn and Dr Ciarán Ó'Riain). Twelve patients were enrolled to the study at SLRON. Leiden University Medical Centre is the international sponsor.

Breast News: *SASCIA (20-24)*

The SASCIA study is making great strides since the last DSSG Digest, which reported NREC and HPRA approval. Since then, six of seven sites have been initiated (St James's Hospital Dublin, initiated this week, leaving on the Mater to undergo SIV).

To date, three patients have been randomised to the study – two in St Vincent's Hospital, and one in Beaumont. A further four patients are in screening, one each in Cork University Hospital, University Hospital Limerick, University Hospital Waterford, and St Vincent's Hospital in Dublin. 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.

Breast News: *FEATURE / EA1183*

The FEATURE study is a phase II imaging trial which studies how well FDG-PET/CT works in assessing the response of patients with breast cancer that has spread to the bones or mostly to the bones (bone-dominant metastatic breast cancer). Diagnostic procedures, such as FDG-PET/CT, may work better in measuring breast cancer activity before and after treatment compared to other standard imaging tests and this study is evaluating whether FDG-PET/CT imaging can be used to serially measure and classify the response of bone metastases from breast cancer to systemic therapy. The study team will assess if the categories of metabolic response measured by FDG-PET/CT are predictive of key clinical endpoints: progression free survival (PFS), time to skeletal related events (SRE), and overall survival (OS).

Study received St. Luke's Radiation Oncology Network Research Ethics Committee approval and will be open at Cork University Hospital, St. Vincent's University Hospital, St James's Hospital, Mater Misericordiae University Hospital and later at Midland Regional Hospital Tullamore.

Academic Publications from Cancer Trials Ireland Investigators

Aisling Mellerick, Trial Coordinator (Cancer Trials Ireland)

Breast

Cancer Trials Ireland Study Number: short name. 15-16: FLIPPER
Albanell, J., M. T. Martínez, M. Ramos, M. O'Connor, L. de la Cruz-Merino, A. Santaballa, N. Martínez- Jañez, F. Moreno, I. Fernández, J. Alarcón, J. A. Virizuela, J. de la Haba-Rodríguez, P. Sánchez-Rovira, L. González-Cortijo, M. Margelí, A. Sánchez-Muñoz, A. Antón, M. Casas, S. Bezares and F. Rojo (2022). "Randomized phase II study of fulvestrant plus palbociclib or placebo in endocrine-sensitive, hormone receptor-positive/HER2–advanced breast cancer: GEICAM/2014–12 (FLIPPER)." Eur J Cancer, 161: 26-37.

Genitourinary

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 and 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. 97-01: Prostate
Kishan, A. U., Y. Sun, H. Hartman, T. M. Pisansky, M. Bolla, A. Neven, A. Steigler, J. W. Denham, F. Y. Feng, A. Zapatero, J. G. Armstrong, A. Nabid, N. Carrier, L. Souhami, M. T. Dunne, J. A. Efstathiou, H. M. Sandler, A. Guerrero, D. Joseph, P. Maingon, T. M. de Reijke, X. Maldonado, T. M. Ma, T. Romero, X. Wang, M. B. Rettig, R. E. Reiter, N. G. Zaorsky, M. L. Steinberg, N. G. Nickols, A. Y. Jia, J. A. Garcia, D. E. Spratt and MARCAP Consortium group (2022). "Androgen deprivation therapy use and aduration with definitive radiotherapy for localised prostate cancer: an individual patient data meta-analysis." Lancet Oncol. 23(2): 304-316.

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 and 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

Schmidinger, M., R. J. Motzer, F. Rolland, M. Staehler, M. Rink, M. Retz, T. Csoszi, J. A. McCaffrey, U. De Giorgi, C. Caserta, I. Duran, F. Benzaghou, D. O. Clary, L. Albiges, T. K. Choueiri and N. M. Tannir (2022). "Analysis by region of outcomes for patients with advanced renal cell carcinoma treated with cabozantinib or everolimus: a sub-analysis of the METEOR study." Acta Oncol. 61(1): 52-57.

Lung

Cancer Trials Ireland Study Number: Short Name. 12-53: ETOP SPLENDOUR
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 and 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 SPLENDOUR and AMGEN-249 trials." Lung Cancer 161: 76-85.

Cancer Trials Ireland Study Number: Short Name. 16-61: ETOP BOOSTER
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Episode 1

Listen Now

The HSE National Framework for the Governance, Management and Support of Health Research

Dr Ana Terrés and Eibhlín Mulroe (CEO, Cancer Trials Ireland) have a conversation about health research in Ireland, beginning with the publication of a National Framework for Governance, Management and Support of Health Research. Along the way, Dr Terrés describes her own path into health research, and her current role, and what she does to de-stress (including inflatable paddle-boarding!)

Episode 2

Listen Now

Pancreatic Cancer & Uses of the Pat Smullen Fund

Prof Austin Duffy explains the nature of pancreatic cancer and the particular challenges of treating it – and how a new study (PATCH) hopes to address some of these challenges, thanks to the Pat Smullen Fund. He is followed by Anna Shevlin of Cancer Trials Ireland, who outlines the other ways that the Pat Smullen Fund has contributed to pancreatic cancer studies.

NOTE: This episode was recorded on Oct 28th. Since that time, a study discussed in the podcast (Paricalcitol) was closed to recruitment following an interim statistical analysis.

Episode 3

Listen Now

PPI from an Investigator's Perspective

Eibhlín Mulroe talks to Prof Sean Dinneen, a Consultant Endocrinologist based in Galway & NUIG. They discuss Public & Patient Involvement. "(Patients) have been co-researchers, and co-investigators," says Prof Dinneen. "They have been a huge part of what we have achieved over the years, and we have completed and published a pilot of a random control trial of that intervention... Recognising early on that we (healthcare professionals) were not going to crack this on our own is how I got involved in PPI and it has been one of the most rewarding things I have done."

Cancer Retreat 2022: May 20th

It is my great pleasure to bring you further news about the Cancer Retreat in 2022. After a tremendous inaugural event last year, we are keen to repeat the Retreat and establish it as a regular fixture in the clinical oncology research calendar.

This time however we will be hosting a shorter, more community-focused event – and crucially we will be asking people to attend in person. Virtual attendance will still be a possibility, the event will be live-streamed for those who cannot come on the day, but if at all possible we encourage you to come in person and experience the collegiality of friends and peers after an immensely challenging few years of relative isolation and remote work. I think we are all being reminded of the richness and value of in-person meetings with restrictions lifted in recent times.

The Retreat itself will be a half-day event, opening with a catch-up on the key points from the last Retreat, and what progress (if any) has been made. Certainly things are looking clearer in terms of translational research, and congratulations to Prof Liam Gallagher and all the members of AICRI on their recent grant awards from the North-South Research Programme.

As Prof McDermott describes in his Clinical Lead address on page two, the key topic at the Retreat is accruals. For more detail on that I invite you to read Prof McDermott's article. Outside of accruals, the agenda includes an update from CEO Eibhlin Mulroe on strategy; and session about Public & Patient Involvement, and a session about the Molecular Tumour Board, which is opening up to national participation

Vice-Clinical Lead Prof Seamus O'Reilly



following a successful pilot period.

The contributors to each session are still being confirmed, but I can report that registration for the Retreat will open in a matter of days. I am also very much looking forward to introducing the new PPI Co-ordinator for Cancer Trials Ireland, Caroline Oates, who will be heavily involved in the PPI session. While I look forward to a time when PPI is recognised and valued for the real benefits it provides – evidence shows strong PPI increases accruals and funding – for now we must accept that the community participation in PPI is driven by the stick of HRB metrics, rather than the carrot of partnering with patients to produce better trials and research.

I greatly look forward to engaging with all of you in advance of the Retreat, and on the day itself – in person, I very much hope.

2022

Cancer Retreat

savethedate

20.05.22

cancer trials ireland

Retreat #2

A half-day event for the clinical oncology community - oncologists (medical, radiation, surgical), haematologists, researchers, research nurses, site managers, teams, & patients

Agenda publishing soon!

The Cancer Retreat is supported by the Cancer Trials Ireland's Just Ask campaign to raise awareness of clinical trials around International Clinical Trials Day, May 20th, 2022. The Just Ask campaign is supported by:

abbvie BAYER MSD INVENTING FOR LIFE NOVARTIS Pfizer Roche

Fundraising news

Nestlé staff choose Cancer Trials Ireland

We are delighted to officially announce that the 60+ staff of Nestlé Ireland voted to make Cancer Trials Ireland their staff charity for the next three years. That will make cancer trials the lucky recipient of a range of fundraisers and promotions that Nestlé's team will undertake – and already that has begun. One staff member, Jim Giles, will be cycling from Malin to Mizen over the Easter weekend, while an internal committee in the company will meet to develop a range of fundraisers and events in support of cancer trials. We are indebted to Andy Creevy, husband of Louise Creevy for championing us among his colleagues in Nestlé, and we look forward to sharing more Nestle updates in the near future.



Eibhlin Mulroe & Nestlé CEO Kieran Conroy, February 2022

O'Flaherty Fund / Breast Cancer

As in 2021, Cancer Trials Ireland will be the fortunate recipient of a further €30,000 for breast cancer clinical trials, thanks to the generosity of the philanthropic O'Flaherty Foundation. Already those funds have been put to good use, and we look forward to supporting new breast cancer trials in 2022, thanks to this significant second donation.

Pancreatic Cancer – Noel Connellan

Noel Connellan is a pancreatic cancer survivor, and following successful surgery he has undertaken a fundraising drive on behalf of Cancer Trials Ireland. That effort is underway at the time of writing, we will on it's conclusion in due course, and want to take this opportunity to talk Mr Connellan for supporting Cancer Trials Ireland.

Brian Lenihan Fund – thank you

The friends of Brian Lenihan were instrumental in funding the first phase of the Paricalcitol study. As many of their donations were large, they qualified for tax relief claims, which Cancer Trials Ireland are ultimately the beneficiaries of. In order to receive this money, people who have already given their time, and money, must engage with Revenue on our behalf as individuals and we want recognise this extra effort, and report that it led to a further €6,873 being raised.

Thanks also to:

- **Cavan Angles - €3,500**
- **Donegal Shines a light on lung cancer - €400**
- **Friends of Cancer Trials Ireland - €1,675**
- **Olive Lynch Fund - €600**

Pat Smullen Fund: Update

Since its establishment in late 2019, the Pat Smullen Fund has sought to administer the €2.6m raised for pancreatic cancer trials to the benefit of pancreatic patients in Ireland. That contributed significantly to the opening of the paricalcitol study, which enrolled 15 patients in 2020-2021. In May 2022, we hope to announce that the PaTcH is open in two sites, the Mater, and St Vincent's, offering new treatment options to up to 22 patients. The study is based on an exciting publication in Nature on the use of Trametinib and Hydroxychloroquine for the treatment of pancreatic cancer, and drug for the trial has been secured. The protocol is currently under review in NREC and HPRA and will target a similar patient

A third study, FEED, is also scheduled to open in May. FEED aims to explore the impact of a multi-modal nutritional intervention in patients undergoing chemotherapy for pancreatic cancer, following a successful pilot study, and inspired by similar successful studies in other forms of cancer. A fourth study (radiotherapy) is in the protocol development stage and the committee continues to review



Eibhlin Mulroe & Pat Smullen at the Derrinstown Stud, Nov 2019

proposals for the future, including a collaborative group study from Australia, and potentially a specialist nurse based in St Vincent's hospital.

Select double-page View for full tables

Cancer Trials Ireland studies open to accrual (as of March 9th, 2022)

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

DSSG	General Group	Cancer Trials Ireland No:	Study Name:	Total Accru-al	TUH	Beacon	BH	BonS
Breast	Trans	09-07	Breast Cancer Proteomics and Molecular Heterogeneity	4155			2451	
Breast	Clinical	17-15	IMpassion030/ ALEXANDRA	17			13	
Breast	Clinical	18-05	KEYNOTE-756	7				3
Breast	Clinical	19-35	CA209-7FL	2			1	
Breast	Surgical	20-13	LigaSure	76			76	
Breast	Clinical	20-24	SASCIA	2			1	
Breast	Clinical	20-25	CARABELA	0				
Breast	Clinical	21-04	GO42784/ TRIO 045	5			1	4
Breast	Clinical	21-05	DESTINY-Breast12	2				
Breast	Clinical	21-15	DESTINY-Breast05	1				
Breast	Clinical	21-16	ZEST/ GSK 213831	0			Open	
Breast	Clinical	21-31	KEYNOTE-B49	0				
GI	Clinical	11-32	Lithium	3				
GI	Clinical	19-07	MK3475-937 (KEYNOTE-937)	1	Open			
GI	Clinical	18-08	BMS CA209-8HW	1				
GI	Clincial	19-33	Paricalcitol (closed to accrual Nov-2021)	15	Closed to accru-al		4	
GI	Clinical	18-44	Astellas 8951-CL-5201	0				Open
GI	Clinical	21-07	DESTINY DS8201-A-U306	0	TBI		Open	
GI	Clinical	21-34	LEAP-015 (MK-7902-015)	1	TBI		1	
GI	Clinical	18-10	FIDES-01 (ARQ 087-301)	0				
GU	Clinical	11-34	TIGER	3				
GU	Radio	15-46	PACE C	20		6		
GU	Clinical	16-21	PEACE III	14	1			
GU	Clinical	19-32	DASL HiCaP	8	Initiated but not active	Initiated but not active		
GU	Clinical	20-14	MK3475-641	14	12		1	
GU	Clinical	20-15	MK3475-866	13	6			
GU	Clinical	20-16	MK3475-905	3	Open			
GU	Clinical	20-20	TRITON-3 (Closed to accrual Feb-2022)	27	13			
GU	Clinical	21-17	MK 6482- 011	0				
GU	Clinical	21-19	MK6482-013 (Closed to accrual)	5	3			
GU	Clinical	21-20	MK3475- 365	0	TBI			
GU	Clinical	21-18	MK 6482- 012	0				
GU	Clinical	21-36	MK3475-B61 (Closed to accrual)	0	0			
GU	Clinical	21-37	MK6482-022	0				
GU	Clinical	21-38	IMvigor011 B042843	0				
GU	Clinical	21-39	BMS CA209-67T	2	2			
GU	Clinical	20-32	PEACE 6: UNFIT	0				
GU	Trans	17-30	IRONMAN	74	32	6		
GU	Radio	18-02	NRG GU005	22		22		
Gynae	Trans	18-01	tBRCA Study (Closed to accrual Nov 2020)	200				15
Gynae	Radio	18-27	PORTEC-4a (closed to accrual 24-Dec-21)	12				
Gynae	Clinical	19-20	ENGOT-en9 / MK-7902-001/ LEAP-001	3				
Gynae	Clinical	20-06	Soraya	5			1	2
Gynae	Clinical	18-35	ENGOT CX8	9				
H & L	Clinical	19-17	CPD-DARA	4			1	
H & L	Clinical	19-34	Isa-RVD	0			To open	
H & L	Clinical	18-15	Paradigme	7				
H & L	Clinical	19-40	FEDR-MF-002 (FREEDOM2)	7				
H & L	Clinical	18-47	MO40598	4				
H & L	Trans	20-33	Irish & ASH COVID Registry	102	Open		2	4
H & L	Clinical	20-35	MOR208C310	0			Open	
H & L	Trans	21-24	COVID Vaccine	58				
H & L	Clinical	19-18	Hovon 150	3			Open	
H & L	Clinical	19-16	Hovon 156	4	Open		Open	
H & L	Clinical	20-22	CLL17	50			10	
H & L	Clinical	21-11	BGB-3111-306	4				
H & L	Clinical	20-34	INDEPENDENCE ACE-536-MF-002	2				

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

BonS/ UPMC	CUH	UHG	LUH	Mater	MRH	MUH	OLLHD	OLCHC	UHL	SLRON	SJH	SUH	SVUH	UHW	Whit	Interna-tional Sites
	960								385		closed		Open	359		
				4					closed							
											4					
	TBI										1					
	Open			TBI					Open		TBI		1	Open		
	TBI	TBI									TBI		Initiated	TBI		
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		TBI							TBI		Open		TBI			
									58							
	1	To open									2					
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	7	Open		7					7		14		TBI	5		
	1			Open					1		2					
	To open			Open							2					

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Cancer Trials Ireland studies open to accrual (as of March 9th, 2022)

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

DSSG	General Group	Cancer Trials Ireland No:	Study Name:	Total Accru-al	TUH	Beacon	BH	BonS
H & L	Clinical	21-08	GMI-1271-301	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	
H & L	Clinical	21-22	MK1026-003	0			ISU	
H & L	Clinical	21-21	ME-401-004/The COASTAL Study	0				
Head & Neck	Clinical +	17-14	CompARE	0				
Head & Neck	Clinical +	19-39	Keynote 689 (MK-3475-689)	1				
Head & Neck	Clinical	20-08	Keynote 630 (MK-3475-630)	0				
Head & Neck	Radio	20-04	PRESERVE	0				
Lung								
Lung	Clinical	17-37	MK3475-671	3				
Lung	Radio	18-33	SOURCE Lung	8		0		
Lung	Clinical	18-49	AbbVie M14-239	0				
Lung	Clinical	19-25	BMS CA209-73L	2				
Lung	Clinical	19-26	BMS CA209-77T	0	0			
Lung	Trans	20-02	TERAVOLT	4				
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				
Melanoma	Clinical	18-50	R2910-ONC-1788	0				
Melanoma	Clinical	18-51	BMS CA045-001	0				
Melanoma	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
Basket	Clinical	18-29	CUPISCO - MX39795					
Basket	Radio	19-21	SABR COMET-3	2		0		
Basket	Clinical	19-22	PUMA-NER (SUMMIT) (closed to accrual)	5				
Paeds	Trans	16-34	LLR Leukaemia Cell bank	103				
Paeds		16-37	EWOG-MDS-2006	10				
Paeds	Clinical	16-39	LTI 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				

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

BonS/ UPMC	CUH	UHG	LUH	Mater	MRH	MUH	OLLHD	OLCHC	UHL	SLRON	SJH	SUH	SVUH	UHW	Whit	International Sites
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				Open							TBI					
						To open			ISU		ISU					
	ISU	ISU									ISU					
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	ISU	ISU								ISU	ISU					
										Screen-ing only	1					
										Screen-ing only	0					
	ISU									Initiated but not active						
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What are the latest figures?

The figures below relate to the **full year of 2021**, from January 1st – December 31st. They include every type of trial, Clinical Trials (interventional / drug trials / combination drug and radiotherapy trials), radiotherapy trials, medical devices, translational trials (biomarker and observational studies) and registries. The numbers also include academic and industry trials. The data for the same period in 2020 is included for comparative purposes.

STUDY TYPE	**Total for 2021**	vs. 2020	**Non-CTRIAL 2021**	vs. 2020	**CTRIAL 2021**	vs. 2020
Clinical Trial	**302**	310	**14**	28	**288**	282
Radiotherapy	**61**	10	**0**	0	**61**	10
Medical Device	**26**	30	**0**	0	**26**	30
Translational	**703**	688	**315**	97	**388**	591
Registry	**230**	1	**174**	1	**56**	0
TOTALS:	**1,322**	1,039	**503**	126	**819**	913

What does 'CTRIAL' mean?

This refers to studies that have a Cancer Trials Ireland code, because it is a study in which we play an active part, or because it is a study we have 'adopted' into our portfolio, in order to include it in DSSG meeting discussions, and for other reasons.

What does 'Non-CTRIAL' mean?

This refers to studies whose recruitment numbers we track, but which Cancer Trials Ireland is not involved with in any capacity. Our objective in tracking recruitment numbers on these trials, and CTRIAL trials, is to provide the fullest picture possible for the number of people joining cancer trials in Ireland.

Pictured on back cover:

Top row (L-R): Dr Mark Doherty (SVUH); Prof Michaela Higgins (SVUH); Prof Janice Walshe (SVUH); Amy Mahon (SVUH)

Bottom row (L-R): Susan Cairney & Jo Ballot (SVUH); Dr Vitaliy Mykytiv (CUH); Kate Lyons (CUH); Dr Mohd Syafawi Mat Samuji (Bons/UPMC)



cancer trials ireland

Together, we're finding answers to cancer.