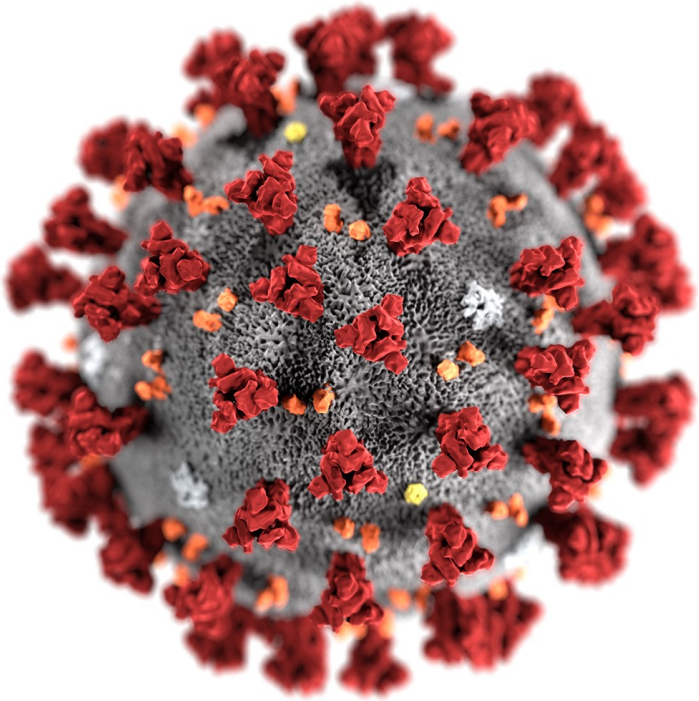
DSSG Digest

Spring 2021

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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Clinical Lead: Professor Ray McDermott

Welcome to the DSSG Digest for Spring 2021. I would like to begin with some very positive news, that being an MOU that was signed by Ireland/Northern Ireland/NCI Cancer Consortium last week. The CEO's address has all the details of what the MOU means, and has meant, to the island of Ireland, I just want to recognise its value here, and all the work that went on over the past four years to make it happen.

Approximately 500 clinicians, healthcare professionals and scientists from Ireland were trained in NCI over the past 21 years, as part of the first All-Island Cancer Consortium agreement. It is very encouraging to see it re-established, particularly in light of the firm commitments NCI is making to the Consortium's Implementation Committee. Congratulations to everyone involved.

The value of Irish investigator education abroad is something that was consistently cited as a major asset during a series of interviews Cancer Trials Ireland conducted at the end of 2020 with the regulator, funders, industry and investigators. The high standing of Irish trainees in America, and the networks that our investigators have fostered with global centres of excellence have contributed to Ireland's reputation as a good location to open clinical trials.

But I do accept that we still face challenges in Ireland. First and foremost, we need predictable processes – in regulation, and in ethical approval. The haematology study EMN18 was recently withdrawn from Ireland by the sponsor due to delays with regulatory approval. That loss is not as disappointing as it might be, a new study (ISARVD) is scheduled to open that will cater to the same patient population.

In terms of ethical approvals, it is encouraging to see the Office for National Research Ethics committees be established, and we have met with representatives of that office already this year. NREC is committed to a 60-day turnaround on applications, and I can also confirm that the existing RECs will be asked by the Department of Health to continue their work to the end of this year while the national office finds it feet. Cancer Trials Ireland is also involved in a pilot project with NREC and HPRA to approve two studies in parallel and try to establish that consistency of approach that would make Ireland's regulatory environment predictable to those groups and companies considering trials here.

No question that these are positive steps driven by the right intentions, but we still face major challenges on the ground, not least with issues around monitoring and site access due to the pandemic and the restrictions it forces on us. Cancer Trials Ireland continues to experience issues accessing sites, even as we saw industry accruals to trials climb year on year in 2020. I would urge investigators to advocate for Cancer Trials Ireland at sites to the CEOs of hospital sites, where possible. Cancer Trials Ireland has written to the head of the NCCP seeking hospital administrator support for Cancer Trials Ireland site access.

The team in central office is trying to close several studies in order to improve future capacity, but this work depends on site access, and the documentation associated with studies now in follow up. That may seem like less urgent work, but if we are to build our capacity to open new trials – and CTI is committed to opening 21 new studies – we need close other studies quickly.

Finally, I want to encourage all investigators, research nurses, scientists, data managers and others to attend the upcoming Cancer Retreat this May. This is an opportune moment for the community to engage at a strategic level about the next five years ahead of changes to the HRB funding model. As Prof Seamus O'Reilly describes on page 15, the Retreat is a chance to talk about the form and function of the DSSGs themselves, and also the ongoing logistical challenges we face at sites. I urge you to take part in that discussion if at all possible and look forward to seeing you there.

CTRIAL-IE 19-32 DASL HiCaP – Opening soon

The DASL HiCaP trial is planned to commence initiations in Q2 of 2021 across 8-9 sites in Ireland and at number of sites across the UK including a site in Northern Ireland. It 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 will be 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 will be stratified into three categories as follows; previous radical prostatectomy, planned use of adjuvant docetaxel and clinical or pathological pelvic nodal involvement.

The Primary endpoint for this study is metastasis free survival (MFS) with secondary endpoints including measuring overall, cause-specific and PSA-progression free survival, time to castration resistance and health related quality of life information.

This trial is a multisite, international investigator initiated study led by the Australian and New Zealand Urogenital and Prostate (ANZUP) Cancer Trials Group in collaboration with the University of Sydney National Health & Medical Research Council (NHMRC) Clinical Trials Centre (CTC) with Cancer Trials Ireland acting as regional coordinating centre (RCC) and EU Sponsor.

The target enrolment for Ireland and the UK is 200 participants, the overall global target is 1100. The study is also due to open in the US and Canada in Q2 2021 and is currently open in Australia and New Zealand (ANZ). As of March 1st 2021 the trial had recruited 125 participants in ANZ.

CEO:

Eibhlín Mulroe

Cancer research on the island of Ireland received a significant boost last week (March 16th) with the renewal of an MOU between Ireland, Northern Ireland and the National Cancer Institute in America.

The 'Ireland – Northern Ireland – National Cancer Institute Cancer Consortium' (formerly the All-Island Cancer Consortium) MOU was signed by Ministers Stephen Donnelly, Robin Swann, and Dr Ned Sharpless, Director of the National Cancer Institute (US) at a virtual ceremony which also included video messages of support from An Taoiseach Micheál Martin, First Minister Arlene Foster, deputy First Minister Michelle O'Neill, and the Acting Secretary for the US Department of Health & Human Services, Norris Cochran.

Significantly, Dr Ned Sharpless announced a solid commitment to forming a Consortium Implementation Committee by appointing two members of the NCI team to it – Dr Satish Gopal (the National Cancer Institute's Director of the Centre of Global Health) and Dr Bill Dahut, a long-time advocate and supporter of the Consortium in its current and previous forms.

Dr Sharpless identified three key areas of focus for the Consortium:

- Improving access to cancer clinical trials
- Overcoming barriers to data sharing
- Accelerating opportunities for education and training

This builds on the work of the previous agreement and MOU which, over the past 21 years, helped 35,000 people on the island of Ireland access a cancer clinical trial. It also helped educate around 500 clinicians, healthcare professionals and scientists in a series of short stay programmes at the National Cancer Institute in Washington DC, and subsequently embed their learning back in Ireland.

The tripartite Agreement originally establishing the Consortium was first signed in 1999, in the aftermath of President Clinton's visit to Ireland and Northern Ireland in 1998. The purpose of the agreement was – and is – to establish the Consortium and reduce cancer incidence and mortality on the island of Ireland through cross-border and transatlantic collaborations in cancer research and education.

In 2020, a landmark study analysed the impact of the AICC from 1999-2019 on cancer research, education and care across the island. Published in the European Journal of Cancer (April 2020) 2, it found that AICC facilitated a doubling of the quantity of collaborative cancer research performed on the island of Ireland. Research quality was significantly increased, being published in much higher impact scientific and medical journals.

The MOU/agreement lapsed in 2016, but since then through a series of meetings and calls spread across the world, the groups involved have worked tirelessly to bring all the right people to the table, with the support of their organisations, governments, and InterTrade Ireland, which co-ordinated the signing ceremony on March 16th. I want to pay particular tribute to Dr Bill Dahut in NCI and Prof Mark Lawler in Queens University Belfast for their energy, enthusiasm, and close collaboration.

This partnership between Ireland, Northern Ireland and the US gives us the opportunity to get the best possible care for our patients. A patient in Cork should have the same opportunity to be involved in a clinical trial as a patient in Dublin, Derry, Belfast, or indeed Washington. Cancer knows no borders, neither should we.

This iteration of the MOU is four years in the making. In 2016 the then Vice-President, Joe Biden spoke at the ASCO conference about a moon-shot to irradicate cancer. It is so gratifying for the parties involved to see the work of the intervening years culminate today. An Taoiseach, Micheál Martin, TD, was the first Minister for Heath to fund Cancer Trials Ireland (then ICORG) back at the turn of the century. It really does feel like the stars aligned.

Recording of the ceremony, and all speaker video messages available here.

Patrick Kivlehan
Patients Consultation Committee,
Cancer Trials Ireland

Cancer knows no borders - neither should we.

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Prostate: *CTRIAL-IE 13-21*

A Phase II Study of Radium-223 in Combination with Enzalutamide in Progressive Metastatic Castrate-Resistant Prostate Cancer.

Prostate cancer is the most common invasive cancer afflicting men (National Cancer Registry of Ireland data, 2012). Over 75% of patients are over the age of 65 at diagnosis. Although radical prostatectomy or radiotherapy for localised disease offers high probability for long-term survival and cure, 15% of these men would eventually experience disease recurrence. Advanced and recurrent prostate cancers are typically sensitive to androgen deprivation therapy. Nonetheless, resistance to androgen deprivation generally develops, so called castration resistant prostate cancer (CRPC). Metastatic dissemination commonly involves the bones in over 80% of cases, which contributes to significant morbidity. Salvage therapy options for patients with metastatic CRPC include second-line hormonal therapy, systemic chemotherapy, external beam radiotherapy or best supportive care.

In recent years, a number of new agents have been developed which have demonstrated significant symptomatic and survival benefits in patients with advanced CRPC when administered prior to and/or post chemotherapy. These also include the anti-androgen enzalutamide and the radioisotope radium-223 dichloride.

Enzalutamide is a potent androgen receptor signalling inhibitor that blocks several steps in the androgen receptor signalling pathway. Enzalutamide treatment decreases the growth of prostate cancer cells and can induce cancer cell death and tumour regression. The efficacy and safety of enzalutamide has been demonstrated across the spectrum of CRPC in a number of large randomized controlled trials.

Radium -223 dichloride is a therapeutic alpha particle-emitting pharmaceutical. It mimics calcium and selectively targets bone, specifically areas of bone metastases. The cancer cells in the bone take up radium 223 and it then releases radiation which travels a very short distance. This means that the cancer cells receive a high dose of radiation which can destroy them. And healthy cells receive only a low dose or no radiation. Radium -223 dichloride has been approved for the treatment of adults with castration-resistant prostate cancer, symptomatic bone metastases and no known visceral metastases.

Given their differing modes of action and non-overlapping toxicity profiles, there is considerable interest in defining the correct combination or sequencing of these novel

approaches. The combination of radium-223 dichloride and enzalutamide is of particular interest as they are well tolerated agents which have differing modes of action, leading to the potential for synergy and deliverability. The ERA-223 trial exploring the combination of radium-223 and abiraterone acetate reported an unexpected increase in fractures, leading to early unblinding of the trial. The ongoing phase 3 EORTC 1333/PEACE III trial (NCT02194842) is examining the combination of radium-223 and enzalutamide and now mandates the use of bisphosphonates in all patients.

A phase II trial of Radium-223 in combination with enzalutamide for patients with metastatic castration-resistant prostate cancer (mCRPC) (CTRIAL-IE (ICORG) 13-21) enrolled 45 patients with mCRPC to bone with or without visceral/lymph node involvement who had progressed on androgen deprivation therapy. The primary objective of this clinical research study was to determine the safety and tolerability of Radium-223 when administered in combination with enzalutamide in progressive metastatic castrate-resistant prostate cancer. The secondary objectives are to examine the objective time to clinical/radiological progression of patients treated with Radium-223 in combination with enzalutamide in progressive metastatic castrate-resistant prostate cancer, to examine the objective time to PSA progression, to assess PSA response (50% reduction from baseline), to assess change in alkaline phosphatase, to measure the time to first skeletal-related event, to assess pain, to measure overall survival and to examine potential biomarkers of enzalutamide resistance in circulating tumour cells, whole blood, plasma and serum. Previously presented abstracts in relation to this study at the 2018 ASCO Annual Meeting and 2019 Genitourinary Cancers Symposium have suggested this combination to be safe and well tolerated. The final data analysis is ongoing and will be published later this year.

Add Aspirin (CTRIAL-IE 16-19)

Add-Aspirin is a phase III basket trial assessing daily aspirin for preventing recurrence and improving survival following primary treatment for early stage breast, colorectal, gastro-oesophageal or prostate cancer. In response to the COVID-19 pandemic, the sponsor paused recruitment between April and June 2020. Recruitment is now back to pre-pandemic levels in the Republic of Ireland and 36 patients have been enrolled in Ireland since recruitment resumed. The trial is currently open at the following sites: Beaumont Hospital, Bon Secours Hospital Cork, Cork University Hospital, The Mater Misericordiae University Hospital, University Hospital Limerick, St Luke's Radiation Oncology Network at St Luke's Hospital, St Vincent's University Hospital, The Mater Private Hospital, Sligo University Hospital, Tallaght University Hospital and University Hospital Waterford.

DSSG updates: *Breast - New studies*

SASCIA

Neoadjuvant chemotherapy (NACT) allows monitoring of tumor response to treatment and a pathological complete response (pCR) is associated with superior survival. This association is strongest in the most aggressive subtype, i.e. in patients with triple-negative breast cancer (TNBC). Patients with TNBC not achieving a pCR have a 5-year event free survival rate of about 50%. The association between pCR and prognosis is less pronounced in HR-positive/HER2-negative patients.

A potential strategy to improve outcome in patients with residual disease after NACT is to offer additional adjuvant treatment, an approach described as “post-neoadjuvant therapy”.

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.

In Ireland this study will be open at 7 sites and aim to accrue 40 patients.

DECRESCENDO BIG 19-02

Decrescendo (BIG 19-02) study is an open-label, dual-phase single-arm phase II trial evaluating neoadjuvant treatment with 12 administrations of weekly intravenous (IV) paclitaxel (or IV docetaxel) combined with subcutaneous (SC) fixed dose combination (FDC) of pertuzumab and trastuzumab for 4 cycles. Additional cycles of pertuzumab and trastuzumab FDC SC may be administered after the completion of chemotherapy, before surgery, in case surgical delay occurs.

Surgery will be performed in all subjects after neoadjuvant treatment. After surgery, subjects who achieve a pathologic complete response (pCR), will receive adjuvant pertuzumab and trastuzumab FDC SC for additional 14 cycles. Subjects with residual disease will receive salvage adjuvant trastuzumab emtansine (T-DM1) for 14 cycles. In subjects whose residual disease is classified per Residual Cancer Burden (RCB) score as ≥2, 3 to 4 cycles of standard of care anthracycline-based chemotherapy may be administered, at the investigator’s discretion, before the administration of 14 cycles of T-DM1.

The main objective of the DECRESCENDO study is to attempt to expand chemotherapy de-escalation to subjects with ER-negative tumors ranging from 15 to 50 mm in diameter and node-negative, with a treatment consisting in weekly paclitaxel for 12 weeks (or 4 cycles of docetaxel every 3 weeks) and dual HER2-blockade with pertuzumab and trastuzumab FDC SC for one year.

In Ireland this study will be open at 8 sites.

CARABELA

In early BC (EBC), use of neoadjuvant therapy is an attractive option to facilitate breast conservation and, critically, enables the assessment of in vivo biomarkers to identify proof of-principle activity or predict responsive or resistant subgroups of tumors.

CARABELA study is an open-label, randomized phase II study in the neoadjuvant setting for breast cancer patients.

Approximately 200 premenopausal and postmenopausal women with Hormone Receptor (HR)-positive/Human Epidermal Growth Factor Receptor 2 (HER2) negative Breast Cancer (BC) of intermediate/high risk determined by Ki67 index ≥ 20% on untreated breast tissue and centrally assessed, with indication of neoadjuvant treatment, will be included.

Patients will be stratified according to the disease stage (II vs. III), menopausal status (premenopausal vs. postmenopausal) and Ki67 index (Ki67 < 30% vs. Ki67 ≥ 30%).

Once the screening process (locally at site and at the central laboratory) is completed, fully eligible patients will be randomized in a 1:1 fashion to the control arm with standard Chemotherapy (CT) based on anthracyclines and taxanes or to the experimental arm with letrozole + abemaciclib.

After the last dose of any of the drugs in the neoadjuvant combinations, in both treatment arms definitive surgery will be performed. Primary Objective in this study is to assess the Residual Cancer Burden (RCB) 0-I rate in both treatment arms.

In Ireland this study will be open at 5 sites and aim to accrue 41 patients.

CLOSED TO ACCRUAL: *PantHER*

Cancer Trials Ireland in-hose study for metastatic breast cancer patients called PantHER - Phase Ib/II clinical trial of copanlisib in combination with trastuzumab in pretreated recurrent or metastatic HER2-positive breast cancer -has completed its accrual in November 2020. Initially in phase Ib this study has determined the maximum tolerated dose (MTD) of copanlisib in combination with trastuzumab. In Phase II the primary objective is to evaluate the anti-tumour efficacy of copanlisib in combination with trastuzumab in terms of Clinical Benefit Rate (CBR) in patients with PIK3CA wild type and mutated histologically confirmed HER2-positive breast cancer that are metastatic or incurable recurrent, following disease progression during, or after, treatment with at least one systemic treatment regimen in the metastatic or recurrent setting.

Radiotherapy updates: *Team Update March 2021*

Oral presentation at ASTRO 2020: Spinal Cord Retreat - CTRIAL-IE (ICORG) 07-11

Phase II Trial Evaluating Radiobiological Based Reirradiation Strategy for Patients with Malignant Spinal Cord Compression (MSCC)

MSCC represents a common cancer-related neurological complication, with a functional and vital prognosis. When occurring within a previously irradiated spinal segment, direct decompressive surgery is usually considered as first line therapy. For patients not considered for decompressive surgery, primary palliative re-irradiation (with steroids) remains the only therapeutic option. However the efficacy and toxicity of the latter need to be better evaluated, as well as the optimal radiotherapy modality and radiation schedule.

The objective of the Cancer Trials Ireland 'in-house' 07-11 study, led by Prof Pierre Thirion in SLRON, was to prospectively evaluate the efficacy and toxicity of External Beam Radiotherapy (EBRT) based re-irradiation in non-operable patients with MSCC occurring in a previously irradiated spinal segment. 22 patients were enrolled in SLRON and UHG between 2008 and 2016.

The study demonstrated that EBRT re-irradiation provides similar response rate than the one reported in the previously reported CTRIAL-IE (ICORG) 05-03 Spinal Cord Compression trial (https://pubmed.ncbi.nlm.nih.gov/29419331/) with irradiation-naïve MSCC pts, however the observed Radiation-Induced Myelopathy was higher than predicted, demonstrating the importance of prospective trials. In clinical practice, re-irradiation should be considered, however caution should be used if prescribing a total biologically effective dose of 120 Gy_2.

CTRIAL-IE (ICORG) 07-11: Phase II Trial Evaluating Radiobiological Based Reirradiation Strategy for Patients with Malignant Spinal Cord Compression

P. Thirion,[1,2] M. Dunne,[2] I. Parker,[1] C. Small,[3] A.M. Shannon,[1] A. Clayton-Lea,[2] M. Parker,[4] C.D. Collins,[2] J. Coffey,[2] N. Elbeltagi,[2] D. Fitzpatrick,[2] O. McArdle,[2] M. Stevenson,[5] A. Alvarez-Iglesias,[6] M. Moriarty,[2] O. Salib,[2] C. Gillham,[2] and J.G. Armstrong[2]; *[1]Cancer Trials Ireland, Dublin, Ireland, [2]St. Luke's Radiation Oncology Network, Dublin, Ireland, [3]University Hospital Galway, Galway, Ireland, [4]SDMO, The Royal Hospital, Belfast, United Kingdom, [5]Centre for Public Health Queen's University, Belfast, United Kingdom, [6]HRB Clinical Research Facility, NUI Galway, Galway, Ireland*

This study was selected for presentation in an Oral Scientific Session during the 2020 Annual Meeting of the American Society for Radiation Oncology (ASTRO) held in October 2020. This was quite an accomplishment as over 3,300 abstracts were submitted, peer reviewed, and only 280 were selected for this highest-level oral presentation type. The abstract was published in the Red Journal supplement (Volume 108 Number 3S), as well as posted online on the Red Journal website.

PACE C (CTRIAL-IE 15-46)

Prostate Advances in Comparative Evidence: International randomised study of prostatectomy vs SBRT and conventional RT vs SBRT for organ-confined prostate cancer is a UK Cooperative group study. PACE C (CTRIAL-IE 15-46) is an amendment to PACE B which is in follow-up, and compares Image-Guided Conventional RT vs Stereotactic RT for intermediate/high risk prostate cancer patients. PACE C has been re-activated at Beacon Hospital and is pending at SLRON (RTQA is ongoing). Ethics approval is awaited for the UPMC Hillman Cancer Centre at Bon Secours. Prof Armstrong is the Irish Study CI.

SOURCE Lung (CTRIAL-IE 18-33)

The new SOURCE Lung in-house study Stereotactic Ablative Radiation Therapy Of UltRacentral Non-Small CEll LUNG Cancer (CTRIAL-IE 18-33) is now open at SLRON and Beacon Hospital, and feasibility questionnaires are being completed by other sites. This study aims to assess the safety/impact on side effects of delivering the same overall dose of RT, in fewer fractions, to lung tumours, through stereotactic RT. Stereotactic ablative RT (SABR) is a highly 'conformal' external beam RT (EBRT) technique. Prof Armstrong is the Study CI.

NRG/NSABP StudyUpdate

NRG GU005 (CTRIAL-IE 18-02) examines how well Stereotactic ablative RT (SABR) 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 Q1 2019 under the Irish Study CI Dr Alina Mihai, and is currently the 4th highest recruiting centre of over 100 international sites. Congratulations to Dr Mihai and her team!

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 reduces side effects and compare the effectiveness of the two radiation options. The study has ethics approval to open in SLRON and CUH (RTQA is ongoing), and contracts are awaited from the sponsor. Dr Sinéad Brennan is the Irish Study CI.

Radiotherapy updates: TROG 07.01 DCIS: CTRIAL-IE 10-06

Individualising radiotherapy for women with DCIS of the breast reduces recurrence after surgery

TROG 07.01 DCIS: CTRIAL-IE (ICORG) 10-06: A randomised phase III study of radiation doses and fractionation schedules for ductal carcinoma in situ (DCIS) of the breast.

DCIS of the breast is characterised by abnormal cells in the milk ducts which have not spread into the breast tissue. After surgery alone, about one-third of DCIS will recur, of which half would be in the form of invasive breast cancer with the potential to spread to other organs. Radiotherapy to the breast reduces recurrence but may lead to over-treatment in some patients and unnecessary costs.

Patients from 11 countries including Ireland participated in the TROG 07.01 (BIG 3-07) clinical trial involving 1,608 patients. The study investigated if a radiation "boost" to the part of the breast where the DCIS was, in addition to whole breast radiotherapy after surgery, would further decrease recurrence. The study also tests if a shorter course of whole breast radiotherapy is as effective as the usual longer course to improve patient outcomes and use of healthcare resources. In addition, investigators of this study have developed a resource of DCIS tumour samples to enable research that aims to identify a test that predicts recurrence risks in individual patients. The goal is to minimise the risk of developing invasive breast cancer in patients with high-risk DCIS, and spare unnecessary treatment side-effects in low-risk patients.

In December 2020, Prof Boon Chua (study CI) presented the results of the main analysis at the San Antonio Breast Cancer Symposium. The study demonstrated that higher radiation doses (after breast-conserving surgery) to the part of the breast where the DCIS was found, in addition to radiotherapy of the whole breast, significantly reduced its risk of returning in patients with higher-risk DCIS. Compared to 5 weeks of whole breast radiotherapy, the study also showed that the shorter, more convenient 3 weeks of radiotherapy did not increase recurrence.

The results of the study will likely have a significant impact on how patients with DCIS are best managed worldwide. It could also lead to better use of healthcare resources by minimising over or under-treatment of patients with DCIS.

Professor Boon Chua, M.D., PhD, Principal Investigator of the DCIS study, Director of Cancer and Haematology Services at UNSW (University of New South Wales) and Prince of Wales Hospital, Sydney, Australia:

"The study demonstrates the importance of tailoring radiation treatment of patients with DCIS according to their risks of recurrence to avoid over- or under-treatment. As the majority of these patients are, fortunately, long-term survivors, we need to minimise not only the risk of recurrence but also the long-term side effects of treatment to give them the best quality of life possible".

Dr Joseph Martin in UHG is the Irish Chief Investigator for this study. 79 patients were enrolled in UHG, SLRON and CUH between 2011 and 2014. Cancer Trials Ireland was the study sponsor in Ireland, and coordinated the ethics and set-up/ monitoring activities at site. Cancer Trials Ireland was the collaborating group with the highest overall accrual/site ratio, while Ireland as a country had the second highest accrual/site ratio (of 11 countries).

Other new studies in set-up

Other new studies in set-up include SABR COMET-3 (CTRIAL-IE 19-21): 'Stereotactic Ablative Radiotherapy for Comprehensive Treatment of Oligometastatic (1-3 Metastases) Cancer', EXPERT BIG (CTRIAL-IE 19-03) 'Examining Personalised Radiation Therapy for Low-risk Early Breast Cancer', and CompARE (CTRIAL-IE 17-14) 'Phase III randomised controlled trial Comparing Alternative Regimens for escalating treatment of intermediate and high-risk oropharyngeal cancer'.

Closed to accrual

NSABP B-51 (CTRIAL-IE 15-03) closed to accrual at the end of 2020. It was open at SLRON and GUH since 2016 (Irish CI is Dr Joseph Martin), and evaluates standard or comprehensive radiation therapy in treating patients with early-stage breast cancer who have undergone surgery and chemotherapy. Dr Orla McArdle is PI at SLRON, which was the joint 11th highest recruiting centre of over 400 international sites. Well done to Dr McArdle and her team!

Lymphoma and Haematology DSSG portfolio:

CTRIAL-IE 19-17 CPD-DARA

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. It is expected to enrol the first patient at the beginning of the second quarter of 2021. Recruitment will be for 12 months and 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%. 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.

CTRIAL-IE 20-22 CLL 17

The CTRIAL-IE 20-22 CLL 17 study is a University of Cologne sponsored study which is being coordinated in Ireland by Cancer Trials Ireland. It is a phase 3 multicentre, randomized, prospective, open-label trial of Ibrutinib monotherapy versus fixed-duration Venetoclax plus Obinutuzumab versus fixed-duration Venetoclax plus Ibrutinib in patients with previously untreated chronic lymphocytic leukaemia (CLL).

The National Coordinating Investigator in Ireland is Professor Patrick Thornton (Beaumont Hospital).

The primary objective of the study is to compare the efficacy of continuous ibrutinib monotherapy (I) withfixed-duration venetoclax plus obinutuzumab (VG) and fixed-duration venetoclax plus ibrutinib (VI) by measuring progression-free survival (PFS) in patients with previously untreated CLL.

This study will run in the following eight sites in Ireland: Beaumont Hospital, Cork University Hospital, Mater Misericordiae University Hospital, St James's Hospital, University Hospital Waterford, University Hospital Galway, University Hospital Limerick and St Vincent's University Hospital. It is expected to open in the coming weeks. It is planned that 40 patients will be enrolled in the study in Ireland.

This is a global study which will run in 10 other EU countries and in Switzerland, Norway and Israel. The overall enrolment target is 897 patients.

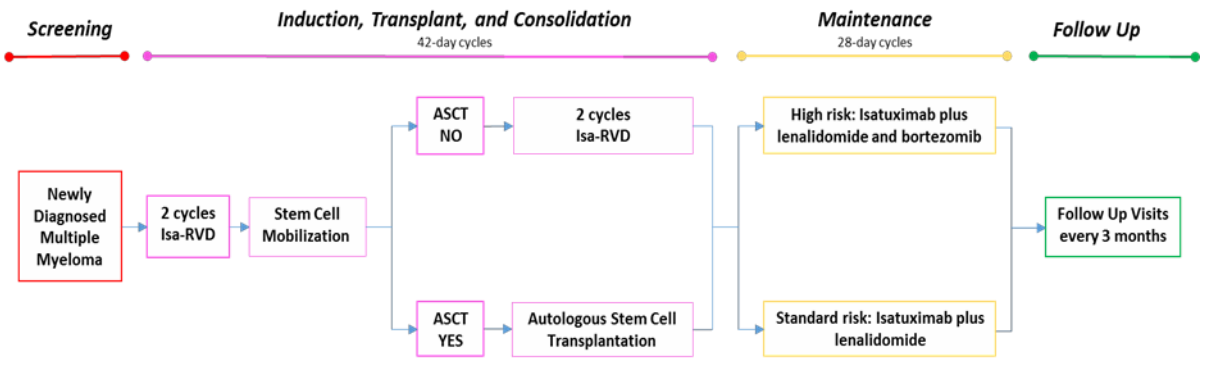
CTRIAL-IE 19-34 Isa-RVD

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 and University Hospital Waterford and is expected to open later in 2021. This study may also be opened at sites in Denmark. Recruitment will be for 18 months and a maximum of 43 patients will be enrolled in the study.



After completion of Cycle 2 and at the discretion of the PI, participants will undergo stem cell mobilization with cyclophosphamide and filgrastim or other agent(s) at the investigator's discretion. Stem cell collection should be performed and stem cells frozen according to institutional standards.
Stem Cell Mobilization/HDT and ASCT will be performed as per institutional standards.

Academic Publications from Cancer Trials Ireland Investigators

Dr Orla Casey, Translational Project Manager & Andrea Lydon, Trial Coordinator (Cancer Trials Ireland)

Breast

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 and 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. 15-17: PALLAS
Mayer, E. L., A. C. Dueck, M. Martin, G. Rubovszky, H. J. Burstein, M. Bellet-Ezquerra, 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 and 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
Sun, Z., S. M. Niman, O. Pagani, A. H. Partridge, H. A. Azim, F. A. Peccatori, M. Ruggeri, A. Di Leo, M. Colleoni, R. D. Gelber, M. M. Regan & P. S. Committee (2020) **"Estimation of historical control rate for a single arm de-escalation study - Application to the POSITIVE trial"**. Breast, 53, 1-7.
*Cancer Trials Ireland author (member of the Positive Steering committee) listed in the appendix

Cancer Trials Ireland Study Number: short name. 12-09: CharactHer
Walsh, N., C. Andrieu, P. O'Donovan, C. Quinn, A. Maguire, S. J. Furney, G. Gullo & J. Crown (2020) **"Whole-exome sequencing of long-term, never relapse exceptional responders of trastuzumab-treated HER2+ metastatic breast cancer."** Br J Cancer, 123**,** 1219-1222.

Gynaecological

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 and A. R. Clamp (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
van den Heerik, A. S. V. M., N. Horeweg, R. A. Nout, L. C. H. W. Lutgens, E. M. van der Steen-Banasik, G. H. Westerveld, H. A. van den Berg, A. Slot, F. L. A. Koppe, S. Kommoss, J. W. M. Mens, M. E. Nowee, S. Bijmolt, D. Cibula, T. C. Stam, I. M. Jurgenliemk-Schulz, A. Snyers, M. Hamann, A. G. Zwanenburg, V. L. M. A. Coen, K. Vandecasteele, C. Gillham, C. Chargari, K. W. Verhoeven-Adema, H. Putter, W. B. van den Hout, B. G. Wortman, H. W. Nijman, T. Bosse and C. L. Creutzberg (2020). **"PORTEC-4a: international randomized trial of molecular profile-based adjuvant treatment for women with high-intermediate risk endometrial cancer."** Int J Gynecol Cancer 30(12): 2002-2007.

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. Kommoss, K. Vandecasteele, V. Tomancova, C. L. Creutzberg, R. A. Nout and P. S. Group (2020). **"Brachytherapy quality assurance in the PORTEC-4a trial for molecular-integrated risk profile guided adjuvant treatment of endometrial cancer."** Radiother Oncol 155: 160-166.

Genitourinary

Cancer Trials Ireland Study Number: short name. 15-21: The ExPeCT Trial
Brady, L., B. Hayes, G. Sheill, A. M. Baird, E. Guinan, B. Stanfill, T. Vlajnic, O. Casey, V. Murphy, J. Greene, E. H. Allott, J. Hussey, F. Cahill, M. Van Hemelrijck, N. Peat, L. Mucci, M. Cunningham, L. Grogan, T. Lynch, R. P. Manecksha, J. McCaffrey, D. O'Donnell, O. Sheils, J. O'Leary, S. Rudman, R. McDermott & S. Finn (2020) **"Platelet cloaking of circulating tumour cells in patients with metastatic prostate cancer: Results from ExPeCT, a randomised controlled trial."** PLoS One, 15**,** e0243928.

Cancer Trials Ireland Study Number: short name. 08-17: IMRT Prostate
Medipally, D. K. R., D. Cullen, V. Untereiner, G. D. Sockalingum, A. Maguire, T. N. Q. Nguyen, J. Bryant, E. Noone, S. Bradshaw, M. Finn, M. Dunne, A. M. Shannon, J. Armstrong, A. D. Meade & F. M. Lyng (2020) **"Vibrational spectroscopy of liquid biopsies for prostate cancer diagnosis."** Ther Adv Med Oncol, 12**,** 1758835920918499.

Cancer Trials Ireland Study Number: short name. 97-01: Prostate
Xie, W., M. M. Regan, M. Buyse, S. Halabi, P. W. Kantoff, O. Sartor, H. Soule, D. Berry, N. Clarke, L. Collette, A. D'Amico, R. A. Lourenco, J. Dignam, M. Eisenberger, N. James, K. Fizazi, S. Gillessen, Y. Loriot, N. Mottet, W. Parulekar, H. Sandler, D. E. Spratt, M. R. Sydes, B. Tombal, S. Williams, C. J. Sweeney and I. W. Group (2020). "Event-Free Survival, a Prostate-Specific Antigen-Based Composite End Point, Is Not a Surrogate for Overall Survival in Men With Localized Prostate Cancer Treated With Radiation." J Clin Oncol **38**(26): 3032-3041.

Head & Neck

Cancer Trials Ireland Study Number: short name. 20-04: PRESERVE
Lang, P., J. Contreras, N. Kalman, C. Paterson, H. Bahig, A. Billfalk-Kelly, S. Brennan, K. Rock, N. Read, V. Venkatesan, J. Sathya, L. C. Mendez, S. D. MacNeil, A. C. Nichols, K. Fung, A. Mendez, E. Winquist, S. Kuruvilla, P. Stewart, A. Warner, S. Mitchell, J. A. Theurer and D. A. Palma (2020). **"Preservation of swallowing in resected oral cavity squamous cell carcinoma: examining radiation volume effects (PRESERVE): study protocol for a randomized phase II trial."** Radiat Oncol 15(1): 196.

Oesophageal: *NeoAegis closed to recruitment*

Based on the recommendations from the Neo-Aegis Data Safety Monitoring Board, the Neo Aegis study closed to recruitment Jan 2021 with 377 of the planned 540 patients recruited. This recommendation is not based on safety concerns or the futility of either arm but on analysis of data and the predicted likelihood of the trial completing in a reasonable timeframe. The recent 2nd futility analysis results are clinically very interesting, and the Neo-Aegis team are preparing a submission for ASCO 2021. For patients currently on study, study treatment and follow-up will continue as planned until LPLV, 23-Jun-22. Primary analysis will be completed at this timepoint.

'Just Ask' Campaign: Cancer Trials Ireland & Public Awareness of Clinical Trials in Ireland - by Eibhlin Mulroe, CEO

In November 2020, Cancer Trials Ireland commissioned public attitude research into clinical trials in Ireland among 1,000 nationally representative people. Where possible, this research was benchmarked against similar research undertaken by the Irish Platform for Patient Organisations, Science & Industry (IPPOSI) in 2009.

The 2020 research revealed a steady increase in public understanding and support for clinical trials, as we shall see, both in terms of a growth in positive sentiments and a decline in negative sentiments. But before we do the comparison, it is worth considering some of the questions, and answers, that were not benchmarked against 2009, and what they might say. They appear to indicate an encouraging and robust understanding of clinical trials and related matters in Ireland.

First and foremost, nearly three quarters of the population (72%) agree that clinical trials 'provide access to treatments not otherwise available'. 27% strongly agree with that statement, and 15% cited this very fact as the reason they would take part in a trial.

This is remarkable. Even when one considers how the question was put to respondents, i.e. as a statement with which one could agree or disagree with across a range, only 1 in 20 people did disagree. And only 1 in 4 (23%) said they didn't know.

You could of course argue that the public is well-versed in research questionnaires and can instinctively find the answers surveyors seem to want – and perhaps that's part of it. We can only hypothesise so far, and one wonders how many people could, unprompted by a statement, identify clinical trials as a path to treatments otherwise unavailable.

Except that of the 48% of people who said they would take part in a clinical trial (another very encouraging number), 15% of them – or almost a third of people (31%) willing to participate in a trial said they would do it to access treatments they could not otherwise get.

I think that goes beyond guesswork – and it might point to something more broadly uplifting: that people are increasingly, and reassuringly, clear about the value of the scientific process on a personal level. In light of how prevalent contrary, or even conspiratorial, voices can be in media and especially online, it comes as a relief to see attitudes in Ireland are trending in the right direction over the past decade, when it comes to trials.

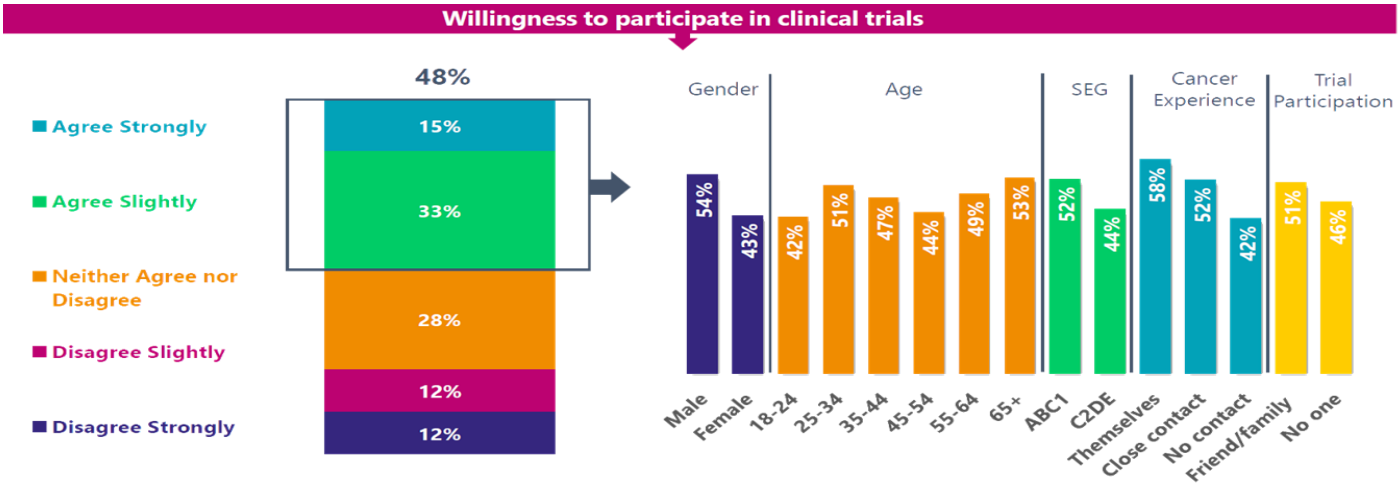
And indeed there are more examples of this heart-warming, if slightly incongruous, public common sense at work. Take data privacy: In 2009, this was an abstract concept we couldn't connect with personal experience. 11 years on, we understand that data is the price we pay for 'free' services, and platforms like Gmail, YouTube, and Facebook. We know that this data – our personal data – is what now fuels the world's most powerful companies. In that context you might expect people to have grown more reluctant to share the most sensitive data they have – their medical information.

Not so. 72% of people said they would share their medical information for research, if it was kept confidential – that's up from 65% in 2009. And this isn't a case of winning over the undecided people either. In 2009, nearly one in five (19%) people said they would not share their medical information. In 2020 that was down to 11%. You see similar changes in public willingness to donate blood for clinical research. 70% said they would in 2009, and that climbed to 76% in 2020. In 2009, 18% said they would not give blood for research, and that is now down to 9%.

There is no question that the COVID-19 pandemic has propelled medical science and clinical trials into the public consciousness like nothing else (73% agreed the pandemic highlighted the importance of clinical trials). Similarly, the past five years has seen an increasing number of drug access stories – often featuring the technical details of health technology assessments – penetrate the mainstream media. But whatever the reasons, the net effect for people working in clinical trials has never been better. So, I reiterate: One in two people in Ireland (48%) say they would take part in a clinical trial.

This is a far cry from the days where lay conversations about trials did not go long before the phrase 'guinea pig' was used, and that attitude does still exist. But so does an increased understanding of the term 'clinical/medical trial' (80%; up from 73% in 2009). So does recognition that trials are events in which drugs/medicines are tested on humans (72%; up 12% since 2009). So does the understanding that trials undergo an ethical review process (58%; up from 50% in 2009). At Cancer Trials Ireland we will keep build public awareness, knowledge, and most important of all, trust.

Finally, I am delighted to report that public awareness of Cancer Trials Ireland is very high (63%) which is a credit to the Just Ask campaigns since 2016 - and also to the late, great Pat Smullen, whose efforts brought us into so many people's minds.



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Cancer Trials Ireland studies open to accrual

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

DSSG	General Group	Cancer Trials Ireland No:	Study Name:	Total Accrual	TUH	Beacon	BH	BonS
Breast	Trans	09-07	Breast Cancer Proteomics and Molecular Heterogeneity	3099			1521	
Breast	Trans	10-16	Ovarian Reserve	216	22	4	59	31
Breast	Trans	15-34	Recurrence Score	87			15	
Breast	Clinical	15-02	PantHER (closed to accrual 30-Oct-2020)	26			15	
Breast	Clinical	17-13	Panthera (closed 30-Oct-2020)	2			1	
Breast	Radio	15-03	NSABP B-51 (closed to accrual Dec 2020)	20				
Breast	Clinical	17-15	IMpassion030/ALEXANDRA	14			10	
Breast	Clinical	17-33	VIOLETTE (closed to accrual 10-Nov-2020)	5				
Breast	Clinical	18-05	KEYNOTE-756	6				2
Breast	Clinical	18-41	NATALEE	95			17	
Breast	Radio	19-03	EXPERT BIG	0				
Breast	Clinical	19-35	CA209-7FL	1			1	
Breast	Clinical	19-36	KEYLYNK-009	10				
Breast	Surgical	20-13	LigaSure	50			50	
CNS	Radio	15-41	ROAM	1				
GI	Clinical	10-14	Neo-AEGIS	377			1	
GI	Clinical	11-32	Lithium	0				
GI	Trans	17-26	COLOSSUS	14	Open		1	2
GI	Clinical	18-12	MK 3475-811	9	2		3	
GI	Clinical	18-30	MK3475-859	22	7		4	
GI	Clinical	18-43	MK 7902-002	5				
GI	Clinical	19-23	MK3475-966	4	1			Open
GI	Clinical	19-07	MK3475-937	1	Open			
GI	Clinical	19-08	SOLSTICE	2	Open			Open
GI	Clinical	18-08	BMS CA209-8HW					
GI	Clincial	19-33	Paricalcitol	0	Open		3	
GI	Clinical	18-45	Incyte INCB 54828-30	0				
GI	Clinical	18-44	Astellas 8951-CL-5201	0				Open
GI	Clinical	20-05	Cosmic-312 study	1				
GI	Clinical	18-10	FIDES-01 (ARQ 087-301)	0				
GU	Clinical	11-34	TIGER	3				
GU	Clinical	13-23	Neo-adjuvant Abiraterone prostate (closed to accrual July 2020)	45				
GU	Radio	15-46	PACE C	0		Open		ISU
GU	Clinical	16-21	PEACE III	6	1			
GU	Clinical	16-70	BMS CA209-274 (Accrual now closed)	12	8			
GU	Clinical	17-04	Bayer 17403/ FORT- (Study now closed)	6	3			
GU	Clinical	20-14	MK3475-641	10	9		1	
GU	Clinical	20-15	MK3475-866	4	4			
GU	Clinical	20-16	MK3475-905	0	Open			
GU	Clinical	20-17	MK3475-921	8	6			
GU	Clinical	20-18	MK3475-991	3	2		1	
GU	Clinical	20-19	MK7339-010:	13	13			
GU	Clinical	20-20	TRITON-3	0	Open			
GU	Radio	19-38	Bioprotect ProSpace Balloon	2				
GU	Trans	17-30	IRONMAN	43	18	6		
GU	Radio	18-02	NRG GU005	13		13		
GU	Clinical	18-31	Keynote-564 (Accrual now closed)	1	Initiated			
Gynae	Trans	18-01	tBRCA Study (Closed to accrual Nov 2020)	200				15
Gynae	Radio	18-27	PORTEC-4a	4				
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				

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

CUH	UHG	LUH	Mater	MRH	MUH	OLLHD	OLCHC	UHL	SLRON	SJH	SUH	SVUH	UHW	Whit	International Sites
838								385		Open		Open	355		
22						13				6	21	30	8		
16	6	3	5					10		11		12	9		
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17			13					4		8		27	9		
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TBI										Open					
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7	1								Reg via SJH	125					243
Open															
	Open											1			10
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			1									4			
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Open			1							Open			1		
5			2										2		

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Cancer Trials Ireland studies open to accrual

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

DSSG	General Group	Cancer Trials Ireland No:	Study Name:	Total Accrual	TUH	Beacon	BH	BonS
H & L	Clinical	18-48	CALLS (INCB 84344-401)	9			TBI	
H & L	Clinical	19-17	CPD-DARA	0			ISU	
H & L	Clinical	19-34	Isa-RVD	0			ISU	
H & L	Clinical	18-15	Paradigme	5				
H & L	Clinical	19-40	FEDR-MF-002 (FREEDOM2)	2				
H & L	Clinical	18-47	MO40598	2				
H & L	Clinical	20-33	Irish & ASH COVID Registry	83			2	4
Head & Neck	Clinical + Radio	17-14	CompARE	0				
Head & Neck	Clinical + Radio	19-39	Keynote 689 (MK-3475-689)	0				
Head & Neck	Clinical	19-14	INDUCE-3 (GSK 209229)	0			0	
Head & Neck	Clinical	19-15	GSK 209227	2				
Head & Neck & Melanoma	Clinical	20-08	Keynote 630 (MK-3475-630)	0				
Head & Neck	Radio	20-04	PRESERVE	0				
Lung	Clinical	17-34	MK3475-495 (closed in Ireland 05-Dec-2020)	0				
Lung	Clinical	17-37	MK3475-671	0				
Lung	Radio	18-33	SOURCE Lung	0		Open		
Lung	Clinical	18-49	AbbVie M14-239	0				
Lung	Clinical	19-25	BMS CA209-73L	2				
Lung	Clinical	19-26	BMS CA209-77T	0	Open			
Lung	Trans	20-02	TERAVOLT	2				
Lung	Clinical	20-21	BLU-667-2303	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	4	Open			2
Basket	Clinical	16-19	Add-Aspirin	125	10		5	9
Basket	Clinical	18-29	CUPISCO - MX39795					
Basket	Radio	19-21	SABR COMET-3	0				ISU
Basket	Clinical	19-22	PUMA-NER (SUMMIT)	7				
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	mvechild	18				
Paeds	Trans	16-51	MESTRAT study *closed to recuitment 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

CUH	UHG	LUH	Mater	MRH	MUH	OLLHD	OLCHC	UHL	SLRON	SJH	SUH	SVUH	UHW	Whit	International Sites
TBI			TBI					Open		3		TBI	6		
ISU	ISU														
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1			Open							1					
										2					
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ISU	ISU								ISU	ISU					
									To open	To open					
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										2					
									Screen-ing only	0					
ISU									ISU						
								0		0					
TBI								Closed		Initiated					
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In just under two months (Fri May 21st) the cancer research community will convene at Ireland's first Cancer Retreat. This is a valuable opportunity for us all to reflect on our work and the environment in which it is delivered as we head into a new five-year HRB funding cycle.

The new HRB funding model redefines the cancer trials community into 'clusters' of trial sites, and a supporting network – the role currently played by Cancer Trials Ireland. This new model will change how we interact, and will no doubt create new challenges. But it will also give rise to opportunities, not least the chance afforded by this Retreat to debate what we – the providers of a vital service to people with cancer in Ireland – should collectively work towards and how we could work more optimally

At heart, that is what this Cancer Retreat is for: developing a shared vision.

In support of that vision, the Retreat's organising committee, which is diverse in terms of specialty, and geography, has designed a day-long event broken into three sessions:

1. Setting the scene for the next five years
2. DSSG form & function and how it could be enhanced
3. Trial logistics and how they could be optimised

While sessions two and three are open to healthcare professionals working in cancer, and members of Cancer Trials Ireland, session one will be open to a wider range of stakeholders, patients and members of the public.

Save the date

Cancer Retreat 21.05.21

Vice-Clinical Lead:
Professor
Seamus O'Reilly

As a community we share a sense of what is and is not working on our trials, whether that is the frequency of the various committee meetings, or the limited time for discussion and exploration such meetings were originally intended to foster. Before we delve into those and other matters in sessions two and three, it behoves us to listen to the people for whom we ultimately do this work (the patients) and the stakeholders who feed into it (regulators, RECs, industry, translational researchers).

This approach will, we hope, guide a useful and actionable series of discussions culminating in a paper, and a blueprint for how we as a community could and should work together in the coming five years.

You will shortly receive an invitation to take part in the Cancer Retreat, I very much hope you will accept it and look forward to integrating your suggestions into clinical trials for our patients.

Fundraising News

Friends of Cancer Trials Ireland

While the pandemic halted plans to host the third annual gala lunch of the Friends of Cancer Trials Ireland last November, nevertheless the group has been busy on our behalf. Since the date of the postponed lunch, the Committee contacted previous gala attendees to ask if they might continue their support of Cancer Trials Ireland in the absence of an event. Their community responded well, raising almost €12,000 (€11,976) since then. Speaking on behalf of the Friends of Cancer Trials Ireland committee, Grace McDermott thanked the donors for their generosity and signalled the group's intention to host a gala lunch event in whatever restricted capacity is possible this coming November. As ever, Cancer Trials Ireland is extremely grateful for the efforts of the Friends.

Thanks also to:

- **Horse Racing Community (Pat Smullen):** €3773.23 (since Nov 2020)
- **Donegal Shines a Light on Cancer:** €1,000

Tea Breakers Run to Paris (AIG)

We have been the benefactor of an increasing number of GoFundMe campaigns in recent years, and we are so grateful to Patricia Redmond, her family and friends, and her colleagues in AIG for the GoFundMe campaign they ran on behalf of their colleague who is taking part in a cancer clinical trial at present. The concept they created was to cover the distance to Paris and back on foot (1,064km) which they achieved. In so doing, they attracted almost 400 donations amounting to a remarkable €27,257 at the time of writing. Once again, thank you to everyone involved, we are humbled by your support.

The late Brian Lenihan, TD

A group of friends of the late Finance Minister, Brian Lenihan, who died from pancreatic cancer in 2011, have just met a commitment they made in 2020 to raise €100,000 for pancreatic cancer trials. Contributions came from a wide range of friends from different parts of his life. The promise of this funding was instrumental in getting the first stage of the Paricalcitol trial under way in late 2020. That trial has since accrued five patients and is now open at six sites. Cancer Trials Ireland wishes to express its gratitude for the efforts of the group, and our sympathy as they remember Brian on the tenth anniversary of his death this coming June

Reminder:

Save the date

Cancer Retreat 21.05.21

A day-long event for the entire oncology community - oncologists, researchers, research nurses, site managers and teams, pathologists, radiologists, pharmacists and patients.

cancer trials ireland

Together, we're finding answers to cancer.