DSSG Digest

Spring 2018 – Vol 13 Issue 1

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

Prof Richard Wilson (left), Clinical Director, Northern Ireland Cancer Trials Network, and Dr Melanie Morris, Operational Director, Northern Ireland Cancer Trials Network, met with Prof Hennessy, (right) Clinical Lead, Cancer Trials Ireland, in Dublin recently along with central office colleagues to advance collaboration between our organisations and the development of all- Ireland cancer trials. (See Prof Hennessy commentary on the importance of collaboration on page 2)

Hyperlinks to cancer trials in Ireland on pages 12 & 13.

cancer trials ireland

Together, we're finding answers to cancer.

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The benefits and challenges of cancer trials research collaboration

Prof Bryan Hennessy, Clinical Lead, Cancer Trials Ireland, and Consultant Oncologist, Beaumont Hospital.

Last month I had the opportunity to participate in a panel discussion at the Bio-Pharma Ambition 2018 conference on how to unlock the collaborative potential of clinical research. Our CEO, Eibhlin Mulroe, chaired the session. Among the speakers was Dr Richard Schilsky, Senior Vice President and Chief Medical Officer, American Society of Clinical Oncology (ASCO).

It was a very thought provoking session and an opportune time to reflect on the benefits and challenges of cancer trials research collaborations.

The first thing to say is that we do a lot of collaboration with research organisations around the world. Collaborating is a very important part of our work.

Over 30 per cent of the cancer trials that we open in Ireland are the results of collaborations with research organisations around world.

We work closely with international collaborative groups such as ECOG-ACRIN and NRG in the US, ANZUP (Australia & New Zealand), TROG, NCRN, BIG, TRIO, GEICAM — all EU groups, and the main global pharmaceutical companies.

Every year we attend international conferences not only to present our findings, but equally importantly we work hard to generate collaboration leads and opportunities to open trials that will benefit patients in Ireland.

Benefits and challenges

Collaboration brings many benefits. Not only does it bring novel and promising treatments to people with cancer, who would otherwise not avail of these treatments, it enables us to explore new ground with our colleagues around the world, develop ideas and answers we could not do in isolation and ensure that we achieve the highest levels in cancer research.

The work we are doing with our nearest neighbour in Northern Ireland to work more closely together is very exciting and hopefully will enable us to develop an all-Ireland cancer trials portfolio.

Underpinning the need for collaboration is the recognition that cancer is a global issue and finding solutions requires a global effort. We cannot mobilise a global effort without collaboration.

But collaboration requires an upfront investment. It requires time and energy. And when we are involved in collaboration we are not spending time in our clinics or laboratories, or with patients. The challenge is how do we create more time?

The National Cancer Strategy commits to creating more protected time for oncologists to enable them to devote time to cancer trials research rather than squeezing it into their demanding clinical commitments. We look forward to seeing the follow through on this as soon as possible.

Building on our experience and expertise

We have highly educated and experienced oncologists and cancer trials researchers.

Uniquely we have a national network of research units which means that our whole population can be accessed through one point of entry.

Very few countries offer this. It is the result of many years of investment by dedicated consultants and their research teams.

30 years ago our Industrial Development Authority (IDA) sold Ireland abroad as having a uniquely young and highly educated workforce. As a result of decades of very hard work by its teams around the world we have huge pharmaceutical and information technology industries. They are creating thousands of jobs and igniting many spin off industries. This did not happen by accident. It was underpinned by effective government policy and driven by very capable people.

The challenge is how do we build on our cancer trials experience and expertise, like the IDA did 30 years ago, and make Ireland a go-to place for cancer trials.

The main driver for me for growing our collaborations is the patients I meet every day in my clinic. I want to offer more options and I know increased clinical trial activity and collaborations can do exactly that.

The two challenges are how do we create more time and how do we build on our expertise and track record? We are actively seeking to address these by having our voice heard and recently met the Minister for Health, Simon Harris, to reinforce the need for cancer trials to be funded properly.

The Government's policy on cancer trials targets is full of possibilities

Eibhlin Mulroe, CEO, Cancer Trials Ireland.

The National Cancer Strategy, which sets out Government policy on cancer up to 2026, is ambitious, forward thinking and full of possibilities.

When published, we called it a potential game changer.

We are very anxious to partner with the Government through the National Cancer Control Programme (NCCP) and the HSE to maximise the strategy's impact.

Of particular significance is the strategy's target to open more trials - Key Performance Indicator No. 20 is to double the number of patients on cancer drug trials by 2020.

We've engaged with Minister Harris, his officials, and the Director of the NCCP, Dr Jerome Coffey, on how we can help to support this policy target.

The biggest constraint we face in supporting this policy target is the shortage of funding we receive from the Health Research Board (HRB) to support core central office trials functions and the infrastructure in the research centres around the country. Our 2016-2018 grant was cut by 20% which equates to approx. €750,000 pa.

So while Government policy is to double the number of patients on cancer trials we are facing the dilemma of having to say no to opening some new cancer trials.

For example we were unable to progress a number of academic studies in 2016 and 2017 due to the reduction in the core grant funding we receive from the HRB.

It is easy to forget the implications of these decisions and it is important to remind ourselves how life changing trials can be. The following is a selection of case studies from patients taking part in Cancer Trials Ireland trials. It is important to reflect on the real health impact of the work we do in our Central Office and at Research Units throughout the country

Patient A - *A mother in her 30s with a young child. Diagnosed with Breast Cancer in 2010. She received standard treatment however, 6 months post treatment she was told her disease had progressed and spread to her liver. This new diagnosis had a very poor prognosis in 2010.*

She signed up to a cancer trial and had an excellent response for two and a half years. She subsequently joined a new trial which has now given her immense health benefits. She said her old chemotherapy regime had given her benefit but was a physically tough experience during the treatment. On the new trial she feels energised and she can go for a run the day after treatment.

She said, "I am surviving my cancer well, I have a great quality of life, I can look after my child, I can go for a run, I have never been this well".

Patient B - *A father and grandfather.*
Diagnosed with Malignant Melanoma in 2006, he received the standard treatment. He was told the cancer had spread to his bones in 2010 and that he would only have "months to live".

He signed up for a cancer trial and was treated with a new immunotherapy drug. He has been on the trial for over 7 years. "The trial allowed me to spend time on the important things, family…I have seen my grandchildren grow, I have seen my team win a few titles, all because I was on the trial."

Patient C - *A man in his mid-50s.*
He was diagnosed with Advanced Melanoma, an aggressive disease with a very poor prognosis. He signed up to a cancer trial involving a combination of two immunotherapy drugs. He has so far had a reduction of 60% to 70% in his disease burden. He has an excellent quality of life and cycles around 200km per week.

Patient D - *A 70 year old man.*
He was diagnosed with Multiple Myeloma: "The hardest part of the diagnosis for me was seeing how my wife took the news, she was so upset".

He jumped at the chance to sign up to a cancer trial. He knew he would be receiving a new cutting-edge treatment and that his involvement in the trial would also benefit others getting the same diagnosis in the future.

"I am celebrating my 70th thanks to a cancer trial"

While not all participants on cancer trials can report such positive outcomes they draw into sharp focus how cancer trials can potentially benefit patients.

On the one hand Ireland has a very welcome and ambitious policy that could see many more patients experience similar benefits. On the other hand, due to funding cuts, we can't open trials that could realise the Government's policy target.

The question is how do we square this circle?

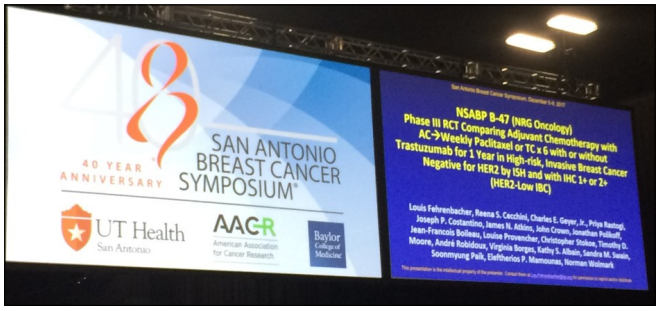
Cancer Trials Ireland features at SABCS's 40th Anniversary

Andrés Hernando, Clinical Project Manager, Cancer Trials Ireland and Breast DSSG Operations Lead.

San Antonio Breast Cancer Symposium (SABCS), one of the most important international scientific events in breast cancer, celebrated its 40th Anniversary last year. Over 7,000 people from more than 90 countries attended the land mark symposium; up to 40 of them from Ireland.

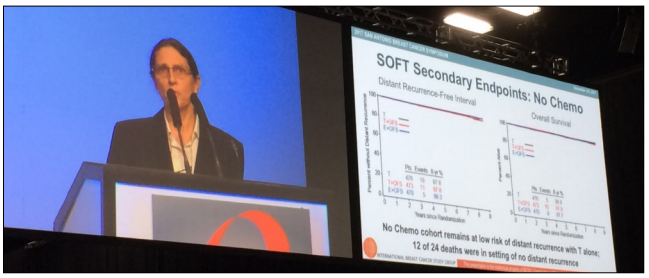
Although there were no practice-changing studies presented at the symposium, several studies presented, some of which Cancer Trials Ireland actively participated, provided key points to better understand breast cancer and how best to treat it.

The first is the NSABP B-47 (CTRIAL-IE 11-24) study (GS1 -02) that compared adjuvant chemotherapy with or without trastuzumab for 1 year in high-risk, invasive breast cancer negative for HER2 by ISH and with IHC 1+ or 2+ (HER2-Low IBC). The main conclusion was that there is no benefit to trastuzumab therapy in this setting. Prof John Crown was a co-author of this trial.



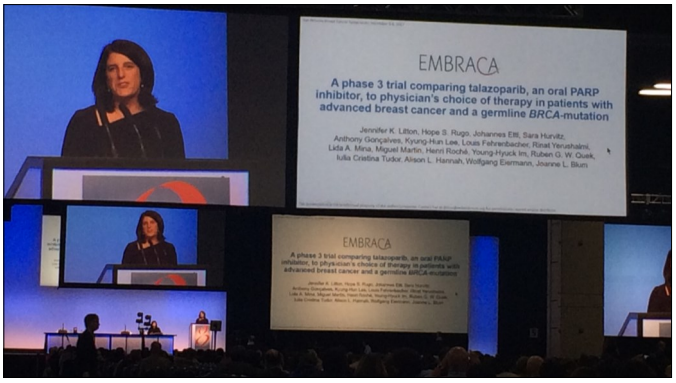
NSABP B-47 presentation by Louis Fehrenbacher, MD of Kaiser Permanente, Northern California.

Another presentation was an update on the results of the SOFT (CTRIAL-IE 06-02) trial (GS4-03) that compared adjuvant tamoxifen with or without ovarian function suppression in premenopausal women with hormone receptor-positive early breast cancer. The results with an additional follow-up of a median of 8 years support the value of ovarian function suppression for some premenopausal women. Cancer Trials Ireland contributed to the study's patient recruitment.



SOFT presentation by Gini Fleming, MD of The University of Chicago Medicine.

In the area of metastatic cancer, the EMBRACA (CTRIAL-IE 14-01) results (GS6-07) were presented. It found that Talazoparib significantly prolonged progression free survival in HER2-negative advanced breast cancer and a germline BRCA mutation. Cancer Trials Ireland participated in patient recruitment for this study.



EMBRACA presentation by Jennifer Litton, MD of The University of Texas M.D. Anderson Cancer Center

It should be noted that the number of trials with immunotherapy has increased over the past years and currently there are trials in both early and metastatic disease as well as combinations of treatments (e.g. alternate chemotherapy, with PARP inhibitors, with CDK4/6 inhibitors.).

As a summary of the Symposium I would like to highlight that nine abstracts were submitted to SABCS in which Cancer Trials Ireland was represented among the authors. One oral presentation (NSABP B-47) (CTRIAL-IE 11-24); two poster discussion (BIG 02-98 (PD6-07) (ICORG 98-01) and EORTC 10085 (ICORG 12-40) (PD7-12)); and 6 posters (IBCSG 42-12/BIG 2-12 SNAP (P5-18-02) (CTRIAL -IE 12-45), PALOMA-2 (P5-19-01 and P5-21-25) (CTRIAL-IE 09-01), CXCL16/CXCR6 expression in HER2+ BC (P5-11-03) (CTRIAL-IE 10-05), pregnancy associated breast cancer study (P6-08-17) and PantHER (OT3-06-05) (CTRIAL-IE 15-02)).

Dr Niamh Keegan and Dr Patrick Morris, Beaumont Hospital, with the PantHER poster presentation. Prof Bryan Hennessy is the Principal Investigator on this trial.

Another key purpose of this Symposium was to make contact with colleagues and collaborators from other research groups and create the connections that could lead to future collaborations. Meetings with the Spanish Breast Cancer Research Group (GEICAM), Translational Research in Oncology (TRIO) and Fondazione Michelangelo were organised during this Symposium to discuss future proposals and on-going studies.

CyBorD-DARA trial features at American Society of Haematology (ASH) meeting

Grace Hirakata, Senior Clinical Research Associate, Cancer Trials Ireland and Lymphoma and Haematology DSSG co-ordinator.

The American Society of Haematology (ASH) is the world's largest professional society concerned with the causes and treatment of blood disorders.

Its annual meetings highlight ground-breaking scientific research and the latest advances in patient care.

The 2017 ASH Annual Meeting (59th Annual Meeting) was held in Atlanta last December. More than 25,000 experts in the field from around the world attended this meeting.

Nearly 5,000 scientific abstract presentations were submitted covering malignant and non-malignant blood diseases, from cutting-edge advances in gene therapy to practice-changing discoveries in immunotherapies.

Pictured at the ASH meeting with CyBorD-DARA trial poster presentation (l to r) Dr Cian McEllistrim, (first author), Prof Michael O'Dwyer (Chief Investigator) and Dr Serika D Naicker (the researcher who conducts the translational research element of the trial).

CyBorD-DARA

Prof Michael O'Dwyer (Chief Investigator at the University Hospital Galway and Director of Blood Cancer Network Ireland) and Dr Cian McEllistrim (Former Sub-Investigator at the University Hospital Galway) submitted an abstract on their CyBorD-DARA (CTRIAL-E16-02) trial that was accepted as a poster presentation at the meeting.

This trial is a Phase Ib study of weekly Cyclophosphamide-Bortezomib-Dexamethasone with Daratumumab (DARA) in transplant eligible patients with newly diagnosed Multiple Myeloma. It is managed in collaboration with Cancer Trials Ireland. The translational component in the CyBorD-DARA trial was submitted and accepted as an oral presentation at the meeting.

Preliminary data was presented on the first 6 patients who completed induction treatment (4 cycles) on the trial. The combination shows a promising response rate among these patients and that it is well tolerated.

The translational research, conducted by Dr Serika D Naicker at the Biomedical Sciences Institute at NUI Galway, confirmed the previous in vitro findings which support the combination of cyclophosphamide and daratumumab. It was shown that cyclophosphamide potentiates macrophage mediated antibody-dependent cellular cytotoxicity (ADCP) of daratumumab.

Connections

Another important aspect of the meeting was connecting with the haematologist consultants, colleagues from pharmaceutical industries (such as Roche, AbbVie, Celgene and Sanofi) and other collaborative groups (such as Dana Farber Cancer Institute) to review current as well as potential trials that could be brought to Ireland.

CAR-T

For me the highlights of the meeting were the talks on the most revolutionary treatments for malignant blood diseases. What seems to be the most innovative treatment at the moment is the chimeric antigen receptor or CAR-T cell therapy, which is a cellular immunotherapy. The US Food and Drug Administration (FDA) has recently approved this therapy.

The CAR-T cell therapy is focused on genetically transforming a patient's own T cells, which will carry a protein called chimeric antigen receptor (the CAR in CAR-T) on their surface that recognises the cancer cells and kills them effectively. This therapy can, however, like all cancer therapies, cause sometimes severe side effects. One of the most frequent and important side effects is the cytokine release syndrome (CRS). Management of these side effects was discussed at the meeting.

This therapy is unfortunately not available in Ireland yet. Prof Michael O'Dwyer is trying to bring clinical trials with CAR-T cells to Ireland.

This was the first time I attended the ASH annual meeting and it was very interesting to watch the world's top experts talk about the different haematologic malignant diseases and the most innovative treatments available (either commercially or through clinical trials).

This was a very good experience and certainly contributed to my professional development as the Cancer Trials Ireland Lymphoma and Haematology DSSG co-ordinator.

First trial on the effect of swallow-sparing strategies in pharyngeal cancers opens

Dr Sinead Brennan (Irish Chief Investigator), Consultant Radiation Oncologist, St Luke's Radiation Oncology Network (SLRON) and Dr Aoife Shannon, Clinical Project Manager, Cancer Trials Ireland.

Sponsored in Ireland by Cancer Trials Ireland, the DARS radiotherapy trial has opened at St Luke's Radiation Oncology Network (SLRON) in Rathgar, Dublin.

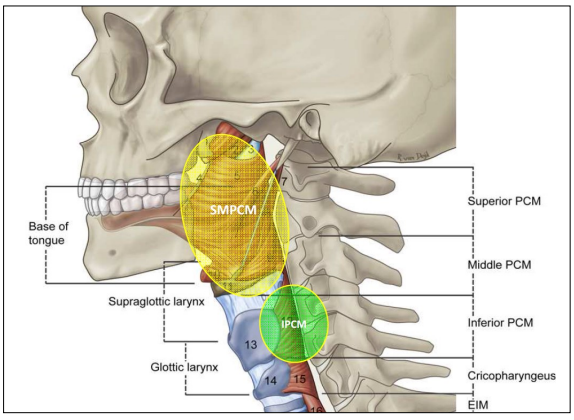
DARS (CTRIAL-IE 16-23) is the first randomised controlled trial (RCT) investigating the effect of swallow-sparing strategies on improving long-term swallowing outcomes in pharyngeal cancers. This trial could lead to more accurate treatment of pharyngeal cancers and better quality of life outcomes for patients.

Cancers of the oropharynx are increasing rapidly in incidence in the western world due to the Human Papilloma Virus (HPV) pandemic. Cigarette smoking and alcohol consumption are the other major risk factors. Approximately 500 Irish patients are diagnosed with cancer of the mouth or pharynx annually.

For most newly diagnosed patients, radiotherapy (RT) or chemoradiation is the treatment of choice. This is curative for the majority of patients. One of the most common long-term side effects of RT to the pharynx is dysphagia (difficulty swallowing), which is largely related to radiation of the pharyngeal musculature responsible for the initiation and completion of natural swallowing.

The clinical consequences of post-RT swallowing dysfunction can be mild, with restriction of diet or modification of swallowing function, or may be severe, particularly if swallow is so badly affected that aspiration of food into the lungs is a risk resulting in the requirement for a permanent gastrostomy tube and long term supportive care.

Intensity modulated radiotherapy (IMRT) is the most widely used RT technique for treating head and neck cancer in Ireland. Dysphagia optimised IMRT (Do-IMRT) is a novel radiation technique, which reduces radiation dose to the pharyngeal muscles known as the Dysphagia/Aspiration Risk Structures (DARS) *(See Figure)*.



Anatomy of superior, middle, and inferior constrictors (Dysphagia/Aspiration Risk Structures (DARS)) implicated in radiation-related pharyngo-oesophageal stricture.

DARS (CTRIAL-IE 16-23): A phase III, randomised, multicentre study of dysphagia optimised intensity modulated radiotherapy (Do-IMRT) versus standard intensity modulated radiotherapy (S-IMRT) in head and neck cancer.

For more information contact: Dr Sinead Brennan.

It is hypothesised that Do-IMRT will reduce long term swallowing problems compared to standard IMRT. Phase 2 single arm studies suggest that improvements in swallow function may be achieved by sparing the DARS, however it remains unclear as to whether sparing the DARS leads to significant improvements in swallow function following RT. The DARS trials (funded by Cancer Research UK, reference CRUK/14/014, coordinated by the Institute of Cancer Research Clinical Trials & Statistics Unit: https://www.icr.ac.uk/our-research/our-research-centres/clinical-trials-and-statistics-unit/clinical-trials/dars) is designed to answer this important clinical question (*Petkar I, et al. DARS: a phase III randomised multicentre study of dysphagia-optimised intensity-modulated RT (Do-IMRT) versus standard intensity-modulated RT (S-IMRT) in head and neck cancer. BMC Cancer. 2016; 16(1): 770*).

This is a phase III multicentre RCT for patients undergoing primary (chemo) radiotherapy for T1-4, N0-3, M0 pharyngeal cancers. Patients are randomised (1:1 ratio) to either standard IMRT (S-IMRT) or Do-IMRT. Radiotherapy doses are the same in both groups; however in patients allocated to Do-IMRT, irradiation of the pharyngeal musculature will be reduced by delivering IMRT identifying the pharyngeal muscles as organs at risk.

The primary endpoint of the trial is the difference in the mean MD Anderson Dysphagia Inventory composite score, a patient-reported outcome, measured at 12 months post RT. Secondary endpoints include prospective and longitudinal evaluation of swallow outcomes incorporating a range of subjective and objective assessments, quality of life measures, loco-regional control and overall survival. Patients and speech and language therapists will both be blinded to treatment allocation arm to minimise outcome-reporting bias.

It is anticipated that the use of Do-IMRT techniques will improve the accuracy of treatment and lead to benefits for patients in terms of both reduced exposure of normal tissue to high doses of RT that may well have benefits in terms of improved swallowing function and quality of life.

Accrual to the trial is likely to close ahead of the May 2018 target. The study strengthens Cancer Trials Ireland's collaborative links with UK-based trials and increases opportunities for Irish patients to participate in future head & neck clinical trials. Selection of SLRON to participate in trials such as DARS demonstrates that Ireland has achieved the international standards of excellence required to take part in these potentially practice changing trials.

First international atypical meningioma cancer trial in Ireland opens

Dr David Fitzpatrick (Irish Chief Investigator), Consultant Radiation Oncologist, St Luke's Radiation Oncology Network (SLRON) and Dr Aoife Shannon, Clinical Project Manager, Cancer Trials Ireland.

ROAM (CTRIAL-IE 15-41): Radiation versus Observation following surgical resection of Atypical Meningioma: a randomised controlled trial
For more information contact: Dr David Fitzpatrick

The first international atypical meningioma cancer trial in Ireland has opened at St Luke's Radiation Oncology Network (SLRON) at Beaumont Hospital in Dublin. Sponsored in Ireland by Cancer Trials Ireland, the ROAM radiotherapy trial (CTRIAL-IE 15-41) will involve a total of 190 patients in 54 centres in Ireland, UK, mainland Europe and Australia.

Atypical meningioma is a brain tumour that arises from the meninges. These are rare tumours, with approximately 20 new cases per year in Ireland. They tend to affect adults with a peak incidence at age 40-60 years. The primary treatment for symptomatic or enlarging atypical meningioma is surgical excision, and the completeness of the resection is an important prognostic factor. The 5-year tumour recurrence rates are reported as between 39 and 58%, and in those patients with residual solid tumour, radiotherapy is administered to reduce the risk of recurrence. However, in patients with gross total resection the role of early adjuvant radiotherapy has not been defined.

Meningioma

A systematic review concluded that since atypical meningioma preferentially recur within 5 years, future studies should investigate the role of early adjuvant radiotherapy (RT) in these patients. There have been no randomised controlled trials (RCT) in this tumour population. Currently the treatment decision for adjuvant RT varies according to the patient, surgeon, and Radiation Oncologist's preference. Some European expert opinion recommends that all atypical meningioma patients should have postoperative RT. Whilst the use of RT may avoid the need for further surgical procedures, this must be balanced against the potential risks of RT, which include temporary partial hair loss, neurocognitive impairment, hypopituitarism, focal neurocognitive deficits, and radiation-induced tumours. Equally, tumour recurrence can also affect neurocognitive function and quality of life. Tumours that recur can be treated with further surgery and RT.

The ROAM/EORTC-1308 trial is funded by the National Institute of Health Research Health Technology Assessment programme (12/173/14) to determine whether early adjuvant RT reduces tumour recurrence compared to active monitoring in patients with newly diagnosed atypical meningioma who have undergone gross total resection *(Jenkinson MD, et al. Radiotherapy versus Observation following surgical resection of Atypical Meningioma (the ROAM trial). Neuro-Oncology. 2014 16(11): 1560-1561*). The international sponsor is the Walton Centre, and the study is coordinated by Clinical Trials Research Centre at University of Liverpool (http://roam-trial.org.uk/). A total of 190 patients will be recruited from 20 adult regional neurosurgery units in the UK and Ireland. As part of an intergroup collaboration with the European Organisation for Research and Treatment of Cancer (EORTC) the trial will also open in 22 centres in mainland Europe and up to 12 sites in Australia via collaboration with the TransTasman Radiation Oncology Group (TROG).

Adult patients undergoing gross total resection of intracranial atypical meningioma are eligible. Patients with multiple meningioma, optic nerve sheath meningioma, previous intracranial tumour, previous cranial RT and neurofibromatosis will be excluded. Informed consent will be obtained from patients who will be randomised 1:1 between early adjuvant fractionated external beam RT for 6 weeks (60 Gy in 30 fractions) and active surveillance with serial MRI scans.

The primary outcome measure is time to MRI evidence of tumour recurrence (progression-free survival). Secondary outcome measures include assessing the toxicity of the RT, the quality of life, neurocognitive function, time to second line treatment, time to death (overall survival) and incremental cost per quality-adjusted life year gained.

It is estimated that approximately 3-4 patients per annum will be enrolled in SLRON per year and the trial will run for a total of 10 years; it is currently open in 25 sites and 22 patients have been recruited.

Cancer Trials Ireland is delighted to be forging these strong collaborative links with UK-based trials which may open opportunities for Irish patients to participate in future brain tumour trials. The best outcomes for brain tumour patients are when they are treated by specialised multi-disciplinary teams in large units; incorporating diagnostics, treatment, participation in international clinical trials and follow-up. The study also helps raise awareness of this uncommon group of cancers.

€6 million international study to improve treatment for colorectal cancer

Cancer Trials Ireland is delighted to be a member of the 14 strong consortium of international partners from 8 countries leading the €6 million "COLOSSUS" project.

The 5 year project, which includes a translational trial run in Ireland, Germany and Spain, aims to provide new and more effective ways to classify and treat patients with colorectal cancer.

The project brings together a multi-disciplinary team with expertise in cancer immunology, systems biology, computational modelling, bioinformatics, 'omics analysis, clinical oncology/pathology, pre-clinical research, medical imaging, clinical trials, health economics and patient engagement.

The project is led by Professor Annette Byrne, Associate Professor, RCSI Dept of Physiology and Medical Physics and RCSI Centre for Systems Medicine.

Dr Verena Murphy, Translational Research Leader, is Cancer Trials Ireland's representative on the project. She said that the project will focus on a genetically defined form of colorectal cancer which is incurable once patients develop resistance to existing therapies.

Dr Verena Murphy
Translational Research Leader

"This particular form of colorectal cancer is called microsatellite stable RAS mutant (MSS RAS mt) disease. The ultimate aim of this new project is to better classify subtypes of this condition and deliver new personalised treatments and improved patient outcomes specifically for this patient sub-group," she said.

The team has secured approximately €6 million in competitive non-exchequer funding for the "COLOSSUS" project which is supported by the European Commission's Horizon 2020 programme.

Colorectal cancer is the third most common cancer in Europe with an estimated 420,000 cases and 150,000 related deaths (2012). Metastatic colorectal cancer (mCRC) is a complex disease with high prevalence, substantial human cost and significant economic impact, both in Europe and globally. Of total colorectal cancer cases, it is thought that approximately 50-55 % involve RAS mutations, the form of mCRC addressed in the project.

The COLOSSUS consortium will study patient samples and apply advanced multi-omic computational modelling approaches to identify new MSS RAS mt specific subtypes.

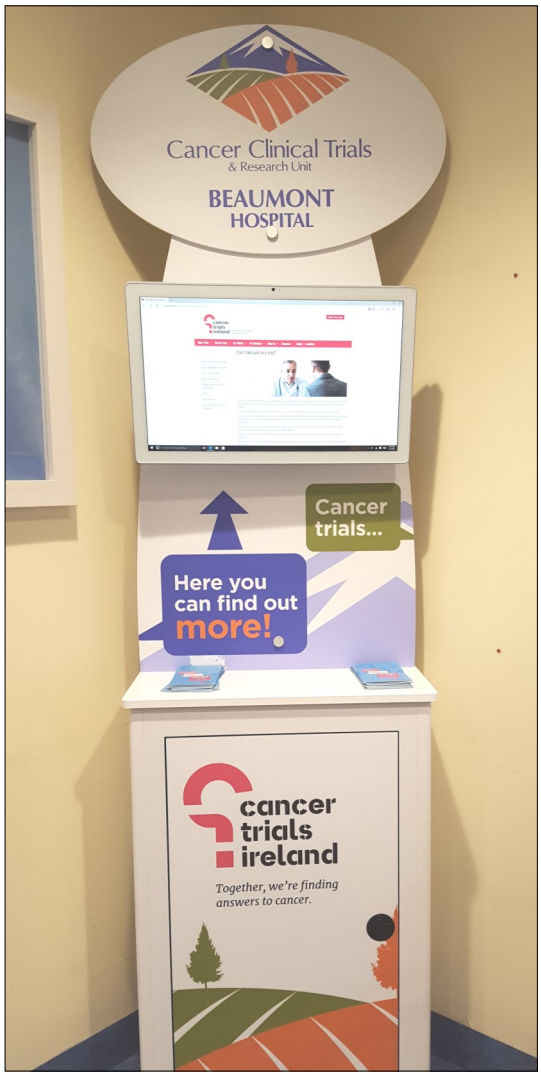
This strategy will predict patient response and enable the design of more targeted and personalised treatments. Newly described MSS RAS mt classifiers will be validated as novel patient stratification tools within the COLOSSUS trial, a multicentre clinical study for advanced MSS RAS mt mCRC patients.

Professor Annette Byrne (RCSI), Professor Jochen Prehn (RCSI) and Dr Rodrigo Dienstmann (Vall D'Hebron Institute of Oncology, Spain) are the Scientific Leads for the project.

Prof Josep Taberno (Spain), Prof Matthias Ebert (Germany) and Prof Ray McDermott (Ireland) are the Chief Investigators for the associated study protocol, which will be co-ordinated, managed and sponsored by Cancer Trials Ireland.

The full project team comprises researchers from RCSI; Vall D'Hebron Institute of Oncology, Spain; University College Dublin, Ireland; Institute Of Cancer Research - Royal Cancer Hospital, UK; VIB, Belgium; Ruprecht-Karls-Universitaet Heidelberg, Germany; Universita Degli Studi Di Torino, Italy; Institut National De La Sante Et De La Recherche Medicale, France; Cancer Trials Ireland; Optimata Ltd, Israel; Genexplain Gmbh, Germany; Haliodx, France; Epigenomics AG, Germany; and Pintail Ltd, Ireland.

Beaumont Online



The oncology unit at Beaumont Hospital in Dublin has installed a purpose built booth to enable patients access online information and videos on cancer trials during their visit—a great new initiative from the team.

First Ronnie Cox Award goes towards gastrointestinal translational study

In 2017 Cancer Trials Ireland received a very generous donation from family and friends of Ronnie Cox who sadly passed away in June 2016.

The donation was raised through a fundraiser with the Lough Conn Anglers which Ronnie organised before he died.

The Lough Conn Anglers have decided to continue to raise money for Cancer Trials Ireland, for which we are greatly appreciative.

To ensure Ronnie's legacy is remembered and its impact identifiable, we have established the Ronnie Cox Award. Dr Cha Len Lee is the first recipient of the Award and she will be using the Award to part fund her pilot study among patients on the TRI-LARC trial (CTRIAL-IE 12-38).

The study is designed to determine the utility of circulating tumour DNA (ctDNA) to track clonal evolution in locally advanced rectal cancer.

Unfortunately, only 15-30% of patients with locally advanced rectal cancer reach a complete pathological response to the current standard therapy, which means that after treatment there is no residual tumour visible.

In these patients a high rate of relapse and death is seen which might be attributed to a subpopulation of tumour cells which are resistant to the current standard therapy.

It is known that certain tumours shed cells into the blood stream, which are called 'circulating tumour cells'. These cells can either stay intact or break up and release their DNA; both represent a good source to study the tumour without taking repeated biopsies from the tumour itself. In rectal cancer it has been shown that the level of circulating tumour cells/circulating tumour DNA in the blood correlates with the amount of residual tumour in the body.

The present pilot study will focus on the circulating tumour DNA in 10 patients who are enrolled in the TRI-LARC clinical trial. Blood samples will be collected before, during and after treatment and will be analysed for mutations and markers, which could give further information about the characteristics and behaviour of the resistant sub population of tumour cells from residual tumour.

Dr Cha Len Lee said she was honoured to receive the Ronnie Cox Award as it not only recognised the clinical relevance and importance of her research but also reflects positively on her commitment to advance patient-focused research in gastrointestinal malignancies.

"The Award signifies that young oncologists in training like me can and should become involved in cancer research projects and make a meaningful contribution at an early stage of their career", she said.

"In the short term, it will assist me to commit to this translational work opportunity full-time and the newfound knowledge I will acquire during the course of this project will open up multiple opportunities for me to pursue collaborations with other centres and build on my career as a cancer scientist."

This pilot study will significantly expand our understanding of treatment responsiveness and resistance in locally advanced rectal cancer and may identify novel targets for early identification of resistance to neoadjuvant chemoradiotherapy and modulation of treatment sensitivity in this disease.

The identification of mutations and copy number aberrations that emerge or enrich during treatment will allow us to design future studies to validate the roles played by these processes in disease resistance and progression to the metastatic setting.

Any novel mutations that we find and then validate will be functionally studied in the future, and those mutations that enrich or occur de novo in residual resistant tumours at surgery (suggesting a role in neoadjuvant chemoradiotherapy (NACRT) resistance) will be prioritised. The potential role of these aberrations as clinically useful biomarkers and as new treatment targets for future drug development will also need to be interrogated.

CLL trial paper wins Award

Congratulations to Dr Niamh Appleby who was first author on a paper on the CLL-Ireland trial, led by Professor Elisabeth Vandenberghe, which won the RCPI Faculty of Pathology John D. Kennedy Medal award.

Pictured with Prof Hilary Humphreys (Dean) at the Faculty of Pathology Symposium is (left) Dr Niamh Appleby and (right) Dr Siobhan Glavey (winner of the George Greene Medal).

The award winning paper was entitled: "Risk adjusted therapy in chronic lymphocytic leukemia: a phase II cancer trials Ireland (CTRIAL-IE [ICORG 07-01]) study of fludarabine, cyclophosphamide, and rituximab therapy evaluating response adapted, abbreviated frontline therapy with FCR in non-del(17p) CLL".

Bon Secours celebrates 20 years of Oncology Clinical Trials

Aoife O'Shea, Oncology Trials Coordinator at the Bon Secours Hospital, Cork.

This year we are celebrating 20 years of Oncology Clinical Trials at the Bon Secours Hospital, Cork, so when I was asked to write this article, I was only too delighted to highlight our work.

Thankfully, the Bon Secours Hospital management team has been very supportive of the service we provide and since I started in the research department in 2012 we have had a significant expansion of our service.

We have expanded from one research nurse to two full time research nurses, a data manager and a part-time trials pharmacist. The team also consists of four Investigators, dedicated radiologists, pathologists, laboratory staff, surgeons and oncology nurses.

Through a lot of hard work, and with these extra resources, it is now evident that our reputation is growing as a clinical research site of interest, both for Cancer Trials Ireland and for commercial sponsors.

At the end of 2016 we set a goal of expanding our clinical trial portfolio from breast and colon cancer trials to ovarian and pancreatic cancers. We also set goals to commence trials involving immunotherapy to give our patients access to better drugs. As a result, we opened the B9991010 Javelin 100 trial (CTRIAL-IE 16-15) of immunotherapy in combination with chemotherapy for newly diagnosed ovarian cancer at the end of 2016. In the space of 12 months we signed 8 patients on to the protocol with 4 patients randomised. This phase III randomised controlled trial (RCT) has given our patients access to a potential breakthrough treatment for ovarian cancer and all patients remain on trial.

> "As the oncology clinical trial service has expanded so has the need to be innovative ….."

We further expanded the profile of clinical trials in the Gynaecology DSSG and opened the Forward-1 trial (CTRIAL -IE 16-68) . This was of particular interest as we were conscious of the need for better treatments for our patients with platinum resistant ovarian cancer for whom the treatment options are so limited.

The Forward-1 trial gives our patients access to mirvetuximab soravtansine, an anti-body drug conjugate which targets folate receptor-α on the surface of the cancer cell. Ireland has the highest accrual per capita with 9 patients on treatment, 7 of whom are at the Bon Secours Hospital, Cork. Dr Murphy is now the Irish Chief Investigator for the Forward-1 trial and is hopeful to bring further trials with this unique anti-body drug conjugate to Ireland as we strengthen ties with Immunogen.

As the oncology clinical trial service has expanded so has the need to be innovative to ensure high standards of care. It has been a challenging period of growth but we see the challenges as opportunities for development of the service. Several innovations such as the expanded role of the research nurse and the creation of the weekly research clinics have improved patient satisfaction. Another key change in recent times has concerned the management of trial blood samples. Previously, these samples were logged on paper biological sample log forms. While this system was satisfactory when we had few patients on trials, we needed a more efficient system as the numbers of patients rose and we found we were spending too much time tracking samples.

(l to r) Dr Conleth Murphy (Consultant Oncologist and Principal Investigator), Aoife O'Shea (Trials Coordinator), and Dr Brian Bird (Consultant Oncologist and Principal Investigator).

> "…. we are a team passionate about improving the options for our patients."

In collaboration with the pathology department we initiated electronic trackers for samples (blood, tumour tissue, etc.) from patients participating in all clinical trials. This electronic system has made a huge difference. The research nurse no longer needs to spend time daily in the pathology department.

It has also eased the burden of trial work on the staff in the specimen reception area. We can be confident that samples collected from patients participating in clinical trials are being handled correctly to ensure that the data generated is of high quality as befits the generosity of the patients donating these samples for research.

All of this activity represents serious hard work but we are a team passionate about improving the options for our patients. The patients remain at the centre of every decision we make regarding clinical trials, and we have looked after some incredible people. I would like to take this opportunity to thank our patients and Cancer Trials Ireland which are such a wonderful resource for everyone involved in cancer research in Ireland.

Academic publications from Cancer Trial Ireland Investigators

Dr Orla Casey, Translational Project Manager, Cancer Trials Ireland

Here's a list of publications, since our last DSSG Digest, in leading academic peer reviewed journals in cancer research in which Cancer Trials Ireland investigators have participated.

For further information in relation to these publications or if you would like your publications included in our next listing please contact orla.casey@cancertrials.ie

Breast

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

Colleoni, M., W. Luo, P. Karlsson, J. Chirgwin, S. Aebi, G. Jerusalem, P. Neven, E. Hitre, M. P. Graas, E. Simoncini, C. Kamby, A. Thompson, S. Loibl, J. Gavilá, K. Kuroi, C. Marth, B. Müller, S. O'Reilly, V. Di Lauro, A. Gombos, T. Ruhstaller, H. Burstein, K. Ribi, J. Bernhard, G. Viale, R. Maibach, M. Rabaglio-Poretti, R. D. Gelber, A. S. Coates, A. Di Leo, M. M. Regan, A. Goldhirsch and S. Investigators (2018). "**Extended adjuvant intermittent letrozole versus continuous letrozole in postmenopausal women with breast cancer (SOLE): a multicentre, open-label, randomised, phase 3 trial.**" Lancet Oncol 19(1): 127-138.

Cancer Trials Ireland Study Number: short name. 98-01: BIG 2-98

Sonnenblick, A., R. Salgado, S. Brohée, T. Zahavi, T. Peretz, G. Van den Eynden, G. Rouas, A. Salmon, P. A. Francis, A. Di Leo, J. P. A. Crown, G. Viale, L. Daly, B. Javdan, S. Fujisawa, E. De Azambuja, A. Lieveke, M. J. Piccart, J. F. Bromberg and C. Sotiriou (2018). **"p-STAT3 in luminal breast cancer: Integrated RNA-protein pooled analysis and results from the BIG 2-98 phase III trial."** Int J Oncol **52**(2): 424-432.

Genitourinary

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

Medipally, D. K., A. Maguire, J. Bryant, J. Armstrong, M. Dunne, M. Finn, F. M. Lyng and A. D. Meade (2017). "**Development of a high throughput (HT) Raman spectroscopy method for rapid screening of liquid blood plasma from prostate cancer patients.**" Analyst 142(8): 1216-1226.

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, N. W. Clarke, L. Collette, J. J. Dignam, K. Fizazi, W. R. Paruleker, H. M. Sandler, M. R. Sydes, B. Tombal, S. G. Williams, C. J. Sweeney and I. W. Group (2017). "**Metastasis-Free Survival Is a Strong Surrogate of Overall Survival in Localized Prostate Cancer.**" J Clin Oncol 35(27): 3097-3104.

* Cancer Trials Ireland author listed in supplementary materials

Gynaecological

Disease Area Consensus Document

Karam, A., J. A. Ledermann, J. W. Kim, J. Sehouli, K. Lu, C. Gourley, N. Katsumata, R. A. Burger, B. H. Nam, M. Bacon, C. Ng, J. Pfisterer, R. L. M. Bekkers, A. Casado Herráez, A. Redondo, H. Fujiwara, N. Gleeson, O. Rosengarten, G. Scambia, J. Zhu, A. Okamoto, G. Stuart, K. Ochiai and p. o. t. t. O. C. C. Conference (2017). "**Fifth Ovarian Cancer Consensus Conference of the Gynecologic Cancer InterGroup: first-line interventions.**" Ann Oncol 28(4): 711-717.

Cancer Trials Ireland Study Number: short name. 10-12: ANZGOG-0701 symptom benefit study

King, M. T., M. R. Stockler, R. L. O'Connell, L. Buizen, F. Joly, A. Lanceley, F. Hilpert, A. Okamoto, E. Aotani, J. Bryce, P. Donnellan, A. Oza, E. Avall-Lundqvist, J. S. Berek, J. Sehouli, A. Feeney, D. Berton-Rigaud, D. S. J. Costa, M. L. Friedlander and G. S. B. group (2018). **"Measuring what matters MOST: validation of the Measure of Ovarian Symptoms and Treatment, a patient-reported outcome measure of symptom burden and impact of chemotherapy in recurrent ovarian cancer."** Qual Life Res 27(1): 59-74.

Cancer Trials Ireland Study Number: short name. 10-12: ANZGOG-0701 symptom benefit study

Roncolato, F. T., D. Berton-Rigaud, R. O'Connell, A. Lanceley, J. Sehouli, L. Buizen, A. Okamoto, E. Aotani, D. Lorusso, P. Donnellan, A. Oza, E. Avall-Lundqvist, J. Berek, F. Hilpert, J. A. Ledermann, M. C. Kaminsky, M. R. Stockler, M. T. King and M. Friedlander (2018). **"Validation of the modified Glasgow Prognostic Score (mGPS) in recurrent ovarian cancer (ROC) - Analysis of patients enrolled in the GCIG Symptom Benefit Study (SBS)."** Gynecol Oncol 148(1): 36-41.

Lung

Cancer Trials Ireland number: short name: 14-13: MSD MK-3475-024 / KEYNOTE-024

Brahmer, J. R., D. Rodríguez-Abreu, A. G. Robinson, R. Hui, T. Csőszi, A. Fülöp, M. Gottfried, N. Peled, A. Tafreshi, S. Cuffe, M. O'Brien, S. Rao, K. Hotta, J. Zhang, G. M. Lubiniecki, A. C. Deitz, R. Rangwala and M. Reck (2017). "**Health-related quality-of-life results for pembrolizumab versus chemotherapy in advanced, PD-L1-positive NSCLC (KEYNOTE-024): a multicentre, international, randomised, open-label phase 3 trial.**" Lancet Oncol 18(12): 1600-1609.

Cancer Trials Ireland number: short name: 99-09: 3DCRT Lung

Cagney, D. N., P. G. Thirion, M. T. Dunne, C. Fleming, D. Fitzpatrick, C. M. O'Shea, M. A. Finn, S. O'Sullivan, C. Booth, C. D. Collins, S. J. Buckney, A. Shannon and J. G. Armstrong (2018). "**A Phase II Toxicity End Point Trial (ICORG 99-09) of Accelerated Dose-escalated Hypofractionated Radiation in Non-small Cell Lung Cancer**." Clin Oncol (R Coll Radiol) 30(1): 30-38.

Cancer Trials Ireland Study Number: short name. 06-36: ECOG E1505

Wakelee, H. A., S. E. Dahlberg, S. M. Keller, W. J. Tester, D. R. Gandara, S. L. Graziano, A. A. Adjei, N. B. Leighl, S. C. Aisner, J. M. Rothman, J. D. Patel, M. D. Sborov, S. R. McDermott, R. Perez-Soler, A. M. Traynor, C. Butts, T. Evans, A. Shafqat, A. E. Chapman, S. S. Kasbari, L. Horn, S. S. Ramalingam, J. H. Schiller and ECOG-ACRIN (2017). "**Adjuvant chemotherapy with or without bevacizumab in patients with resected non-small-cell lung cancer (E1505): an open-label, multicentre, randomised, phase 3 trial.**" Lancet Oncol 18(12): 1610-1623.

Cancer Trials Ireland studies open to accrual

Purple = Industry studies Green = Cancer Trials Ireland studies Orange = Collaborative Group studies

DSSG	General Group	Cancer Trials Ireland No:	Study Name:
Breast	Trans	09-07	Breast Cancer Proteomics and Molecular Heterogeneity
Breast	Trans	10-11	Circulating miRNA
Breast	Trans	10-15	Exosomal HER2
Breast	Trans	10-16	Ovarian Reserve
Breast	Trans	12-09	CharactHer
Breast	Trans	12-30	TAILORx Tissue Bank
Breast	Trans	15-34	Recurrence Score
Breast	Trans	12-40	EORTC 10085
Breast	Clinical	15-17	PALLAS
Breast	Clinical	15-49	NeoTRIP
Breast	Clinical	14-11	PENELOPE-B
Breast	Clinical	14-22	16298 Radium 223 in BC (Bayer) (closed to accrual Nov 2017
Breast	Clinical	15-02	PantHER
Breast	Radio	15-03	NSABP B-51
Breast	Clinical	15-16	FLIPPER
Breast	Clinical	16-20	POSITIVE
Breast	Clinical	17-08	KEYNOTE-522 in TNBC (MSD)
CNS	Trans	08-13	Serum Protein Markers for Glioma
CNS	Clinical	15-29	M13-813 INTELLANCE 1
CNS	Radio	15-41	ROAM **(New)**
GI	Clinical	10-14	Neo-AEGIS
GI	Trans	12-27	CRAC Plasma Biomarkers
GI	Trans	12-31	PDAC Plasma Biomarkers
GI	Radio	12-38	TRI-LARC
GI	Clinical	14-19	BMS CA209-142 (CheckMate 142)
GI	Clinical	14-20	GERCOR STRATEGIC-1
GI	Clinical	16-29	MK 3475-181
GI	Clinical	16-73	BMS CA209-577
GI	Clinical	16-77	ARMO Artist **(New)**
GI	Clinical	16-58	MErCuRIC **(New)**
GU	Clinical	11-34	TIGER
GU	Clinical	13-09	PEACE-1
GU	Clinical	13-23	Neo-adjuvant Abiraterone prostate
GU	Trans	14-04	iPROSPECT
GU	Clinical	14-07	ENZARAD
GU	Clinical	15-19	CARD
GU	Radio	15-46	PACE (closed to recruitment 05-Jan-2018)
GU	Trans	16-07	IPCOR
GU	Clinical	16-21	PEACE III
GU	Clinical	16-27	Keynote 426 (closed to recruitment 24-Jan-2018)
GU	Clinical	16-62	Roche MO29983/ Saul
GU	Clinical	16-63	Roche IMmotion010
GU	Clinical	16-69	Eisai E7080-G000-307
GU	Clinical	16-70	BMS CA209-274
GU	Clinical	17-03	Roche C039303
GU	Clinical	17-05	MSD MK3475-361/ KEYNOTE-361
GU	Clinical	17-40	MSD MK3475-698/KEYNOTE-698
GU	Clinical	17-41	MSD MK3475-672/KEYNOTE-672
Gynae	Radio	09-06	Endometrial - IMRT v 3D RT
Gynae	Clinical	11-29	ICON8B
Gynae	Clinical	14-02	SHAPE
Gynae	Clinical	16-04	PRIMA

Cancer Trials Ireland studies open to accrual

Purple = Industry studies Green = Cancer Trials Ireland studies Orange = Collaborative Group studies

DSSG	General Group	Cancer Trials Ireland No:	Study Name:
Gynae	Clinical	16-05	JAVELIN 100
Gynae	Clinical	16-68	FORWARD 1
H & L	Clinical	15-09	ARROVEN PASS Study (closed to recruitment since last DSSG)
H & L	Clinical	15-38	CHRONOS-3
H & L	Clinical	15-36	Protocol 04-30 (INSPIRE)
H & L	Clinical	16-02	CyBorD-DARA
H & L	Clinical	16-09	Astellas 2215 CL 0301
H & L	Clinical	16-60	CLL13
H & L	Clinical	16-79	M15-550 (VENICE 1) (closed to recruitment since last DSSG)
H & L	Clinical	17-06	CHRONOS 4
H & L	Clinical	17-07	CheckMate 744
Head & Neck	Clinical	16-54	BMS CA209-714
Head & Neck	Clinical	17-20	BMS CA 209□651 **(New)**
Head & Neck	Radio&IMP	17-22	JAVELIN 100 Head and Neck **(New)**
Head & Neck	Radio	16-23	DARS **(New)**
Lung	Clinical	12-53	ETOP SPLENDOUR (closed to recruitment since last DSSG)
Lung	Radio	15-05	Oligo-Recurrent Metastatic Disease
Lung	Radio	15-47	INTENSE (on hold)
Lung	Clinical	17-10	MK3475-604
Lung	Clinical	16-61	ETOP BOOSTER
Lung	Clinical	15-40	MK3475-091 (PEARLS)
Lung	Clinical	17-36	MK3475-654
Lung	Clinical	16-25	Roche MO29872
Lung	Clinical	17-35	MK3475-715
Lung	Clinical	16-80	Abbvie Meru M16-298
Lung	Clinical	17-23	BMS CA209-9LA
Melanoma	Trans	13-22	SYS-ACT
Melanoma	Trans	17-25	DESCRIBE III
Melanoma	Clinical	17-39	BMS CA017-055
Basket	Trans	08-40	SNP Study
Basket	Clinical	15-42	LOXO-101
Basket	Clinical	16-64	Roche MO29518
Paediatric	Translational	16-30	AALL08B1
Paediatric	Clinical Trial	16-31	AALL0932
Paediatric	Clinical Trial	16-32	AALL1131
Paediatric	Clinical Trial	16-33	UKALL 2011
Paediatric	Translational	16-34	LLR Leukaemia Cell bank
Paediatric	Translational	16-36	EuroNet PHL-C1 (HD 2007 10)
Paediatric	Clinical Trial	16-38	NBL.HR-NBL-1.7/Siopen
Paediatric	Clinical Trial	16-39	LTI Study
Paediatric	Clinical Trial	16-40	NBL BEACON
Paediatric	Clinical Trial	16-41	LINES
Paediatric	Translational	16-42	IMPORT
Paediatric	Translational	16-43	Tumour Banking Study
Paediatric	Translational	16-44	EU-Rhabdoid Registry
Paediatric	Translational	16-45	FACT
Paediatric	Translational	16-46	EWOG-SAA 2010
Paediatric	Clinical Trial	16-47	STS 2006 04 - RMS 2005
Paediatric	Clinical Trial	16-50	AZA-JMML-001
Paediatric	Translational	16-51	MESRAT Study
Paediatric	Clinical Trial	16-52	EURO EWING 2012
Paediatric	Clinical Trial	16-53	Interfant 06

Collaboration at BioPharma Ambition 2018

Cancer Trials Ireland and the InterTrade Ireland team have been working together since first meeting at the 2016 BioPharma Ambition conference.

The goal is to develop a strategic cross border partnership with our colleagues in the Northern Ireland Cancer Trials Network (NICTN).

Our clinical leads, Prof Bryan Hennessy and Dr Linda Coate, in collaboration with the team in Northern Ireland including Professors Richard Wilson, Joe O'Sullivan and Melanie Morris – have identified a number of trials which can be opened on an all-island basis.

Further to these discussions, there will be a delegation from NICTN attending our Spring DSSG. InterTradeIreland is interested in cancer trials because in 2015 it published a report that identified the potential for closer cooperation between Northern Ireland and Ireland in a number of sectors. One of these areas identified was Cross-border interoperable clinical trial networks – to reduce the fragmentation and offer patient recruitment at a more efficient scale.

We are grateful to Karen McCallion and Aidan Gough at InterTrade Ireland for their continued support. Thanks to them, we were delighted to have been part the important

discussion on unblocking the potential of collaboration at this year's BioPharma Ambition Conference (2018).

Session participants included (l to r) Dr Muhammed Ali, Executive Director, Regional Healthcare Solutions Strategy, MSD International; Dr Richard L. Schilsky, Senior Vice President and Chief Medical Officer, American Society of Clinical Oncology (ASCO); Eibhlín Mulroe, CEO, Cancer Trials Ireland and session chair; Dr Janice Bailey, Assistant Director, HSC R & D, Public Health Agency; Dr Pat O' Mahony, Chief Executive, Clinical Research Development Ireland (CRDI) and Prof Bryan Hennessy, Clinical Lead, Cancer Trials Ireland.

Some recently opened trials

ETOP 10-16 BOOSTER (CTRIAL-IE 16-61)
The purpose of the trial is to compare osimertinib and bevacizumab versus osimertinib alone for patients with advanced non-small cell lung cancer

E7080-G000-307 (CTRIAL-IE 16-69)
The main purpose of this trial is to assess the safety and efficacy of the drug lenvatinib in combination with everolimus or pembrolizumab versus sunitinib alone in first-line treatment of participants with advanced renal cell carcinoma.

BMS CA 209-651 (CTRIAL-IE 17-20)
The main purpose of this trial is to compare the effectiveness of nivolumab and ipilimumab with the EXTREME study regimen as first line treatment in patients with recurrent or metastatic squamous cell of the head and neck cancer.

Roche M029872 (CTRIAL-IE 16-15)
The main purpose of this trial is to compare atezolizumab versus single agent chemotherapy in patients who have not yet received any treatment for locally advanced or metastatic Non-Small Cell Lung Cancer (NSCLC) who are unsuitable for platinum-containing therapy.

BMS CA 209-9LA (CTRIAL IE 17-23)
A Study of Nivolumab plus Ipilimumab in Combination with Chemotherapy vs Chemotherapy alone as First Line Therapy in Stage IV Non-Small Cell Lung Cancer (NSCLC).

MErCuRIC1 (CTRIAL-IE 16-58)
The main purpose of this trial is to test a new combination of two drugs, Binimetinib and Crizotinib for treatment of colorectal cancer.

DARS (CTRIAL-IE 16-23)
The aim of the trial is to compare the people having the Do-IMRT with those having standard IMRT treatment for head and neck cancer in or close to the throat

ARMO Artist (CTRIAL-IE 16-77)
This trial aims to compare the effectiveness of a drug called AM0010 in combination with FOLFOX with FOLFOX alone. measured by overall survival, in patients with metastatic pancreatic cancer.

CA017-055 (CTRIAL-IE 17-39)
This trial aims to demonstrate that treatment with IDO1 inhibitor BMS-986205 in combination with nivolumab will have clinical activity in participants with previously untreated, unresectable or metastatic melanoma.

DSSG Meetings

In line with practices in other international research groups, in future we will be holding just 2 face to face DSSG meetings per year. The next face to face meeting will be in October 2018—date will be confirmed shortly. The various DSSG groups will hold online WebEx meetings as required between the March and October 2018 meetings.