



*Publications update* (Pages 10-11)

# DSSG *Digest*

*Members only version*

*Accruals data & hyperlinks to online  
trials details on pages 12-15.*

**Autumn 2017 – Vol 12 Issue 3**

The DSSG Digest has the most up to date news and listing of cancer trials that are underway in Ireland. It is published by Cancer Trials Ireland three times a year.



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

Supported by





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

## The recently approved performance metrics will ensure funding to our research units is equitable

In our Summer DSSG Digest I outlined the changes we have made to the Terms of Reference of the Clinical Executive Committee (CEC). These are being implemented and are working well, evidenced by the outputs of our most recent meeting which was very productive.

The August meeting elected the following modality representatives to the CEC:

- Dr Pierre Thirion; Radiation Oncology.
- Prof Ronan Cahill; Surgery.
- Prof Bill Watson and Prof Joe Duffy; As two nominations were received for Translational there was an election. Prof Watson was elected as a voting member and Prof Duffy as a non-voting member.

The CEC considered and approved a Policy for the conduct of trials involving Investigational Medicinal Product (IMP) and Radiotherapy (RT).

A Collaboration Agreement for the conduct of a combination IMP/RT trial was also considered and approved to form the basis of the relationship between investigators working on multi-modality trials.

The committee received nominations for DSSG Translational Co-Chairs from :

- Prof Bill Watson; GU
- Prof Jochen Prehn; GI
- Prof Maureen O'Sullivan; Paediatric:
- Prof Liam Gallagher and Prof Joe Duffy, Breast

The CEC is now seeking nominations for DSSG Translational Co-Chairs in the following areas: Lung, Melanoma, Central Nervous System, Head & Neck, and Lymphoma & Haematology. If you would like to discuss being nominated please feel free to contact me.

The CEC also received a very considered presentation from Prof John Reynolds who is Chief Investigator on the NeoAegis cancer trial. This is the largest in-house sponsored trial and members of the CEC provided very helpful guidance on the trial's progression.

The other significant item discussed at the meeting was the great progress being made with our performance metrics.

Following the decision by the Board that future HRB grants would be issued to our research units around the country in two tranches (a core payment and a performance related payment), the CEC received an update on the development of performance metrics to inform the second payment.

These metrics currently cover three areas of performance.

1. Study start up/timelines; time from final approval being received to site activation; 60 day target.
2. Accrual of patients to trials; variance from target.
3. DSSG attendance & engagement; Consultant Members to attend in person for 2 out of 3 DSSG meetings annually, Members of the CEC to attend CEC meetings in person or remotely for 4 out of 5 meetings and sites to participate, contribute or present at local events during International Clinical Trials Day.

Data collection and quality will be included as a fourth performance metric during 2018.

Draft data for Jan to Jun 2017 was presented to the meeting. It showed that 31 new trials were opened during this period and six research units had not opened any new trials.

While the data requires further validation, it provides a good indication where improvements are needed. For example, it shows that where there is a concerted effort by research units and the HQ team, trials can be activated within the 60 day activation target from final approval being received.

The data shows that, even though most research units have not met this target during the first six months of this year, it is a realistic goal.

An example of a performance dashboard that is being developed to present the compiled data in a meaningful way was also presented.

This is a really important project and we look forward to receiving the next update at the end of the year.

It will ensure that funding can be allocated equitably based on performance.

# Ambitions in new cancer strategy will remain aspirations if not funded



*Eibhlin Mulroe, CEO,  
Cancer Trials Ireland.*

The National Cancer Strategy is a potential game changer. Its implementation could take us significantly closer to finding successful treatments for all types of cancer.

We are very pleased with its recommendations in the cancer trials arena. It recommends establishing a National Cancer Research Group and we look forward to working with colleagues at the National Cancer Control Programme (NCCP) to get the Group up and running.

The strategy acknowledges that cancer trials should be a core activity of cancer centres and recommends that they be fully integrated into cancer care delivery. This will ensure cancer trials are central to the treatment options available to people with cancer and are not outliers.

The recommendation to find a way to protect the time of newly appointed cancer consultants and Advanced Nurse Practitioners for research will bring more career stability. We would like to see this expanded to existing consultants.

The target to double the number of people with cancer who can access therapeutic cancer trials, from the current 3% to 6% by 2020 will not only save the HSE millions of euro in drug costs (currently at least €6.5 million annually) it will provide more patients with access to promising new treatments that would otherwise not be available.

## **Funding Barrier**

However, there is a significant barrier to implementing these recommendations and KPIs. In a nutshell, it's funding.

Given that Cancer Trials Ireland must play a central role in enabling the NCCP meet its target of doubling the number of people with cancer who can access therapeutic cancer trials, the absence of adequate funding is a barrier that will make it impossible for the NCCP to achieve this target.

In 2015 the HRB reduced its grant to Cancer Trials Ireland by 20% for the grant period 2016-2018. In concrete terms this is a cut of approximately €750,000 per year.

While having to adjust to cope with these cuts, we have also had to do a lot more with less.

Following the international peer review in 2015 as part of its grant process, the HRB required Cancer Trials Ireland to

introduce a range of additional and significant management and governance processes.

In addition, we must fully comply with the HPRA regulatory requirements in relation to opening and running cancer trials.

While these initiatives introduced by the HRB and the HPRA requirements are positive, they are costly to implement.

In addition to the declining grants, additional governance requirements, the funding that is available from sources such as international collaborative groups and pharmaceutical companies is contracting.

While we very much welcome the latest cancer strategy, we look forward to seeing the budget supports to enable its implementation.

## **Requirements**

To support the NCCP in achieving the stated cancer trials KPI we require the following:

- Reverse the funding cut to our cancer trials research units and head office.
- An additional €1.2 million per year to support cancer trials research units and head office over the next 3 years.
- Protected time for clinicians and medical teams so they can do more research and foster a greater culture of research in our hospitals.
- Ring-fence multi-annual funding to which cancer trials research units can apply for capital and staff.
- A uniform process for contracts relating to clinical trials between Pharma/ International Collaborative Groups/CROs and Hospitals.

Meeting these requirements will enable Cancer Trials Ireland and other clinical research organisations extend the impact of the Exchequer's investment in cancer and clinical trials for the economy and for patients with cancer.

Without them, the ambitions of the National Cancer Strategy will remain aspirational.



## Prostate trial extended to St Luke's Radiation Oncology Network

The first large scale trial to test the benefits of using a specialised type of radiotherapy to treat early stage prostate cancer has been extended to include St Luke's Radiation Oncology Network (SLRON) in Dublin. The trial was opened in Beacon Hospital, Dublin, earlier this year,

The PACE trial is being led internationally by The Royal Marsden NHS Foundation Trust in the UK, and is coordinated by The Institute of Cancer Research, London. In Ireland, the trial is managed by Cancer Trials Ireland.

The trial will involve 860 men across the UK, Ireland and Canada. It is expected 6-8 men in Ireland will take part. Dr Alina Mihai, who is leading the trial in the Beacon Hospital, has recruited 4 patients since opening the trial in March.

The trial will compare the benefits of Stereotactic Body Radiotherapy (SBRT) with conventional radiotherapy for patients with early stage prostate cancer.

SBRT was first used in the treatment of brain tumours, and more recently in early stage, medically inoperable, lung cancers.

It differs from conventional radiotherapy as it delivers high doses of radiation to small tumours from different directions at the same time, with a high degree of accuracy. It has been shown to minimise the potential damage to surrounding healthy tissue thereby reducing side effects.

The trial's Lead Investigator in Ireland is Professor John Armstrong, Consultant Radiation Oncologist at Beacon Hospital and SLRON, and Director of Research at SLRON.

"SBRT has been effective for use in treating small tumours in the brain and lung where surgery is not an option.

"The trial arm in which Irish sites are participating compares the outcomes for patients who are randomly selected for conventional radiotherapy or SBRT.

"While we know that both treatments offer benefits for patients, we do not know if one is slightly better than the other," Professor Armstrong said.

"Also, we know that the side effects may be different, but we don't know to what extent and which treatment offers the fewest side effects.

"This trial will hopefully help us answer these important questions and ultimately improve treatment results for men with early stage prostate cancer in the future," he said.

With conventional radiotherapy, radiation is delivered to the tumour in relatively small doses over several weeks. During the PACE trial one group of patients will receive this type of radiotherapy five days a week for eight weeks.

With SBRT, higher doses of radiation are delivered to the tumour and involve fewer treatments. The group of patients who receive this type of treatment will receive 5 treatment sessions spread over 1-2 weeks.

Depending on which group patients are in, patients will be on treatment for either 2 or 8-9 weeks of treatment with a follow up period of 10 years.

### Recurrence Score

This is a Cancer Trials Ireland sponsored in-house study supported by Genomic Health, with Dr Patrick Morris, Consultant Oncologist, Beaumont Hospital, as the Chief Investigator.



*Dr Patrick Morris,  
Consultant Oncologist*

After a diagnosis of breast cancer and any lymph glands have been surgically removed, further (adjuvant) treatment is generally given to reduce the risk of cancer recurrence. For patients with estrogen receptor (ER) positive breast cancer, this treatment has traditionally been chemotherapy and hormone therapy.

However, it is increasingly recognised that tumours which are ER positive and negative for the human epidermal growth factor receptor 2 (HER2), are relatively resistant to chemotherapy. It is likely that many more people are exposed to the risks of chemotherapy than ever benefit from it. In order to select patients who will get more benefit from chemotherapy and to spare those who get very little benefit from side effects, risk assessment tools are being developed.

This study is examining one such risk assessment tool called the 21 gene Recurrence Score (OncotypeDx®) and its impact on a Medical Oncologist's decision to recommend chemotherapy. The 21 Gene Recurrence Score is a test that examines tumour genes to estimate the risk of the tumour relapsing and possible chemotherapy benefits.

For patients it can help in deciding who should get chemotherapy. Patients with low scores can sometimes avoid chemotherapy. In some countries, this test is offered to almost all patients with ER positive breast cancer, irrespective of whether the cancer has spread to lymph nodes or not. However, in Ireland this test is not standardly available for patients who have breast cancer involving lymph nodes.

The study will recruit 150 patients in Ireland. It has already completed accrual of the 75 patients in the postoperative cohort in only 6 months. The study remains open for patients treated in the preoperative setting. The study will open in the following hospitals in Dublin; Beaumont Hospital, Mater University Hospital, St James's Hospital, St Vincent's University Hospital, as well as Bon Secours Hospital, Cork, Cork University Hospital, Letterkenny University Hospital, University Hospital Limerick, University Hospital Galway and University Hospital Waterford.



*Professor John Armstrong,  
Consultant Radiation  
Oncologist*

## ETOP 10-16 BOOSTER opens in Dublin and Limerick

Lung cancer remains the most common cause of cancer death. It is estimated to be responsible for nearly one in five cancer deaths (1.59 million deaths globally).

Non-small cell lung carcinoma (NSCLC) represents approximately 80% to 85% of all lung cancers. Unfortunately, at the time of diagnosis approximately 70% of NSCLC patients already have advanced or metastatic disease not amenable to surgical resection. Furthermore, a significant percentage of early stage NSCLC patients who have undergone surgery subsequently develop distant recurrence and die as a result of their lung cancer. Patients presenting with unselected advanced NSCLC have a median overall survival of 10 to 12 months. Developments in targeted therapy have identified groups of patients who may have a much better outcome. Investigating groups like this remains a core priority for Cancer Trials Ireland's lung cancer group.

The ETOP 10-16 BOOSTER trial will assess the efficacy of the combination of osimertinib and bevacizumab versus osimertinib alone in terms of progression-free survival among patients with NSCLC. Osimertinib (Tagrisso®) is a new so called selective third-generation TKI. Osimertinib has an increasingly established role in the treatment of a subgroup of NSCLC (EGFR t790 mutation). It is currently not available as a funded treatment in Ireland.

Bevacizumab (Avastin®) is an antibody targeting the vascular endothelial growth factor (VEGF) and thereby inhibiting the

growth of the tumour's blood vessels. osimertinib and bevacizumab are both approved by the European Medicines Agency for the treatment of NSCLC.

This trial is sponsored by ETOP. A total of 154 patients from centres around Europe, Singapore and South Korea are expected to be enrolled in this study over a period of 3 years. This study follows on from the BELIEF trial where Irish patients had the possibility to be exposed to a forerunner of osimertinib in conjunction with bevacizumab. This study was reported at the World Lung Cancer Conference in Denver in 2015. Successful participation in this previous study has informed the invitation for Irish patients to participate in the BOOSTER trial which it is hoped will benefit this group of lung cancer patients.

In Ireland, Dr Linda Coate, Consultant Medical Oncologist, University Hospital Limerick, is the Chief Investigator. The trial is open in St James's Hospital, Dublin (Investigator is Dr Sinead Cuffe, Consultant Medical Oncologist) and University Hospital Limerick (Investigator is Dr Linda Coate). It is planned that 6 patients will take part. The study will take approximately 5 years to complete.



*Dr Linda Coate,  
Consultant Oncologist*

### Cancer trial MK3475-604

Lung cancer trial MK3475-604 has opened at St Vincent's University Hospital. Dr Emer Hanrahan, Consultant Medical Oncologist, St Vincent's University Hospital, is the Principal Investigator.



*Dr Emer Hanrahan,  
Consultant Oncologist*

This is an industry (MSD) sponsored phase III randomized, double-blind, placebo-controlled trial. Its global recruitment target is 430 and has a target of 4 for Ireland.

The purpose of this trial is to assess the safety and efficacy of pembrolizumab (MK-3475) in combination with etoposide/platinum (cisplatin or carboplatin) for the first-line treatment of patients with newly diagnosed extensive stage small cell lung cancer who have not previously received systemic therapy for their cancer.

This study will compare standard of care (SOC) etoposide/platinum (cisplatin or carboplatin) plus either pembrolizumab or placebo.

It is hypothesised that pembrolizumab plus SOC chemotherapy prolongs Progression Free Survival and Overall Survival compared with placebo plus SOC chemotherapy in adult participants with extensive stage small cell lung cancer.

### FORWARD 1 recruiting

Sponsored by ImmunoGen, the FORWARD 1 trial has opened in Ireland (to date trial is open in Bon Secours Hospital, Cork, Mater Hospital, Dublin), with 4 patients enrolled so far.



*Dr Paula Calvert,  
Consultant Oncologist.*

Dr Paula Calvert, Consultant Oncologist, (University Hospital Waterford) is the Principal Investigator.

The recruitment target for Ireland is 20 and 333 internationally.

The purpose of the trial is to compare the safety and efficacy of IMGN853 to that of selected single-agent chemotherapy in women with platinum-resistant FR-alpha positive advanced epithelial ovarian cancer, primary peritoneal cancer or fallopian tube cancer.

Eligible patients will be randomized (at 2:1 ratio) to either IMGN853 (administered once every three weeks) or investigator's choice chemotherapy (Paclitaxel, Pegylated Liposomal Doxorubicin, or Topotecan).

Patients will continue to receive treatment as long as their cancer is not getting worse or they do not have serious side effects.

## Trial to investigate chemotherapy-free treatments for leukaemia opens in Ireland

The Irish arm of an international cancer trial that is investigating promising cures for leukaemia has opened in six cancer trials research units in Ireland.

The trial aims to test treatments for leukaemia that could be more effective and have fewer side effects than standard chemotherapy treatments.

It is expected that up to 60 patients in Ireland with a type of leukaemia known as CLL (Chronic Lymphocytic Leukaemia) will participate in the trial. It will be opened to eligible patients in Cork University Hospital, University Hospital Waterford, University Hospital Galway, and in Dublin at St James' University Hospital, the Mater Hospital and Beaumont Hospital.

CLL is the most common type of leukaemia in the western world with most cases developing in people over 55. About 200 people in Ireland are diagnosed each year with CLL which affects the blood, lymph glands and bone marrow.

The international trial is being led internationally by the German CLL Study Group (GCLLSG). This group is the world's leading authority on CLL research.

Professor Patrick Thornton, Consultant Haematologist, Beaumont Hospital, who has collaborated with the German Study Group on previous trials, is the Chief Investigator for the trial in Ireland. The trial is being coordinated by Cancer Trials Ireland.

"This is a very significant trial because of the positive results the treatments we'll be comparing have already achieved, and its size, in terms of the number of countries, research units and patients. I'm confident it will deliver a new standard

of care", Professor Thornton said.

"To be invited to open a trial of this significance in Ireland is a great vote of confidence in Ireland's cancer trials research community and our ability to contribute to the global effort to find answers to cancer.

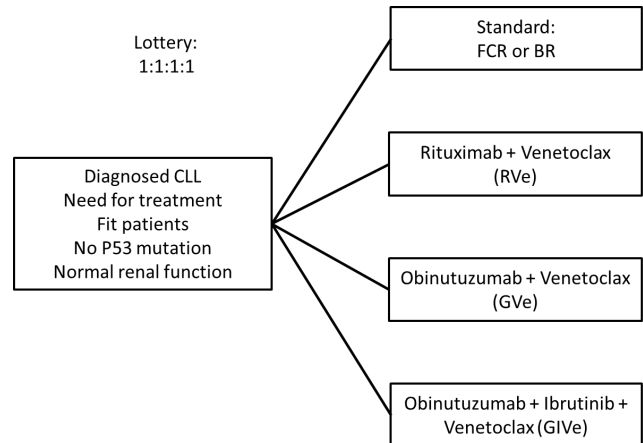
"Not only does it help us contribute our expertise to finding better treatments, it enables our patients to

access promising treatments at no cost which they would otherwise not be able to access for many years."

Almost 1000 patients from 160 research units across 10 countries will participate in the trial. Participating countries include Ireland, Austria, Belgium, Denmark, Germany, Finland, Israel, Netherlands, Sweden and Switzerland. Patients will be on the trial for up to 5 years.

"Chemoimmunotherapy is the standard initial (first-line) treatment for patients with CLL and with it many patients can achieve good remissions. Unfortunately, it can be too toxic

for some patients because they can be less fit and unable to tolerate intensive regimens. So there is a pressing need for alternative chemotherapy-free treatments," Professor Thornton said.



"In this trial we are testing a number of oral non-chemo treatments and new antibodies which have proven to be effective and safe as second line treatments (treatments given when initial treatments don't work) with little side effects.

"We'll determine which treatment is more effective and has fewer side effects than the standard chemoimmunotherapy", he said.

The trial will compare the current standard chemoimmunotherapy treatment for physically fit patients with CLL, (chemoimmunotherapy with either Fludarabine plus Cyclophosphamide plus Rituximab (FCR) or Bendamustine plus Rituximab (BR)) with three new and different combination of drugs (obinutuzumab, ibrutinib and venetoclax) as a first line treatment.

There is also a translational dimension to the trial as it will look at the modern molecular markers for example NOTCH1 which effect treatment response and remission duration and survival.

**Rituximab:** this drug is directed against a molecule called CD20 (expressed on the surface of CLL cells) and kills the CLL cells in combination with the patient's own immune system.

**Venetoclax:** this drug blocks a protein in the body called "BCL-2". This protein helps blood cancer cells survive. Blocking this protein helps to kill and lower the number of cancer cells. It also slows down the worsening of the disease.

**Obinutuzumab:** this drug is (Rituximab) an antibody which binds to a specific molecule on the surface of CLL cells and then destroys them.

**Ibrutinib:** this drug inhibits a certain protein (Bruton tyrosine kinase) of the cell metabolism in CLL cells. This protein is needed for growth and survival of cells, therefore the intake of Ibrutinib leads to their death.



Professor Patrick Thornton,  
Consultant Haematologist



## St Luke's Radiation Oncology Network opens first international adult sarcoma trial in Ireland: A Study of IMRT in Primary Bone and Soft Tissue Sarcoma (IMRiS)

**Dr Charles Gillham and Dr Jill Nicholson, St Luke's Radiation Oncology Network (SLRON)**

Sarcomas are malignant tumours that arise from transformed cells of mesenchymal origin such as muscle, fat, cartilage or bone. Approximately 80% arise in soft tissue and 60% occur in the lower limb. Soft tissue sarcomas may occur at any age, although are most common in middle aged and older adults. They account for 7–10% of paediatric malignancies. Primary bone tumours are less common than soft tissue sarcomas, but they represent a significant percentage of the cancer burden in young people under the age of 20 years. In Ireland, approximately 200-250 people are diagnosed with some type of sarcoma each year.

The standard approach to local management of sarcomas arising in the limb is limb-sparing surgery with the addition of neo-adjuvant or adjuvant radiotherapy (RT) for patients deemed at high risk of local recurrence. Until recently RT has routinely been delivered using 3-dimensional conformal RT (3DCRT). Five-year local recurrence free survival rates ranging from 80% to 90% are reported with this approach. In order to deliver the required dose to the tumour with 3DCRT (typically to a dose of 50Gy pre-operatively and 60 to 66Gy post-operatively), large volumes of adjacent normal soft tissue and bone can potentially receive high RT doses. This may lead to long term side effects such as lymphoedema, subcutaneous and muscle fibrosis, joint stiffness and bone fractures. These may manifest as pain, stiffness, difficulty walking or carrying out normal activities of daily living.

Intensity modulated radiotherapy (IMRT) is an advanced radiotherapy technique that can deliver a highly conformal dose to a target with improved sparing of the surrounding normal tissues from moderate to high radiation doses.

IMRT is likely to be of benefit for tumours that have complex shapes, or those in close proximity to sensitive normal tissues and critical organs. Reducing the dose to normal tissues may in turn reduce the acute and late side effects of treatment.

IMRiS is an international prospective multicentre phase II trial that aims to identify whether using highly conformal IMRT will help lessen these long-term effects.

The study is sponsored by University College London and organised by Cancer Research UK. The study is coordinated in Ireland by Cancer Trials Ireland.

Three separate sarcoma cohorts are being studied and will be analysed separately.

The theoretical advantage to IMRT is the potential reduction in late toxicity and subsequent potential for functional improvement.

IMRT is being used increasingly in Europe and the USA to treat extremity

soft tissue sarcomas, but there have been no randomised controlled trials directly comparing IMRT with 3DCRT.

For cohort 1 patients, the aim will be to establish if the use of IMRT will reduce late normal tissue toxicity.

In cohorts 2 and 3, the aim is to determine whether the use of IMRT will enable the achievement of a radiotherapy treatment plan that delivers the optimal dose while keeping within normal tissue tolerances.

There is very little published evidence on the use of IMRT in Ewing's sarcoma or high-grade bone lesions. It is important to establish the feasibility of IMRT to achieve the required radiation doses to the tumour, and to prospectively document the side effects of treatment in this setting.

Cohort 1 of the trial opened in SLRON at St Luke's Hospital, Dublin, and is the first international adult sarcoma trial in the country. Five patients were enrolled at the SLRON centre, and the study recently reached its accrual target.

There are invaluable benefits to this trial having taken place in Ireland.

From a radiotherapy quality perspective, we are now – based on the IMRiS trial protocol – standardising and optimising the way in which we deliver and plan treatment. This will undoubtedly be beneficial for future patients even if they are not part of the study.

The study strengthens our collaborative links with UK-based trials and may open opportunities for Irish patients to participate in future sarcoma clinical trials.

There is a wealth of international literature demonstrating that the best outcomes for patients with sarcoma 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 helps raise awareness of this uncommon group of cancers and helps to ensure patients are referred to one of the two main multidisciplinary teams in Dublin or Cork.

### Cohort 1

- Patients with Limb/limb girdle soft tissue sarcoma receiving (neo)-adjuvant radiotherapy

### Cohort 2

- Patients with Ewing sarcoma of the spine/pelvis receiving definitive radical or (neo)-adjuvant radiotherapy

### Cohort 3

- Patients with non-Ewing primary bone sarcomas of the spine/pelvis receiving definitive radical or adjuvant radiotherapy

## CHRONOS-4 Opens at the Mater Hospital Dublin

Sponsored by Bayer, CHRONOS-4 has opened for recruitment at the Mater University Hospital, Dublin, with Dr Anne Fortune as the Principal Investigator.

The recruitment target for Ireland is 3 and 676 internationally.

The trial is for patients with indolent (slow-growing) Non-Hodgkin's Lymphoma that has returned after previous treatment.

The purpose of this study is to evaluate the efficacy and safety of copanlisib in combination with standard immunochemotherapy (rituximab in combination with bendamustine [R-B] and rituximab in combination with a 4 drug combination of cyclophosphamide, doxorubicin, vincristine and prednisone/prednisolone [R-CHOP]) compared with placebo in

combination with standard immunochemotherapy (R-B or R-CHOP).

Eligible patients should be in need of and fit for immunochemotherapy and should not be resistant to rituximab (resistance defined as lack of response, or progression (disease becomes worse) within 6 months of the last course of treatment with a rituximab containing regimen).

This trial has two parts: Safety run-in and phase III part. Ireland will participate in the phase III part of this study.

In phase III, patients will be randomly assigned to blinded treatment arms of copanlisib plus R-B or R-CHOP or placebo plus R-B or R-CHOP.

## A familiar face returns

We are delighted to announce the appointment of Derval Kehily to the role of Regional Cancer Trials Co-ordinator, Western Seaboard.

Derval is a RGN with an MSc in Healthcare Management and comes to the organisation with over 16 years of cancer clinical trials research behind her.

Derval is very well-known among the wider Cancer Trials Ireland team as she is the former Clinical Research Nurse Co-ordinator & Cancer Clinical Trials Unit Manager at Beaumont Hospital, Dublin.

The role of Regional Cancer Trials Co-ordinator is a first for our organisation and it will involve Derval working closely with colleagues across the four Cancer Trials Research Units along the Western Seaboard (University Hospital Limerick, University Hospital Galway, Sligo University Hospital, and Letterkenny University Hospital).

Some of Derval's key roles are to;

- Oversee and review cancer clinical trials activities pertaining to Cancer Trials Ireland trials (In-house sponsored trials, Collaborative trials, and adopted trials) across the region.
- Continually monitor site performance, design remedial action plans and make formal recommendations to local management for changes in processes and work flows to deliver improvements in trial management at sites
- Ensure assigned trials are conducted in line with Cancer Trials Ireland's Standard Operating Procedures (SOPs) and/or other Sponsor SOPs if applicable.
- Promote the highest Good Clinical Practice (GCP) standards, ensure these standards are met and maintained across the Cancer Trials Research Units within the defined area.

Derval is engaging with the Cancer Trials Research Units to help them to;

- Maximise clinical trial access for as many patients as possible across the region.
- Keep cancer trial patients as near to home as possible for their treatment.
- Bring more cancer trials sponsor companies to the Research Units across the Western Seaboard.

Please join us in welcoming Derval back to the Cancer Trials Ireland family and we wish her every success in her new role.



*Derval Kehily (left) - Regional Cancer Trials Co-ordinator - Western Seaboard, along with the Galway based cancer trials team (left to right) Marian Jennings - Clinical Trials Co-ordinator, Ann Wright - Oncology Clinical Trials Administrator, Swapnil Gaware - Research Assistant/Data Officer, Shauni Fitzgerald - Research Assistant, Grainne Gannon - Clinical Trials Co-ordinator, Blood Cancer Network Ireland, Jess Walsh - Research Nurse, Blood Cancer Network Ireland, Carmel O'Toole - Data Officer, Olive Forde - Clinical Trials Co-ordinator, Orlaith Cormican - Research Associate/Research Nurse and Prof Maccon Keane - Consultant Medical Oncologist.*



# Strengthening our Translational Research portfolio

Earlier this year a Translational Strategic Working Group was established to strengthen our translational research portfolio. Members of the Group represent three academic institutions and five hospitals (see side panel). The group held its first meeting in April and formulated the following recommendations.

**1. Appoint a dedicated person in Cancer Trials Ireland to support new proposal developments, facilitate the engagement of industry in translational studies/Investigator Initiated Trials (IIT) and serve as the liaison between this group and the Clinical Executive Committee.**

Dr Verena Murphy was appointed Translational Research Leader in May 2017 to take on this role. Verena joined Cancer Trials Ireland in 2009 as Translational Research Coordinator and since has developed the translational department to its current stage. Verena comes from a scientific



Dr Verena Murphy  
Translational Research Leader

background with a PhD from the University of Zurich and post-doctoral research time in Switzerland, Canada and Ireland. Her involvement in cancer research dates back more than 20 years. Her national and international network enabled Cancer Trials Ireland to be a partner in two substantial EU grants.

**2. Replace the translational DSSG meeting with allocated time slots in each of the other DSSG meetings to facilitate discussion of relevant translational studies and appoint Translational Co-Chairs for each DSSG.**

At the Autumn 2017 DSSG meeting Translational Co-Chairs (see Prof Bryan Hennessy's article on page 2) will attend and input to the Breast, GU, GI and Paediatric DSSG groups. We hope these changes will encourage closer collaboration and more active discussion between our academic and clinical members resulting in more transfer from bench to bedside and back to bench.

**3. Presentation of an overview of all biological samples collected through our trials and studies.**

During the Summer DSSG meeting the Patient Advocate and the Stakeholder meetings focused on Cancer Biomarkers and Basket studies including an overview of all biological samples collected through our trials and studies. It is important that our academic members know what is available for future research studies to enable them to plan new projects and apply for research funding.

**4. Formation of a Biobank Sub-Group to serve as an infrastructure and platform for interactions between scientists and clinicians.**

The tasks of the Biobank Sub-group will include i) overview of sample availability, ii) access to samples, iii) advise on the

## Members of the Translational Strategic Working Group

- Prof Bryan Hennessy (Chair and Clinical Lead, Beaumont Hospital, Dublin)
- Dr Linda Coate (Vice Clinical Lead, University Hospital Limerick)
- Prof Bill Watson (Former Chair of Translational DSSG, Conway Institute, UCD)
- Prof Liam Gallagher (Conway Institute, UCD)
- Prof Jochen Prehn (RCSI)
- Dr Roisin Dwyer (University College Galway)
- Prof Stephen Finn (St James's Hospital, Dublin)
- Dr Derek Power (Cork University Hospital)
- Dr Brian O'Neill (Beaumont Hospital, Dublin)
- Dr Verena Murphy (Translational Research Leader)

feasibility of including translational arms into clinical studies, iv) advise on the development of Investigator Initiated Trials (IIT) with industry support. At this point six people have agreed to be part of this group: Prof Liam Gallagher, Prof Bill Watson, Prof Ray McDermott, Prof Leonie Young, Dr Richard Flavin and Prof Bryan Hennessy. The group will have its first meeting in November.

The Translational Strategic Working Group is planning its next meeting in November. Particular focus will be given to decision making on new studies using samples collected through trials and studies and the financing of translational/academic studies.

Watch this space!

## Spring 2018 DSSG Meeting

Our first DSSG meeting of 2018 will be held in our new offices at Innovation House, Old Finglas Road, Glasnevin, Dublin 11.

We look forward to welcoming you and will confirm the exact date soon.



## Academic publications from Cancer Trial Ireland Investigators

**Dr Orla Casey, Translational Project Manager, Cancer Trials Ireland**

So far this year we have had a great publication record in leading academic peer reviewed journals in cancer research.

In addition, our investigators have presented their work at many international conferences and meetings which included the American Society of Clinical Oncology (ASCO) and the European Society for Medical Oncology (ESMO). They have also presented many abstracts and posters

This strong publication record reflects the quality of the cancer research our teams are undertaking. 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](mailto:orla.casey@cancertrials.ie)

### Breast

Cancer Trials Ireland Study Number: 04-02

Earl, H. M., L. Hiller, H. C. Howard, J. A. Dunn, J. Young, S. J. Bowden, M. McDermaid, A. K. Waterhouse, G. Wilson, R. Agrawal, S. O'Reilly, A. Bowman, D. M. Ritchie, A. Goodman, T. Hickish, K. McAdam, D. Cameron, D. Dodwell, D. W. Rea, C. Caldas, E. Provenzano, J. E. Abraham, P. Canney, J. P. Crown, M. J. Kennedy, R. Coleman, R. C. Leonard, J. A. Carmichael, A. M. Wardley, C. J. Poole and t. t. collaborators (2017).

**"Addition of gemcitabine to paclitaxel, epirubicin, and cyclophosphamide adjuvant chemotherapy for women with early-stage breast cancer (tAnGo): final 10-year follow-up of an open-label, randomised, phase 3 trial."** [Lancet Oncol](#) 18(6): 755-769.

Cancer Trials Ireland Study Number: 07-02

Sonnenblick, A., D. Agbor-Tarh, I. Bradbury, S. Di Cosimo, H. A. Azim, D. Fumagalli, S. Sarp, A. C. Wolff, M. Andersson, J. Kroep, T. Cufer, S. D. Simon, P. Salman, M. Toi, L. Harris, J. Gralow, M. Keane, A. Moreno-Aspitia, M. Piccart-Gebhart and E. de Azambuja (2017). **"Impact of Diabetes, Insulin, and Metformin Use on the Outcome of Patients With Human Epidermal Growth Factor Receptor 2-Positive Primary Breast Cancer: Analysis From the ALTTO Phase III Randomized Trial."** [J Clin Oncol](#) 35(13): 1421-1429.

Cancer Trials Ireland Study Number: 10-05

Toomey, S., A. J. Eustace, J. Fay, K. M. Sheehan, A. Carr, M. Milewska, S. F. Madden, A. Teiserskiene, E. W. Kay, N. O'Donovan, W. Gallagher, L. Grogan, O. Breathnach, J. Walshe, C. Kelly, B. Moulton, M. J. Kennedy, G. Gullo, A. D. Hill, C. Power, D. Duke, N. Hambly, J. Crown and B. T. Hennessy (2017). **"Impact of somatic PI3K pathway and ERBB family mutations on pathological complete response (pCR) in HER2-positive breast cancer patients who received neoadjuvant HER2-targeted therapies."** [Breast Cancer Res](#) 19(1): 87.

### Gastrointestinal

Cancer Trials Ireland Study Number: 12-16

Moran, B., S. Das, D. Smeets, G. Peutman, R. Klinger, B. Fender, K. Connor, M. Ebert, T. Gaiser, J. H. Prehn, O. Bacon, E. Kay, B. Hennessy, V. Murphy, B. Ylstra, D. Lambrechts, A. T. Byrne, W. M. Gallagher and D. P. O'Connor (2017).

**"Assessment of concordance between fresh-frozen and formalin-fixed paraffin embedded tumor DNA methylation using a targeted sequencing approach."** [Oncotarget](#) 8(29): 48126-48137.

Cancer Trials Ireland Study Number: 14-19

Overman, M. J., R. McDermott, J. L. Leach, S. Lonardi, H. J. Lenz, M. A. Morse, J. Desai, A. Hill, M. Axelson, R. A. Moss, M. V. Goldberg, Z. A. Cao, J. M. Ledezine, G. A. Maglinte, S. Kopetz and T. André (2017). **"Nivolumab in patients with metastatic DNA mismatch repair-deficient or microsatellite instability-high colorectal cancer (CheckMate 142): an open-label, multicentre, phase 2 study."** [Lancet Oncol](#) 18(9): 1182-1191.

Cancer Trials Ireland Study Number: 10-14

Reynolds, J. V., S. R. Preston, B. O'Neill, L. Baeksgaard, S. M. Griffin, C. Mariette, S. Cuffe, M. Cunningham, T. Crosby, I. Parker, K. Hofland, G. Hanna, L. B. Svendsen, C. L. Donohoe, C. Muldoon, D. O'Toole, C. Johnson, N. Ravi, G. Jones, A. K. Corkhill, M. Illsley, J. Mellor, K. Lee, M. Dib, V. Marchesin, M. Cunnane, K. Scott, P. Lawner, S. Warren, S. O'Reilly, G. O'Dowd, G. Leonard, B. Hennessy and R. Mc. Dermott (2017). **"ICORG 10-14: NEOadjuvant trial in Adenocarcinoma of the oEsophagus and oesophagoGastric junction International Study (Neo-AEGIS)."** [BMC Cancer](#) 17(1): 401.

### Genitourinary

Cancer Trials Ireland Study Numbers: 97-01, 02-01, 05-04, 06-15, 06-16, 08-17

Cagney, D. N., M. Dunne, C. O'Shea, M. Finn, E. Noone, M. Sheehan, L. McDonagh, L. O'Sullivan, P. Thirion and J. Armstrong (2017). **"Heterogeneity in high-risk prostate cancer treated with high-dose radiation therapy and androgen deprivation therapy."** [BMC Urol](#) 17(1): 60.

Cancer Trials Ireland Study Number: 11-05

Motzer, R. J., N. B. Haas, F. Donskov, M. Gross-Goupil, S. Varlamov, E. Kopyltsov, J. L. Lee, B. Melichar, B. I. Rini, T. K. Choueiri, M. Zemanova, L. A. Wood, M. N. Reaume, A. Stenzl, S. Chowdhury, H. Y. Lim, R. McDermott, A. Michael, W. Bao, M. J. Carrasco-Alfonso, P. Aimone, M. Voi, C. Doehn, P. Russo, C. N. Sternberg and P. investigators (2017). **"Randomized Phase III Trial of Adjuvant Pazopanib Versus Placebo After Nephrectomy in Patients With Localized or Locally Advanced Renal Cell Carcinoma."** [J Clin Oncol](#): JCO2017735324.

## Academic publications from Cancer Trials Ireland Investigators

### Cancer Trials Ireland Study Number: 15-21

Sheill, G., L. Brady, E. Guinan, B. Hayes, O. Casey, J. Greene, T. Vlajnic, F. Cahill, M. Van Hemelrijck, N. Peat, S. Rudman, J. Hussey, M. Cunningham, L. Grogan, T. Lynch, R. P. Manecksha, J. McCaffrey, L. Mucci, O. Sheils, J. O'Leary, D. M. O'Donnell, R. McDermott and S. Finn (2017). **"The ExPeCT (Examining Exercise, Prostate Cancer and Circulating Tumour Cells) trial: study protocol for a randomised controlled trial."** [Trials](#) 18(1): 456.

### Gynaecological

#### Cancer Trials Ireland Study Number: 10-12

Roncolato, F. T., F. Joly, R. O'Connell, A. Lanceley, F. Hilpert, L. Buizen, A. Okamoto, E. Aotani, S. Pignata, P. Donnellan, A. Oza, E. Avall-Lundqvist, J. S. Berek, F. Heitz, A. Feeney, D. Berton-Rigaud, M. R. Stockler, M. King, M. Friedlander and G. S. B. group (2017). **"Reducing Uncertainty: Predictors of Stopping Chemotherapy Early and Shortened Survival Time in Platinum Resistant/Refractory Ovarian Cancer-The GCIG Symptom Benefit Study."** [Oncologist](#) 22(9): 1117-1124.

### Lung

#### Cancer Trials Ireland Study Number: 12-25

Peters, S., R. A. Stahel, U. Dafni, S. Ponce Aix, B. Massuti, O. Gautschi, L. Coate, A. Lopez Martin, R. van Heemst, T. Berghmans, P. Meldgaard, M. Cobo Dols, J. Garde Noguera, A. Curioni-Fontecedro, D. Rauch, M. T. Mark, S. Cuffe, B. Biesma, A. M. van Henten, O. Juan Vidal, R. Palmero Sanchez, J. C. Villa Guzman, R. Collado Martin, S. Peralta, A. Insa, Y. Summers, I. Lang, A. Horgan, F. Ciardiello, S. de Hosson, R. Pieterman, H. J. Groen, P. M. van den Berg, C. C. Zielinski, Y. Chittazhathu Kurian Kuruvilla, A. Gasca-Ruchti, M. Kassapian, S. Novello, V. Torri, Z. Tsourtis, V. Gregorc, E. F. Smit and E. M. -I. C. Group (2017). **"Randomized Phase III Trial of Erlotinib versus Docetaxel in Patients with Advanced Squamous Cell Non-Small Cell Lung Cancer Failing First-Line Platinum-Based Doublet Chemotherapy Stratified by VeriStrat Good versus VeriStrat Poor. The European Thoracic Oncology Platform (ETOP) EMPHASIS-lung Trial."** [J Thorac Oncol](#) 12(4): 752-762.

### Cancer Trials Ireland Study Number: 12-24

Rosell, R., U. Dafni, E. Felip, A. Curioni-Fontecedro, O. Gautschi, S. Peters, B. Massuti, R. Palmero, S. P. Aix, E. Carcereny, M. Früh, M. Pless, S. Popat, A. Kotsakis, S. Cuffe, P. Bidoli, A. Favaretto, P. Froesch, N. Reguart, J. Puente, L. Coate, F. Barlesi, D. Rauch, M. Thomas, C. Camps, J. Gómez-Codina, M. Majem, R. Porta, R. Shah, E. Hanrahan, R. Kammler, B. Ruepp, M. Rabaglio, M. Kassapian, N. Karachaliou, R. Tam, D. S. Shames, M. A. Molina-Vila, R. A. Stahel and B. c. group (2017). **"Erlotinib and bevacizumab in patients with advanced non-small-cell lung cancer and activating EGFR mutations (BELIEF): an international, multicentre, single-arm, phase 2 trial."** [Lancet Respir Med](#) 5 (5): 435-444.

### Lymphoma and Blood Cancer

#### Cancer Trials Ireland Study Number: 07-01

Appleby, N., D. O'Brien, F. M. Quinn, L. Smyth, J. Kelly, I. Parker, K. Scott, M. R. Cahill, G. Crotty, H. Enright, B. Hennessy, A. Hodgson, M. Leahy, H. O'Leary, M. O'Dwyer, A. Hayat and E. A. Vandenberghe (2017). **"Risk adjusted therapy in chronic lymphocytic leukemia: a phase II cancer trials Ireland (CTRIL-IE [ICORG 07-01]) study of fludarabine, cyclophosphamide, and rituximab therapy evaluating response adapted, abbreviated frontline therapy with FCR in non-del(17p) CLL."** [Leuk Lymphoma](#): 1-10.

### Melanoma

#### Cancer Trials Ireland Study Number: 13-02

Sznol, M., P. F. Ferrucci, D. Hogg, M. B. Atkins, P. Wolter, M. Guidoboni, C. Lebbé, J. M. Kirkwood, J. Schachter, G. A. Daniels, J. Hassel, J. Cebon, W. Gerritsen, V. Atkinson, L. Thomas, J. McCaffrey, D. Power, D. Walker, R. Bhore, J. Jiang, F. S. Hodi and J. D. Wolchok (2017). **"Pooled Analysis Safety Profile of Nivolumab and Ipilimumab Combination Therapy in Patients With Advanced Melanoma."** [J Clin Oncol](#): JCO2016721167.

## Out and about @

### Irish Cancer Society's National Conference for Cancer Survivorship

Cancer Trials Ireland's CEO, Eibhlin Mulroe, (top) and Consultant Oncologist, (University Hospital Waterford), Dr Miriam O'Connor (right) made presentations on the role of cancer trials in cancer research to the hundreds of cancer survivors, their families, friends and carers who gathered for the two day event.

As part of our Just Ask! public information campaign we presented a display and issued information on cancer trials.





# 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:	Total Accrual	AMNCH	Beacon	BH	BonS	CUH
Breast	Trans	09-07	<a href="#">Breast Cancer Proteomics and Molecular Heterogeneity</a>	1791			800		525
Breast	Trans	10-11	<a href="#">Circulating miRNA</a>	203			8	20	
Breast	Trans	10-15	<a href="#">Exosomal HER2</a>	292	51	Open	65	57	11
Breast	Trans	10-16	<a href="#">Ovarian Reserve</a>	177	22	Open	49	26	21
Breast	Trans	12-09	<a href="#">CharactHer</a>	181			9		
Breast	Trans	12-30	<a href="#">TAILORx Tissue Bank</a>	579	23		33	14	72
Breast	Trans	15-34	<a href="#">Recurrence Score</a>	57			15		10
Breast	Trans	12-40	<a href="#">EORTC 10085</a> (Closed to recruitment since last DSSG)	15			3		4
Breast	Clinical	14-01	<a href="#">EMBRACA/ MDV 673-301 (TRIO 023)</a> (Closed to recruitment since last DSSG)	6					
Breast	Clinical	15-17	<a href="#">PALLAS</a>	56			16		7
Breast	Clinical	15-49	<a href="#">NeoTRIP</a>	8			1		Open
Breast	Clinical	14-11	<a href="#">PENELOPE-B</a>	43			2	3	4
Breast	Clinical	14-21	<a href="#">NALA</a>	5					Open
Breast	Clinical	14-22	<a href="#">16298 Radium 223 in BC (Bayer)</a>	3					1
Breast	Clinical	15-02	<a href="#">PanthER</a>	12			8		
Breast	Clinical	15-33	<a href="#">KEYNOTE-119 in mTNBC (MSD)</a> (Closed to recruitment since last DSSG)	8					
Breast	Radio	15-03	<a href="#">NSABP B-51</a>	10					
Breast	Clinical	15-16	<a href="#">FLIPPER</a>	10			Open	1	
Breast	Clinical	16-20	<a href="#">POSITIVE</a>	3					TBI
Breast	Clinical	17-08	<a href="#">KEYNOTE-522 in TNBC (MSD) (New)</a>	0				Open	
CNS	Trans	08-13	<a href="#">Serum Protein Markers for Glioma</a>	110			110		
CNS	Clinical	15-29	<a href="#">M13-813 INTELLANCE 1</a>	7			7		
GI	Clinical	10-14	<a href="#">Neo-AEGIS</a>	194			1		6
GI	Trans	12-27	<a href="#">CRAC Plasma Biomarkers</a>	87	3	Open	27	17	
GI	Trans	12-31	<a href="#">PDAC Plasma Biomarkers</a>	121	40	Open	12	16	
GI	Radio	12-38	<a href="#">TRI-LARC</a>	41					
GI	Clinical	14-17	<a href="#">Exelixis Celestial Study</a>	2					
GI	Clinical	14-19	<a href="#">BMS CA209-142 (CheckMate 142)</a>	21			2		
GI	Clinical	14-20	<a href="#">GERCOR STRATEGIC-1</a>	5	Open			2	1
GI	Clinical	16-28	<a href="#">MK 3475-177</a>	4	1				
GI	Clinical	16-29	<a href="#">MK 3475-181</a> (Closed to recruitment since last DSSG)	3	2				
GI	Clinical	16-73	<a href="#">BMS CA209-577</a>	3			3		Open
GI	Clinical	16-66	<a href="#">MK3475-240 (New)</a>	2					
GU	Clinical	11-34	<a href="#">TIGER</a>	0					
GU	Clinical	13-09	<a href="#">PEACE-1</a>	46	5				14
GU	Clinical	13-21	<a href="#">Radium-223 &amp; Enzalutamide mCRPC</a>	47	27				9
GU	Clinical	13-23	<a href="#">Neo-adjuvant Abiraterone prostate</a>	14					7
GU	Trans	14-04	<a href="#">iPROSPECT</a>	55	26	Open	Open		3
GU	Clinical	14-06	<a href="#">ENZAMET</a> (Closed to recruitment since last DSSG)	196	30	0	3		
GU	Clinical	14-07	<a href="#">ENZARAD</a>	131		17			22
GU	Clinical	15-19	<a href="#">CARD</a>	1	1				
GU	Trans	15-21	<a href="#">ExPeCT study</a> (Closed to recruitment since last DSSG)	30	12		1		
GU	Radio	15-46	<a href="#">PACE</a>	4		4			
GU	Trans	16-07	<a href="#">IPCOR</a>	3,628	Open	Open	Open	Open	Open

## Open Studies

## Studies To Be Initiated

## Studies Pending

UHG	LUH	Mater	MRH	MUH	OLLDH	UHL	SLRON	SJH	SUH	SVUH	UHW	Whit	International Sites	Other
						385		11		Open	70			
133			Open					30	10	Open	2			
	11				7			2	36	41	11			
					4			6	12	29	8			
		6						6	TBI	160			Italy 19	
66	14	79		Open		12		37	32	167	30			
2	Open					7		10		7	6			
		Open						1		5	2			
1		3				Closed				2				
		10						8		9	6			
CLOSED		3						2		Open	2			
9		7						8		8	2			
Open		Open				Open		2		3				
		2					Open							
Open										4				
		8								0				
4							6							
2		3				Not active		Closed			4			
Open						Open		Open		3	Open			
										Open				
1							Open	87					99	
11	3	3						Open	13	2	8			
3	TBI									43	7			
							41							
		2												
1										19				
Open		Open						1		1	Open			
								3						
								1						
Open														
										2				
								Open						
1		21								5				
		3					Open			8				
2							5							
TBI		5						Open	6	14	1			
2		24						0		11	12		UK 10 sites (114)	
5		2					14						UK 10 sites (71)	
		Open												
		4					1	12					UK 37	
							TBI							
Open		Open	Open	Open	Open	Open		Open	Open	Open	Open	Open		Open

# 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:	Total Accrual	AMNCH	Beacon	BH	BonS	CUH
GU	Clinical	16-27	<a href="#">Keynote 426</a>	11	9				
GU	Clinical	16-62	<a href="#">Roche MQ29983 (SAUL)</a>	9	7				2
GU	Clinical	16-63	<a href="#">Roche IMmotion010</a>	1	1				TBI
GU	Clinical	16-69	<a href="#">E7080-G000-307 (New)</a>	2	Open		2		TBI
GU	Clinical	16-70	<a href="#">BMS CA209-274</a>	5	3				2
GU	Clinical	17-05	<a href="#">MSD MK-3475-361/ KEYNOTE-361</a>	7	7				Open
Gynae	Radio	09-06	<a href="#">Endometrial - IMRT v 3D RT</a>	73					
Gynae	Clinical	11-29	<a href="#">ICON8B</a>	22				3	
Gynae	Clinical	14-02	<a href="#">SHAPE</a>	10					
Gynae	Clinical	16-04	<a href="#">PRIMA</a>	0					Open
Gynae	Clinical	16-05	<a href="#">JAVELIN 100</a>	7				2	Open
Gynae	Clinical	16-68	<a href="#">FORWARD 1 (New)</a>	4				4	
H & L	Clinical	12-02	<a href="#">E3A06</a> (Closed to recruitment since last DSSG)	3					
H & L	Clinical	15-08	<a href="#">ROBUST</a> (Closed to recruitment since last DSSG)	3					Open
H & L	Clinical	15-09	<a href="#">ARROVEN PASS Study</a>	13			8		
H & L	Clinical	15-10	<a href="#">OPTIMISMM</a> (Closed to recruitment since last DSSG)	10					
H & L	Clinical	15-37	<a href="#">CHRONOS-2</a> (Closed to recruitment since last DSSG)	0			Open		
H & L	Clinical	15-38	<a href="#">CHRONOS-3</a>	3			Open		
H & L	Clinical	15-36	<a href="#">Protocol 04-30 (INSPIRE)</a>	1	1				Open
H & L	Clinical	16-08	<a href="#">P2001 Pevonedistat</a> (Closed to recruitment since last DSSG)	1	1				
H & L	Clinical	16-10	<a href="#">KEYNOTE 185</a> (Closed to recruitment since last DSSG)	1			1		
H & L	Clinical	16-02	<a href="#">CyBorD-DARA</a>	14			2		3
H & L	Clinical	16-09	<a href="#">Astellas 2215 CL 0301</a>	0			Open		
H & L	Clinical	16-60	<a href="#">CLL13 (New)</a>	2			Open		
H & L	Clinical	16-79	<a href="#">M15-550 (VENICE 1)</a>	11			5		
H & L	Clinical	17-06	<a href="#">CHRONOS 4</a>	0					
H & L	Clinical	17-07	<a href="#">CheckMate 744</a>	1					
Head & Neck	Clinical	16-54	<a href="#">BMS CA209-714</a>	5					
Head & Neck	Clinical	16-11	<a href="#">NRG HN-002</a> (Closed to recruitment since last DSSG)	1					
Lung	Clinical	12-53	<a href="#">ETOP SPLENDOUR</a>	27	1		Open		4
Lung	Radio	15-05	<a href="#">Oligo-Recurrent Metastatic Disease</a>	22		22			
Lung	Clinical	15-27	<a href="#">BMS CA209-227 (CheckMate 227) (Parts 1 and 2)</a>	25			4		
Lung	Radio	15-47	<a href="#">INTENSE</a>	2					
Lung	Clinical	16-18	<a href="#">BMS CA209-451 (CheckMate 451)</a>	15	5				7
Lung	Clinical	17-Oct	<a href="#">MK3475-604 (New)</a>	0					
Lung	Clinical	16-16	<a href="#">MSD MK3475-189</a> (Closed to recruitment since last DSSG)	11			Open		3
Lung	Clinical	16-61	<a href="#">ETOP BOOSTER (New)</a>	0					
Lung	Clinical	15-40	<a href="#">MK3475-091 (PEARLS)</a>	11					2
Melanoma	Trans	13-22	<a href="#">SYS-ACT</a>	12					
Melanoma	Clinical	16-14	<a href="#">CheckMate 401</a> (Closed to recruitment since last DSSG)	29			5		6
Basket	Trans	08-40	<a href="#">SNP Study</a>	137	17		4	34	1
Basket	Clinical	15-42	<a href="#">LOXO-101</a>	0					
Basket	Clinical	16-64	<a href="#">Roche MQ29518</a>	7					



## Open Studies

## Studies To Be Initiated

## Studies Pending

UHG	LUH	Mater	MRH	MUH	OLLDH	UHL	SLRON	SJH	SUH	SVUH	UHW	Whit	International Sites	Other
		2												
TBI														
			TBI				73							
3		11						0			5			
								10						
TBI								Open			open			
		4						1		Open				
		TBI									Initiated			
2		1												
1		Open						1		1				
		2						3						
3		4						3						
		Open												
1		1						1		Open				
Open											Open			
Open		Open												
9														
		Open						2			Open			
								6						
		Open												
								1						
								5						
							1							
2		1				9		6		Closed	4			
5						7		9						
							2							
2						1								
								TBI		Open				
						3		2		3				
						Open		Open						
		1				1		6		Open	1			
4										8				
3		7						1		7				
22		2							21	Pend	36			
										0				
								1		6				

## Out and about @

# ESMO 2017

The ESMO (European Society for Medical Oncology) 2017 Congress was this year's most influential annual meeting for oncology professionals in Europe.

It brought 24,000 cancer researchers and clinicians together to enable collaboration and the exchange of ideas, from the laboratory to the bedside and back. This exciting partnership created a unique cancer congress with huge scientific reach and the true potential to improve the lives of cancer patients.

During the joint ESMO-ESTRO (the European Society for Radiotherapy & Oncology) symposium entitled Lung cancer: Recent developments of multimodal treatments symposium, Dr Linda Coate, Consultant Oncologist, University Hospital Limerick, and Vice Clinical Lead with Cancer Trials Ireland, presented the paper *Oligometastatic NSCLC: When and how to combine systemic therapy and radiotherapy?*

Dr Cathy Kelly, Consultant Oncologist, Mater Misericordiae University Hospital and UCD Associate Clinical Professor presented two poster abstracts *Do oncology patients understand clinical trials?* and *A nationwide study by Cancer Trials Ireland and Decisions and supports around clinical trial participation: A national study by Cancer Trials Ireland.*

Reviewing Dr Kelly's posters at ESMO 2017 (left to right) Dr Kathleen Scott, Head of Operations and Clinical Programs, Cancer Trials Ireland; Eibhlin Mulroe, CEO, Cancer Trials Ireland, Dr Cathy Kelly, Consultant Oncologist, Mater Hospital, Dublin, and Prof Liam Gallagher, Director of the UCD Conway Institute of Biomolecular and Biomedical Research.



Dr Linda Coate, Consultant Oncologist, University Hospital Limerick, and Vice Clinical Lead with Cancer Trials Ireland presenting at ESMO 2017.



## Clinical Research Graduates

Congratulations to Sandra Boldrin (left) Quality and Training Associate II, and Carrie Gilligan, (right) Trainee Clinical Research Associate, who have graduated from the UCD Graduate Certificate in Clinical Research.

Cancer Trials Ireland, Charity No. CHY12492  
Innovation House, Old Finglas Road,  
Glasnevin, Dublin 11.  
Tel: +353 (0)1 6677211 info@cancertrials.ie  
www.cancertrials.ie Twitter: @cancertrials\_ie