



# DSSG DIGEST

**Autumn 2016**

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## CONTENT

News & Features	2
Trials open to accrual	12
Trials Round-up	
Breast	14
Translational	17
Melanoma	18
Basket	18
Lung	19
Paediatric	21
Genitourinary	24
Head & Neck	26
Central Nervous System	27
Gastrointestinal	28
Gynaecological	31
Lymphoma/Haematology	32
Notes	33
News	36

Cancer Trials Ireland is supported by



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

# Call for proposals for investigator initiated interventional trials



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

The era of large scale trials is declining for research groups like Cancer Trials Ireland.

The industry is moving towards finding the genes and proteins that trigger cancer rather than simply targeting the site of the cancer.

Trials are becoming more precise, niche and complex.

The landscape of clinical trials is changing as we move away from treatments based on tumour site of origin and more towards studies in small numbers of patients spanning disease sites but sharing common mutations.

In certain cancer types, patients are doing better than 20 years ago. Treatments are licensed for breast cancer that didn't exist 20 years ago.

We are seeing a marked shift in Cancer Trials Ireland accruals.

Disease areas like genitourinary, lymphoma and haematology are accruing increasing numbers of patients.

In parallel, cancer areas such as lung and melanoma are being targeted due to high incidence and number of deaths in Ireland.

Basket trials, which look at multiple disease types in the one study have also been introduced such as CTIRAL-IE 15-42 Loxo101 which encompasses multiple cohorts covering lung, thyroid, sarcoma, colorectal, salivary, biliary and primary CNS.

Over the course of the next 3-5 years we expect to see an increase in studies in breast, lung, melanoma and colorectal. It is expected that these developments will result in increasing accrual numbers.

## Investigator led trials

One area that we are very keen to encourage is investigator initiated interventional trials.

We currently support a number of these types of trials such as PanHER, Pazopanib, IMRT Prostate, Neo-adjuvant abiraterone prostate, Radium-223 & Enzalutamide mCRPC, and Spinal Cord Retreat; the details are included in this DSSG Digest.

These types of trials are very important. They enable investigators pursue new avenues which are not solely

reliant on pharmaceutical companies or international collaborative groups, yet may have a considerable impact at a clinical level.

They are also important for our reputation as an organisation committed to pioneering scientific discovery.

## Share your ideas

If you have an idea that you would like to pursue we would like to hear from you.

The first step is to discuss your idea with the chair of the Disease Specific Sub-Group (DSSG) you are aligned to or you can contact me directly. I would be delighted to offer any advice I can.

Our very knowledgeable and experienced staff at Group Central Office are also available for advice, particularly in the area of protocol development and data and statistical analysis.

If your DSSG chair is supportive of your proposal the next step is to develop a concept submission which is submitted formally to a DSSG meeting for discussion. The DSSGs meet three times a year.

If your DSSG supports your concept it then gets sent out for international peer review. If the response is favourable the next stage is for your concept to go before the Scientific Management Group. This group evaluates all study proposals put forward by DSSGs and ratifies studies which meet its scientific and resource criteria, and strategic objectives.

Funding can naturally be a stumbling block but we can also help you navigate your way through the possible funding streams. These can include the Health Research Board, the Irish Cancer Society and pharmaceutical companies which may be interested in supporting your idea.

So if you have an idea why not come to the next DSSG meeting and discuss it with your colleagues.

## Time to mainstream cancer trials



*Eibhlín Mulroe, CEO*

Over the past 20 years Ireland has built up a huge reservoir of expertise and experience in opening and running cancer trials.

As reported in our Summer DSSG Digest 2016, cancer trials not only contribute to the well-being of patients by giving them access to treatments they could not get through any other avenue, they contribute to Ireland's economy and intellectual capital.

Cancer trials will save the HSE more than €6.5 million this year in cancer drugs costs alone. They will generate €4.5 million in inward investment, add a total of €16.5 million to Irish GDP per annum, and generate tax revenues for the Exchequer of €5.8 million per annum.\*

### Opportunity

We have the capability to take further advantage of the opportunities cancer trials give patients and the wider economy.

If, as part of Ireland's national health policy, cancer trials are treated as an integral part of the available cancer treatment modalities, it is likely that more patients will be available to participate in trials.

It will then be possible to open more trials and provide more patients with access to new promising treatments that are not yet available.

It will also be possible to develop further our expertise in this area and attract more investment from pharmaceutical companies and international collaborative groups. If we can attract this investment we can open more trials, and the cycle repeats itself.

From our conversations with the IDA and some of the presentations during the recent Biopharma Ambition Conference 2016, it is clear that hosting cancer and clinical trials in Ireland has great potential for Ireland.

### Submission

To assist in advancing this important conversation, we made a submission to The Oireachtas Committee on the Future of Healthcare.

The Committee is examining future models of health care in Ireland. It is seeking to achieve cross-party consensus on a single long-term vision for health care and health policy in Ireland.

In our submission we argued that cancer trials should be integrated into the National Cancer Control Programme at a national policy level and promoted to all clinicians as a mainstream treatment option.

Consideration of a cancer trial as a treatment option should not be seen as a last resort or reliant on a patient's treating clinician's awareness of available cancer trials. They should be considered as an option for all patients with cancer.

We also recommended that the pending National Cancer Strategy sets a target of 5% for the number of people diagnosed with cancer who participate in cancer drugs trials. The current participation rate is 3%.

We also suggested that the opening of more cancer trials in Ireland by pharmaceutical companies and international collaborative research groups should be an objective integral to Ireland's strategy to further develop our Life Science industry. We pointed out that Denmark's success in this area illustrates the potential for Ireland.

While we do not expect an immediate response from the Committee we hope we have triggered an important conversation.

### Staff

I would like to take this opportunity to commend our staff at the Group Central Office in Dublin and all of the research teams around the country for actively engaging with our change programme which has been underway for over 12 months.

We have made many changes to the way we are run and how we manage our activities. We have also been more actively engaging with our stakeholders.

We are also working more closely with research teams in hospitals around the country to enable us share best practices and develop as a cohesive team.

Work is ongoing with the development of Cancer Trials Ireland and I have no doubt with your continued support and contribution we can continue to have a significant impact on the global search for more answers to cancer.

\* Health and Economic Impacts of Cancer Trials in Ireland, DKM Economic Consultants (2016).

## Cancer Trials Ireland calls for a €1 million fund to boost cancer trials in Pre-Budget 2017 Submission

In its pre-Budget 2017 submission, Cancer Trials Ireland has called for the establishment of a €1 million fund to enable cancer specialists open more cancer trials in Ireland.

It has also called for a ring-fenced fund of €1.4 million within the HSE for the development of the existing 14 cancer trials research centres in hospitals around the country.

Its submission argues that this investment will reduce the HSE's cancer drug costs, provide people with cancer with access to promising treatments not normally available and attract more inward investment from pharmaceutical companies and international research organisations.

Cancer Trials Ireland CEO, Eibhlin Mulroe, said that investing in Ireland's cancer trials infrastructure made sense at a number of levels.

"Our recent independent report by DKM Economic Consultants shows that for every €1 the Exchequer invests in cancer trials it saves more than €2 in cancer treatment costs.

"This year cancer trials will save the HSE more than €6.5 million in cancer drugs costs alone," she said.

"We are also able to multiply the impact of the Government's investment by attracting investment from pharmaceutical companies and international research groups.

"In 2016 we will receive just over €3 million from the Exchequer and generate an additional €4.5 million from other sources.

"If we can get support for the initiatives in our submission we can save the State more in drugs costs, give patients more options and further develop our trials infrastructure," she said.

There is strong evidence to show that when cancer specialists such as oncologists have access to protected time they source and open more cancer trials in their areas of specialisation.

The €1 million fund Cancer Trials Ireland is calling for would be available for oncologists for resources to support their cancer research. It suggests this fund could be administered by the National Cancer Control Programme or the Health Research Board.

Cancer Trials Ireland has called for a ring-fenced fund of €1.4 million within the HSE for capital and staff costs to bolster the existing network of cancer trials research units. It is seeking a once off allocation of €700,000 to upgrade existing research facilities, which in some instances are housed in temporary buildings, and €700,000 towards staff costs. This investment will enable Ireland's cancer trials infrastructure better compete with facilities in other countries and encourage global pharmaceutical companies and

international research organisations to open more cancer trials in Ireland.

Cancer Trials Ireland CEO, Eibhlin Mulroe said: "If the right research facilities are in place we can not only attract more valuable inward investment but we can offer cancer patients treatments which may otherwise only be available to patients in other countries."

The third element of Cancer Trials Ireland's pre-Budget 2017 submission is an investment in an integrated trial data management system to enhance the organisation's proposition when seeking to attract new global trials to Ireland.



## World Congress



*Dr Cathy Kelly and Professor Michael Kerin were on Faculty and speakers at the 2nd World Congress on Controversies in Breast Cancer (CoBrCa) held in Barcelona in September.*

Dr Kelly is Chair of the Breast DSSG and a member of the Board of Cancer Trials Ireland. She is a Medical Oncologist at The Mater Misericordiae University Hospital and Mater Private Hospital, Dublin. Prof Michael Kerin, Co-Chair of the Breast DSSG, is Consultant Breast Surgeon and Director of the Lambe Institute for Translational Research at Galway University Hospital. Professor Kerin is a speaker at the Autumn DSSG conference during the Stakeholder Engagement Meeting on the subject of Translational research in cancer.



## Irish patients among the first to access new drug combination as a first line treatment

Cancer Trials Ireland has opened the Irish arm of a European breast cancer trial to test the effectiveness of a new combination of drugs as a first line treatment for advanced breast cancer.

Known as The FLIPPER Study, the trial is sponsored by GEICAM, the Spanish Breast Cancer Group, and will involve 190 patients across Europe, with 40 from Ireland.

The trial will investigate the added benefit of combining the new drug palbociclib with an existing drug fulvestrant. Fulvestrant is currently used to treat postmenopausal women with hormone receptor (HR)-positive advanced breast cancer.

Palbociclib is approved in the USA by the US Food and Drug Administration (FDA) but is not yet approved in Europe for treating HR-positive, HER2-negative advanced breast cancer. As a result Irish patients who receive this new drug combination during the trial will be the first in Ireland to do so as a first line treatment for their advanced breast cancer.

The new drug combination will be tested among postmenopausal women with advanced breast cancer, who have had at least 5 years of standard hormonal treatment and have remained disease free for more than 12 months, but have subsequently suffered a relapse or are diagnosed with new cancer which has spread to other parts of their body.

The trial is expected to continue over the next 4 years with 8 hospitals in Ireland participating. These include St. James's

Hospital, Dublin; St Vincent's University Hospital, Dublin; Mater Misericordiae University Hospital, Dublin; Beaumont Hospital, Dublin; Bon Secours Hospital, Cork; University Hospital Galway; University Hospital Waterford; and University Hospital Limerick.

The study's Principal Investigator in Ireland is Dr Miriam O'Connor, Consultant Medical Oncologist, at University Hospital Waterford.

Dr O'Connor said that the growing data about the clinical



Dr Miriam O'Connor

activity of fulvestrant, together with the efficacy data for palbociclib, support their combined use in women with HR-positive, HER2-negative advanced breast cancer.

"There is an unmet need for effective, non-toxic therapy for women with this type of breast

cancer. We hope the study will provide new data to assist physicians in their management of patients with advanced breast cancer and help us find more answers," she said.

AstraZeneca and Pfizer are collaborating in the funding of this trial.

**To find out more about this trial contact Dr Miriam O'Connor at University Hospital Waterford: [Miriam.OConnor2@hse.ie](mailto:Miriam.OConnor2@hse.ie) or the Cancer Trials Ireland Project Manager: Andres Hernando: [Andres.Hernando@cancertrials.ie](mailto:Andres.Hernando@cancertrials.ie)**

## Trial builds on promising laboratory based research

Building on his previous laboratory research, funded by the Health Research Board (HRB) and the Irish Cancer Society, Prof. Bryan Hennessy, Clinical Lead with Cancer Trials Ireland, and Consultant Oncologist, Beaumont Hospital has opened a trial to test for the first time the use of copanlisib in combination with trastuzumab to treat advanced HER2-positive (HER2+) breast cancer which has progressed or recurred in patients during or following standard anti-HER2+ treatment.

The trial is sponsored by Cancer Trials Ireland and supported by Bayer HealthCare AG. It is expected that up to 34 patients will take part in the trial which will be conducted over the next 2-3 years in Beaumont Hospital, Dublin, St Vincent's University Hospital, Dublin, St. James's Hospital, Dublin, University Hospital Galway and Cork University Hospital.

Current treatments that specifically target HER2+, such as trastuzumab, are effective at helping to slow or even stop the growth of breast cancer cells. However, resistance to HER2+ targeted treatments can develop, meaning that current treatments can become ineffective.

Prof. Hennessy said that copanlisib could help to reverse the resistance of some HER2+ breast cancers to trastuzumab and lead to a new therapy for advanced HER2+ breast cancer.

"It is known that HER2+ breast cancer can become resistant to current therapies. We are now learning how this happens. The switching on of a pathway called the PI3K pathway in cancer cells is often responsible. One of the possible ways this happens is through mutations (changes) that occur in a gene called PIK3CA.

Research studies that we have carried out at the laboratory level have suggested that blocking the abnormal activity of the PI3K pathway in cancer cells, may help to reverse the resistance of some HER2+ breast cancers to treatments including trastuzumab," he said.

"Copanlisib blocks the abnormal activity in the PI3K pathway and it is currently being tested in a variety of cancers. By combining copanlisib and trastuzumab, this trial will evaluate whether copanlisib will block the abnormal activity of the PI3K pathway and allow trastuzumab to work effectively," he said.



Prof. Bryan Hennessy

**To find out more about this trial contact Prof. Bryan Hennessy at Beaumont Hospital: [Bryan.Hennessy@hse.ie](mailto:Bryan.Hennessy@hse.ie) or the Cancer Trials Ireland Project Manager: Andres Hernando: [Andres.Hernando@cancertrials.ie](mailto:Andres.Hernando@cancertrials.ie)**

## Cancer Research Team Development Programme launched



*Shane Ring, Business Development Manager.*

We launched our Development Programme for cancer research teams around the country and head office (GCO) staff in September.

The get together marked the first in a series of three workshops we plan to host during the next 12 months.

The idea for the Development Programme came about from my discussions with Team Leaders, Data Managers, Research Nurses and Research Radiation Therapists over the past few months.

During our conversations the value of a forum for the Cancer Research Teams to meet and discuss issues, share ideas and network with colleagues working in the same role in other parts of the country became apparent.

We have designed the Development Programme to foster closer working relationships between colleagues in the cancer research units around the country and GCO. It is also envisaged that they will provide a forum to discuss existing processes and procedures and share best practices and problem solving techniques between colleagues.

I would like to thank all who took part in our inaugural development day and contributed to making it a success. I look forward to meeting you at the next Workshop in January 2017.



*(l to r) Orla Casey, Translational Co-ordinator (GCO), Eimear Sills, Research Assistant and Jessica-Claire Long, Clinical Data Manager, both from St. Vincent's University Hospital, Dublin, and Olwyn Deignan, Senior Clinical Project Manager (GCO).*



*(l to r) Donnacha Dunne, Data Manager, St James's Hospital, Dublin, Aishling Ryan, Team Leader, Our Lady's Children's Hospital, Crumlin, Jacinta Marron, Data Manager (GCO) and Corrina Philips, Data Manager / CRA, Our Lady's Children's Hospital, Crumlin.*



*(l to r) Research Radiation Therapists from St. Luke's Radiation Oncology Network with Eibhlin Mulroe, CEO of Cancer Trials Ireland (second from the right), Martina Sheehan, Emer Corcoran, Lesley McDonagh and Lydia O'Sullivan.*





(l to r) Lisa Tucker, Clinical Project Manager (GCO) with Claire Temple, Pharmacist, St James' Hospital, Dublin.



(l to r) Members of the University Hospital Galway team with Eibhlin Mulroe, CEO of Cancer Trials Ireland (third from the left), Helen O'Reilly, Research Nurse, Olive Forde, Research Nurse, Swapnil Gaware, Data Manager, Mary Byrne, Team Leader, and Caroline Whiskey, Pharmacist.



Members of the Cork University Hospital team (L to r) Katrina Falvey, Research Nurse, Liz Lenihan, Research Nurse, Debra O'Hare, Team Leader, Anna Cole, Data Manager and Karen Molen, Trials Radiation Therapist. (Inset) Clinician and executive coach Phil Shovlin facilitated a workshop during the Development Day on Appreciative Inquiry to positively flesh out issues concerning participants.

## Thanks to our sponsors

The Research Team Development Days have been very kindly supported by the following companies. Their support is very much appreciated.

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*Emma Noone, Research Radiation Therapist at St. Luke's Hospital, Rathgar with one of the new signs.*

## A sign of the times!

As part of our campaign to increase the profile of Cancer Trials Ireland around the country we have commissioned new indoor signs for display in the 14 cancer trials research units in hospitals around the country.

The signs will be displayed in the Oncology Day Units, research units and where possible in hospital foyers.

"It's all part of our activities to raise our profile and get our name in front of as many people as possible," said Shane Ring, Business Development Manager, who is organising the initiative. Lapel badges (inset) are now also available for staff to make themselves more identifiable when meeting with patients.



Call us on (01) 6677211 and we can send you some.



*Shane Ring, Business Development Manager, pictured with Debra O'Hare, Team Leader, at Cork University Hospital.*



*Pictured at the Bons Secours in Cork with their new sign (l to r) Marie Casey, Research Nurse, Aoife O'Shea, Research Nurse, and Dr Conleth Murphy, Consultant Medical Oncologist.*

## In remembrance



Colm Devon was the much loved husband of Tara and devoted father of Ryan and Kian. He was a committed patient advocate and friend to Cancer Trials Ireland.

Colm played a huge part in the launch of Cancer Trials Ireland's new name in the Mansion House on 20th May on International Clinical Trials Day 2016.

He and Tara shared their journey with pancreatic cancer with the country through newspaper interviews and video recordings. He encouraged those who had the opportunity to take part in a cancer trial, to take it.

One of Colm's wishes was that his young sons would remember their Dad. He said the trial gave him some more time, not enough, to create these memories.

Sadly Colm passed away on 15th September 2016. One of the things he prepared before he died was a time capsule for his sons to open when they are 18. Included were the newspaper cutting and the photographs of his role in International Clinical Trials Day 2016.

We extend our deepest sympathies to Tara, Kian and Ryan on the passing of a true gentleman.

Ar dheis Dé go raibh a anam



## A warm welcome to new additions to our GCO team

**Ide Fagan, HR Partner**

**And welcome back to...**

**Grace Hirakata, Senior CRA**

**Lisa Tucker, Clinical Project Manager**

**Aoife Vaughan, CRA (translational)**

## Congratulations

Congratulations to Sandra Boldrin and Carrie Gilligan who have been awarded scholarship places on UCD's Online Graduate Certificate in Clinical Research. The two places have been kindly sponsored by UCD.



*Carrie Gilligan, CTA*



*Sandra Boldrin, Quality & Training Associate II*

The programme features expert-led modules in clinical research management, biostatistics and data management and clinical trials, as well as additional lectures delivered from subject matter experts to contextualise the core learning in actual clinical trial settings.

By using e-learning content and online delivery the programme is flexible to fit in around a busy schedule.

Regular assessment and weekly contact with tutors enables participants to progress through the programme. Weekly delivery of content allows the student to view lectures in their own time.

## Promotions

A number of Cancer Trials Ireland GCO team members have received well deserved promotions.

### **Dr Ronán Feighery promotion to CRA II:**

Ronán joined us in January 2014 and was promoted to CRA the following year. Since then, he has been responsible for all breast cancer studies within the translational portfolio and has successfully set up a complex melanoma study. In addition, he is the coordinator of the translational DSSG and has been instrumental in the timely preparation of the agenda, slides and minutes.



### **Liz Coghlan promotion to CRA II:**

Liz joined Cancer Trials Ireland in June 2015 as a CRA. She has worked previously as a CRA in industry and as a clinical research coordinator at UCD. She has more than 15 years experience in nursing and midwifery. Liz hit the ground running with the TRIO 023/EMBRACA trial which has been both demanding and fulfilling, given its niche population. Liz has also been joint CRA on the RsqVD and the THL trials, responsible for sites in Ireland. Liz will soon be working on the POSITIVE trial which will complement her midwifery background.



### **Ausra Teiserskiene promotion to CRA II:**

Ausra Teiserskiene joined Cancer Trials Ireland over 5 years ago as Clinical Trial Administrator. She entered the tCRA training program in 2014 and transitioned to the role of CRA in 2015.

Ausra has successfully met the TCHL (CTRIAL 10-05) timelines for primary endpoint and safety collection earlier this year, while also closing out the study and taking over complete responsibility of the GU 13-21 study (7 sites). Ausra has recently been appointed as the CRA for the PanHER study, a very important in house trial for Cancer Trials Ireland. In addition to all of these tasks, Ausra is also the Genitourinary DSSG coordinator.

Additional promotions include Luke Heaphy to CTA and Emma Farrell to tCRA.

## Tribute

We would like to pay tribute to Colum Diamond, former Director at AON Insurance who passed away suddenly on 23<sup>rd</sup> of August.

Colum was well known by both GCO and research teams in hospitals around the country, in his role overseeing the Clinical Indemnity Scheme and sponsor and institutional clinical trials insurance.

Colum always endeavoured to overcome the obstacles which may have arisen, from an insurance perspective, in the course of running trials. Colum was a great support to Cancer Trials Ireland for many years and will be greatly missed.

## Leading the way in prostate cancer trials

By Olwyn Deignan B.Sc., Senior Clinical Project Manager, Cancer Trials Ireland

The 2<sup>nd</sup> John Fitzpatrick Irish Prostate Cancer Conference held in Dublin earlier this year, brought together leading Irish and UK health care professionals with an international faculty of oncology and urology experts from around the world.

Prostate Cancer is the most commonly diagnosed cancer among men, affecting one in six men in Ireland and the US.

This year it is estimated that more than 180,000 men will be diagnosed with prostate cancer in the US while more than 3000 men will be diagnosed in Ireland.

Prostate cancer is treatable if detected early, however where the cancer has spread to other parts of the body, survival rates and outcomes are poorer.

Speaking at the conference Professor Ray McDermott, Medical Oncologist and Vice Clinical Lead with Cancer Trials Ireland chaired the Trials and Outcomes session and spoke of the first wave of newer hormonal agents. These newer hormonal therapies are expected to have better side effect profiles and to be more efficacious.

Professor John Armstrong, Consultant Radiation Oncologist and Director of Research at St. Luke's Hospital Dublin and founding member of Cancer Trials Ireland gave a complete overview of the radiotherapy trials for prostate cancer in Ireland.

Professor Armstrong has been instrumental in the roll out of new procedures involving high tech radiation therapy procedures such as Intensity Modulated Radiation Therapy (IMRT) and Stereotactic radiosurgery over the last 20 years.



Cancer Trials Ireland, through the support of the pharmaceutical industries in Ireland and our continued successful international collaborations with other prominent cooperative cancer clinical trial groups and hospitals, has led to a significant increase in the number of prostate cancer trials currently active in Ireland in 2016. This in turn opens up opportunities for patients to get early access to treatments that would otherwise not be available to them.

Cancer Trials Ireland's current prostate cancer trials cover the following areas of disease: localised high risk prostate cancer (prostate cancer which has not spread to other parts of the body), metastatic prostate cancer (prostate cancer which has spread to other parts of the body) both hormone sensitive and castration resistant. These trials are introducing the newer hormonal therapies highlighted by Professor

McDermott and therefore allow earlier access to these treatments for Irish patients.

The results of these trials may have the power to change standard of care globally. A recent example of this, presented at the conference by Professor Christopher J. Sweeney MBBS, Medical

Oncologist from the Dana Farber Institute, was the results of the CHAARTED trial. This trial was carried out to determine if treatment with standard hormone therapy plus docetaxel would result in longer overall survival than that with hormone therapy alone. Standard hormone therapy had been the backbone of treatment for metastatic prostate cancer since the 1940s.

The conclusion of the CHAARTED trial was that six cycles of docetaxel at the beginning of standard hormone therapy for metastatic prostate cancer resulted in significantly longer overall survival than that with hormone therapy alone.

The results of this trial has changed standard of care and Cancer Trials Ireland adapted all of our in-house ongoing metastatic prostate cancer trial protocols to include this as an allowed therapy.

It was also evident through our role as European Sponsor on one of the ongoing collaborative metastatic prostate cancer trials how quickly this new treatment option became standard of care in Ireland and the UK.

Cancer Trials Ireland is also running cancer trials in the area of translational research which are specific to prostate cancer.

These trials are contributing to the ongoing important research to make it possible to better select patients for a particular drug based on their prostate cancer phenotype.

Professor Stephen Finn, Pathologist and co-director of the Cancer Molecular Diagnostic Laboratory at St. James's hospital and member of Cancer Trials Ireland, presented new translational studies for prostate cancer patients involving exercise both of which are being run in conjunction with Cancer Trials Ireland.

Cancer Trials Ireland is at the centre of prostate cancer research in Ireland. We continue to strive for patient access to the best treatments available globally and keep up to date with changes in standard practice which is constantly evolving in the area of prostate cancer.

References:

<http://www.irishprostatecancerconference.org/programme.html>

<http://www.nejm.org/doi/full/10.1056/NEJMoa1503747>



*Olwyn Deignan, Senior Clinical Project Manager*



*Dr Ronán Feighery, one of our team of Clinical Research Associates II, specialises in translational research. He tells us about a typical week at Cancer Trials Ireland*



*Dr Ronán Feighery,  
CRA II*

#### **Monday:**

A very busy start to the week. I was out of the office on Friday so there are lots of e-mails to respond to.

A shipment of samples from the long-running TAILORx study (ICORG 06-31) was arranged. There has been a lot of communication with ECOG, Biomnis and our research units over the last few weeks on issues such as collection timings, sample tracking and costs.

I contacted some research units regarding the remaining CRQ surveys. The CRQ survey study (CTRIAL-IE (ICORG) 15-43) aims to evaluate oncology patients' understanding of the term 'clinical trials' and their attitudes towards personal participation in cancer clinical research. The response rate has been excellent and we have received a lot of positive feedback regarding this study and its implementation. When we were developing this study, many research teams around the country kindly offered advice on target numbers and patient recruitment. More data entry is on the agenda this week – we hope to have results later in the year.

Recently, I have received numerous Case Report Forms (CRFs) that have come in for the Circulating miRNA study (CTRIAL-IE (ICORG) 10-11). Remote monitoring is an effective use of our resources for translational studies across multiple hospital. However we depend greatly on the research teams to send us CRFs on a regular basis to enable this. This collaboration is essential in avoiding backlogs when a study reaches maturity.

#### **Tuesday**

Today I started work on a substantial amendment to the Exosomal study (CTRIAL-IE (ICORG) 10-15) which will hopefully streamline processes for the participating Dublin hospitals. A huge amount of our time goes towards preparing ethics submissions. Each initial submission (and subsequent amendment) needs approval from the Research Ethics Committee in each participating hospital. Consequently, there is a huge amount of administrative work. It's very important that we get the protocol right the first time and avoid having to go back to each committee to get amendments approved! A centralised ethics process for translational studies would be ideal!

#### **Wednesday**

A few minor problems with the TAILORx sample collection but Biomnis informed me that the samples are on the way to ECOG and everyone is happy.

With the Autumn DSSG meeting approaching fast, I spent most of today preparing the slides, agenda and portfolio map for the Translational DSSG meeting so that we can provide participants with a comprehensive overview of what is happening with our studies. I also submitted the substantial

amendment for the Exosomal study to seven Research Ethics Committees.

#### **Thursday**

I spent most of this morning entering data for the CRQ Survey study. A bit tedious but imperative that it's correct.

I was in contact with Prof. Young's research team in RCSI concerning the numbers for the Proteomics & Molecular Heterogeneity (CTRIAL-IE (ICORG) 09-07) study for the upcoming DSSG. This study is the largest translational study in our portfolio and recruitment is expected to increase with the opening of the study at St Vincent's University Hospital. Some translational studies require close collaboration between the surgical team, the pathology team and the oncology team. For these studies our team develops hospital-specific strategies with the medical staff involved to ensure that the study work flow is followed. This process has worked very well in some hospitals but has been more difficult to implement in others.

#### **Friday**

A big part of my job is to continuously monitor each study for accrual activity and performance. Regular update e-mails are sent to research teams in each hospital to keep them informed of the status of each study. Today, I contacted a number of research teams who have not yet sent FFPE tissue blocks for the TAILORx Tissue Bank study (CTRIAL-IE (ICORG) 12-30). The researchers first started to receive these blocks from hospitals participating in this study as far back as 2014. These types of delays can have a knock on effect causing delays for the researchers, and subsequently delays in returning the blocks to each hospital.

Research teams often focus on clinical trials ahead of translational studies so moving these studies forward can be challenging, but is all part of the job. While translational studies may not have an immediate benefit for a patient, they have the potential to pave the way for revolutionary treatments which can have a long lasting benefit. The prospect of being part of a team that made ground breaking progress on how we treat cancer is a great motivator.

*Dr Ronán Feighery joined Cancer Trials Ireland in January 2014 and since January 2015 he is responsible for all breast cancer studies within the translational portfolio and has successfully set up a complex melanoma study. Ronán was recently promoted to CRA II.*

# 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
Breast	Trans	09-07	Breast Cancer Proteomics and Molecular Heterogeneity	1426			560	
Breast	Trans	10-11	Circulating miRNA	187			4	16
Breast	Trans	10-15	Exosomal HER2	228	43	Open	51	45
Breast	Trans	10-16	Ovarian Reserve	123	19	Open	29	16
Breast	Trans	12-09	CharactHer	187			6	
Breast	Trans	12-30	TAILORx Tissue Bank	567	23		33	14
Breast	Trans	12-40	EORTC 10085	14			3	
Breast	Clinical	14-01	EMBRACA/ MDV 673-301 (TRIO 023)	5				
Breast	Clinical	15-17	PALLAS	0			TBI	
Breast	Clinical	15-49	NeoTRIP	0			TBI	
Breast	Clinical	14-11	PENELOPE-B	16			2	Open
Breast	Clinical	14-21	NALA	3				
Breast	Clinical	14-22	16298 Radium 223 in BC (Bayer)	0				
Breast	Clinical	15-02	PantHER	2			2	
Breast	Clinical	15-33	KEYNOTE-119 in mTNBC (MSD)	6				
Breast	Radio	15-03	NSABP B-51	2				
Breast	Clinical	15-16	FLIPPER	1			TBI	Open
CNS	Trans	08-13	Serum Protein Markers for Glioma	77			77	
CNS	Clinical	15-28	M13-813 INTELLANCE 1	4			4	
CNS	Clinical	15-29	M14-483 INTELLANCE 2	7			5	
GI	Clinical	10-14	Neo-AEGIS	130			1	
GI	Clinical	11-32	Lithium Autophagy Study	0			TBI	
GI	Trans	12-27	CRAC Plasma Biomarkers	75	3	Open	24	11
GI	Trans	12-31	PDAC Plasma Biomarkers	80	36	Open	5	3
GI	Radio	12-38	TRI-LARC	30				
GI	Clinical	14-19	BMS CA209-142 (CheckMate 142)	16			2	
GI	Clinical	14-20	GERCOR STRATEGIC-1	0	Initiated			Initiated
GI	Clinical	16-28	MK 3475-177	1	1			
GU	Trans	12-29	IMPACT study	23				
GU	Clinical	13-09	PEACE-1	27	2			
GU	Clinical	13-21	Radium-223 & Enzalutamide mCRPC	30	19			
GU	Clinical	13-23	Neo-adjuvant Abiraterone prostate	4				
GU	Trans	14-04	iPROSPECT	55	26	Open	Open	
GU	Clinical	14-06	ENZAMET	126	22	Open	2	
GU	Clinical	14-07	ENZARAD	41		8		
GU	Trans	15-21	ExPeCT study	21	5		1	
GU	Trans	16-07	IPCOR	1003	21	70	79	64
Gynae	Radio	09-06	Endometrial - IMRT v 3D RT	64				
Gynae	Clinical	11-29	ICON8B	11				2
Gynae	Clinical	14-02	SHAPE	7				
Gynae	Clinical	15-22	JAVELIN 200	0				
H & L	Clinical	12-02	E3A06 Lenalidomide in Smoldering Myeloma (ECOG-ACRIN)	3				
H & L	Clinical	15-08	ROBUST Lenalidomide plus RCHOP in ABC DLBCL (Celgene)	1				
H & L	Clinical	15-09	ARROVEN Brentixumab Vedotin PASS Study in HL (Millennium)	8			5	
H & L	Clinical	15-10	OPTIMISMM Pomalidomide Study in rel/ref MM (Celgene)	6				
H & L	Clinical	15-37	CHRONOS-2 Copanlisib v placebo in rituximab refractory iNHL (Bayer)	0			Open	
H & L	Clinical	15-38	CHRONOS-3 Copanlisib v placebo + rituximab in relapsed iNHL (Bayer)	2			Open	
H & L	Clinical	15-11	MMY3008 Daratumumab in Multiple Myeloma (Janssen)	7				
H & L	Clinical	15-36	Rigosertib versus Physicians Choice in MDS (Onconova)	0	Open			
H & L	Clinical	16-08	Millennium P2001 Pevonedistat	0	Open			
H & L	Clinical	16-10	KEYNOTE - 185	0			Open	
H & L	Clinical	16-02	CyBorD with Daratumumab in transplant eligible patients with newly diagnosed MM	0				
Head & Neck	Clinical	12-39	De-ESCALaTE HPV	15			2	
Lung	Clinical	12-53	ETOP SPLENDOUR	20	1		Open	
Lung	Radio	15-05	Oligo-Recurrent Metastatic Disease	7		7		
Lung	Clinical	15-27	BMS CA209-227 (CheckMate 227)	5			1	
Lung	Radio	15-47	INTENSE	0				
Lung	Clinical	16-18	BMS CA209-451 (CheckMate 451)	1	Open			
Lung	Clinical	16-16	MSD MK3475-189	0			TBI	
Lung	Clinical	15-40	EORTC 1416 (PEARLS) study	2				
Melanoma	Trans	13-22	SYS-ACT	9			TBI	
GU	Radio	07-11	Spinal Cord Retreat	22				
Survey	Trans	15-43	CRQ Survey	796	100	Open	100	100
Other	Trans	08-40	SNP Study	115	17		3	24
GI	Clinical	14-17	Exelixis Celestial Study	2				
Basket	Clinical	15-42	LOXO-101	0				
Melanoma	Clinical	16-13	Keynote-252	1				
Melanoma	Clinical	16-14	CheckMate 401	0			TBI	



CUH	UHG	LUH	Mater	MRH	MROC	MUH	UHL	SLRON	SJH	SUH	SVUH	UHW	Whit	International Sites	Other
400							385		11		Open	70			
	127								30	8	Open	2			
10		7							2	23	36	11			
20									6	8	18	7			
			6						6		153			Italy 16	
72	66	14	79			Open	Open		37	32	167	30			
4			Open						1		4	2			
	1		3				Closed				1				
TBI			TBI						TBI		TBI	TBI			
TBI	TBI		TBI						TBI		TBI	TBI			
Open	6		3				TBI		2		3	Open			
Open	Open		Open				Open		2		1				
Open			Open												
	Open										Open				
			5								Open				
	Open							2							
	TBI		Open				TBI		Open		TBI	1			
2															
TBI	1							Open	74					54	
TBI									TBI						
	11	3	3						Open	9	2	9			
	3	TBI									26	7			
								30							
	1										13				
Initiated	Initiated		TBI						Initiated		Initiated	Initiated			
									Initiated						
			1						22						
9	1		12								3				
4	TBI		2					Open			5				
Open	1							3							
3	TBI		5						Open	6	14	1			
	TBI		15						Open		9	9		UK 10 sites (69)	
13	1		2					5					TBI	UK 7 sites (12)	
			3					TBI	12					UK 16	
61	262		162			81	1		28		43				131
					TBI			64							
	Open		7				TBI		Open			2			
									7						
			Open						Open		TBI	TBI			
	2		1												
Open	Open		Open						1		1				
			Open						3						
	3		4						3						
			TBI												
	1		1						Open		Open				
	5		2												
Open	Open											Open			
	TBI		Open												
TBI	TBI		TBI												
								13							
3	2		1				5		6		Open	2			
	2						1		1						
								Open							
Open	1										TBI				
							Open		TBI		TBI				
Open			1				Open		1		Open	Open			
TBI	2										7	TBI			
	3							18							
50	Open	50	100					Open	100	47	100	49			
1	21		2							19	Pend	28			
			2												
											0				
Open	Open		TBI								1				
Open	TBI		Open						TBI		TBI				

## Breast Cancer Trials




Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>NALA CTRIAL-IE (ICORG) 14-21</b> PI: Prof John Crown Type: Industry Sponsored Sponsor: PUMA	Global: Mar 2013  <b>Ireland</b> Feb 2016	CUH, UHG, Mater, UHL, SJH, SVUH.	600	N/A	18	<b>3</b> SVUH 1 SJH 2	Dec 2016
<b>Title:</b> Randomized, multi-center, multinational, open-label, active-controlled, parallel design study of the combination of neratinib plus capecitabine versus the combination of lapatinib plus capecitabine in HER2+ MBC patients who have received two or more prior HER2 directed regimens in the metastatic setting.							
<b>Comment:</b> Accrual extended to December 2016. Global accrual figures not released by company.							
<b>Penelope B CTRIAL-IE (ICORG) 14-11</b> PI: Dr Cathy Kelly Type: Collaborative Group Sponsor: German Breast Group	Global: Apr 2013  <b>Ireland</b> Sept 2015	BH, BonS, CUH, UHG, Mater, UHL, SJH, SVUH, UHW	800	624	20	<b>16</b> UHG 6, Mater 3, BH 2, SJH 2, SVUH 3,	Sep 2017
<b>Title:</b> Phase III study evaluating palbociclib (PD-0332991), a Cyclin-Dependent Kinase (CDK) 4/6 Inhibitor in patients with hormone-receptor-positive, HER2-normal primary breast cancer with high relapse risk after neo-adjuvant chemotherapy “Penelope B”.							
<b>Comment:</b> 8 sites activated.							
<b>MDV 673-301/ TRIO 023 / EMBRACA Study CTRIAL-IE (ICORG) 14-01</b> PI: Prof John Crown Type: Industry Sponsored/ Collaborative Group Sponsor: MEDIVATION in collaboration with TRIO	Oct 2013  <b>Ireland</b> June 2014	UHG, Mater, SVUH	429	235	2 Pts per site per year	<b>5</b> Mater 3, SVUH 1, UHG 1	Dec 2016
<b>Title:</b> A Phase III, Open-Label, Randomised, Parallel, 2-Arm, Multicentre Study of BMN 673 versus Physician’s Choice in Germline BRCA Mutation Subjects with Locally Advanced and/or Metastatic Breast Cancer, who have received no more than 2 prior Chemotherapy Regimens for Metastatic Disease.							
<b>Comment:</b> Referral of patients to open sites encouraged.							
<b>PanTHER CTRIAL-IE (ICORG) 15-02</b> PI: Prof Bryan Hennessy Type: In-House Sponsor: 	August 2016	BH, SVUH, UHG	N/A	N/A	31	<b>2</b> BH 2	Dec 2019
<b>Title:</b> Phase Ib/II clinical trial of copanlisib in combination with trastuzumab in pretreated recurrent or metastatic HER2-positive breast cancer.							
<b>Comment:</b> Referral of patients to open sites encouraged.							
<b>Protocol 16298 CTRIAL-IE (ICORG) 14-22</b> PI: Dr Jennifer Gilmore Type: Industry Sponsored Sponsor: Bayer	<b>Ireland</b> Feb 2016	MPH, CUH, SLRON	227	26	5	<b>0</b>	October 2017
<b>Title:</b> A phase II randomized, double-blind, placebo-controlled trial of radium-223 dichloride vs. placebo when administered to Her 2 negative hormone receptor positive breast cancer with bone metastases treated with standard of care hormonal treatment							
<b>Comment:</b> MMUH to potentially open .							






## Cancer Trials Round Up—Open and Closed since last DSSG Meeting

## Breast Cancer Trials

Chairs of Breast DSSG: Dr Cathy Kelly & Dr Patrick Morris Co-ordinators: Paulina Lawner/Andrés Hernando


Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>KEYNOTE 119</b> <b>CTRIAL-IE (ICORG) 15-33</b> PI: Dr Cathy Kelly Type: Industry Sponsored Sponsor: MSD	Global: Oct 2015  <b>Ireland</b> Dec 2015	SVUH, Mater	600	166	8	<b>6</b> Mater 6, SVUH 0.	Oct 2016
<b>Title:</b> A Randomized Open-Label Phase III Study of Single Agent Anti-PD1 versus Single Agent Chemotherapy per Physician's Choice for Metastatic Triple Negative Breast Cancer (mTNBC) <b>Comment:</b> Patient referrals welcome.							
<b>NSABP B51</b> <b>CTRIAL-IE (ICORG) 15-03</b> PI: Dr Joseph Martin Type: Collaborative Group Sponsor:	Global: Aug 2013  <b>Ireland</b> Feb 2016	SLRON, UHG	1636	430	Not specified	<b>2</b> SLRON 2	2018
 <b>Title:</b> A Randomised Phase III Clinical Trial Evaluating Post-Mastectomy Chestwall and Regional Nodal XRT and Post-Lumpectomy Regional Nodal XRT in Patients with Positive Axillary Nodes Before Neoadjuvant Chemotherapy Who Convert to Pathologically Negative Axillary Nodes After Neoadjuvant Chemotherapy <b>Comment:</b> CUH interested in participating.							
<b>EORTC 10085 Male Breast Cancer</b> <b>CTRIAL-IE (ICORG) 12-40</b> PI: Dr Cathy Kelly Type: Collaborative Group Sponsor: EORTC	Feb 2014	BH, CUH, Mater, SJH, SVUH, UHW	N/A	387	N/A	<b>14</b> BH 3, CUH 4, SJH 1, SVUH 4, UHW 2	Feb 2017
<b>Title:</b> EORTC 10085 – Male Breast Cancer: Clinical and biological characterization of Male Breast Cancer: an international EORTC, BIG, TBCRC and NABCG intergroup study. <b>Comment:</b> Study will close to recruitment on 28-Feb-2017.							
<b>Proteomic/Molecular Breast</b> <b>CTRIAL-IE (ICORG) 09-07</b> PI: Prof Leonie Young & Prof Bryan Hennessy Type: In-House Sponsor:	Jan 2013	BH, CUH, SJH, SVUH, UHL, UHW	N/A	N/A	N/A	<b>1426</b> BH 560; CUH 400; SJH 11; UHL 385; UHW 70	N/A
 <b>Title:</b> Breast cancer proteomics and molecular heterogeneity. <b>Comment:</b> SVUH is now open and will begin recruitment soon.							
<b>Circulating miRNA</b> <b>CTRIAL-IE (ICORG) 10-11</b> PI: Prof Michael Kerin Type: In-House Sponsor:	May 2011	BH, BonS, UHG, SJH, SUH, SVUH, UHW	N/A	N/A	Cohort 1: 122 (closed) Cohort 2: 122 Cohort 3: 122	<b>187</b> BH 4, BonS 16, UHG 127, SJH 30, SUH 8, UHW 2	TBC
 <b>Title:</b> Circulating miRNAs: Novel breast cancer biomarkers and their use for guiding and monitoring response to therapy. <b>Comment:</b> Accrual needs to improve.							

## Breast Cancer Trials

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>FLIPPER</b> <b>CTRIAL-IE (ICORG) 15-16</b> PI: Dr Miriam O'Connor Type: Collaborative Group Sponsor: GEICAM  <b>Title:</b> A randomized, double-blind, parallel-group, multicentre, phase II study to compare the efficacy and tolerability of fulvestrant (Faslodex™) 500mg with placebo and fulvestrant (Faslodex™) 500mg in combination with PD-0332991 (Palbociclib) as first line treatment for postmenopausal women with hormone receptor-positive metastatic breast cancer, who have completed at least 5 years of adjuvant endocrine therapy and remained disease free for more than 12 months following its completion or have “de novo” metastatic disease.  <b>Comment:</b> 4 sites initiated to date (SJH, Mater, BonS and UHW).	May 2016	SJH, Mater, BH, SVUH, BonS, UHG, UHW, UHL	190	32	40	<b>1</b> UHW 1	February 2017
<b>Ovarian Reserve</b> <b>CTRIAL-IE (ICORG) 10-16</b> PI: Dr Janice Walshe & Prof Bryan Hennessy Type: In-House Sponsor:   <b>Title:</b> A study to determine alteration of hormone levels in premenopausal patients receiving adjuvant or neo-adjuvant chemotherapy for breast cancer.  <b>Comment:</b> Accrual going well.	Oct 2012	AMNCH, Beacon, BH, BonS, CUH, SJH, SUH, SVUH, UHW	N/A	N/A	250	<b>123</b> AMNCH 19, BH 29, BonS 16, CUH 20, SJH 6, SUH 8, SVUH 18, UHW 7	TBC
<b>CharactHER</b> <b>CTRIAL-IE (ICORG) 12-09</b> PI: Prof Giuseppe Gullo & Prof John Crown Type: In-House Sponsor:   <b>Title:</b> A study of the molecular and cytogenetic characteristics of HER2-positive breast cancers to predict durable complete response after chemotherapy and trastuzumab.  <b>Comment:</b> Additional Italian site will open soon.	May 2014	BH, Mater, SJH, SVUH, Milan, Italy	N/A	181	Cohort 1&3: 100  Cohort 2: 200	<b>171</b> BH 6, Mater 6, SJH 6, SVUH 153  <b>16</b> Milan	TBC
<b>TAILORx Tissue Bank</b> <b>CTRIAL-IE (ICORG) 12-30</b> PI: Dr Cathy Kelly & Dr Darran O'Connor Type: In-House Sponsor:   <b>Title:</b> TAILORx Tissue Bank: Breast Cancer Bank of Tissue from Trial Assigning Individualized Options for Treatment.  <b>Comment:</b> All FFPE blocks should be sent to Dr Darran O'Connor.	May 2014	AMNCH, BH, BonS, CUH, UHG, LUH, Mater, SJH, SUH, SVUH, UHW	N/A	N/A	691	<b>567</b> AMNCH 23, BH 33, BonS 14, CUH 72, UHG 66, UHL 14, Mater 79, SJH 37, SUH 32, SVUH 167, UHW 30	TBC





## Breast Cancer Trials

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>Exosomal HER2 CTRIAL-IE (ICORG) 10-15</b> PI: Dr Lorraine O'Driscoll & Prof John Crown Type: In-House Sponsor: 	Oct 2012	AMNCH, Beacon, BH, BonS, CUH, LUH, SJH, SUH, SVUH, UHW	N/A	N/A	HER2+: 300  HER2-: 30 (closed)	<b>228</b> AMNCH 43, BH 51, BonS 45, CUH 10, LUH 7, SJH 2, SUH 23, SVUH 36, UHW 11	TBC
<b>Title:</b> Exosomal and Free Extracellular RNAs and Proteins as Predictive Biomarkers for HER2 Therapies in Breast Cancer.							
<b>Comment:</b> HER2+ accrual is excellent.							

## Translational Cancer Trials


Co-ordinator: Ronán Feighery

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>SNP study</b> <b>CTRIAL-IE (ICORG) 08-40</b> PI: Dr Michael Martin Type: In-House Sponsor: 	May 2011	AMNCH, BH, BonS, CUH, Mater, SUH, UHG, UHW	N/A	N/A	150	<b>115</b> AMNCH 17, BH 3, BonS 24, CUH 1, Mater 2, SUH 19, UHG 21, UHW 28	TBC
<b>Title:</b> SNP Study: Correlation of Single Nucleotide Polymorphism (SNP) profile of domain III of EGFR to skin and/or eye toxicity and disease response to treatment with Cetuximab or Panitumumab.							
<b>Comment:</b> 4 patients accrued since Summer DSSG meeting. Accrual has slowed since the last DSSG.							
<b>CRQ Survey</b> <b>CTRIAL-IE (ICORG) 15-43</b> PI: Dr Cathy Kelly Type: In-House Sponsor: 	April 2016	AMNCH, Beacon, BH, BonS, CUH, LUH, Mater, OLLHD, SJH, SLRON, SUH, SVUH, UHG, UHW	N/A	N/A	1000	<b>796</b> AMNCH 100, BH 100, BonS 100, CUH 50, UHL 50, Mater 100, SJH 100, SUH 47, SVUH 100, UHW 49	Dec 2016
<b>Title:</b> CRQ Study: Clinical Research Questionnaire of Oncology Patients – A Nationwide Survey.							
<b>Comment:</b> Exceptional accrual across all sites.							

## Melanoma Cancer Trials

Co-ordinator: Catherine Dolphin

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
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<b>SYS-ACT CTRIAL-IE (ICORG) 13-22</b> PI: Dr Markus Rehm Type: In-House Sponsor: 	August 2014	SVUH, UHG	N/A	N/A	Case: 60 Controls: ~20	<b>9</b> SVUH 7, UHG 2	TBC
<b>Title:</b> SYS-ACT: A Translational Systems Medicine Approach to provide Predictive Capacity for Therapy Responsiveness in Advanced or Meta-static Malignant Melanoma.							
<b>Comment:</b> SVUH and UHG have developed working models requiring inter-departmental collaboration that could be replicated at other sites.							

## New Addition

<b>KEYNOTE-252</b> <b>CTRIAL-IE 16-13</b> PI: Prof. John Crown Type: Industry Sponsor: MSD	<b>July 2016</b> (May 2016 globally)	SVUH, Mater, CUH, UHG.	600	200	16	<b>1 (SVUH)</b>	June 2017
<b>Title:</b> KEYNOTE-252: A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study of Pembrolizumab (MK-3475) in Combination With Epacadostat or Placebo in Subjects with Unresectable or Metastatic Melanoma.							
<b>Comment:</b> SVUH, CUH and UHG opened recently, with 1 patient enrolled at SVUH. Mater to be opened soon. Global recruitment is ahead of schedule.							

## New Addition

<b>CheckMate 401</b> <b>CTRIAL-IE 16-14</b> PI: Dr. Derek Power Type: Industry Sponsor: BMS	August 2016	SVUH, BH, Mater, UHG, CUH, SJH.	768 enrolled, 615 treated	0	Cap of 5 patients per site	0	December 2016
<b>Title:</b> CheckMate 401: Clinical Trial of Nivolumab Combined with Ipilimumab Followed by Nivolumab Monotherapy as First-Line Therapy of Subjects with Histologically Confirmed Stage III (Unresectable) or Stage IV MelanomaEYNOTE-252: A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study of Pembrolizumab (MK-3475) in Combination With Epacadostat or Placebo in Subjects with Unresectable or Metastatic Melanoma.							
<b>Comment:</b> Mater and CUH opened recently. The remaining sites to be opened soon. Accrual closing date is expected to be extended.							

## Basket Cancer Trials

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
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<b>CTRIAL-IE 15-42 Loxo101</b>	US Sept 2015	SVUH	226 (18 per cohort + 25 Other Tu-mour NOS)	Ahead of target of 1 patient per month	2-3 melanoma patients (6 across all cohorts)	<b>0</b>	2 years
PI: Prof Ray McDermott Type: Industry sponsored Sponsor: Loxo Oncology	<b>EU</b> May 2016						
<b>Title:</b> A Phase II Basket Study of the Oral TRK Inhibitor LOXO-101 in Subjects With NTRK Fusion-Positive Tumours							
<b>Comment:</b> This is a basket study encompassing multiple cohorts covering lung, thyroid, sarcoma, colorectal, salivary, biliary, primary CNS, other tumours NOS.							

## Cancer Trials Round Up—Open and Closed since last DSSG Meeting

### Lung Cancer Trials

Chair of Lung DSSG: Dr Linda Coate

Co-ordinator: Jillian Burns

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>ETOP 5-12 SPLENDOUR CTrial-IE (ICORG) 12-53</b> PI: Dr Linda Coate Type: Collaborative Group Sponsor: ETOP <b>Title:</b> A randomized phase III trial evaluating the addition of denosumab to standard first-line anticancer treatment in advanced NSCLC. <b>Comment:</b> 7 sites actively recruiting, however recruitment is now behind schedule. Protocol amendment planned for release later this year. 1 patient enrolled since the Summer DSSG meeting.	International Q1 2015  <b>Ireland</b> <b>Q3 2015</b>	AMNCH, BH, CUH, UHG, Mater, UHL, SJH, UHW, SVUH	1000	413	70	<b>20</b> UHL 5, CUH 3, SJH 6, AMNCH 1, Mater 1, UHW 2, UHG 2	Jan 2018
<b>MK3475-091 PEARLS Study CTrial-IE (ICORG) 15-40</b> PI: Dr Linda Coate Type: Industry Sponsor: MSD <b>Title:</b> Immunotherapy with anti-PD-1 monoclonal antibody (pembrolizumab) versus placebo for patients with early NSCLC After Resection and completion of standard adjuvant therapy: A randomized double blind phase III trial in Lung cancer (The PEARLS trial). <b>Comments:</b> Recruitment slow; referrals of eligible patients welcome.	International Nov 2015  <b>Ireland</b> <b>Jan 2016</b>	MMUH, UHL, SVUH, UHW, SJH, CUH	1380	25	20/site	<b>2</b> Mater 1, SJH 1	Jan 2021
<b>BMS CA 209-227 Study CTrial-IE (ICORG) 15-27</b> PI: Dr Sinead Cuffe Type: Industry Sponsored Sponsor: BMS <b>Title:</b> An Open-Label, Randomized Phase 3 Trial of Nivolumab and Nivolumab plus Ipilimumab versus Platinum Doublet Chemotherapy in Patients with Chemotherapy-Naïve Stage IV or Recurrent Non-Small Cell Lung Cancer (NSCLC) <b>Comment:</b> Recruitment to PDL-1+ group will close shortly due to faster than anticipated recruitment. 5 further patients are in screening in Ireland. A high screen failure rate of 49% is noted.	International Aug 2015  <b>Ireland</b> <b>Q1 2016</b>	SJH, UHL, BH, UHG	2475 enrolled  1980 treated	2109 enrolled  1127 randomised	20	<b>5</b> BH 1, SJH 1, UHG 2, UHL 1	TBC
<b>BMS CA209-451 (CheckMate-451) SCLC study CTrial-IE (ICORG) 16-18</b> PI: Dr Deirdre O'Mahony Type: Industry Sponsored Sponsor: BMS <b>Title:</b> A Randomized, Multicenter, Double-Blind, Phase 3 Study of Nivolumab, Nivolumab in Combination with Ipilimumab, or Placebo as Maintenance Therapy in Subjects with Extensive-Stage Disease Small Cell Lung Cancer (ED-SCLC) after Completion of Platinum-based First Line Chemotherapy. <b>Comments:</b> Issues with pharmacy in SVPH is preventing activation at present. Well behind in recruitment-please ensure to refer eligible patients.	International Sep 2015  <b>Ireland</b> <b>Q2 2016</b>	AMNCH, CUH, SVPH, UHG	810	211	16	<b>1</b> UHG 1	Apr 2017
<b>MK3475-189 Study CTrial-IE (ICORG) 16-16</b> PI: Dr Emer Hanrahan Type: Industry sponsored Sponsor: Merck <b>Title:</b> A Randomized, Double-Blind, Phase III Study of Platinum+ Pemetrexed Chemotherapy with or without Pembrolizumab (MK-3475) in First Line Metastatic Non-squamous Non-small Cell Lung Cancer Subjects (KEYNOTE-189) <b>Comments:</b> Study is fully open in UHL; referrals of eligible patients welcome.	International Jan 2016  <b>Ireland</b> <b>Q3 2016</b>	UHL, SJH, BH, SVUH	570 screened 420 randomised	395 screened 237 randomised	16	<b>0</b>	Dec 2016



## Cancer Trials Round Up—Open and Closed since last DSSG Meeting


### Lung Cancer Trials


Chair of Lung DSSG: Dr Linda Coate

Co-ordinator: Jillian Burns

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
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<b>Javelin 100 Avelumab study</b> <b>CTRIAL-IE (ICORG) 16-15</b> PI: Dr Emer Hanrahan Type: Industry sponsored Sponsor: Merck Serono	International Q1 2016  <b>Ireland</b> <b>Q4 2016</b>	SVUH, AMNCH	420	149	2	0	Dec 2016
<b>Title:</b> A Phase III, open-label, multicenter trial of avelumab (MSB0010718C) versus platinum-based doublet as a first-line treatment of recurrent or Stage IV PD-L1+ non-small cell lung cancer  <b>Comments:</b> Sponsor is hoping to initiate SVUH in October. A substantial amendment will increase the recruitment period.							

<b>INTENSE</b> <b>CTRIAL-IE (ICORG) 15-47</b> PI: Prof John Armstrong Type: In-house Sponsor: 	Jul 2016	SLRON	104	N/A	104	0	Q2 2020
<b>Title:</b> A Phase I/II Study of Inhomogeneous Targeted Dose Escalation in Non-Small Cell Lung Cancer  <b>Comments:</b> Study initiated in July in SLRON and patients are being actively screened.							

<b>UPCI 10-028</b> <b>Oligo-Recurrent Stereotactic Radiotherapy</b> <b>CTRIAL-IE (ICORG) 15-05</b> PI: Dr Alina Mihai Type: Collaborative Group Sponsor: 	International Jun 2011  <b>Ireland</b> <b>Jan 2016</b>	Beacon	175	118	TBC	7 Beacon 7	Q4 2016
<b>Title:</b> Phase II study of stereotactic radiosurgery for patients with oligo-recurrent disease.  <b>Comments:</b> Study recruiting well in the Beacon Hospital.							

<b>'ASTRIS' (D5160C00022)</b> <b>CTRIAL-IE (ICORG) 15-39</b> PI: Dr Emer Hanrahan Type: Industry Sponsored Sponsor: AstraZeneca	Globally: Sep 2015  Ireland: Q1 2016	SVUH	1325	TBC	5	10 SVUH 10	Closed
<b>Title:</b> Open Label, Multinational, Multicenter, Real World Treatment Study of Single Agent AZD9291 for Patients with Advanced/Metastatic Epidermal Growth Factor Receptor (EGFR) T790M Mutation-Positive Non-Small Cell Lung Cancer (NSCLC) Who Have Received Prior Therapy with an EGFR Tyrosine Kinase Inhibitor (EGFR-TKI).  <b>Comment:</b> Excellent recruitment of 10 patients in SVUH far exceeded the target of 5-7 patients.							

New Addition

New Addition

## Paediatric Cancer Trials

Chair of Paediatric DSSG: Dr Aengus O'Marcaigh

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>AALL0932</b> <b>CTRIAL-IE 16-31</b> PI: Drs Aengus O'Marcaigh / Owen Smith Type: Collaborative Group <b>Title:</b> Treatment of Patients with Newly Diagnosed Standard Risk B-Lymphoblastic Leukemia (B-ALL) or Localized B-lineage Lymphoblastic Lymphoma (B-LLy).	Ireland May 2015	OLCHC	N/A	N/A	N/A	21	N/A
<b>AALL1131</b> <b>CTRIAL-IE 16-32</b> PI: Drs Aengus O'Marcaigh / Owen Smith Type: Collaborative Group <b>Title:</b> A Phase III Randomised Trial for Newly Diagnosed High Risk B-Lymphoblastic Leukemia (B-ALL) Testing a Purine Nucleoside Anti-metabolite in the Very High Risk Stratum.	Ireland May 2015	OLCHC	N/A	N/A	N/A	14	N/A
<b>UKALL2011</b> <b>CTRIAL-IE 16-33</b> PI: Drs Aengus O'Marcaigh / Owen Smith Type: Collaborative Group <b>Title:</b> United Kingdom National Randomised Trial for Children and Young Adults with Acute Lymphoblastic Leukaemia and Lymphoma 2011.	Ireland April 2013	OLCHC	N/A	N/A	N/A	102	N/A
<b>Interfant 06</b> <b>CTRIAL-IE 16-53</b> PI: Dr Owen Smith Type: Collaborative Group <b>Title:</b> International collaborative treatment protocol for Infants under one year with Acute Lymphoblastic or Biphenotypic Leukemia.	Ireland Nov 2014	OLCHC	N/A	N/A	N/A	3	N/A
<b>NBL—HR-NBL-1.7/SIOPEN</b> <b>CTRIAL-IE 16-38</b> PI: Dr Cormac Owens Type: Collaborative Group <b>Title:</b> High Risk Neuroblastoma Study 1.7 of SIOP-EUROPE (SIOPEN).	Ireland Sep 2004	OLCHC	N/A	N/A	N/A	60	N/A
<b>NBL LTI Study</b> <b>CTRIAL-IE 16-39</b> PI: Dr Cormac Owens Type: Collaborative Group <b>Title:</b> A Phase I/II Dose Schedule Finding Study of Monoclonal Antibody Continuous Infusion Combined With Subcutaneous Aldesleukin (IL-2) in Patients with Primary or Relapsed Neuroblastoma.	Ireland Aug 2013	OLCHC	N/A	N/A	N/A	7	N/A
<b>NBL BEACON</b> <b>CTRIAL-IE 16-40</b> PI: Dr Cormac Owens Type: Collaborative Group <b>Title:</b> A randomised phase IIb trial of trial of VEGF Inhibitor added to Temozolomide ± Irinotecan for children with refractory/relapsed Neuroblastoma.	Ireland May 2014	OLCHC	N/A	N/A	N/A	4	N/A
<b>NBL LINES</b> <b>CTRIAL-IE 16-41</b> PI: Dr Cormac Owens Type: Collaborative Group <b>Title:</b> European Low and Intermediate Risk Neuroblastoma - A SIOPEN Study.	Ireland Feb 2016	OLCHC	N/A	N/A	N/A	1	N/A

## Cancer Trials Round Up—Open and Closed since last DSSG Meeting

### Paediatric Cancer Trials

Chair of Paediatric DSSG: Dr Aengus O'Marcaigh

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>EpSSG / RMS 2005</b> <b>CTRIAL-IE 16-47</b> PI: Dr Cormac Owens Type: Collaborative Group <b>Title:</b> A protocol for non-metastatic rhabdomyosarcoma (incorporates RMS-MET2008: Treatment Arm for Metastatic Disease).	Ireland Oct 2011	OLCHC	N/A	N/A	N/A	<b>17</b>	N/A
<b>EpSSG / NRSTS 2005</b> <b>CTRIAL-IE 16-48</b> PI: Dr Jane Pears Type: Collaborative Group <b>Title:</b> A Protocol for Non-Rhabdomyosarcoma Soft Tissue Sarcomas.	Ireland Oct 2012	OLCHC	N/A	N/A	N/A	<b>4</b>	N/A
<b>LLR Cell Bank</b> <b>CTRIAL-IE 16-34</b> PI: Drs Aengus O'Marcaigh/ Owen Smith Type: Collaborative Group <b>Title:</b> Leukaemia and Lymphoma Research (LLR) Childhood Leukaemia Cell Bank.	Ireland Feb 2013	OLCHC	N/A	N/A	N/A	<b>85</b>	N/A
<b>JMML-Mesrat Study</b> <b>CTRIAL-IE 16-51</b> PI: Dr Owen Smith Type: Collaborative Group <b>Title:</b> DNA methylation signatures and response to the azacitidine therapy in juvenile myelomonocytic leukaemia (JMML) Classification of Newly Diagnosed Acute Lymphoblastic Leukemia (ALL) - AALL08B1.	Ireland June 2015	OLCHC	N/A	N/A	N/A	<b>1</b>	N/A
<b>HD Interim Study</b> <b>CTRIAL-IE 16-36</b> PI: Dr Jane Pears Type: Collaborative Group <b>Title:</b> EuroNet Paediatric Hodgkin's Lymphoma Interimphase study following closure of EuroNet PHL-C1 (HD 2007 10) Trial.	Ireland Mar 2013	OLCHC	N/A	N/A	N/A	<b>26</b>	N/A
<b>EWOG-MDS-2006</b> <b>CTRIAL 16-37</b> PI: Drs Aengus O'Marcaigh / Owen Smith Type: Collaborative Group <b>Title:</b> Prospective non-randomised multi-center study for epidemiology and characterisation of Myelodysplastic Syndrome (MDS) and Juvenile Myelomonocytic Leukemia (JNML) in childhood.	Ireland Jan 2012	OLCHC	N/A	N/A	N/A	<b>3</b>	N/A
<b>Renal IMPORT</b> <b>CTRIAL-IE 16-42</b> PI: Dr Jane Pears Type: Collaborative Group <b>Title:</b> Improving Population Outcomes for Renal Tumours of Childhood.	Feb 2015	OLCHC	N/A	N/A	N/A	<b>14</b>	N/A
<b>OLCHC Tumour Bank</b> <b>CTRIAL-IE 16-43</b> PI: N/A Type: Collaborative Group <b>Title:</b> Procedure agreed for Tumour tissue and matched blood-DNA banking at OLCHC.	Ireland Oct 2012	OLCHC	N/A	N/A	N/A	<b>92</b>	N/A





## Cancer Trials Round Up—Open and Closed since last DSSG Meeting

### Paediatric Cancer Trials




Chair of Paediatric DSSG: Dr Aengus O'Marcaigh

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>EU-RHAB</b> <b>CTRIAL-IE 16-44</b> PI: Dr Michael Capra Type: Collaborative Group <b>Title:</b> European Rhabdoid Registry. A Multinational registry for rhabdoid tumours of any anatomical site.	Ireland Oct 2012	OLCHC	N/A	N/A	N/A	6	N/A
<b>AALL08B1</b> <b>CTRIAL-IE 16-30</b> PI: Drs Aengus O'Marcaigh/ Owen Smith Type: Collaborative Group <b>Title:</b> Classification of Newly Diagnosed Acute Lymphoblastic Leukemia (ALL)	Ireland Oct 2012	OLCHC	N/A	N/A	N/A	6	N/A
<b>FACT Study</b> <b>CTRIAL-IE 16-45</b> PI: N/A Type: Collaborative Group <b>Title:</b> Factors associated with Childhood Tumours Study.	Ireland April 2006	OLCHC	N/A	N/A	N/A	28	N/A
<b>EWOG-SAA-2010</b> <b>CTRIAL 16-46</b> PI: Dr Owen Smith Type: Collaborative Group <b>Title:</b> Genetic & Immunological Characterisation of Acquire Severe Aplastic Anaemia (SAA) in Children & Adolescents.	Ireland April 2012	OLCHC	N/A	N/A	N/A	15	N/A
<b>NBL Registry</b> <b>CTRIAL-IE 16-49</b> PI: Dr Cormac Owens Type: Collaborative Group <b>Title:</b> Prospective Study Registry of Peripheral Neuroblastic Tumours Presenting with Spinal Canal Involvement (SCI).	Ireland April 2015	OLCHC	N/A	N/A	N/A	1	N/A
<b>AZA-JMML-001</b> <b>CTRIAL-IE 16-50</b> PI: Dr Owen Smith Type: Industry sponsored Sponsor: Celgene <b>Title:</b> A Phase 2, multicentre, open-label study to evaluate the pharmacokinetics, pharmacodynamics, safety and activity of azacitidine and to compare azacitidine to historical controls in paediatric subjects with newly diagnosed advanced MDS or JMML before HSCT.	Ireland June 2015	OLCHC	N/A	N/A	N/A	1	N/A
<b>EBMT</b> <b>CTRIAL-IE 16-35</b> PI: Dr Owen Smith Type: Collaborative Group <b>Title:</b> EBMT.	Ireland April 2015	OLCHC	N/A	N/A	N/A	1	N/A
<b>EURO-Ewing 2012</b> <b>CTRIAL-IE 16-52</b> PI: Dr Cormac Owens Type: Collaborative Group <b>Title:</b> International Randomised Controlled Trial for the Treatment of Newly Diagnosed Ewing's Sarcoma Family of Tumours	Ireland April 2015	OLCHC	N/A	N/A	N/A	1	N/A

## Genitourinary Cancer Trials

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>IMRT Prostate CTRIAL-IE (ICORG) 08-17</b> PI: Prof John Armstrong Type: In-House Sponsor: 	<b>Ireland</b> Jan 2009	SLRON, Beacon, CUH	N/A	N/A	248	<b>251</b> SLRON 213, Beacon 23, CUH 15	July 2016 (closed)
<b>Title:</b> A Prospective Phase II Dose Escalation Study using IMRT for High Risk N0 M0 Prostate Cancer. <b>Comment:</b> Accrual now achieved and study has closed since the Summer DSSG meeting.							
<b>IMPACT study CTRIAL-IE (ICORG) 12-29</b> PI: Dr David Gallagher Type: Collaborative Group Sponsor: ICR	<b>Ireland</b> Oct 2005	Mater, SJH	>1700	3384	N/A	<b>23</b> Mater 1, SJH 22	Dec 2016
<b>Title:</b> The IMPACT study – Identification of Men with a genetic predisposition to ProstAte Cancer: Targeted Screening in men at higher genetic risk and controls. <b>Comment:</b> Study will close in Dec 2016. In follow up until Dec 2019.							
<b>iProspect CTRIAL-IE (ICORG) 14-04</b> PI: Prof Ray McDermott Type: In-House Sponsor: 	Feb 2015	AMNCH, Beacon, BH, CUH, UHG, Mater, SJH, SUH, SVUH, UHW	N/A	N/A	Cohort 1: 15 (closed); Cohort 2: 45	<b>55</b> AMNCH 26, CUH 3, Mater 5, SUH 6, SVUH 14, UHW 1	TBC
<b>Title:</b> Irish Programme for Stratified Cancer Therapy. <b>Comment:</b> Accrual on hold pending protocol amendment.							
<b>ENZAMET CTRIAL-IE (ICORG) 14-06</b> PI: Prof Ray McDermott Type: Collaborative Sponsor: ANZUP	International Feb 2014  <b>Ireland</b> Dec 2014,  UK 2015	AMNCH, BH, UHG, Beacon, Mater, SJH, SVUH, UHW  UK sites	1100	802	275	<b>126</b> AMNCH 22, BH 2, Mater 15, SVUH 9, UHW 9, UK Sites 69.	Q1 2017
<b>Title:</b> Randomised Phase III trial of enzalutamide in first line androgen deprivation therapy for metastatic prostate cancer. <b>Comment:</b> Accrual going very well, expect study to finish accrual by Feb 2017.							
<b>ENZARAD CTRIAL-IE (ICORG) 14-07</b> PI: Dr Paul Kelly Type: Collaborative Sponsor: ANZUP	International March 2014  <b>Ireland</b> April 2015 UK Sept 2015	CUH, UHG, Mater, Beacon, SLRON, Whitfield,  UK sites	800	284	200	<b>41</b> CUH 13, Mater 2, Beacon 8, UHG 1, SLRON 5, UK sites 12.	2018
<b>Title:</b> Randomised Phase III trial of enzalutamide in androgen deprivation therapy with radiation therapy for high risk, clinically localised, prostate cancer. <b>Comment:</b> Accrual has increased on this study since the Summer DSSG meeting, accrual now going well.							

## Genitourinary Cancer Trials


Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>Neo-adjuvant abiraterone prostate study</b> <b>CTRIAL-IE 13-23</b> PI: Dr Pierre Thirion Type: In-House Sponsor: 	<b>Ireland</b> May 2015	CUH, SLRON (SLH), UHG	N/A	N/A	36 evaluable	<b>4</b> SLRON (SLH) 3, UHG: 1	Q2 2017
<b>Title:</b> Phase II Non-randomised single arm study evaluating Neo-adjuvant (pre-radical radiotherapy) Abiraterone acetate (plus prednisolone) and Gonadotropin-releasing hormone (GnRh) agonist in Localised Prostate Cancer. <b>Comment:</b> Protocol Version 5 approved by HPRAs. Recruitment behind target for this study.							
<b>ExPeCT study</b> <b>CTRIAL-IE (ICORG) 15-21</b> PI: Prof Stephen Finn Type: In-House Sponsor: 	<b>Ireland</b> Jan 2016	AMNCH, BH, Mater, SJH, SLRON , UK sites	200	37	133	<b>21</b> AMNCH 5, BH 1, Mater 3, SJH 12	March 2017
<b>Title:</b> ExPeCT: Exercise, Prostate Cancer and Circulating Tumour Cells. <b>Comment:</b> SLRON pending initiation. Accrual has slowed.							
<b>PEACE-1 study</b> <b>GETUG-AFU 21</b> <b>CTRIAL-IE 13-09</b> PI: Prof Ray McDermott Type: Collaborative Sponsor: UNICANCER	<b>Ireland</b> Oct 2014	AMNCH, CUH, UHG, Mater , SLRON, SVUH	916	529	60	<b>27</b> AMNCH 2, CUH 9, UHG 1, Mater 12, SVUH 3	May 2017
<b>Title:</b> A prospective randomised Phase III study of androgen deprivation therapy with or without local radiotherapy with or without abiraterone acetate and prednisone in patients. <b>Comment:</b> Accrual has increased since the last DSSG. Study on track to complete by May 2017.							
<b>Radium-223 &amp; Enzalutamide mCRPC study</b> <b>CTRIAL-IE (ICORG) 13-21</b> PI: Prof Ray McDermott Type: In-house Sponsor: 	<b>Ireland</b> June 2015	AMNCH, CUH, UHG, Mater, SLRON, SVUH	N/A	N/A	44	<b>30</b> AMNCH 19, CUH 4, Mater 2, SVUH 5	Dec 2016
<b>Title:</b> A Phase II Study of Radium-223 in Combination with Enzalutamide in Progressive Metastatic Castrate-Resistant Prostate Cancer. <b>Comment:</b> Accrual rate of 4 patients per month needed for this study between now and Dec 16.							



## Cancer Trials Round Up—Open and Closed since last DSSG Meeting

### Genitourinary Cancer Trials

Chairs of GU DSSG: Prof Ray McDermott & Dr Paul Kelly Co-ordinators: Olwyn Deignan/Ausra Teiserskiene

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>Spinal Cord Retreat study CTRIAL-IE (ICORG) 07-11</b> PI: Dr Pierre Thirion Type: In-House Sponsor: 	Oct 2007	SLRON (3 sites), UHG	N/A	N/A	25 evaluable	<b>21</b> (10 evaluable) SLRON 19, UHG 3.	TBC
<b>Title:</b> A Phase II trial evaluating the efficacy of a radio-biological based re-irradiation strategy for patient with malignant spinal cord compression. A palliative cancer trial. <b>Comment:</b> Once 14 evaluable patients enrolled, an interim analysis will be performed.							
<b>IPCOR CTRIAL-IE (ICORG) 16-07</b> PI: Mr David Galvin Type: Collaborative Sponsor: IPCOR	Feb 2016	17 Irish sites	N/A	N/A	>3000 per annum	<b>1003</b>	TBC
<b>Title:</b> IPCOR – Irish Prostate Cancer Outcome Research <b>Comment:</b> Please address queries for this study to IPCOR.							

### Head & Neck Cancer Trials

Chair of Head & Neck DSSG: Dr Sinead Brennan

Co-ordinator: Niall Fox

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>De-ESCaLaTE HPV CTRIAL-IE (ICORG) 12-39</b> PI: Dr Sinéad Brennan Type: Collaborative Group Sponsor: University of Warwick	<b>Ireland</b> Jan 2015  <b>Globally</b> Oct 2012	SLRON (SLH & BH)	304	321	<b>20</b>	<b>15</b> SLH 13 BH 2	Q1 2017
<b>Title:</b> Determination of Epidermal growth factor receptor-inhibitor (cetuximab) versus Standard Chemotherapy (cisplatin) early And Late Toxicity Events in Human Papillomavirus-positive oropharyngeal squamous cell carcinoma. <b>Comment:</b> Study expected to close to accrual once 334 patients have been recruited.							
<b>DARS CTRIAL-IE (ICORG) 16-23</b> PI: Dr Sinéad Brennan Type: Collaborative Group Sponsor: 	<b>Ireland</b> Q4 2016  <b>Globally</b> May 2016	SLRON	102	5	<b>24</b>	<b>0</b>	Q2 2018
<b>Title:</b> 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 . <b>Comment:</b> Awaiting contracts for site activation.							

## Cancer Trials Round Up—Open and Closed since last DSSG Meeting

### Head & Neck Cancer Trials

Chair of Head &amp; Neck DSSG: Dr Sinead Brennan

Co-ordinator: Niall Fox

Trial	Date	Participating	Global	Global	Ireland	Ireland	Accrual
	Open	Cancer Research	Accrual	Accrual	Accrual	Accrual	Closing
		Units	Target	Current	Target	Current	

<b>NRG-HN002</b> <b>CTRIAL-IE (ICORG) 16-11</b> PI: Dr Sinéad Brennan Type: Collaborative Group Sponsor:	<b>Ireland</b> Q4 2016  <b>Globally</b> Oct 2014	SLRON (SLH)	296	221	<b>8 -12</b>	<b>0</b>	Q1 2017
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**Title:** A Randomized Phase II Trial for Patients with p16 Positive, Non-Smoking Associated, Locoregionally Advanced Oropharyngeal Cancer

**Comment:** Study is expected to open for accrual in SLRON SLH in the near future.

New Addition

<b>BMS CA209-714 1st Line</b> <b>Nivo Vs. Nivo+Ipi</b> <b>CTRIAL-IE (ICORG) TBC</b> PI: Dr Cliona Grant Type: Industry sponsored Sponsor: BMS	<b>Ireland</b> Q4 2016  <b>Globally</b> Sep 2016	SJH	315	0	<b>0</b>	<b>0</b>	Q4 2017
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**Title:** A Double-Blind, Randomized, Two Arm Phase 2 Study of Nivolumab in Combination with Ipilimumab versus Nivolumab monotherapy in Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN)

**Comment:** Ethics and Regulatory Submissions underway.

New Addition

### Central Nervous System Cancer Trials

Chair of CNS DSSG: Dr Stephen McNally

Co-ordinator: Lorraine Carrabine

Trial	Date	Participating	Global	Global	Ireland	Ireland	Accrual
	Open	Cancer Research	Accrual	Accrual	Accrual	Accrual	Closing
		Units	Target	Current	Target	Current	

<b>Serum Protein Markers for Glioma</b> <b>CTRIAL-IE (ICORG) 08-13</b> PI: Dr Verena Murphy Type: In-House Sponsor:	July 2009	BH	N/A	N/A	Cohort 1: 100 Cohort 2: 30	<b>77</b> Cohort 1: 61, Cohort 2: 1, Control: 15	TBC
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**Title:** Glioma Study: Are gliomas in adults associated with a unique identifying serum protein signature?


**Comment:** Protocol amendment and submitted to REC.

## Cancer Trials Round Up—Open and Closed since last DSSG Meeting

### Central Nervous System Cancer Trials

Chair of CNS DSSG: Dr Stephen McNally

Co-ordinator: Lorraine Carrabine


Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>M14-483 INTELLANCE-2 CTrial-IE (ICORG) 15-29</b> PI: Dr Patrick Morris Type: Industry sponsored Sponsor: ABBVIE <b>Title:</b> ABT-414 alone or ABT-414 plus temozolomide versus lomustine for recurrent glioblastoma: a randomised phase II study of the EORTC Brain Tumour Group <b>Comment:</b> Trial closed to recruitment in July 2016. Ireland treated 3% of global patients. Paediatric trial commencing (Ireland not participating).	Ireland Jul 2015 International Feb 2015	BH, CUH	240	260	8-12	7 BH 5, CUH 2	Q3 2016
<b>M13-813 INTELLANCE 1 CTrial-IE (ICORG) 15-28</b> PI: Dr Patrick Morris Type: Industry sponsored Sponsor: ABBVIE <b>Title:</b> A Randomized, Placebo Controlled Phase 2b/3 Study of ABT-414 in Subjects with Newly Diagnosed Glioblastoma Multiforme (GBM) with Epidermal Growth Factor Receptor (EGFR) Amplification. <b>Comment:</b> Only 1 site in Ireland has been selected—Beaumont Hospital. 2nd Top recruiting site in the world, ahead of global Chief Investigator	Q1 2016	BH	720	84	10	5 BH 5	Q3 2017
<b>ROAM CTrial-IE (ICORG) 15-41</b> PI: Dr David Fitzpatrick Type: Collaborative Group Sponsor:  <b>Title:</b> Radiation versus Observation following surgical resection of Atypical Meningioma: a randomised controlled trial <b>Comment:</b> SLRON BH expected to be activated Q4 2016 once contracts have been finalised with the UK Cooperative Group	Ireland Q4 2016 International Q2 2016	SLRON BH	190	2	0	0	Q1 2020

New Addition

### Gastrointestinal Cancer Trials

Chairs of GI DSSG: Dr Gregory Leonard &amp; Dr Brian O'Neill





Co-ordinators: Laura Maher &amp; Gráinne O'Dowd

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>SNP Study CTrial-IE (ICORG) 08-40</b> PI: Dr Michael Martin Type: In-House Sponsor:  <b>Title:</b> Correlation of Single Nucleotide Polymorphism (SNP) profile of domain III of EGFR to skin and/or eye toxicity and disease response to treatment with Cetuximab or Panitumumab <b>Comment:</b> 4 patients accrued since last DSSG meeting. Accrual has slowed since the last DSSG.	May 2011	AMNCH, BH, BonS, CUH, Mater, OLLOH, SVUH, UHG, UHS, UHW,	N/A	N/A	150	115 AMNCH 17, BH 1, BonS 24, CUH 1, Mater 2, OLLOH 2, UHG (21), UHS (19), UHW 28	2016



## Gastrointestinal Cancer Trials

Co-ordinators: Laura Maher & Gráinne O'Dowd


Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
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<b>NeoAEGIS CTRIAL-IE (ICORG) 10-14</b> PI: Prof John Reynolds Type: In-House / Investigator Led Sponsor: 	January 2013	SJH, SLH, BH, CUH, UHG,  UK (41); Denmark (13); France (0)	594	130	180	<b>75</b> SJH 74, BH 1, UHG 1	2018
<b>Title:</b> Randomised Clinical Trial of neoadjuvant and adjuvant chemotherapy (Modified MAGIC regimen) vs. neoadjuvant chemoradiation (CROSS protocol) in adenocarcinoma of the oesophagus and oesophago-gastric junction.							
<b>Comment:</b> 15 UK sites now open to recruitment. CRF version 7 released to sites. eCRF system undergoing testing. Accrual needs to increase.							
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<b>CRAC Plasma Biomarker Study CTRIAL-IE (ICORG) 12-27</b> PI: Prof Ray McDermott Type: In-House Sponsor: 	October 2013	AMNCH, BH, BonS, UHG, Mater, SUH, SVUH, UHW, LUH, OLLOH (TBI), Beacon, SJH	N/A	N/A	150	<b>75 (1)</b> AMNCH 3, BH 24, BonS 11 (1), UHL3, Mater 3, SUH 9, UHG 11, UHW 9, SVUH 2,	2017
<b>Title:</b> Identification of Plasma Biomarkers in Early Detection of Colorectal Adenocarcinoma Recurrence (CRAC Plasma Biomarker Study).							
<b>Comment:</b> Protocol amendment ongoing. The initiation OLLOH is pending.							
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<b>PDAC Plasma Biomarker Study CTRIAL-IE (ICORG) 12-31</b> PI: Prof Ray McDermott Type: In-House Sponsor: 	October 2013	AMNCH, Beacon, BH, BonS, UHG, LUH (TBI), OLLOH (TBI), SVUH, UHW	N/A	N/A	290	<b>80</b> AMNCH 36, BH 5, BonS 3, SVUH 26, UHG 3, UHW 7	2018
<b>Title:</b> Identification of Predictive Plasma Biomarkers in Pancreatic Ductal Adenocarcinoma.							
<b>Comment:</b> Only two centres (LUH and OLLOH) remaining to be initiated.							
<hr/>							
<b>TRI-LARC CTRIAL-IE (ICORG) 12-38</b> PI: Dr Brian O'Neill Type: In-House Sponsor: 	August 2014	SLRON (BH & SJH)	N/A	N/A	268	<b>30</b> SLRON (BH) 30	August 2020
<b>Title:</b> Randomised Phase II Clinical Study; 3-D Conformal Chemo-Radiotherapy (current standard) versus IMRT (Intensity Modulated Radiotherapy) for Pre-operative Chemo-Radiotherapy for Locally Advanced Rectal Cancer.							
<b>Comment:</b> Approval received for protocol version 4 allowing translational components to be optional. SLRON SJH and SLRON SLH to open.							

## Cancer Trials Round Up—Open and Closed since last DSSG Meeting

### Gastrointestinal Cancer Trials

Chairs of GI DSSG: Dr Gregory Leonard &amp; Dr Brian O'Neill


Co-ordinators: Laura Maher &amp; Gráinne O'Dowd

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>Exelixis Celestial CTrial-IE (ICORG) 14-17</b> PI: Dr David Gallagher Type: Industry sponsored Sponsor: Exelixis  <b>Title:</b> Phase III Placebo Controlled Trial evaluating a tyrosine kinase inhibitor in HCC patients previously treated with Sorafenib.  <b>Comment:</b> No update provided by Exelixis. No new patients recruited to the study in Ireland last four months.	Unknown	Mater	760	N/A	N/A	2 Mater 2	October 2016
<b>BMS CA209-142 CTrial-IE (ICORG) 14-19</b> PI: Prof Ray McDermott Type: Industry sponsored Sponsor: Bristol-Myers Squibb  <b>Title:</b> A Phase II Clinical Trial of Nivolumab and Nivolumab Plus Ipilimumab in Recurrent and Metastatic Microsatellite High (MSI-H) Colon Cancer  <b>Comment:</b> Database lock successfully met for current cohort. New cohort to start soon pending protocol amendment approval.	March 2014	BH, SVUH, UHG	300	267	8	19 BH 2, SVUH 16, UHG 1	July 2017
<b>STRATEGIC-1 CTrial-IE (ICORG) 14-20</b> PI: Dr Greg Leonard Type: Collaborative Group Sponsor: GERCOR &    <b>Title:</b> Multi-line Therapy Trial in Unresectable Wild-Type RAS Metastatic Colorectal Cancer.  <b>Comment:</b> Protocol Amendment 7 (removal of optional tumour sub-study) and GSA v2 approved. Sites to be activated late October.	January 2015	UHG, UHW, AMNCH, BonS, SVUH, CUH, Mater, SJH	500	236	40	0	June 2017
<b>LOXO 101 CTrial-IE (ICORG) 15-42</b> PI: Prof Ray McDermott Type: Collaborative Group Sponsor: LOXO  <b>Title:</b> Multi-line Therapy Trial in Unresectable Wild-Type RAS Metastatic Colorectal Cancer.  <b>Comment:</b> Protocol amendment 6.2 released. LOXO designated FDA breakthrough status. Next DSMC end of October.	May 2016	SVUH	226	TBC	7 all cohorts (2-3 GI cohort )	0	May 2018
<b>MK 3475-177 CTrial-IE (ICORG) 16-28</b> PI: Dr David Gallagher Type: Industry Sponsor: Merck  <b>Title:</b> Phase II/III Study of Pembrolizumab vs. Chemotherapy in MSI-H CRC  <b>Comment:</b> Approved at SMG and opened site initiated in July.	July 2016	AMNCH, SJH	270	44	4	1	Sep 2017

## Cancer Trials Round Up—Open and Closed since last DSSG Meeting

### Gynaecological Cancer Trials


Chair of Gynaecological DSSG: Dr Dearbhaile O'Donnell Co-ordinator: Beata Sapetto-Rebow

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>Endometrial IMRT</b> <b>CTRIAL-IE (ICORG) 09-06</b> PI: Dr Charles Gillham Type: In-House Sponsor: 	Feb 2010	SLRON (3 sites)	N/A	N/A	154 (142 evaluable)	<b>64</b> SLRON (SLH 53, BH 7, SJH 4)	TBC
<b>Title:</b> Prospective Randomised Phase II Study evaluating Adjuvant Pelvic Radiotherapy using either IMRT or 3-Dimensional Planning for Endometrial Cancer. <b>Comment:</b> Following the Safety Committee review the study re-opened in SLRON in September 2016.							
<b>ICON8B</b> <b>CTRIAL-IE (ICORG) 11-29</b> PI: Dr Dearbhaile O'Donnell Type: Collaborative Group Sponsor: MRC	Sep 2015	BonS, UHG, Mater, SJH, UHW	1170	270	30	<b>11</b> BonS 2, Mater 7, UHW 2	2019
<b>Title:</b> A Phase III randomised trial investigating the combination of close-fractionated chemotherapy and VEGF monoclonal antibody compared to either strategy alone for first-line treatment of women with newly diagnosed high-risk stage III-IV epithelial ovarian, fallopian tube or primary peritoneal cancer. <b>Comment:</b> Protocol Amendment V6 approved by HPRA (06-Sep-16) and EC (10-Aug-16). Amendment includes changes to eligibility criteria, pharmacy guidelines, safety monitoring, schedule of assessments, QoL and protocol treatment discontinuation.							
<b>SHAPE</b> <b>CTRIAL-IE (ICORG) 14-02</b> PI: Dr Noreen Gleeson Type: Collaborative Group Sponsor: NCIC	Sep 2014	SJH	700	226	10	<b>7</b> SJH 7	2019
<b>Title:</b> A Randomised Phase III Trial Comparing Radical Hysterectomy and Pelvic Node Dissection vs Simple Hysterectomy and Pelvic Node Dissection in Patients with Low-Risk Early Stage Cervical Cancer. <b>Comment:</b> Sites are encouraged to refer eligible patients to SJH.							
<b>JAVELIN 200</b> <b>CTRIAL-IE 15-22</b> PI: Prof. J. McCaffrey Type: Industry Sponsored Sponsor: Pfizer	Sep 2016	SJH, Mater	550	29	23	<b>0</b>	June 2017
<b>Title:</b> A phase 3, multicenter, randomised, open-label study of Avelumab (MSB0010718C) alone or in combination with pegylated liposomal doxorubicin versus pegylated liposomal doxorubicin alone in patients with advanced-stage platinum-resistant /refractory ovarian cancer. <b>Comment:</b> SVUH and UHW planned to be activated shortly.							

## Cancer Trials Round Up—Open and Closed since last DSSG Meeting

### Lymphoma/Haematology Cancer Trials

Chair of Lymphoma/Haematology DSSG: Prof Michael O'Dwyer Co-ordinator: Grace Hirakata

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>MMY3008</b> <b>CTRIAL-IE (ICORG) 15-11</b> PI: Prof Michael O'Dwyer Type: Industry Sponsored Sponsor: Janssen <b>Title:</b> A Phase 3 Study Comparing Daratumumab, Lenalidomide, and Dexamethasone (DRd) vs Lenalidomide and Dexamethasone (Rd) in Previously Untreated Multiple Myeloma who are Ineligible for High Dose Therapy. <b>Comment:</b> Janssen will start slotting procedure to control the number of patients consented for the study. The LPI projection currently shows 6th Dec 2016.	Ireland Feb 2016	UHG, Mater	730	782 screened and 587 randomised	15	7 UHG 5 Mater 2	Dec 2016
<b>RsqVD Study</b> <b>CTRIAL-IE (ICORG) 13-17</b> PI: Prof Peter O'Gorman Type: In-House Sponsor:  <b>Title:</b> A phase II study of the Efficacy and Safety of lenalidomide, subcutaneous bortezomib, and dexamethasone combination therapy for patients with newly diagnosed multiple myeloma. <b>Comment:</b> Recruitment closed.	Ireland Nov 2014	AMNCH, BH, CUH, UHG, Mater, MRH, UHL, SJH, UHW	N/A	N/A	42	42 BH 5, CUH 6, UHG 11, Mater 14, MRH 2, UHL 1, SJH 2, UHW1	Closed
<b>ROBUST</b> <b>CTRIAL-IE (ICORG) 15-08</b> PI: Dr Cliona Grant Type: Industry Sponsored Sponsor: Celgene <b>Title:</b> Phase III Randomised, Double-Blind, Placebo Controlled, Multicentre Study to Compare the Efficacy and Safety of Lenalidomide (CC-5013) Plus R-CHOP Chemotherapy (R2-CHOP) Versus Placebo Plus R-CHOP Chemotherapy in Subjects With Previously Untreated Activated B-Cell Type Diffuse Large B-Cell Lymphoma. <b>Comment:</b> Protocol amendment released should improve accrual.	Ireland Feb 2015	CUH, Mater, SJH, SVUH, UHG	560	261	15	2 SJH 1, SVUH 1	Oct 2017
<b>ARROVEN PASS Study</b> <b>CTRIAL-IE (ICORG) 15-09</b> PI: Prof Elisabeth Vandenberghe Type: Industry Sponsored Sponsor: MILLENNIUM <b>Title:</b> Observational Cohort Study of the Safety of Brentuximab Vedotin in the Relapsed of Refractory CD30+ Hodgkin Lymphoma and Relapsed or Refractory Systemic Anaplastic Large Cell Lymphoma. <b>Comment:</b> No other site will be activated in Ireland.	Ireland Sep 2015	SJH, BH, Mater	500	208	9 (3 per site)	8 BH 5, SJH 3	TBC
<b>Protocol 04-30</b> <b>CTRIAL-IE (ICORG) 15-36</b> PI: Prof Helen Enright Type: Industry Sponsored Sponsor: Onconova <b>Title:</b> A Phase III International Randomised Controlled Study of Rigosertib versus Physicians Choice in MDS After Failing A Hypermethylating Agent <b>Comment:</b> Protocol Amendment 2 was recently approved by EC and the HPRA. Patients up to 81 years old will now be included in the study. No Irish patients screened to date.	May 2016	AMNCH, CUH, UHG, UHW	225	35	12	0	Dec 2017



## Cancer Trials Round Up—Summer 2016

### Lymphoma/Haematology Cancer Trials

Chair of Lymphoma/Haematology DSSG: Prof Michael O'Dwyer Co-ordinator: Grace Hirakata

Trial	Date Open	Participating Cancer Research Units	Global Accrual Target	Global Accrual Current	Ireland Accrual Target	Ireland Accrual Current	Accrual Closing
<b>OPTIMISMM CTrial-IE (ICORG) 15-10</b> PI: Dr Patrick Hayden Type: Industry Sponsored Sponsor: CELGENE  <b>Title:</b> A Phase III, Multicentre, Randomised, Open-Label Study to compare the Efficacy and Safety of Pomalidomide, Bortezomib and Low-Dose Dexamethasone Versus Bortezomib and Low-Dose Dexamethasone in Subjects with Relapsed or Refractory Multiple Myeloma  <b>Comment:</b> Recruitment could close as early as December 2016.	Jun 2015	UHG, Mater, SJH	450	400	18	<b>10</b> UHG 3, Mater 4, SJH 3	Jan 2017
<b>ECOG E3A06 CTrial-IE (ICORG) 12-02</b> PI: Prof Michael O'Dwyer Type: Collaborative Group Sponsor: ECOG  <b>Title:</b> Randomised Phase III Trial of Lenalidomide Versus Observation Alone in Patients with Asymptomatic High-Risk Smoldering Multiple Myeloma.  <b>Comment:</b> Protocol Addendum 12 has been approved by EC and HPRA	International Oct 2010  <b>Ireland</b> Mar 2014	UHG, Mater	180 (revised from 380)	164	10	<b>3</b> MMUH 1, UHG 2	Apr 2017
<b>CHRONOS-2 CTrial-IE (ICORG) 15-37</b> PI: Prof Liam Grogan Type: Industry Sponsored Sponsor: Bayer  <b>Title:</b> Bayer 17322: A randomized, double-blind phase III study of copanlisib versus placebo in patients with rituximab-refractory indolent B-cell non-Hodgkin lymphoma (iNHL)  <b>Comment:</b> Mater to be opened very soon.	Feb 2016	BH, Mater	189	13	4	0	Dec 2018
<b>P2001 CTrial-IE (ICORG) 16-08</b> PI: Prof Helen Enright Type: Industry Sponsored Sponsor: Millenium  <b>Title:</b> Phase 2, Randomized, Controlled, Open-Label, Clinical Study of the Efficacy and Safety of Pevonedistat Plus Azacitidine Versus Single-Agent Azacitidine in Patients With Higher-Risk Myelodysplastic Syndromes, Chronic Myelomonocytic Leukemia, and Low-Blast Acute Myelogenous Leukemia  <b>Comment:</b> Study recently opened. AMNCH and Mater active. UHG not yet active.	Sep 2016	AMNCH, Mater, UHG	117	27	1-2 patients per site	0	Apr 2017
<b>CHRONOS-3 CTrial-IE (ICORG) 15-38</b> PI: Prof Elisabeth Vandenberghe Type: Industry Sponsored Sponsor: Bayer  <b>Title:</b> 17067: A Phase III, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of copanlisib in combination with rituximab in patients with relapsed indolent B-cell non-Hodgkin's lymphoma (iNHL)  <b>Comment:</b> To screen 29 for 18 patients randomised.	Oct 2015	UHG, SJH, Mater, SVUH, BH	567	62	18	<b>2</b> UHG 1; Mater 1	Jun 2019
<b>KEYNOTE 185 CTrial-IE (ICORG) 16-10</b> PI: Dr John Quinn Type: Industry Sponsored Sponsor: MSD  <b>Title:</b> A phase III study of Lenalidomide and low-dose Dexamethasone with or without Pembrolizumab (MK3475) in newly diagnosed and treatment naïve Multiple Myeloma  <b>Comment:</b> Study recently opened.	Sep 2016	BH	640	123	4	0	Mar 2018

DSSG NOTES—Autumn 2016

DSSG NOTES—Autumn 2016



At the Patients Driving Health Innovation Conference marking the 10th Anniversary of IPPOSI—The Irish Platform for Patient Organisations, Science and Industry—Dr. Michael Griffith, Founder of IPPOSI (second from left) was presented with a gift from Jim Breslin, Secretary General, Department of Health. Also pictured is (left) Dr Derick Mitchell, CEO, IPPOSI and Eibhlin Mulroe, CEO, Cancer Trials Ireland.



David Higgins, Trainee QA Auditor pictured with Ann Marinus, Assistant Director, Head of Clinical Operations at European Organisation for Research and Treatment of Cancer (EORTC). David recently attended a training course in Brussels with colleagues from around Europe. One of the many interesting topics explored was the different regulatory processes required in multicentre Pan-European trials.

David hopes to visit EORTC again to further the ongoing collaboration with Cancer Trials Ireland.

## Dates for your Diary

**2017 DSSG Meetings**

**Friday, 17<sup>th</sup> February**

**Friday, 23<sup>rd</sup> June**

**Friday, 20<sup>th</sup> October**

**Venue will be confirmed closer to the date**

## Patient advocate: *There are no silly questions in cancer!*



Cancer Trials Ireland partnered with the Irish Cancer Society in August to host a public talk on cancer trials as part of its series on Decoding Cancer.

The talk was open to the public and included a panel of experts (pictured above l to r); Cancer Trials Ireland patient advocate Alan Pearson, Dr Cathy Kelly, Consultant Medical Oncologist at the Mater Misericordiae University Hospital, Dublin, Elaine Kelly, patient representative and a cancer trial participant, and Dr Jennifer Westrup, Consultant Medical Oncologist at Beacon Hospital, Dublin.

Alan highlighted that his daughter would not have been able to access the drug she is on if she was not on a trial. He recommended that people should ask questions and know that there are no silly questions in cancer.

Elaine said that she declined the offer of a trial when the option was first offered to her, however she eventually jumped at opportunity and said it was the best decision she ever made. She said that the beauty of being on the trial was that a month after coming off the trial the drug was approved and available through the health service.

Both Drs Cathy Kelly and Jennifer Westrup highlighted the importance of cancer trials which can be traced back to biblical times. Dr Kelly remarked on how important GPs are in helping families understand the options available.

Dr Kelly said that there was a concern among some patients that on a trial they would get the treatment being trialled or nothing, which she said was not the case. At minimum patients get the current standard of care for their disease. She found from her research that 95.7% of patients would like to participate in another trial if it was an available option.

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